

AUTONOMY AND BENEFICENCE: STRIKING A BALANCE IN
ALZHEIMER'S DISEASE RESEARCH

by

JUDITH ANNE MOORHOUSE, R.N., B.A., M.A., M.H.SC.

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AUTHOR: **Judith Anne Moorhouse, B.A. (McMaster University)**
R.N. (George Brown College)
M.A. (McMaster University)
M.H.Sc. (McMaster University)

SUPERVISOR: **Professor J.E. Thomas**

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ABSTRACT

Alzheimer's Disease research is troubled by ethical problems in respect to the research design, subject selection and obtaining a valid consent. In the thesis, these ethical issues are examined with particular attention being paid to the question of whether Alzheimer's Disease patients can be involved in research offering no promise of benefits to these vulnerable subjects.

Drawing from both deontological and consequentialist ethical theories, a resolution of some of the ethical issues is proposed. Although many Alzheimer patients are no longer autonomous, they do continue to have moral worth and therefore, should be respected by society. Also, the requirement of competency for consent to be a research subject is explored and a more demanding standard of competency to consent to research participation is recommended.

The ethical tension in Alzheimer's Disease is not confined to balancing respect for the subject's autonomy with the need to learn more about this devastating disease but also, involves balancing the need to respect and protect a vulnerable population while supporting research striving to reduce the human and economic costs of Alzheimer's Disease.

The proposed resolution of this ethical tension is based on a re-evaluation of the requirements for an ethical design and a valid consent in the context of Alzheimer's Disease.

Recommendations on the conduct of Alzheimer's Disease are proposed which can be integrated into current research guidelines. These recommendations may also be of assistance to researchers working with other vulnerable patients.

Respect for weak and vulnerable subjects is the ethical priority and serves to restrict some types of Alzheimer's Disease. However, it is proposed that Alzheimer's Disease patients may be involved in clinical research not likely to benefit them directly, and is not expected to harm the subject on condition that the proposed, stringent rules regarding their participation are followed.

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Alzheimer's Disease involves the loss of memory and reminds us of the importance of memory. Thus, it is appropriate for me to acknowledge the memory of my grandfather, Harry Moorhouse, who taught me that we should always be engaged in learning and constantly encouraged me in my educational pursuits. In later life he was struck by Alzheimer's Disease. My fond memories of him before and after he developed Alzheimer's Disease, have deepened my understanding of the difficulties of patients, their families and all who work with Alzheimer's Disease patients.

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Chapter I

Introduction: What is Wrong with Trying to do Good?

1.1 Introduction

This thesis undertakes to study the ethical problems associated with the use of human subjects in Alzheimer's Disease research. Senile Dementia of the Alzheimer's type (hereafter referred to as SDAT) research is in its infancy and researchers are confronting important ethical dilemmas when they design SDAT research proposals and seek a valid consent.

Alzheimer's Disease, a progressive, chronic and terminal disease, is an assault on individual autonomy. Thus, many Alzheimer's Disease patients are unable to provide a valid consent, and questions are raised about the design of research involving these vulnerable and weak subjects. When the subject is unable to consent, it is customary to seek surrogate or third party consent. However, in the case of SDAT research, surrogate consent for mentally impaired individuals to be research subjects in non-therapeutic research (i.e. research in which there is no promise of direct benefits to the subject, but there is the expectation of indirect benefits to others) is not permitted for ethical reasons. To volunteer an individual to

be a subject of research offering him no benefit is not considered to be in the subject's best interests and poses a threat to his integrity.¹ Researchers want to conduct both therapeutic research (i.e. with the possibility of some direct benefit to the subject) and non-therapeutic SDAT research, in order to learn about the causes and prevention of the disease. However, their work is thwarted by regulations and ethical concerns prohibiting the association of mentally impaired SDAT patients with non-therapeutic research, and even with therapeutic research if its risk-benefit ratio is unfavourable.² Thus, some types of research that could contribute to reducing the morbidity and mortality rates associated with Alzheimer's Disease are not permitted.

The specific objectives of the introduction are:

- (i) to identify the ethical problems associated with SDAT research
- (ii) to define key terms
- (iii) to review previous work related to the thesis topic
- (iv) to present organization and philosophical approach of thesis.

In this introductory chapter, the ethical problems to be studied will be presented, thus providing the foundation and the background for the investigation of these issues in the following chapters. If these difficult questions are not studied and ways of resolving the issues developed, it is possible that urgent needs, reactive responses and a pragmatic approach

will dictate research policies. Hence, decisions regarding what type of experimental procedures SDAT patients will be associated with, will be reached with little reflection upon the ethical implications of the policy for Alzheimer's Disease patients.

1.2 Ethical Problems Associated with Alzheimer's Disease Research:

The ethical problems and the importance of these issues will be presented in two steps. First, the cardinal features of the Disease will be reviewed. Second, the status of research ethics for SDAT research and the ethical problems associated with conducting Alzheimer's Disease research will be discussed. This two-stage process will illuminate the complexity of the ethical problems associated with conducting SDAT research.

a) Alzheimer's Disease: A Loss of the Self

In 1903, Dr. Alois Alzheimer identified the degenerative brain disorder later named after this German physician. Alzheimer's Disease is a neurodegenerative disease and is the most common form of dementia. It is a devastating illness which leads to a loss of independence and identity. As the disease advances, its victims lose the ability to care for themselves, and they become totally dependent upon others for their safety and well being. The effects of the disease have been described as a "loss of self".³

Alzheimer's Disease is a disease of the elderly. The vast majority of individuals with dementia of the Alzheimer's type are aged over sixty-five. The ravages of Alzheimer's disease causing deterioration in several realms are exacerbated when, as is often the case, the SDAT patient has co-existing health problems.

It is estimated that at least three million North Americans suffer from this terminal and chronic disease. In Canada, 300,000 Canadians have SDAT. It is ranked the fourth or fifth cause of death in Canada.⁴ There is little knowledge about its causes and prevention, and the incidence is expected to continue to rise. The shift in demographics explains the rising incidence of SDAT. With old age comes an increased risk of having Alzheimer's Disease. Not only is the number of elderly people in our society growing, but also the number of persons aged over eighty years (called the old-old) is increasing. Those aged eighty and above are in the highest risk group, having a 20% chance of developing SDAT to some extent, and this group is experiencing the largest increase in its numbers; it is expected to double by the turn of the century. By the year 2000, approximately 25% of Canadians will be aged over sixty-five and five million Canadians will be at risk of having the disease to some extent.⁵ By the year 2021, it is predicted that there will be over 700,000 Canadians with A.D., half of whom will be severely incapacitated and require total nursing care.⁶

These statistics fail to present the human dimension of this tragic illness. The loss of the self causes families to experience grief similar to that accompanying the death of a loved one, yet, in this case, the patient continues to live and need more and more care. Alzheimer's Disease is not suffered alone; the quality of life of the patient and all who and care for the individual is affected.

Family and friends usually assume the onerous role of caregiver supported by health care professions in the community. In most cases, at some time during the progress of the disease, the patient enters an institution. Hence, the human, social and economic costs for the patient, his caregivers and society are immense.

Dr. St. Hyslop (a SDAT researcher) predicts that Alzheimer's Disease will be the major public health and social problem of the next century.⁷ A clustering of inter-related events support this prediction: more elderly individuals are living longer and developing SDAT; the per capita cost of caring for a SDAT patient will increase; and more demands will be placed on already over-worked facilities, services and families to meet the needs of SDAT patients. At present, it is not possible to halt or prevent the development of the disease. As the incidence increases, more health care funding would be needed to meet the needs of SDAT patients whether living in the community or institutions. Consequently, other groups depending on

the health care system will be affected, and questions about resource allocation will be raised.

Considering that eighty years after this debilitating neurogenerative disease was identified, little more is known about preventing or curing the disease, research is considered to be overdue. Pressure for more SDAT research comes from many quarters: patients, their families, health professionals, researchers, health economists, health policy planners and volunteer agencies, such as the Alzheimer's Society of Canada. Wanted is knowledge about the etiology, risk factors and more effective management interventions.

b) Ethical Problems

The Globe and Mail headline, "Alzheimer's Research Hindered by Lack of Competent Patients"⁸ succinctly states the source of ethical problems for SDAT research. Relying exclusively on competent SDAT subjects is neither practical nor ethical. If only competent SDAT patients were research subjects, it would be difficult to obtain statistically significant results. Also, it would be unjust to target a sub-group of the SDAT population to be research subjects and incur all the costs associated with being research subjects.

Why not use incompetent SDAT patients? There are ethical and legal barriers to recruiting mentally incompetent and mentally impaired SDAT patients in most jurisdictions.⁹ First, mentally incompetent individuals are not permitted to be associated with research offering no promise of benefits to the vulnerable research subjects (non-therapeutic research). The SDAT patient is a particularly vulnerable research subject because of his age, mental status, and co-existing health problems. Furthermore, limited financial resources, living in an institution, and not having a next of kin, or having a next of kin who is overburdened with caring for an Alzheimer patient can increase the SDAT patient's vulnerability. Second, surrogates are not permitted to consent to the participation of mentally impaired patients in non-therapeutic research because this research is not in their best interests and is considered a violation of their dignity and integrity. Third parties can only consent for their wards to be subjects in studies having some expectation of directly benefitting the subject (therapeutic research). This leaves a large area of SDAT research, for instance research investigating the causes and prevention of SDAT, inaccessible to researchers.

Furthermore, Alzheimer's Disease patients are terminally and chronically ill and at this time in the history of SDAT research, projects investigating causes and prevention of SDAT will not assist affected

patients. This type of research would be classified as non-therapeutic, and therefore, mentally impaired SDAT patients should not be subjects in research investigating the disease process and disease prevention.

Also, ethical issues arise because Alzheimer's Disease research must rely on the use of human research subjects affected by the disease under investigation. Although researchers rely on laboratory findings and the use of research animals, the information yielded is of limited value because there is not an acceptable animal model for SDAT. Thus, if advances in SDAT research are to be made, it is necessary to use human subjects who are vulnerable. The Medical Research Council of Canada (MRC) considers a vulnerable research subject to be an individual with "restricted ability to give consent...this includes research with children, with the infirm and with those in potentially coercive circumstances such as prisoners".¹⁰ If subjects without SDAT were employed in SDAT research, the results can not be generalized to the SDAT context. Therefore, members of the vulnerable population "must apparently serve as subjects" states the Guidelines.¹¹ Balancing the ethical problems and costs of including or excluding vulnerable subjects, the MRC concludes that research involving vulnerable subjects must continue.

Health sciences research is built on the pillars of an ethical experimental design and a consent mechanism yielding a valid, informed

consent.¹² The problems referred to by the Globe and Mail's terse headline refer to both the research design and the consent process. These serious ethical problems have been identified by the Canadian Medical Research Council (MRC) and other research bodies. In the MRC's latest Guidelines on Research Involving Human Subjects (1987), they state:

Research into disorders of the elderly pose special problems. Research into Alzheimer's Disease, for instance, may require affected subjects to be exposed to uncomfortable and above-minimum-risk procedures. Subjects may not themselves benefit from the results of individual studies, and they may lack competence to give consent. Their guardians, whether de jure guardians such as family members, may not have legal power to give effective consent to invasive procedures. Indeed, mentally and physically-disabled persons' legal protections are strengthened under the Canadian Charter of Rights and Freedoms, reducing the likelihood that provincial public hospital, mental-health or mental incompetency legislation would be construed to allow such research not related to therapy.¹³

The Guidelines take a protectionist position in respect to mentally and physically impaired individuals whom they consider to be highly vulnerable because of their health status and dependency on caregivers and the health care system. Comparing the mentally impaired to prisoners or other institutionalized groups, the Guidelines warn that they are at risk of being influenced and coerced by their environment and their attendants. The SDAT population is weak and vulnerable for a number of related

reasons: diminishing or depleted mental and physical functioning; partial or total dependency on others for basic needs and safety; loss of their civil rights; lacking next of kin to protect their interests; the presence of co-existing health problems; and lack of financial resources. Furthermore, Alzheimer's Disease strikes the patient, his family, and close friends. Family and friends struggle with grief and a sense of loss as they begin to appreciate that the person that they have known for years will be different and more dependent on them for his basic needs. Hence, caregivers have to deal with their own difficulties associated with the loss of their relative or friend and, at the same time, try to accept the onerous responsibilities of caring for an SDAT patient. With good reason was the widely used, practical guide for caregivers of SDAT patients called The Thirty-six Hour Day.¹⁴ Thus, discussion about the vulnerability of the SDAT patient also applies to the caregivers who are also heavily dependent on the health care system and their relative's treatment team. In many cases, it would be imprudent for caregivers to refuse consent despite having reservations about whether the patient would have approved and would be helped by the research intervention.

An example will illustrate the point. A family caring for their father at home would like their father to attend a day hospital programme. During their visit to the day hospital, the director says they have a vacancy,

and at the same time, asks the family if they would consent to their father being a subject in a research project investigating the effectiveness of their interventions. The health-care professional-investigator has a conflict of interests, and the family is being coerced.

The Guidelines state that the “rights to integrity of the mentally disabled” are protected by law and should be respected by researchers and society, and not circumvented by Research Ethics Boards (REB’s). The rights to integrity “cannot be reduced or compromised simply on the basis of decisions of REB’s; only courts have the authority to approve invasive forms of management, and to say what consent process will be adequate for invasive non-therapeutic procedures”, according to Guidelines.¹⁵

Thus, the MRC has raised the following ethical issues:

- (i) Affected subjects might be exposed to uncomfortable and above minimum risk procedures.
- (ii) Subjects may not benefit directly from the results of individual studies.
- (iii) Subjects may lack competence to give consent to research participation.
- (iv) The guardians of subjects whether de jure or de facto guardians (e.g. family members) may not have the legal powers to give effective consent to invasive procedures.
- (v) The legal protection of mentally and physically disabled individuals is strengthened under the Canadian Charter of Rights and Freedoms. Thus, it is unlikely that mental health or mental incompetency legislation could permit non-therapeutic research.

- (vi) The rights to integrity of the mentally disabled are protected by law and the Charter cannot be changed or overridden by a Research Ethics Board.
- (vii) Only courts have the authority to consent for invasive measures and to define an adequate consent process for non-therapeutic procedures.
- (viii) Mentally incompetent adults, on whom research may be legally conducted, are at higher risk than those in free circumstances of being coerced and influenced by the promise of advantages.

Thus, the MRC identified a number of ethical problems that can be categorized in terms of the research's design and the consent process.

Research Design:

- (i) Mentally impaired patients cannot be associated with invasive and non-therapeutic research.

Consent Process:

- (i) Mentally impaired subjects are vulnerable because of their mental status and environment.
- (ii) Surrogates can not consent for mentally impaired individuals to be subjects in non-therapeutic research
- (iii) Consent for the involvement of mentally and physically impaired individuals in non-therapeutic research can only be given by the Court.

However, in the opinion of the MRC, the courts would take a strong protectionist position and not approve the association of mentally or physically impaired individuals with non-therapeutic research. Thus,

advances in SDAT research which have the promise of contributing to benefits at the micro and macro level are blocked by current guidelines and legal regulations.¹⁶

During the course of the thesis, the issues raised by the MRC, especially the “hard case” of the association of the mentally impaired individual with non-therapeutic research, will be studied. In the final chapter I will respond to the concerns of the MRC and the six specific issues that they raised.

Similar issues were raised at an International Summit Conference on Bioethics Towards an International Ethic For Research With Human Beings hosted by the MRC in 1987. In the summit's Proceedings, in the section entitled “Special Topics in Biomedical Research”, the issues raised refer to SDAT patients and others with impaired mental functioning. Research on certain health problems requires subjects who have the disease to be studied (i.e. SDAT patients). When these subjects have limited ability to consent, the following ethical issues were identified.¹⁷

- (i) Under what conditions is research with those with restricted ability to give consent to be permitted?
- (ii) Is the criterion of minimal risk a workable concept for research with such subjects?
- (iii) Who acts on behalf of these subjects?

- (iv) What role, if any, is there for assent, in so far as the potential subject can understand the proposed research?
- (v) How does one weigh the limited potential benefits envisioned for the individual versus those for society?
- (vi) What criteria should/do guide ethics of experimentation with the terminally ill?

Again, it is seen that the questions relate to designing an experiment with an ethical design and securing a valid consent from the subject or his surrogate. The Summit raised the central issue of how society should weigh the expected benefits for society versus the expected costs to vulnerable subjects. In other words, how do we balance promoting the social good versus protecting vulnerable research subjects from harm. The first, second, fifth and sixth questions refer to the design of an experiment and subject selection. Given that mentally impaired individuals will be research subjects, the Summit asks what limits can be placed on their involvement with research. Can they be associated with both therapeutic and non-therapeutic research? If so, what harm-benefit ratio is acceptable when the subject has SDAT? Also, considering that SDAT patients are both chronically and terminally ill, what limits should be placed on their exposure to the risk of harm? This question leads to another one: do the concepts of risk and harm have any meaning for an SDAT patient?

The third and fourth questions call for a re-examination of the consent process and standards of competency. Are current standards too strict or too lax? Assent does not require the subject to appreciate the consequences of his behaviour. Thus, the question arises of whether cooperation has any meaning for SDAT patients? If assent is an acceptable standard of competency, more SDAT patients could consent to be subjects. Consequently, there would be little need for surrogate consent. Only when the prospective subject did not “cooperate” would surrogate consent be sought and then it could become a formality. Hence, the regulations prohibiting surrogates from consenting indirectly for mentally impaired individuals to be subjects in non-therapeutic research would have little or no relevance. On the other hand, it can be argued (and will be) that a valid consent cannot be given without the subject appreciating the consequences of consenting, and a higher standard of competency than assent is required. In addition, lack of “cooperation” should be respected and never be overruled by third party consent. If one takes this line, the surrogate consent becomes more necessary and the thorny issue of whether third parties can consent for mentally impaired individuals to be subjects in non-therapeutic research cannot be avoided. Hence, the Summit echoes the MRC’s concern about the scope of the surrogate’s responsibilities.

The ethical and legal concerns associated with research employing human subjects, and in particular vulnerable subjects has been studied by the Canadian Law Reform Commission. In their recent working paper Biomedical Experimentation Involving Human Subjects, the Commission reviewed legal statutes regarding the involvement of mentally impaired individuals in non-therapeutic research and found that in most jurisdictions, researchers are prohibited from recruiting mentally impaired individuals to be subjects in non-therapeutic research. At the International Summit, it was stated that, for utilitarian reasons, mentally impaired individuals need to be research subjects, but unanswered was how to use this vulnerable population without harming them. Similarly, the MRC sanctions the use of affected patients in research studying their health problems, but also recognizes that there are important unresolved ethical concerns when these vulnerable individuals are subjects.

The Law Reform Commission, however, does more than just agree that research involving vulnerable populations should be conducted in order to reduce the suffering of others; it proceeds to make recommendations on how to protect mentally impaired research subjects. Their recommendations, however, are not supported by arguments justifying the use of vulnerable patients in an activity which the Medical Research Council considers to be a violation of the prospective subject's inviolable

right to dignity and integrity. Thus, current research regulations leave many questions unanswered and do not adequately serve the needs of SDAT patients and their caregivers, researchers or society.

Dr. H. Karlinsky, an Alzheimer's Disease researcher at the University of Toronto, reviewed published findings of thirty-five major drug trials in Canada using Alzheimer's patients for subjects, during the period from 1985 to 1988. He found that few of these studies provided information about how the competency of patients was assessed.¹⁸ He reported that "After reviewing these studies including one that involved inserting an infusion pump into the brain, an under-reporting of the consent issue was found".¹⁹ Admittedly, lack of mention of the consent process does not mean that consent was not obtained, but it is curious that competency and consent were discussed so infrequently when both are major concerns when conducting SDAT research. Pragmatic demands of clinical practice and a lack of helpful recommendations on how to secure valid direct or indirect consent for SDAT research participation are possible explanations for the under-reporting of the subject selection and consent mechanism.

To summarize, the pressing issues regarding SDAT research involving mentally impaired subjects are:

- (i) Should an SDAT patient be involved in non-therapeutic research?
- (ii) Should an SDAT patient be involved in invasive research?

- (iii) Should an SDAT subject be involved in research that poses greater than minimal risk?
- (iv) Is the concept of therapeutic research relevant to the SDAT population?
- (v) Is potentially harmful research justified because of the social good that will ensue?
- (vi) What restrictions should be placed upon researchers and society trying to alleviate the suffering and social costs associated with SDAT?
- (vii) Can a surrogate consent for an SDAT patient to be a subject in non-therapeutic research?

The thesis will respond to the above questions. However, underlying these questions are more fundamental ones about what values and principles, if any, can be compromised or sacrificed in order to gain knowledge to reduce the suffering. The researcher wants to acquire knowledge, the SDAT patients need more effective treatments, and society wants to prevent SDAT being the major public health problem of the next century. In other words, how can the morbidity and mortality associated with Alzheimer's Disease be reduced, the needs of SDAT patients be respected and the interests of researchers and the public be met? Thus, during the unfolding of the investigation, the practical and conceptual questions raised by the MRC and the International Summit will be studied and a possible resolution to these related ethical issues will be proposed.

1.3 Definition of Terms:

In the field of research ethics, terms are used in different ways by different bio-ethicists and researchers, and controversy reigns regarding their meaning. Therefore, it is imperative that the meaning of key terms be clarified. The terms to be discussed are: research, therapy, therapeutic and non-therapeutic research. The accepted, orthodox definitions of these concepts will be presented and later in the dissertation, they will be analyzed further in the context of SDAT research.

a) Research and Therapy:

Throughout the thesis, the term health sciences research is used in place of medical research because the former term is broader including research conducted by physicians, nurses, epidemiologists, physiotherapists, occupational therapists, social workers, psychologists and also, social scientists. Research, states the Medical Research Council of Canada “refers to the generation of data about persons, through interventions or otherwise, that goes beyond that necessary for the individual person’s immediate well-being. Intervention is not just medically defined but includes acts which affect a subject’s interests in, for instance, physical integrity, intellectual and behavioural integrity, and privacy”.²⁰ Health sciences research is scientific research and must follow the rigors of the scientific method and

also ethical regulations. Hence, the risks of research “should be applied to the smallest possible population and not involve unnecessary subjects”, advises the Council.²¹

A subject is an individual who is subjected to the research intervention and thereby provides data for the researcher. In the words of the MRC, a subject is a “human being who directly bears any risk of the research carried out”, and harm encompasses not only physical harm but also “loss of dignity and self-esteem, guilt and remorse, or feelings of exploitation and degradation” states the MRC.²² Similarly, a subject can receive psychological and physical benefits from being a research subject.

The U.S.A.’s National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (the Commission) undertook to clarify the meaning of the concepts of research and therapy. The Commission concluded in the Belmont Report that the two notions when used correctly are distinct. The Belmont Report of the U.S.A., defining research, refers to the scientific method, stating that research is an activity “designed to test a hypothesis, permit conclusions to be drawn and thereby to develop or contribute to generalizable knowledge (expressed, for example, in theories, principles and statements of relationships). Research is usually described in a formal protocol that sets forth an objective and a set of procedures designed to reach that objective”.²³

Therapeutic interventions have the goal of improving the patient's physical and mental health or in other words, their well-being. "Therapy" sometimes called "practice" was defined by the Belmont Report, as interventions "designed solely to enhance the well-being of the individual patient or client and that have a reasonable expectation of success. The purpose of medical or behavioral practice is to provide diagnosis, preventative treatment, or therapy to particular individuals".²⁴ The purpose of therapy is to act in the patient's best interests by using practices with a reasonable chance of success for the patient in order to promote, support and maintain his physical and mental well-being or to use more abstract terms, his integrity and dignity. In addition, depending on the status and prognosis of the patient, the goal of therapy can be palliative, that is to say, enhancing the patient's quality of life as opposed to working for the patient's recovery.

The health professional's actions are grounded in the principle of non-maleficence (to do no harm), and secondly in beneficence (to do good). However, in order to offer therapeutic interventions, his practice must be built on the work of researchers who discover and evaluate the effectiveness of interventions.

b) Therapeutic and Non-therapeutic Research:

Research can be classified as therapeutic or non-therapeutic. Both categories of research use the same principles and have the same goal of seeking new knowledge. However, therapeutic research, in addition to learning new information, will presumably benefit the subject. On the other hand, non-therapeutic research concentrates exclusively on acquiring information that can assist others at some time. Thus, therapeutic research offers the possibility of direct benefits to subjects, but non-therapeutic research can offer indirect benefits. In both cases, state Drs. Thomas and Waluchow, in their book Well and Good, "the investigator has identified a research question and conceived a research protocol to attempt to answer it. The commitment here is to answer the research question".²⁵ In both cases, the researcher's priority is to seek new information while, in contrast, a health care professional's priority is to act in the patient's best interests and do no harm (non-maleficence).

The distinction between the two types of research became formally established in the 1960's. Although the Nuremberg Code (1947) did not distinguish categories of research, the World Medical Association Declaration of Helsinki in 1964 did distinguish therapeutic clinical research combined with professional care from non-therapeutic clinical research and made recommendations in respect to these distinct activities.²⁶

Therapeutic research combined with professional care must meet two requirements. First, the physician must consider the therapeutic intervention to be a way of offering hope of saving life, “re-establishing health, or alleviating suffering”.²⁷ Secondly, the physician can combine clinical research with professional care when the goal is acquiring new knowledge, “only to the extent that clinical research is justified by its therapeutic value for the patient”.²⁸

The Helsinki Declaration’s recommendations regarding conducting non-therapeutic clinical research are more numerous than those for therapeutic research. Two principal points are made. First, “in the purely scientific application of clinical research carried out on a human being”, the doctor’s duty is to protect the well-being of “that person on whom clinical research is being carried out”. Second, a valid consent is essential.²⁹ Thus, the researcher must not sacrifice the subject’s well-being in order to gain new knowledge. The principle of non-maleficence has been carried over to the research realm.

The two distinctions between research and therapy, and between therapeutic and non-therapeutic research, are controversial. For instance, the Belmont Report of the U.S.A. prefers to abandon the distinctions. In the following chapters these categories will be evaluated and found to be in need of revision.

c) Informed Consent

In the western scientific community, research ethics continue to be dominated by the Nuremberg Code (1947) which states that all human subjects must volunteer to participate in a research study and must be fully informed of the risks and benefits attendant upon entering the study. The Nuremberg Code and other codes of research ethics emerge from and express the Western, liberal tradition of respecting individual autonomy, self-determination and inviolable rights.

The consent mechanism or process results in a contractual agreement between two parties, the researcher and the subject (or his surrogate). The process consists of a researcher or his representative informing the prospective subject about the research protocol and then asking for his consent to be a subject. The prospective subject evaluates the relevant information and makes a decision based on an appreciation of the information given and his particular circumstances. The subject should not be coerced overtly or covertly to consent. Also, it is necessary that there be an interactive, dynamic relationship between the researcher and the subject. The term "consent process" is preferable to "consent mechanism" because the former better describes the open ended, dynamic relationship that should exist between both parties. Informed consent, grounded in respect for individual autonomy, is the cornerstone of health sciences

research and what may be called the autonomy model of research. The priority according to this approach is respecting individual self-determinism. Hence, the benefits of research cannot be gained at the cost of compromising or disrespecting the prospective subject's autonomy, for instance, by exerting coercion or not presenting all the relevant information. The absolute necessity of obtaining an informed consent from human subjects is a bequest of the Nazi atrocities and was established as an essential requirement in the Nuremberg Code. The Helsinki Declaration, MRC Guidelines and all research guidelines state that a human subject must voluntarily agree to participate in the project, and that the subject must appreciate his risks and benefits of consenting and refusing to be a subject.

The term valid consent is preferred to informed because it requires that the potential subject not only be informed but also comprehend, critically evaluate the relevant information presented, and make a decision based on this information. Hence, the consent requirement seeks to ensure that the subject understood the information regarding the protocol and appreciates the consequences of his decision. Drs. Thomas and Waluchow state that the requirements for a valid, direct consent from a subject are as follows:³⁰

- (i) voluntariness
- (ii) responsibility
 - (a) legal competence
 - (b) mental competence
- (iii) understanding: adequate information must be *presented* to the patient/subject so that it is *understood* by the patient/subject.
- (iv) confidentiality
- (v) the right to withdraw.

The major reasons for not meeting the criteria are mental incompetence and the inability to understand relevant information.

Considering the nature of Alzheimer's Disease, many SDAT patients will have difficulties and others will be precluded from giving a valid consent.

When the prospective subject cannot meet all of these requirements, the consent is not valid; an indirect consent from a surrogate is necessary. The criteria for third party indirect consent are:³¹

- (i) identification of surrogate - either nearest relative or court appointee
- (ii) qualifications of a surrogate
 - (1) responsibility
 - (a) legal competence
 - (b) mental competence
 - (2) understanding: adequate information must be presented to the surrogate so that it is understood by the surrogate.

(3) role of the surrogate

- (a) to implement the dependent person's previously expressed wishes
- (b) to promote the dependent person's best interests
- (c) to ensure that confidentiality is maintained where relevant
- (d) to exercise the right to withdraw the subject from a research project if deemed appropriate.

The surrogate's role is onerous because frequently the patient's wishes are not known or are ambiguous or ambivalent. Secondly, it can be difficult to know what is in the patient's best interests. Herein lies the rub for SDAT research. The MRC and other authorities do not think that third parties can consent for mentally impaired patients to be subjects in non-therapeutic research because the research does not offer direct benefits to the subjects and, hence, is not in the best interests of the patients. The central chapters of this dissertation will explore the conditions under which surrogate consent for non-therapeutic research can be given.

1.4 Previous Work in the Field:

An extensive literature review revealed that work in respect to the ethical problems associated with conducting Alzheimer's Disease research is very scarce. This area of interest is attracting the attention of a small

number of health care professionals, epidemiologists, lawyers and philosophers. Regarding the broader topic of competency and consent, the majority of work has been done by health care professionals (especially psychiatrists), and lawyers. All agree that SDAT research presents ethical problems. However, the majority of work regarding SDAT research is clinical, from a legal perspective, expository, and/or prescriptive.

The literature review, however, did reveal a consensus that SDAT research presents serious ethical and legal problems. Ethical issues related to securing a valid consent, sound research design, and the appropriateness of surrogate consent have been identified and some practical recommendations have been made which should assist researchers to work with the present regulations. On a few occasions, changes to current guidelines have been proposed, but these proposals are neither supported by a critical analysis of the current guidelines nor justified by arguments based on ethical principles and values. The majority of those studying the problems work within the constraints of the current research codes and guidelines. Tinkering with and fine-tuning, as opposed to studying whether these codes should be followed, challenged or changed, is the dominant theme. The result has been either to reinforce the status quo or transfer the problem to the judiciary.

Richard Ratzan, a medical doctor who has studied the ethical problems associated with research involving elderly subjects, reviewed the topic of research ethics for the elderly and concluded that there is no consensus regarding the use of elderly, demented subjects in research protocols and that SDAT researchers lack direction. "The lack of consensus is not surprising partly because there has been little discussion that would even illuminate the issues" states Ratzan.³²

Why have few philosophers been interested in the problems associated with SDAT research? Probably timing is the principal reason. Alzheimer's Disease has been a sleeping giant. Although SDAT was discovered eighty years ago, only in the past twenty years has a rise in incidence been noticed. Also, only recently has SDAT research commenced in earnest and thus ethical issues identified. The story is a familiar one: health and social sciences forge ahead while moral philosophy arrives late on the scene.

The Canadian Medical Research Council proposes guidelines for researchers using human subjects. However, as discussed, the MRC identifies SDAT research as an area of research troubled by serious ethical problems. The MRC's work is valuable because it identifies key issues regarding the experiment's design and securing a valid consent. However,

it is only a start for further investigations. As the MRC states, they have raised serious ethical issues which have yet to be resolved.

The Council did take a position on the hard case of whether a mentally impaired individual can be associated with non-therapeutic research, advising that only the court can grant permission for these vulnerable individuals to be associated with research that offers the subjects no promise of direct benefits. To date, there has not been a test case before the courts and thus a precedent has not been set. If and when there is a case, the legal advisors will have a daunting decision. On what grounds do they base their argument? Do they present their case using the "best interests" model, the "protectionist" model, or do they use the "substituted judgement" model? The Council supports the protectionist approach.

In the United States, the legal and ethical concerns about SDAT are a burgeoning field, but no firm conclusions have been reached. However, the direction of the discussions has taken a different course than in Canada. The National Institute on Aging (NIA) sponsored a Task Force having the responsibility to design a set of guidelines that can assist SDAT researchers. However, the Task Force was an advisory body and therefore has no regulatory authority. The recommendations are presented in Melnick's important article "Clinical Research in Senile Dementia of the

Alzheimer Type³³ and elaborated further in the book Alzheimer's Dementia: Dilemmas in Clinical Research edited by Melnick.³⁴

Several recommendation made are of interest to this investigation. Regarding the selection of subjects, it was proposed that subjects should be sought from the following four categories:³⁵

- (i) non-institutionalized patients who are competent to consent to research participation.
- (ii) non-institutionalized patients who are incompetent but stated when competent that they wish to be a research subject.
- (iii) non-institutionalized patients with "impaired capacity" yet who express a willingness to be a subject.³⁶
- (iv) other non-institutionalized patients with some capacity to care for themselves and "express a current willingness to participate in research".³⁷

The committee recommended that subjects be sought from the first category and then from the other categories in descending order.

The problem with these recommendations is that they hinge on an assessment of competency, but the criteria of competency are not offered. The recommendations do suggest that assent or co-operation can constitute consent, but, as will be shown in chapters four and five, assent can occur without valid consent. Also, subject selection is unjust because non-institutionalized patients are being made to carry the full burden of SDAT research.

The same report also permits the SDAT patient to be associated with therapeutic research offering “some realistic possibility of direct therapeutic benefit to the subject” posing more-than-minimal risk to the subject on condition that a valid consent is secured and the risk is justified by the promise of benefits for the subject.

Regarding the hard case of invasive, non-therapeutic research posing more than minimal risk, the Commission agrees with the MRC that this research poses “in the most dramatic form the conflict between societal interest in the conduct of important and promising research and the interests of the potential subject”.³⁸ The report states the interests of the research subject are protected by the consent mechanism. They recognize that in some jurisdictions surrogate consent is not recognized and, thus, consent would have to be granted by the court. However, there is a difference between the ethical perspective of the N.I.A.’s report and the MRC’s recommendations. The Report states:

It may be that in at least some instances, the importance of research may ethically justify interventions posing greater than minimal risk on a willing subject who lacks the capacity to grant legally effective informed consent even in the absence of any realistic probability of direct benefit to the subject. Such a conclusion must rest on a thoroughgoing assessment of the risks involved and of the scientific importance of the research. When the local IRB believes these conditions are met, the

sensitivity and the public importance of the issue strongly indicate the advisability of further definitive review of the particular protocol by a national ethics advisory body whose decisions shall be made in the course of a public process....even such a national review may not resolve the legality of the consent under the law of a particular state and that the advice should be sought from competent counsel in all such cases.³⁹

In a similar vein, the fourth recommendation of the U.S.A.'s National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (Section 46.507) proposes permitting the participation of elderly, mentally impaired individuals in research which has greater-than-minimal risk. This category of research is allowed, despite the risk of harm to the subject, if the anticipated knowledge is necessary for acquiring greater understanding and may reasonably be expected to benefit the subject in the future. The subject must either consent or assent (requiring a lower standard of competency, usually co-operation and evidence of a choice). If the subject objects, the guardian's permission or a court order granting consent is required. The difficulty with these recommendations is that the traditional classifications of "therapeutic" and "non-therapeutic" (which will be analyzed in chapters four and five) are not appropriate in the realm of SDAT research and again, the criteria of competency required to consent to research are not established. Although

the N.I.A. recommended approval from local ethics advisory boards, to date neither in Canada nor the United States, has a national ethics review board been established.

These recommendations differ from the Canadian ones in an important way: they would permit invasive, non-therapeutic research with greater than minimal risk involving elderly, mentally incompetent individuals under certain conditions. Lacking are guidelines to assist the courts and other bodies to decide under what conditions social good can rank above protecting vulnerable subjects. For instance, the report states that it “may be that in at least some instance, the importance of research may ethically justify interventions posing greater-than-minimal risk on a cooperative subject who lacks the capacity to grant legally effective informed consent, even in the absence of any realistic probability of direct therapeutic benefit to the subject”.⁴⁰ Also, the report’s perspective is primarily legal and the approach is prescriptive.

The Canadian Law Reform Commission has challenged the MRC’s position. The Law Reform Commission recommends that mentally impaired individuals can be associated with non-therapeutic research on condition that strict regulations regarding the consent process and subject selection are followed. Also, it recommends that research involving vulnerable subjects (e.g. SDAT patients) should be regulated by legal statutes.

Currently, these recommendations are being reviewed by interested parties across Canada. The Law Reform Commission's work is a good beginning. However, once again, there is the lack of an adequate philosophical justification for the proposed recommendations.

In addition, the bulk of work in this field from health professionals struggling with the ethical issues when trying to conduct research has also been expository and prescriptive. At present there is a commitment on the part of clinicians to respect and maximize the subject's autonomy; practical suggestions for promoting autonomy and obtaining a valid, direct consent have been proposed. For example, Ratzan, who opposes the recommendations of the NIA regarding geriatric research, suggests some excellent ways of enhancing the chances of obtaining a valid consent (e.g. large print consent forms, and asking the patient to recall information given).⁴¹

The study of the ethics of SDAT research is a new, relatively unexplored subject. Only recently has there been interest taken in this burgeoning field and in the complex ethical issues troubling SDAT research. Hence, at this early stage, questions and issues are being clarified, but not all are resolved. This conclusion was confirmed at the conference Ethical and Legal Issues in Alzheimer's Disease Research held in Toronto in 1989. Leading SDAT researchers, lawyers and moral philosophers studied the

legal, clinical and moral problems associated with SDAT research; all agreed that there was a pressing need for further clarification and study.

In summary, the focus of previous work by clinicians and lawyers is valuable but has not gone far enough. Left unresolved are ethical issues on the conditions (if any) in which the interests of the weak and vulnerable may be ranked lower than the interests of society. Most of the work in this field is prescriptive; it has not grappled with the questions of what rights (if any), Alzheimer patients have, and if so, how they should they be protected when they are research subjects. Hence, previous work in this area has not examined, from the perspective of moral philosophy, the foundations of research ethics in the field of Alzheimer's Disease research.

1.5 Plan of Study:

This dissertation is about the application of ethical theory to the specific problem of how SDAT patients can be associated with health sciences research in a manner that respects their needs, and, at the same time, serves the public good. I intend to argue for the following conclusion: that SDAT patients are weak and vulnerable individuals requiring protection from exposure to any interventions, including research, which seriously threaten their safety and well-being. However, it will be argued that therapeutic and non-therapeutic research can be conducted if certain

regulations designed to protect the welfare of this vulnerable population are observed. Thus, society may benefit from research being conducted to the extent that vulnerable subjects are protected by research regulations designed to protect them from excessive risk (i.e. risk classified as more than minimum risk associated with daily living).

The resolution of the ethical dilemma of human inviolability versus social gain will be based on:

- (i) a modification to the current system of classifying research, and
- (ii) a higher standard of competency for consenting to be a research subject.

Regarding the hard case of the association of mentally impaired SDAT patients with non-therapeutic research, it will be proposed that this research can be conducted if the proposed regulations respect the subject's basic need to have his welfare needs met which includes protection from exposure to excessive risk.

In the course of the thesis it will be seen that the correct characterization of the ethical dilemma in SDAT research is not between respecting the research subject's autonomy and promoting the social good. To state the obvious, autonomy can no longer be an ethical priority when research subjects have diminishing and depleted autonomy, as is the situation with many SDAT patients. Society and its researchers share the

moral obligation to respect the SDAT subject's fundamental needs and to do no harm to these vulnerable individuals. In other words, moral agents have a moral duty to respect the claims of dependent moral subjects to have their welfare needs, and inviolable rights to dignity and integrity respected.

Concurrently society and researchers have an obligation to do good, grounded in the principle of beneficence, and to work toward reducing the macro and micro costs associated with SDAT. It is recommended that the resolution of society's dilemma of whose interests to rank higher, society's or the vulnerable subject's, is resolved by modifications to the consent process and the ethics of experimental design. Thus, the proposed resolution will widen the scope of SDAT research that can be permitted and hence increase the possibility of SDAT research advances, but not at the cost of seriously harming vulnerable and weak research subjects.

The thesis' philosophical approach is a mix of deontology and consequentialism. The foundation of the thesis is the understanding that man is defined in terms of his autonomy, and that social policies should be designed to protect and respect autonomy and its constituents. The instrumental goods of health, knowledge, universally accessible education and health care systems, a safe environment, and access to a legal system are the constituents of a society that supports the development and maintenance of individual autonomy. This point of departure for ethical

theory was also taken by Kant, Rawls, Engelhardt, Sumner and Hare. Furthermore, in the event that individuals lose their autonomy to some degree, social policies should be implemented to protect these individuals from harm, particularly when involved in research activities. Harm occurs when research subjects are treated merely and exclusively as means to an end.

Pursuing this view of human nature, a rational, autonomous moral agent should develop laws that treat vulnerable subjects in a manner that respects their dignity in the event that they became a dependent moral subject. (Readers will recognize, no doubt, the influence of Rawls' veil of ignorance in the remark). If moral agents did otherwise, it would be inconsistent and it would denigrate autonomous, moral agents. Protective mechanisms such as stringent research guidelines and a social policy supporting a minimum standard of treatment for the mentally impaired should prohibit SDAT patients from being reduced to mere experimental data and being treated merely as a means.

The same conclusion can be reached by some consequentialists. If the society is composed of autonomous agents, then the preservation and promotion of autonomy will enhance general well-being, and it could be argued that protecting weak members of the community promotes social good. From the acknowledgement, it would follow that there would be

obligations supported by conventional rules and social policies to protect SDAT patients in all relevant aspects of their lives, including if they became research subjects. For prudential reasons, the majority would appreciate the benefits for society when the disadvantaged members of the community are respected, as opposed to being exploited for the “benefit” of society.

However, the advantage of the deontological approach is that it acknowledges the intrinsic value of moral subjects. Hence, moral agents have an obligation to act non-maleficently to vulnerable individuals because of the individual’s characteristics. Thus, social policies designed to protect the vulnerable members of the community can be influenced by more than legitimate concerns about how those fortunate enough to enjoy good health today will be treated if they develop Alzheimer’s Disease. The difficulty with the consequentialist position is that the disadvantaged members of the community may be at the mercy of society’s agenda.

The examination of the ethical issues and a proposed resolution of the conflict between society’s and the SDAT subject’s needs will be advanced in several stages, each one corresponding to a chapter in the dissertation.

Chapter I: Identify the ethical issues, review previous work and define the key terms.

Chapter II: Discuss the value of health sciences research and the obstacles preventing these goals being realized in the field of SDAT research.

- Chapter III: Analyze the moral status of Alzheimer patients. Specifically, study the question of what rights, needs and/or interests have individuals (i.e. SDAT patients) with diminishing and depleted autonomy.
- Chapter IV: Examine the obligations of society and researchers to
(i) society in general, and
(ii) Alzheimer patients.
- Chapter V: Propose a resolution of the ethical issues based on modifications to the two pillars of ethical health sciences research: the ethics of experimental design and the consent process. The basis of the resolution is a re-thinking of the traditional way of classifying research and a conjunctive definition of the competency or the capacity to consent to research participation.
- Chapter VI: Summarize the investigation and respond to the specific issues and questions raised by the MRC and the International Summit conference presented in the introductory chapter.

The third, fourth and fifth chapters, constituting the theoretical heart of the thesis, deal with the central question of what rights, if any, SDAT subjects have. Also explored are the nature of society's and the research community's obligations to respect the interests of research subjects, and at the same time, respect the interests of the public who would benefit from research which contributes to reducing the social and economic costs of SDAT.

In chapter five a set of recommendations based on the conclusions reached regarding the involvement of SDAT patients in SDAT research is proposed. These guidelines could be useful to researchers and lawyers

when they are developing regulations and laws regarding the use of human subjects in SDAT research. It will be suggested that Alzheimer's Disease research does not warrant a special category of research regulations but amendments to current guidelines should provide this vulnerable population with sufficient protection.

Ratzan expressed a concern regarding the lack of research regulations to protect elderly research subjects, stating that "at this time there is a lack of guidelines to assist researchers and adequately protect a vulnerable group of human subjects".⁴² Thus, the proposed recommendations should answer this need in respect to SDAT patients. Also, the thesis' conclusions and proposed recommendations provide a way for further investigations to be conducted in the field of Alzheimer's Disease research but not at the expense of harming vulnerable members of society.

Notes

1. Throughout the thesis, his is used in the general sense, that is, referring to women and men.
2. I prefer to use the terms associated or involved with, as opposed to saying that Alzheimer's Disease patients are used in research. The latter term has connotations of exploitation and "objectifies" the research subject.
3. Cohen, C. AlzheimereRapport, vol.12, no. 2, July 1989, p.1
4. This data regarding incidence are provided by the Alzheimer Society of Canada. However, this data are based on information culled from the last Canadian census and could be an underestimate of the incidence. An epidemiological study of SDAT to be conducted across Canada, starting in 1991, will produce more sound data regarding incidence.
5. St. George Hyslop, P. Unpublished paper presented at the conference Legal and Ethical Issues in Alzheimer's Disease Research, held in Toronto, January 20, 1989. Quoted in The Globe and Mail, January 23, 1989, p. 9.
6. Information released by the Alzheimer's Society of Canada. Also, estimates of rate of incidence stated in the paper "The Occurrence of Alzheimer's Disease and Related Diseases in Canada: Rough estimates and Projections into the Future", by Dr. D. Smith quoted in the AlzheimereRapport, vol. 12, no. 2, July, 1989, p. 6.
7. Ibid., p.9.
8. The Globe and Mail, January 23, 1989, p. 9.
9. Throughout the thesis, the term mentally impaired as opposed to mentally incompetent is preferred because the former term is broader and is not a legal definition, as is mental incompetency. Mental impairment can refer to the loss of cognitive abilities which prohibit the individual from conducting tasks ranging from complex to simple and therefore, the term should be qualified. Unless otherwise indicated, in this thesis, a mentally impaired individual refers to someone who is dependent on others for his

safety and welfare. Thus, he would be unable to consent to research participation or to receive medical treatment.

10. Medical Research Council of Canada. Guidelines for Research Involving Human Subjects (hereafter referred to as the Guidelines). Ottawa, 1987, p. 29.

11. Ibid., p. 29.

12. I am indebted to Dr. J. Thomas for conceptualizing the requirements for health sciences research in this manner.

13. Guidelines, p. 31.

14. Mace, N. Thirty-Six Hour Day Johns Hopkins University Press, Baltimore, 1981.

15. Ibid., p. 31.

16. Research which investigates causes and prevention of SDAT is being conducted despite the MRC's recommendations and Canadian legal statutes. Two points can be made about this anomaly. The fact that laws are not observed is not sufficient reason to abandon the recommendations. Instead, it is necessary to investigate what guidelines are needed to address ethical and clinical issues. Secondly, the lack of "teeth" to back up the MRC's recommendations is being addressed by the Law Reform Commission's study of the use of vulnerable individuals in medical research which will be discussed in the thesis.

17. Proceedings, Toward an International Ethic For Research With Human Beings. Medical Research Council Of Canada. Ottawa, 1987, p. 30.

18. Karlinsky, H., Lennox, S. Unpublished Paper. "Clinical Issues in Assessing Competency of Alzheimer's Disease Patients".

19. Ibid., pp. 10-11.

20. Guidelines, p. 7.

21. Ibid., p. 8.

22. Guidelines, p. 7.

23. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research: Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, Washington, DHEW Publication No. (OS) 78-0012, 1978. Hereafter called the Belmont Report.
24. Ibid., pp. 2-3
25. Ibid., p. 9.
26. The Nuremberg Code is reprinted in Medical Ethics and Human Life, by J.E. Thomas, pp. 310-320. Quotations from the Nuremberg Code will be identified by use of the notation system used by the Code.
27. World Medical Association Declaration of Helsinki reprinted in Medical Ethics and Human Life by J.E. Thomas, pp. 321-322. Quotations will be identified by using the notation system of the Declaration.
28. Ibid., II: 1.
29. Ibid., III:1.
30. Thomas, J.E., Waluchow, W. Well and Good. First Edition, Broadview Press Ltd., 1987, p. 104.
31. Ibid., p. 105-106.
32. Ratzan, R., "Being Old Makes You Different". Hastings Center Report, October, 1980, p. 43.
33. Melnick, V. Dubler, N. et al. "Clinical Research in Dementia of the Alzheimer Type: Suggested Guidelines addressing Ethical and Legal names". Journal of the American Geriatric Society, July, vol. 32 (7) pp. 531-536.
34. Melnick V., Dubler, N. (editors) Alzheimer's Dementia: Dilemmas in Clinical Research. Humana Press, Clifton, New York, 1985
35. Op. cit., p. 533.
36. Ibid. p. 533
37. Ibid., p. 533.
38. Ibid., p. 534.

39. Ibid., p. 535.
40. Ibid., p. 535
41. Ratzan, R. "Being Old Makes You Different". supra note 32.
42. Ibid., p. 44. .

Chapter II

Health Sciences Research as a Means to Achieve Social Good

2.1 Introduction:

During the past few years, the “purist” view of science - as a strictly autonomous intellectual enterprise, insulated against the influence of all merely human needs, wishes, and preferences has lost its last shreds of plausibility. Whether we consider the basic concepts of the sciences, the collective enterprises of professional science, or the personal commitments and motivations of individual sciences, we can maintain a strictly value-free (or rather, ethics-free) position only by sticking arbitrarily to one extreme end of that long spectrum.

S. Toulmin¹

Traditionally, the freedom of the researcher to pursue new knowledge is a cherished, western value. However, in the pursuit of knowledge there is a tension between the freedom to conduct research and the need to respect individuals. A high standard is expected of the researchers both in terms of work and results. Health sciences research is scientific enquiry which has to be conducted by competent investigators, in an efficient manner, following an established method, in order to gain

knowledge that can be directed at improving the health status of individuals and the community.

Health sciences research is an instrument for promoting social good and change. An individual's quality of life and the community well-being can be improved as a result of knowledge discovered by health sciences researchers. Also, human subjects can be harmed when involved with a study yielding important or trivial information. Thus, there are regulations regarding the way that research involving human subjects can be conducted.

The objective of this chapter is to first, discuss the values and goals of health sciences research, and second, to explain why Alzheimer's Disease research is frustrated in its attempts to realize these noble ends. The chapter is divided into three sections. In part I, the values and goals of health sciences research will be discussed briefly. The following section will examine the hybrid activity of innovative therapy, and it will be argued that innovative therapy is poorly designed and unregulated research which should be required to meet the criteria of ethical experimental design. The final section will examine the status quo in respect to SDAT research, and thus the ethical and clinical problems will be clarified. An analysis of the Medical Research Council's Guidelines, and the Eve case will illustrate the

impasse facing SDAT researchers when the research is non-therapeutic and needs to recruit mentally-impaired research subjects.

2.2: The Goals and Values of Health Sciences Research.

The time-honoured belief that medicine is engaged in promoting the welfare of people and that research is necessary to this process, is generally accepted. Nevertheless, society is now more aware of the perils inherent to experimentation and is not willing to endorse medical research which is not ethically justified. Experimental medicine entails profound responsibilities which cannot be solely left to the judgement of persons assigned to it. It is clear that research with human subjects must be constantly confronted with bioethical principles.

P. Fasella and U. Bertazzoni²

Science is systematic and formulated knowledge. The goal of science is the attainment of knowledge and increased understanding of the world. This search for knowledge is conducted using an established methodology, called the scientific method. Bernard Barber considers the desire to know to be an innate part of man's nature as a rational being. He writes "...that the germ of science in human society lies in man's aboriginal and unceasing attempt to understand and control the world in which he lives by the use of rational thought and activity".³ The goals are of two kinds. First, there is the global goal of improved knowledge and control of

the environment or particular situation. Second, there is a concrete or topic-specific finding which can be used to predict events, and in some cases, have practical applications.

The MRC states that medical research (health sciences research) “should be a deliberate and careful step into the unknown” and that research is “the generation of data about persons, through interventions or otherwise, that goes on beyond that necessary for the individual person’s immediate well-being”.⁴ Health sciences research being a form of scientific enquiry has a process and a product. The process is the scientific method and the product is evidence which can be used to improve health care. The goal of health sciences research, sometimes called clinical research, is to improve the health status of a target population by reducing morbidity and mortality rates. Also, when the patients are chronically and terminally ill (i.e. SDAT patients), the goal can be improving palliative care by focusing on improving management strategies, and maintaining or improving the patient’s quality of their life, as opposed to curing patients.

More specifically, gerontological health sciences research aims to learn more about the aging process in a variety of contexts. The knowledge gained is applied to maintain or enhance the elderly individual and his caregivers’ quality of life. This field of enquiry is multi-disciplinary, drawing from the health, natural and social sciences. In addition to

studying disease processes in the elderly, such as SDAT, and therapeutic interventions, gerontological research investigates many topics including the determinants of health: housing, transportation, income, environmental factors, degree of independence, and communication.

Modern scientific research, which includes health sciences research, has imposed upon itself a process and a discipline called the scientific method, in order to ensure that the knowledge acquired is logical, valid, based upon sound evidence, can be used to predict behaviour, and can be replicated. The term "method" originates in the two Greek words *meta*, meaning along, and *hodos*, meaning way. Thus, method means "following a way" or an established series of steps in a specific order to achieve a certain end. Also, the scientific method can be understood to be a formal structure having the function of organizing thinking and investigations in an orderly fashion that will yield results that can be evaluated and replicated by other investigators.

Methodology is not a restrictive harness for thinking, but a means of conducting an investigation in a manner that welds together the particular needs of the inquiry and the demands of science for valid and logical results. Hence, health sciences research follows the strict requirements demanded of the scientific method. In addition, the design of the experiment must respect the criteria for an ethical experiment design.

Research must adhere to regulations that ensure that the experiment has an ethical design.⁵

- i) *Either* genuine promise of treatment where none presently exists, *or* genuine doubt about the efficacy of the present treatment where it does not exist.
- (ii) a clearly formulated hypothesis of the form: "If we wish result x, and procedure y is a means to its probable achievement, then do y".
- (iii) a protocol calculated to confirm/refute the hypothesis.
- (iv) favourable risk-benefit ratio.
- (v) monitoring of research.
- (vi) researcher should *not* be the person recruiting subjects.
- (vii) evaluation.

The product of health sciences research is knowledge or data which contributes to improving or enhancing the well-being of individuals which consequently has positive impacts throughout the community. For instance, the recent advances in cystic fibrosis (CF) by a team of investigators in Toronto holds promise of direct benefits for CF patients and their families. Also, the reduction in mortality and morbidity rates associated with CF and the attendant social and financial costs will have benefits at the macro level. Hence, health sciences research is a value-laden activity, as the characterization of its goals as beneficial for individuals and society indicates. In the process of conducting research, human subjects are

required and the product of knowledge is used to assist directly and/or indirectly individuals and communities in general. The entire enterprise of conducting health sciences research is influenced and grounded in ethical principles of respect for persons and self-determinism (autonomy), not harming others (non-maleficence), benefiting others (beneficence), maximizing benefit (utility), and justice.

Health sciences research is goal-directed, and the goal is designated “good”. The good that is being sought by researchers is health and improving the health status of individuals and society. Mill refers to health in Utilitarianism “as means to a collective something termed happiness, and to be desired on that account. They (referring to any given pleasure) are desired and desirable in and for themselves: beside being means, they are a part of the end”.⁶ Thus, from the perspective of medical interventions, health is viewed as a good in itself, but relative to patients, it is an instrumental good, a means to the realization of other values prized by individuals. In summary, the goals of research are to increase knowledge, improve individual well-being and promote society’s welfare. Thus, research is grounded in consequentialism.

Health sciences is value-laden because its *raison d’être* is the promotion of human well-being. Because of the high value placed on autonomy, research must respect and promote autonomy. By means of the

scientific method, health sciences research strives to acquire knowledge that will contribute to promoting individual well-being and the social good. For example, the aim of Alzheimer's Disease research is to alleviate the suffering of SDAT patients, to learn more about the causes and prevention of the SDAT, and to establish prevention programmes. In philosophical terms, the goals are promoting and/or preserving individual well-being of which autonomy is a central feature.

The principles of respect for person, justice and non-maleficence impose side constraints on research. The research's design and the requirement for a valid consent work together to ensure that research's goal is not attained at the cost of disrespecting the integrity and dignity of human subjects, and secondly, that the costs of being a research subject are not unfairly borne by convenient pools of subjects. The regulations regarding the consent process and research design can make the research process more costly in terms of human and financial resources but they are necessary to protect research subjects.

A balance between the process and the product or goals of research is necessary. Otherwise, conducting the research as efficiently and promptly as possible could be at great human costs. To protect human subjects and to assist researchers, codes of research ethics requiring a valid consent from all research subjects or their surrogates, and a sound ethical

experimental design have been developed. Respect for self-determinism, non-maleficence and justice expressed in the requirement for a valid consent and an ethical design tempers the pursuit of knowledge by promoting respect for others and a fair distribution of the benefit and risk of the research. The MRC makes an important association between those who are at risk and those who will receive potential benefits from the proposed research. Human subjects “should carry greater weight (of risk) if the anticipated results can apply directly to the treatment of the subjects themselves”.⁷ Therefore, the reviewers should consider the group from whom subjects will be drawn and who will benefit. The closer the association, the better. The justification of exposing a subject to harm is strongest when the subject is a member of a group who will not only bear the risks but may benefit from the findings. This precaution protects vulnerable groups who could be selected primarily because of their availability and will have implications for SDAT patients who have little to gain from being research subjects, because SDAT is both a terminal and chronic disease.

There is a close relationship between health sciences research and society, each party influencing the other. The results of health sciences research can have a positive effect upon individuals and the entire society, and can be used to improve general well-being. In this sense, health

sciences research promotes social change. For instance, the discovery of the Salk vaccine which led to a drastic decrease in the incidence of polio had far-ranging benefits throughout society. Also, research investigating the determinants of health (for instance, the impact of housing and poverty on the health and independence of the elderly) could lead to changes in social welfare policies that could impact on the elderly population, and, in turn, on society as a whole. Furthermore, society or perhaps more accurately public opinion-makers including the media, can influence the direction of health sciences research.⁸

Society and its members have several roles in respect to research which illustrate the system-like relationship between society and health science research. Dunstan discussed this relationship in his paper “The Role of the Public”, presented at the International Summit Conference on Bioethics. Dunstan proposes that the public has four major roles stating “It stands as a potential beneficiary. It risks being a victim. It has influence as a determinant of policy. It is increasingly a participant in decision”.⁹ In place of the public, I prefer to discuss these issues in terms of the responsibilities of the individual and society. The individual as a beneficiary is a common concept and norm in research. However, the society also has a large interest in research improving the individual and general well-being. Learning more about the prevention and

management of Alzheimer's Disease would have an immense positive impact on society.

Dunstan also proposes that the subjects and society can be victims when the researcher does not follow established codes of conduct and fails to respect values cherished by the community. Researchers failing to inform subjects of the harms and benefits of a research are behaving in a manner that violates research codes by not respecting the subject's autonomy. This is unethical and is not the way to encourage other individuals to be subjects. However, with consent and co-operation, "the research project and the common good stand to gain", states Dunstan.¹⁰

The idea that individuals can be a determinant of public policy is entrenched in the concept of liberal, western democracies. The ideal is that the members of a community are permitted to influence public policy through various channels of communication between the community and the policy makers. Unfortunately, what has happened is that charities compete with each other to receive scarce funding for research. Thus, the charity or organization with access to and influence with decision-makers (often gained through lobbyists) has an advantage over a competitor with less resources.

The fourth role is as a participant. The most important way of participating is to volunteer to be a research subject, as opposed to being

“volunteered”. The commitment from subjects can be considerable, requiring participation over a long period of time in some instances. The MRC recommends strongly that Research Ethics Boards have lay members, allowing another important way for individuals to participate in research.

2.3 Innovative Research or Therapy:

Come, let us go down there and confuse
their speech, so that they will not under-
stand what they say to one another.....

Genesis 11:5-6

In chapter one, research and therapy were defined and the differences between these two distinct activities were discussed. Effective therapies are interventions demonstrated by means of health sciences research, to be effective and reliable methods of ameliorating or curing the patient's disease or ill-health. In some circumstances, therapy serves to make the patient comfortable by providing palliative care. Research's goal is to acquire new information that may be used to develop or improve effective therapeutic interventions.

The Medical Research Council of Canada acknowledges that there can be an “the intersection of therapy and research”. There are three

possible ways of understanding and classifying this “intersection of research and therapy”. Such interventions may be designated:

- (i) “innovative” therapy
- (ii) “experimental” therapy
- (iii) health sciences research

The major purpose of this sub-section is to establish that when therapy and research are mixed together, the intervention is more accurately designated as experimental than therapeutic. Thus, I am disputing the MRC’s claim that interventions combining elements of research and therapy are therapy and also that a new hybrid form of therapy be accepted as a bona fide therapeutic intervention. The second purpose of this section is to show that “innovative” and “experimental” interventions are unregulated research because the investigator is not required to meet the usual stringent regulations governing research design and the consent process. Furthermore, the experiment is not reviewed by an REB.

The nature and purpose of this type of patient-subject intervention needs to be established. Otherwise, there is confusion about what type of intervention the patient-subject is receiving which can have serious consequences for all interested parties, including patients, subjects, investigators and health care professionals. Before defending the position

that this hybrid activity is research, it will be useful to locate the practice in a context in order to appreciate the health care professionals' penchant for "innovative" and "experimental" procedures. Then, it will be apparent that the use of these procedures is self-perpetuating and will not be reduced unless measures are taken to address the reasons why well-intentioned health care professionals employ "innovative" and "experimental" interventions. In a sentence, they are used because therapies known to be effective and reliable in similar situations are not available. The health care professional is in a catch 22 situation. An effective intervention for an elderly patient is not known because of the paucity of investigations involving the geriatric and SDAT populations. Usually, clinical trials and other research studies employ subjects in younger age groups and frequently, the conclusions can not be extrapolated to an older population.

An example will illustrate how research and therapy can intersect and why health care professionals resort to using "experimental" and "innovative" interventions. Doctor Dogood's patient Mrs. Moody has a long history of depression but recently her condition has deteriorated and she has become confused and forgetful. Her physician is puzzled: is she developing SDAT or is her depression presenting as dementia (pseudodementia)? To eliminate the possibility she has SDAT as opposed to depression which can be treated, Dr. Dogood tries her on a series of anti-

depressants but her mood and behaviour remain unchanged. He reads about a new anti-depressant medication which has had impressive results with a younger population but there is little known about its efficacy and side effects with the geriatric population because elderly individuals were not included in the clinical trial. Dr. Dogood decides to put her on a trial of the new medication because he wants to do all that he can to establish that she does not have SDAT and to treat her depression. Is Dr. Dogood offering the patient an “innovative” or “experimental” therapy, or is he conducting an experiment? In this following section, it will be argued that the intervention is experimental.

a) The Fallacy of “Innovative and “Experimental” Therapy:

The first step in demonstrating that the intersection of research and therapy is research, is to present the position of the Medical Research Council. The Council states that “The interaction of therapy and research must be carefully considered. Although separate domains, often the two overlap in human experimentation and perhaps here, more than anywhere else, is the integrity of the physician-researcher tested”.¹¹ The MRC recommends that this interactive type of procedure be considered therapy because this manoeuvre will provide the patient with the maximum

protection of his best interests. The major problem with the MRC's position is that it is a verbal sleight of hand and merely an assertion.

Both "innovative" and "experimental" therapy are misnomers because the interventions which could be innovative and experimental, are not known to be therapeutic. Nevertheless, the MRC states that these practices are considered therapeutic for two related reasons:

- (i) they are provided by a health care professional, and
- (ii) the health care professional's code of ethics demands that he rank avoiding harm and doing good for the patient above acquiring new knowledge.

Thus, the fact that the intervention is given by a health care professional and the motive and ethical priority of the health care professional determines whether the act is therapeutic or not. Hence, in the case of Dr. Dogood although he is testing the effectiveness of the medication because he is a health care professional and his goal is to do good, the intervention would be considered to be therapeutic.

The problem with the MRC's position is that neither the profession of the person providing the intervention nor his commitment to act in the patient's best interests determines that the intervention is therapeutic. The MRC is looking at the issue through the wrong end of the microscope: it is not the profession and the ethical priorities of the person performing the procedures which determines the nature of the activity. Instead, it should

be the method, nature and purpose of the activity that establishes whether the intervention is therapy or research.

Granted that both an investigator and the health care professional have a moral obligation to do good, what the good is and the process of realizing the good are different in both cases. A procedure is therapeutic when it has been tested and it has been established retrospectively that the intervention is effective and reliable. In other words, an intervention is therapeutic when it has been determined by means of health sciences research to have a reasonable chance of effectively improving or curing the patient's ill-health or disease when used in situations similar to the conditions under which the procedure was evaluated and found to be reliable. Research is concerned with testing an intervention but therapeutic practices have already been tested.

Research is the life-line of therapy. The purpose of research is to discover and/or improve therapeutic interventions and thus establish that the intervention has "a reasonable expectation of success".¹² Without the work of clinical investigators, the health care professional cannot fulfil his obligation to do no harm and to do good. The use of a new intervention exposes the patient-subject to an unknown risk which is contrary to the health care professional's duty to avoid harming his patients. An intervention can be new in two senses. First, the practice has not been

tried before and there is little if any evidence regarding its efficacy. Or, the intervention has been tested and found to be effective under different circumstances. Thus, when the intervention is used under novel conditions (perhaps with a different age group), then it is a new or novel intervention.

The MRC distinguishes between therapy and research in the following manner: "The goals of the practice of medicine is to treat the patient and always to act in the best interests of the patient. The researcher's goals are to obtain new information and to answer the research question".¹³ Research differs from therapy in four ways: (i) its purpose, (ii) method, (iii) by whom it is conducted and (iv) relevant code of ethics.

The goal of health sciences research is to acquire new information that can be applied, at some time, to improve the health of affected individuals. In the important work Ethics and the Regulation of Clinical Research, Levine defines research as follows:

The term "research" refers to a class of activities designed to develop or contribute to generalizable knowledge. Generalizable knowledge consists of theories, principles, or relationships (or the accumulation of data on which they may be based) that can be corroborated by accepted scientific observations and inference.¹⁴

In contrast, Levine considers that the practice of medicine "refers to a class of activities designed solely to enhance the well-being of an individual or

client”.¹⁵ After the health care professional makes a diagnosis and discusses treatment options with the patient, “if the patient agrees, measures of therapy in the best interest of the patient are then undertaken” states the MRC.¹⁶ The health care professional’s priority is the patient’s welfare and thus, continues the Council, “Decisions taken must respect the patient’s interest first. In the Committee’s view, it is axiomatic that the treating physician’s duty to act in the best interest of the ill patient must never be compromised”.¹⁷ However, the investigator’s priority is to answer the research question posed and acquire new information.

The method of health sciences research is that of the scientific method: a hypothesis is proposed regarding the therapeutic value of the intervention in a specific situation and the experiment confirms or disconfirms the hypothesis. Information acquired sheds light on the specific situation and could be extrapolated to other situations. In research “the investigator has identified a research question and conceived a research protocol to attempt to answer it. The commitment here is to answer the research question”, states the MRC.

The experiment, by definition, is conducted by a researcher whose goal is to answer a research question. In the process, the subject could benefit directly but this would be a gratuitous benefit. The investigators can be health care professionals, epidemiologists, social scientists and

members of allied health professions. The fourth distinguishing characteristic is that research is guided by regulations specifically governing research as opposed to therapy. For example, the MRC's Guidelines, the Nuremberg Code, the Helsinki Declaration and other research codes make recommendations regarding subject selection, research design and the consent process. The regulations should protect the subject from being associated with research lacking a sound ethical design and being harmed in the enthusiasm to acquire new information. Thus, research guidelines expressing ethical priorities and the values of western, liberal jurisdictions should serve to protect the subject's autonomy and welfare.

The MRC reminds us that therapeutic interventions are used by qualified health care professionals whose ethical priorities, based on the Hippocratic Oath are to do no harm (non-maleficence) and to do good (beneficence). However, they are mistaken when they reason that these innovative practices are therapeutic because they are offered by a health care professional.¹⁸ In order for a health care professional to fulfil his obligation to act in the best interest of his patient he must (i) be armed with an intervention that has been tested and found to be safe and effective, and (ii) have a valid consent from the patient in respect to the proposed therapeutic intervention. In the case of "innovative" and "experimental" therapy both requirements are not met. First, the health care professional

does not know if the intervention has a “reasonable expectation of success” determined by means of clinical research. When the intervention offered is new or secondly, is a familiar practice used in a novel manner, the intervention is experimental because its effectiveness in the given situation is not established. Thus, Dr. Dogood was conducting an experiment when he tried Mrs. Moody on the new medication. His clinical judgement told him that there was a chance that the medication would be effective and considering his limited options, he decided to try her on the medication. He was testing the medication as opposed to using a tested intervention found to be effective and reliable under similar conditions. Hence, he was conducting an experiment with a sample size of one because he did not know if the medication had a reasonable chance of success with an elderly patient. Furthermore, the intervention remains experimental even if his clinical judgement was proven right and the medication assisted Mrs. Moody.

Regarding the requirement for a valid consent, this requirement has not been met because the patient is not informed that his principal role is to be a subject in an investigation, as opposed to being a patient receiving a tested, therapeutic intervention. When a subject is treated like a patient, a valid consent for research participation can not be obtained and the

patient-subject's autonomy has been over-ruled by the health care professional's wish to assist the patient-subject.

b) "Innovative" and "Experimental" Therapy: Unregulated Research

There are a number of consequences when "innovative" and "experimental" therapy is considered to be therapy when it is research. First, the relations between the patient and the health care professional, and also between the subject and the researcher are confused or obscured.

The health care professional and the researcher cannot meet their respective obligations to patients and subjects. In using an experimental procedure, the health care professional exposes the subject-patient to risk and hence, could be doing harm. The safety and welfare of the subject is threatened when the patient receives an intervention whose effectiveness and reliability in the given situation has not been established.

Furthermore, the subject's autonomy is not respected which also contributes to sabotaging the patient-health care provider relationship.

The second consequence is that patients are subjects in research that is unregulated. In most cases, "innovative" and "experimental" therapy has not met the criteria of an ethically designed research study and the requirement for a valid consent has not been met. Unless the research's design is ethically and scientifically sound, the research will not produce the

type of evidence needed to determine whether the intervention is effective and reliable. For instance, the research could have a small sample size (perhaps as small as one) and therefore, would not yield enough data to produce statistically significant results. Poorly designed research does not respect the subject and can place the patient-subject at risk, without his consent. The risk-benefit ratio could be unfavourable and these risks could be considerable: he will be the recipient of an intervention that is untested and of unestablished efficacy. Also, all the subjects could be from a captured population, for instance, all of the SDAT patients on a specific nursing unit. In addition to “innovative” and “experimental” procedures not having to meet the requirements of an ethical design and obtain a valid, appropriate consent from the subject, the experiment has not been reviewed by an Ethics Research Board.

A major source of confusion regarding the classification of “innovative” or “experimental” therapy is the merging of the roles of health care professional and investigator. When the health care professional wears two hats, that of researcher and health care provider, there is a conflict between the respective goals, responsibilities and ethical priorities. In addition, there are two or more regulatory bodies governing his conduct and these codes can be in disagreement. It is important that the procedure be correctly classified, in order that the appropriate ethical priorities and

guidelines prevail. If the right match does not occur, the patient-subject is at risk of being harmed and his autonomy disrespected. Also, when the roles are combined, coercion is often present and thus, it is difficult to obtain a valid consent. The MRC identifies that institutionalized mentally impaired patients are at risk of being coerced because the social milieu encourages conformity and "they may also be induced by the promise of advantages to which those in free circumstances would not respond". However, the problem is exacerbated when the researcher is also a member of the treatment team. They may be induced by the worry of the cost of refusing when they are so heavily dependent on the health care system. For example, when the health care professional asking the family to consent to their father being a research subject, also has a major role in deciding whether their father can be transferred to an institution closer to their home (making it easier for them to visit him), the majority of families would feel pressured to consent.

It is imperative that interventions with patients and subjects be correctly identified in order that the autonomy of patients and subjects be respected, and that they be protected from activities with an unfavourable risk-benefit ratio. Also, the clarification will assist health care professionals and investigators sort out their ethical priorities when, as is often the case, they have a foot in the camp of clinical research and also, of the treatment

team. When research is mistaken for therapy and vice versa, the relevant ethical priorities and codes of practice are obscure or confused. Thus, the players can be playing according to the wrong set of rules which can be a costly mistake for all concerned. Patients could be deprived of receiving an effective and reliable therapeutic intervention and research subjects are denied the opportunity to consent or refuse to be a research subject. The health care professional is frustrated in his attempt to honour his primary obligations to the patient, to do no harm, because he is using an intervention whose efficacy has not been established previously by means of research.

To conclude, the purpose and nature of research and therapy are different, and “innovative” and “experimental” interventions are research. Also, the role of health care professional and investigator, and also patient and subject should remain distinct. These practices and roles should remain differentiated to protect the well-being of both patients and subjects and to assist researchers and health care professionals to honour their respective obligations to patients and subjects. In the realm of SDAT research, the need to clarify and maintain the distinctions in roles is heightened because prospective subjects can not be relied on to differentiate between research and therapy. Also, given that surrogates often provide consent for both research and therapy, it is important to correctly identify

the nature of the activity, because if the intervention is experimental, under current guidelines surrogates can not consent for mentally impaired patients to be subjects in non-therapeutic research. Thus, classifying research as therapy can be an “end run” around current research restrictions preventing mentally impaired patients from being subjects in non-therapeutic research.

The catch 22 position of the health care professional trying to assist patients and turning, with good intentions, to experimental measures has not yet been resolved. Ethical and practical problems associated with research design and the consent process make it difficult to recruit elderly and/or mentally impaired subjects. Undeniably the researcher and the health care professionals are in a difficult position and are frustrated in realizing their respective goals of learning more about SDAT and providing effective and reliable treatment. Unless there are changes in research ethics there is little chance of this “vicious circle” being broken. In chapters four and five, a possible resolution of the ethical problems blocking conducting some types of SDAT research will be proposed.

2.4 The Status Quo: Current Ethical and Legal Rules Regarding Use of Mentally Impaired and Incompetent Human Subjects

Both legislation and codes of ethics addressing the use of human subjects written after World War II have supported the liberal, humanitarian ideal that society's interests do not justify unbridled medical research. In the words of the Canadian Law Reform Commission's working paper Biomedical Research Involving Human Subjects, "unrestricted human experimentation cannot be allowed solely on the basis of general social utility. For experimentation to be legitimate, it must be accompanied by safeguards to ensure respect for the person".¹⁹

Although international and national codes of research ethics cannot be enforced through the courts, they are important for their symbolic value because they express moral ideals. Also, they are important because they lay down conventional guidelines of conduct for the research community. Although there are a number of research codes of ethics and legislation in several jurisdictions, there is disagreement about the use of mentally incompetent subjects. However, in some countries, including Canada, there are statutes and legislation which provide individuals with legal protection relevant to the research context. In Canada, the legal documents take the position that medical research must not rank social good over the interests and rights of research subjects.

Canadian law has two types of documents in respect to regulating human experimentation. First, federal and provincial legislation designate

some types of research interventions as illegal. Also, there are codes of research ethics, such as the MRC's Guidelines, which, though not legally binding, play an important normative role because they enjoin a standard of conventional behaviour appropriate for medical investigators.

In this section, the codes of medical ethics and the legislation to protect vulnerable research subjects will be reviewed. Contradictions, unresolved issues, ambiguities, and lack of direction will be identified. In the following chapters, ways of addressing these difficulties with the status quo will be studied.

The first response to the types of human experimentation conducted by the Nazis was the Nuremberg Code of 1947, which recommended that only subjects who could provide direct consent should be involved in medical research. Under this condition, the majority of Alzheimer's Disease research requiring the use of human subjects would not be permitted. However, subsequent codes of research ethics have permitted mentally incompetent individuals to be associated with medical research under strict conditions. The Helsinki Declaration of 1964, adopted by the World Medical Association, and which was reviewed in Tokyo in 1975 and again in Venice in 1983, is the most widely accepted, international document governing the use of human subjects. This document states that mentally incompetent subjects may be associated with clinical research combined with professional care (therapeutic research) and non-therapeutic

clinical research on condition that a valid surrogate consent is obtained from a legal guardian. Both the competent subject's and the surrogate's consent must meet the same criteria for a valid consent. Special cases such as research subjects with SDAT and paediatric research are not dealt with explicitly in the Helsinki Declaration.

Another international document, the International Covenant on Civil and Political Rights adopted by the United Nations in 1966 and ratified by Canada and other nations, prohibits medical research which has the potential of harming the subject, and recommends that a valid consent be obtained from the subject. A pertinent passage from the documents states:

No one shall be subjected to torture or cruel, inhuman or degrading treatment or punishment. In particular, no one shall be subjected without his free consent to medical or scientific experimentation.²⁰

Again the emphasis is on respecting individual autonomy and the obtaining of a valid, freely-given consent, and also on prohibiting research which will seriously physically and psychologically harm the subject. However, no mention is made of special categories of subjects.

There is some disagreement among foreign research documents about whether mentally-impaired individuals should be subjects in non-therapeutic research. The Nuremberg Code only permits subjects to consent

to their own participation. Consequently, indirect consent is not permitted, and therefore mentally-impaired individuals cannot be research subjects. However, the Helsinki Declaration (Article 11) allows experimentation on a mentally-impaired individual if a valid consent is secured from a surrogate in accordance with local legislation. The Council of Europe's Committee of Ministers took a protectionist stand and recommended that all non-therapeutic research on individuals with mental disorders be prohibited²¹.

Likewise, the Be'mont Report focuses on the question of who decides for the mentally-impaired, and on whether involving the mentally-impaired in non-therapeutic research is permitted. The Report favours legalizing the use of the mentally-impaired in all types of research. (The Report does not recognize the distinction between therapeutic and non-therapeutic research). Recognizing the vulnerability of the mentally impaired, the Report recommended that research involving this population can only occur if the research exposes the subject to no more-than-minimal risk. Regarding who should decide, the Report recommends that a valid consent from subject or surrogate be obtained. However, if the research is of great importance, and it is not possible to secure a third-party consent for research which is not classified as more-than-minimal risk, the investigator is permitted to waive the requirement of a valid consent. The Report bases its recommendations on the consequentialist argument that the costs of not

conducting this research can be higher than not permitting research with mentally-impaired research subjects.

In France and Quebec, a strong position has been taken against conducting any research involving the mentally-impaired. The Law Reform Commission refers to a recent decision made by the French National Ethics Committee in response to a researcher using a patient in a state of brain death as a subject. The French body stated that it is unethical to involve patients in research not directly associated with their illness, and surrogate consent is not acceptable in these cases. Thus, the protectionist position taken, prohibiting the involvement of the mentally-impaired in non-therapeutic research agrees with the MRC's position on the same issue. In addition, the French Conseil d'Etat has stated that it favours an absolute prohibition of non-therapeutic research on mentally-impaired individuals²². To date, Canadian authorities have not made such a strong statement despite their agreement in principle with the French position.

The Quebec Civil Code in article 20 excludes, categorically, mentally disabled individuals from the class of persons who can participate in medical research. However, article 18 does permit medical research on such people on condition that (1) consent is obtained from the court and surrogate and (2) the expected risk is not disproportionate to the expected benefits. Yet article 20 states that the courts should only approve of

applications to involve mentally-impaired individuals in research if the research is “in the interest of the person concerned”.

The Guidelines discuss two classes of legally incompetent individuals: children and mentally incompetent adults. Some of the recommendations for paediatric research apply to mentally incompetent adults. In addition, the MRC Guidelines do have a separate section entitled “Research Involving Mentally-Incompetent Adults” in which problems peculiar to SDAT research are discussed. The Guidelines identify some of the ethical problems associated with SDAT research which fall into two categories: (i) consent mechanism and (ii) research design. For instance, in some cases the protocol could expose the subject to uncomfortable and more-than-minimal risk interventions without offering them any potential benefit. Also, the subject will be unable to provide a valid consent in most instances, because of impaired cognitive functioning.

The problem with obtaining a valid consent from a mentally incompetent individual arises because the individual lacks sufficient autonomy. In the words of the Guidelines, “By definition, a legally incompetent subject is not autonomous and cannot give a legally or ethically valid consent”.²³ If third-party consent was obtained for the use of a mentally incompetent individual for non-therapeutic research, different ethical issues are raised. These are described by the MRC as follows:

Research involving incompetent subjects therefore may raise conflicts on legal and ethical grounds. Strictly interpreted, the law of common assault and the principles of common law preserving autonomy and requiring consent may be seen as proscribing subjecting these people to risks of harm not undertaken in their immediate interest. The great problem for society is that any hope of progress in prevention, diagnosis and treatment of these processes that give rise to the incompetence require research on these same people.²⁴

The types of research that parents and other third parties may consent to on behalf of their wards is a matter of serious ethical and legal concern. The Guidelines state that if present therapeutic measures are to be improved or new measures discovered, subjects will have to be drawn from the population of legally incompetent individuals. Questions then arise as to what types of research mentally-impaired individuals may be allowed to participate in, and how a valid consent is to be procured? The MRC gives a mixed message. While they agree that mentally incompetent individuals can be associated with medical research for utilitarian reasons, they also advise that mentally incompetent subjects should only be subjects for therapeutic but not non-therapeutic research. Thus, they have erected a barrier on one avenue to learning more about the disease and also improving and/or discovering SDAT interventions. Taking the cautious route (when in doubt, seek a surrogate) does not eliminate all of the problems, because the MRC advises restricting the surrogate's jurisdiction

to consent for therapeutic research. In respect to third-party consent for SDAT research, the Guidelines state:

Their guardians, whether *de jure* guardians properly appointed, or *de facto* guardians such as family members, may not have the legal power to give effective consent to invasive procedures. Indeed, mentally and physically disabled persons' legal protections are strengthened under the Canadian Charter of Rights and Freedoms, reducing the likelihood that provincial public hospital, mental-health or mental incompetency legislation would be construed to allow such research not related to therapy. Rights to integrity of the mentally disabled protected by law and the Charter cannot be reduced or compromised simply upon the basis of decisions of Research Ethics Boards; only courts have the authority to approve invasive forms of management, and to say what consent process will be adequate for invasive non-therapeutic procedures.²⁵

The Law Reform Commission is critical of MRC's recommendation made with respect to research involving mentally incompetent adults stating, "The Medical Research Council of Canada has never taken a clear position on the issue.Like the French National Ethics Committee, the Council, in view of the Canadian Charter of Rights and Freedoms, questions the legality of consent by another in these cases. Can the right to integrity be, in effect, subject to waiver by a third party? The Council seems prepared to acknowledge only research involving no risk, but its position remains unclear".²⁶

The Law Reform Commission is making two points. Regarding permitting the prospective subject to provide consent if he has “the necessary capacity and understanding”, they have a valid point. There is a need to move from global competency and incompetency to factual competency and the Commission is correct in choosing to emphasize that competency should be assessed in respect to a specific task. It is encouraging that the Commission has taken this progressive position. If the subject did have a good understanding of the request being made, then he should be deemed competent to perform the task of providing consent to participation in a research study. In the following section the concept of competency will be discussed in more detail and it will be argued that the global model should be replaced by the factual model of competency.

The second point refers to the matter at hand: can surrogates recruit their mentally incompetent wards to be involved in non-therapeutic research? According to the Commission’s reading, the right to integrity contains the right to be protected from unnecessary harm, and they contend that the MRC equivocates on this issue.

Although the Law Reform Commission criticized the MRC for failing to take a clear and strong position in respect to these two related questions, it is more accurate to state that the MRC favours a protectionist position ruling out the involvement of this population in non-therapeutic

research though leaving the final decision to the courts. The MRC supports their recommendations with reference to the Charter and the Eve case. An analysis of the MRC's recommendations, and their reference to the Charter and the Eve case, indicates that the Council did take a clear position -- albeit by reference to the Eve case and the Charter.

The MRC states that in order to get approval to involve mentally incompetent individuals in invasive and/or non-therapeutic research, permission must be granted by the courts. In its working paper, the Law Reform Commission remarks that the courts are unprepared to respond to a request for a judgement on the question of whether a surrogate can provide consent for a ward to be a subject in non-therapeutic research. In the Commission's opinion, this advice is not helpful, because the legal system has not deliberated on the question and first has to struggle with a precedent-setting case if and when one is before the courts.

The MRC recommends that the surrogate be restricted to providing consent to therapeutic and non-invasive research interventions. Again, the recommendation is supported by their interpretation of the Charter, and also, of the Eve case. In addition, the Council advises that the Courts would interpret the Charter in favour of protecting mentally incompetent patients from exposure to invasive and non-therapeutic research. It supports this statement by a reference to a former MRC document and by

reference to the Eve case. Although the Council does not discuss the Charter in detail, the Council states that the Charter is protective of mentally and physically disabled. By referring to the Eve case, the MRC is indirectly referring to sections 7, 13 and 15 of the Charter which were referred to in the Eve case. Later it will be shown that the judge's decision did not rest on an interpretation of the Charter, but instead on the authority of *patriens patriae*.

Section 7 of the Charter refers to legal rights and states:

Everyone has the right to life, liberty and security of the person and the right not to be deprived thereof except in accordance with the principles of fundamental justice.

The MRC interprets this section to extend beyond legal rights to include the right to protect one's person from intrusions which threaten one's life, liberty and security of person. Thus, any experimental activity threatening a protected value is deemed illegal. Section 12 states:

Everyone has the right not to be subjected to any cruel and unusual treatment or punishment.

If current case law is followed, treatment is understood broadly and cannot be limited to therapy, advises the Law Reform Commission in their working paper about biomedical experimentation. Regarding Section 12, the Law Reform Commission states: "As the Commission has already

written with regard to behaviour-alteration techniques, this provision appears sufficiently broad in scope to protect the experimental subject”.²⁷

Equality before and under the law, and equal protection and benefit of the law, are addressed in section 15 of the Charter. Section 15 states:

(1) Every individual is equal before and under the law and has the right to the equal protection and equal benefit of the law without discrimination and, in particular, without discrimination based on race, national or ethnic origin, colour, religion, sex, age or mental or physical disability.

This section could be related to medical research involving mentally incompetent individuals, because the prospective subject, depending upon the legal system, is assured that a request to employ him as a research subject will not discriminate against him because of his mental disability. The use of Section 15 by both sides of the Eve case was dismissed by Justice La Forest in his decision, but this action does not prevent the use of this section at another time, in respect to a clinical research question. More will be discussed later about the use of this section.

Regarding the level of risk that subjects should be exposed to, the Guidelines suggest that a relevant measure for paediatric research is that “society and parents should not expose children to greater risks, for the sake of pure medical research, than the children take in their everyday lives. Parents control this level of exposure now”.²⁸ Determining what

poses “greater risk” than the risks facing a seriously, chronically and/or terminally-ill child and an individual with Alzheimer’s Disease is not as straightforward as the Guidelines indicate. Seriously ill children and patients with SDAT are frequently in hospitals or other institutions for long periods of time, and if they go home, their activities are restrained by health and safety considerations. Thus, trying to evaluate if the risk associated with research participation is comparable to the risk associated with daily living is neither appropriate nor practical when the prospective subjects are chronically and terminally ill. Also, it is reasonable to assume that many parents and family members have a different perception than the MRC regarding how much control they have over their family member’s care. Just as there is an unequal relationship between investigator and subject, in many cases there is an unequal relationship between patient and his family on the one hand, and the treatment team and the health-care system on the other. It is difficult to escape being coerced to conform with the attending staff’s wishes. In the fifth chapter, I shall return to the ubiquitous problem of managing coercion.

The MRC’s position in respect to children participating in non-therapeutic research is relevant to the situation of those with SDAT. States the Guidelines, “the conditions under which children can volunteer for non-therapeutic interventions of no benefit to them are contentious; much

centres upon the level of development of the individual child and the surrounding circumstances"²⁹. Thus, if the child shows that he has matured enough that he is mentally competent, has sufficient autonomy, is responsible and understands the information presented to him, then he can be permitted to provide his own consent. There can be extraordinary cases which break the rules, but exceptions should not make the rules.

The above statement about recruiting incompetent individuals for non-therapeutic research being a contentious issue has a footnote which refers to two other sources: an earlier document of the MRC entitled Ethics in Human Experimentation, and the Supreme Court of Canada's summary of the Eve Case.³⁰ The MRC document reveals that the committee did not reach consensus on the question of the use of mentally incompetent subjects for non-therapeutic research, but that the majority did favour the use of mentally incompetent individuals for non-therapeutic research.

An analysis of the Supreme Court's decision in respect to the Eve case, indicates that the legal system has taken a strong protectionist position when permission has been sought from the courts to permit a non-therapeutic medical intervention involving a mentally incompetent individual. To date, there has not been a test or precedent setting case, so whether the courts would grant permission for a mentally incompetent individual to participate in non-therapeutic research is moot. However, the

ruling in the Eve case indicates that the Courts would take a staunch protectionist stand in respect to the use of mentally-impaired human subjects in non-therapeutic research. In the Eve case, when a guardian sought court-ordered permission to allow the incompetent individual to receive a non-therapeutic intervention, the Supreme Court decided that only the interests of the mentally incompetent individual are to be considered, and that the interests of any other party must not influence the judicial decision. The Supreme Court decision in the Eve case is clear and not contentious: no one may recruit a mentally incompetent individual for a non-therapeutic medical intervention.

The reference to the earlier MRC document Ethical Considerations in Research Involving Human Subjects (1972) is to the section which discusses special subjects of research and, in particular, those incompetent to consent for themselves (chapter IV, section 4 (d), p. 30). This earlier document brings into sharper focus than the Guidelines the ethical issues surrounding the use of incompetent subjects.

In this document, the MRC states that when a prospective research subject is not capable of consenting to be a research subject, then a valid indirect consent can be sought. Regarding evaluating risk and benefit, the Working Group had a minority dissenting opinion. Both positions were duly reported, and the lack of consensus indicates that the central issue is to

what type of research a surrogate may give consent. The two positions are logically inconsistent and are based upon different premises.

The majority position is to “extend the general philosophy...of weighing risks and benefits in relation to the research subject and to the procedures for obtaining a consent”.³¹ The minority position (just as worthy of consideration) opposed any involvement of legally incompetent individuals in non-therapeutic research. It was argued that, because the subject is incapable of providing a valid consent, the responsibility lies with a guardian who has “a fiduciary duty to act in the interest and for the benefit of the beneficiary. Therefore, no one holding this position of trust may expose fetuses, children or the mentally incompetent to the potential risks of an experiment of no direct benefit to them”.³²

Both positions are in agreement on two requirements of the experimental design. First, they agree that legally incompetent individuals are human subjects of the last resort. Accepting that research with physically and mentally-impaired individuals is necessary to improve the status of other individuals affected by the disease, they agree that their use must be within strict limits, in order to prevent the subject from being harmed and disrespected. Hence, they agree that their association with research should be restricted to occasions when no other individual can substitute for the affected patient. SDAT research must rely on the use of

human subjects with SDAT, because animals or individuals free of SDAT will not yield information about the disease. Second, they agree that the subjects can participate in research studies that have the potential to directly benefit the subject. Both positions approve of a research protocol “aimed at the treatment of a disease afflicting the subjects; from such treatments the subjects would be expected to derive direct benefit even if the research would involve definite risks”.³³

There is a major disagreement on the question of whether mentally-impaired patients should be subjects in research involving more-than-minimal risk and/or research that would not necessarily benefit the subject directly. The definition of minimal risk is determined by approximating the degree of risk and comparing it to the risks of everyday life. (More will be discussed later, in chapters four and five, about the difficulties plaguing evaluation of the risk-benefit ratio). The majority position is that proposals for non-therapeutic research involving more-than-minimal risk should be considered by ethics review committees according to the same procedures used to evaluate other research proposals “in which risk and benefit to the individual subject are balanced in the context of the ability of the subject to consent”.³⁴ The minority position recommended prohibiting this specific type of research.

In the earlier work of the MRC on legally incompetent human subjects there are two major issues:

- (i) involvement in any type of research (therapeutic or non-therapeutic) involving greater than negligible risk
- (ii) involvement in non-therapeutic research.

A third issue brought to our attention by the later work of the MRC, in 1987 was whether the same subjects should be associated with intrusive or invasive research. In summary, there are three variables that present ethical problems and one, two or all of these variables may be present in a research proposal. These variables are:

- (i) greater than negligible risk to subject
- (ii) intrusive intervention
- (iii) subjects are not expected to benefit directly but others are expected to benefit indirectly

It is important to separate the issues because it is possible to have a therapeutic research proposal posing greater than negligible risk to the subject. Also, it is possible to have a non-therapeutic research protocol which exposes the subject to less than negligible risk. According to the MRC's recommendations, the former proposal could be approved, but the latter proposal rejected, although the former poses more risk to the subject than the latter. Thus, both MRC documents have failed to clarify the

principal ethical issues regarding the use of SDAT patients who are mentally impaired. Therefore, the MRC has reached a protectionist position regarding mentally-impaired adults. The Law Commission was correct in saying the Council was unclear, but it is the reason for the position and -- not the position itself -- that is unclear.

The second reference made by the MRC Guidelines is to the Eve case. This case is worthy of close analysis because it a precedent setting case in respect to the question of whether a surrogate can provide consent to subject a legally mentally incompetent individual to receive a non-therapeutic medical intervention.³⁵ Thus far, under the new Charter a case has not been brought to the courts regarding the use of legally incompetent individuals for non-therapeutic research. The Court's ruling would discourage researchers from bringing before the courts a request for permission to conduct non-therapeutic research on mentally incompetent individuals. An examination of the Eve case can shed light on how the courts may adjudicate when the same population is considered to be the source of research subjects. Mr. Justice T. David Marshall, executive director of the Canadian Judicial Centre, has stated that he would expect the Canadian courts to be guided by this precedent if a test case in respect to the involvement of mentally incompetent individuals in non-therapeutic research was before the courts. In short, he expects that a

strong protectionist position would be repeated, and the participation of the subject would be prohibited.³⁶

In 1986 the Supreme Court of Canada heard the case of Eve, represented by her guardian, an official trustee (appellant) versus Mrs. E (the respondent) and a group of intervenors including the Canadian Mental Health Association, Consumer Advisory Committee of the Canadian Association for the Mentally Retarded, the Public Trustee of Manitoba and the Attorney General of Canada. The case began with an application by a mother for permission to consent to the sterilization of her daughter, whom the court named Eve to protect her identity. Eve, twenty-four years old at the time of the first application, is mild- to moderately-retarded, and has some limited learning skills. In addition, Eve has a severe case of expressive aphasia, which prohibits her communicating with others. To complicate matters further, it is impossible to confirm that she has understood any information given to her. Thus, it was necessary for a surrogate to provide consent on behalf of Eve for any medical interventions. Mrs. E. stated that she was concerned about the potential for harm to her daughter, because of the emotional effect of the pregnancy and labour upon her daughter.

Eve was described by the defence as an attractive, pleasant woman who was physically capable of bearing a child and under supervision, performing the basic duties of a parent (feeding, bathing). It was argued

that she would be unable to fulfil other more demanding responsibilities associated with being a parent (supervising the child, providing a safe home, meeting the child's emotional needs). These responsibilities would be transferred to Eve's mother, though she did not want such responsibilities because she would find them difficult and burdensome.

The case went on appeal from the Court of Appeal for Prince Edward Island to the Supreme Court of Canada, which agreed with the decision of the Appeal Court to protect the legally incompetent individual from having a non-therapeutic medical intervention. In making its decision, the Supreme Court based its case on authority found in statutes, authority flowing from *parens patriae* power. Interestingly, the Supreme Court did not accept arguments based upon rights guaranteed to the mentally incompetent under section 7 and 15 (1) of the Charter made in support of both sides of the case.

The summary of the P.E.I. court's Judge McQuaid stating why the respondent's request was denied on the grounds of the *parens patriae* authority was reiterated in the Supreme Court's summary. After reviewing Canadian and English case law and finding no governing authorities, the Supreme Court of P.E.I. decided that it should exercise its *parens patriae* jurisdiction and intervene on behalf of Eve. In the opinion of the courts, Eve's inviolable rights could not be overridden because of any social benefits

that would ensue from granting the guardian's wishes. The Judge stated that he was "of the view that Eve, like other individuals, was entitled to the inviolability of her person, a right that superseded her right to be protected from pregnancy. That this might result in inconvenience and even hardship to others was irrelevant. The law must protect those who are unable to protect themselves, it must ensure the protection of the higher right".³⁷ He concluded that a guardian could only provide a valid consent for clinically therapeutic reasons, and that, in the absence of clear and unequivocal statutory authority, the application was denied.

The appeal in P.E.I. was based on a different interpretation of the court's *parens patriae* authority, arguing that this authority should have been used to protect the ward from hardships befalling her if she became pregnant. Their argument hinged on determining what is in the individual's best interests.

When the case came to the Supreme Court, there were several major issues raised in the appeal. The relevant ones to our discussion are:

- (i) In the absence of statutory authority, does the court's *parens patriae* jurisdiction allow the court to consent to sterilization of an adult who is mentally incompetent?
- (ii) Does the Canadian Charter of Rights and Freedoms protect an individual against sterilization without the individual's consent?

- (iii) If the Charter provides such protection, when will it permit the non-therapeutic sterilization of a mentally incompetent who is incapable of giving consent?³⁸

Justice La Forest of the Supreme Court wrote the Court's summary of their decision and agreed with the P.E.I. court's earlier ruling. The proposed sterilization, the Justice commented, "involves the deprivation of a basic human right, namely the right of a woman to reproduce, and therefore it would, if performed on a woman for non-therapeutic reasons and without her consent, be a violation of such right".³⁹ He referred to a similar case in English case law which supported the protectionist position. In referring to the precedent setting case, Justice La Forest repeated the famous maxim made by Lord Eldon LC in his summary of the case: "It has always been the principle of the Court, not to risk the incurring of damage to children which it cannot repair, but rather to prevent the damage being done"⁴⁰.

In summary, Canadian courts have adopted the British tradition of interpreting the *parens patriae* authority in a protectionist manner, and used this authority to block well-intentioned individuals providing consent for non-therapeutic interventions when the patient is legally mentally incompetent, despite any benefits that the intervention may have for the guardians and society.

In contrast, it did not escape the Court's attention that in some jurisdictions in the U.S.A. the *parens patriae* authority has been interpreted

to permit exactly the opposite ruling. In five of the nine states which permit non-consensual sterilization of a mentally incompetent person, the jurisdiction is based “on the inherent equitable powers of the court to act in the best interests of the mentally incompetent person”.⁴¹

The result has led to confusion and uncertainty, and opened the door to the inviolable rights of mentally incompetent individuals being overridden by their guardians’ wishes. In the hands of a skilful lawyer, the guardian’s interests can and have been re-framed in terms of acting in the best interest of the ward. Some American courts have responded by developing guidelines granting them considerable discretion when interpreting the *parens patriae* jurisdiction to act in the ward’s best interests. Another way of defeating the English interpretation of *parens patriae* in the U.S.A. is to take the route of substituted judgments to secure a sterilization. This argument was put forth by the respondents in the Eve case, but to no avail. In the New Jersey Supreme Court in re Grady, the parents of a Down’s syndrome adult daughter were granted permission to have their daughter sterilized. The court ruled that the ward had the right to procreate and to control contraception, which included an affirmative constitutional right to voluntary sterilization. Therefore, the person in question is free to choose which option she prefers. When the individual is

unable to make a choice, the court ruled that the guardians could make a substituted decision on behalf of the mentally incompetent individual.

The purpose of the substituted judgment test is to determine the decision that the mentally incompetent would make, given the particular circumstances. More to the point, this approach allows social and economic factors influencing the guardian's request to become dominant. Given that the mentally incompetent individual cannot exercise her choice, the court strives to ascertain what the individual would have chosen.

The Supreme Court decision favours the traditional interpretation of *parens patriae* exercised in Canada, as opposed to the second interpretation of substitute decision-making gaining favour in the U.S.A. The logical inconsistency of the substituted judgement test that confers on the legally mentally incompetent individual the same rights as a competent person to make choices, was recognized by Justice La Forest.⁴² He identified the sophistry of the test, stating "There is an obvious logical lapse in this argument. I do not doubt that a person has a right to decide to be sterilized. This is his or her free choice. But choice presupposes that a person has the mental competence to make it. It may be a matter of debate whether a court should have the power to make the decision if that person lacks the mental capacity to do so. But it is obviously fiction to suggest that a decision so made is that of the mental incompetent, however much the

court may try to put itself in her place. What the incompetent would do if she or he could make a choice is simply a matter of speculation.”⁴³ Thus, he makes the case that to argue that the surrogate is making a choice for the ward is to misrepresent what is occurring: consent for a ward to have a non-therapeutic medical intervention involves the intrusion of another party’s wishes into the determinism of the first party’s interests.

Justice La Forest rejected the respondent’s arguments, based upon the Charter, that the guardian should be permitted to provide consent for a non-therapeutic intervention. The first argument advanced was that the patient had the right to procreate or not to procreate, and the right to decide whether to procreate or not shifted to a surrogate who could exercise the right on behalf of the patient. In the opinion of the Court, incompetent individuals did not have the ability to choose either of these rights in the first instance, even if they were conferred on the individual. All forms of the substituted decision-maker argument were rejected because they were based on a mistake, that is that the individual had the capacity to make specific decisions and that decision-making can be transferred to a third party. The court’s rejection of substituted decision-making model for making decisions about the care of mentally and physically impaired individuals, and the Court’s preference for the best interests model under the same circumstances, has important implications for SDAT research.

The Supreme Court of Canada rejected the substituted judgement approach for individuals who were never able to express their wishes. However, this approach could have relevance for the SDAT population that we are studying. More will be discussed later about the role of the surrogate in respect to the SDAT population.

Justice La Forest defended the use of the *parens patriae* jurisdiction according to the precedent in English case law in the Eve case. He stated that the jurisdiction was founded on the necessity to act on behalf of those who are unable to care for themselves. The courts, he explained, in the past have often stated “that it is to be exercised in the “best interest” of the protected person for “his or her” “benefit or welfare””.⁴⁴ Furthermore, the court can use the jurisdiction to halt any action that is suspected of being harmful. Justice La Forest also stated that the legal system should not assume nor accept that the jurisdiction could be removed by a piece of legislation because of the continuing need to protect weak and vulnerable individuals unable to defend themselves (e.g. Alzheimer Disease patients). Acknowledging that the scope of the jurisdiction is unlimited, the judge stated that it did not follow that “the discretion to exercise it is unlimited”. It must be exercised in accordance with its underlying principle. Simply put, the discretion is to do what is necessary for the protection of the person for whose benefit it is exercised...”.⁴⁵ The judge emphasized that the

benefits to be considered exclusively are benefits to the incompetent individual, no matter how heavy a burden is placed on other parties when the court protects the ward from receiving a non-therapeutic intervention.

The judge informed the public that great caution must be taken when deliberating on the question of whether a mentally-impaired individual should receive a non-essential medical intervention. The biases he mentions which can influence a surrogate and/or a court's decision are worth citing because they apply to the use of human subjects with SDAT. First, decision-making for mentally-impaired individuals is often biased because of the social climate and historical emphasis upon treating mentally handicapped individuals "as somewhat less than human".⁴⁶ Second, the consequences of surrogate decision-making in respect to consent for the non-therapeutic intervention of a sterilization are always serious. The consequences of providing surrogate consent for participation in non-therapeutic research can vary from being negligible to serious, depending on the degree of risk associated with the research intervention. In the realm of medical practice, the jurisdiction of *parens patriae* empowers the court to not risk incurring damage that it cannot repair, and, instead, to take the safer course of preventing the damage being done in the first place. Relating this advice to SDAT research, non-therapeutic research carrying any risk would be prohibited. In short, if in doubt, no action and no risks

should be taken. Also, the judge wisely emphasized the psychological as well as the physical effects of the elective sterilization. The same point can be made with respect to the risks associated with SDAT research. Although the subjects could be severely cognitively impaired, they can experience emotional distress, anxiety and depression. Relating this court's decision and warning to the SDAT population, the potential deleterious consequences of "participation" on the subject should influence the decision whether to permit a surrogate provide consent for participation in medical research.

The judge's forceful statement on protecting vulnerable individuals from the well-intentioned actions of others ranked the value of respecting the mentally incompetent over the social merits associated with permitting the non-therapeutic intervention. His statement reads:

...The importance of maintaining the physical integrity of a human being ranks high in our scale of values, particularly as it affects the privilege of giving life. I cannot agree that a court can deprive a woman of that privilege for purely social or other non-therapeutic purposes without her consent. The fact that others may suffer inconvenience or hardship from failure to do so cannot be taken into account. The Crown's *parens patriae* jurisdiction exists for the benefit of those who cannot help themselves, not to relieve those who may have the burden of caring for them.⁴⁷

Hence, it is clear that, in respect to the Eve case, the courts focused exclusively on acting in the best interests of the legally mentally

incompetent person, and did not consider the expected social, economic or other benefits to rank higher than the mentally incompetent individual's inviolable rights or interests. The judge's reference to the value of maintaining the physical integrity of the individual can be read to mean that the Crown has the responsibility to protect the individual's interest in not being harmed (according to the moral consequentialism). Similarly, if the position taken is that dependent moral subjects have rights, the judge's statement would be interpreted to mean that the courts must protect their inviolable right to be protected from harm and must ensure that their dignity and integrity is respected. Whether from a consequentialism or deontologist perspective, the judge's decision strongly supports protecting vulnerable, dependent individuals from being harmed unnecessarily and also, for the benefit of others. (Although I think his decision tilts in the direction of deontology.)

The counsel for the appellant also used section seven to argue that the sterilization should not be permitted. Their argument was based again on conferring on the mentally incompetent individual the right to procreate. If the court permitted a sterilization to occur for non-therapeutic purposes, they reasoned that the individual in question would be deprived of her right to procreate. This action, they concluded, would be an infringement of the mentally incompetent individual's right to liberty and security of person

granted by section seven. Justice La Forest rejected this argument also for the same reasons he rejected the respondent's argument based on section 7.

In the opinion of Justice La Forest, section 7 does not bear upon the Eve case because the crucial issue is protection of the vulnerable individual's best interests, and not protection of their rights. He considered the discussion of the patient's rights and transferring the right to make certain decisions to a third-party to be a red herring, distracting attention from focusing on the role of the next of kin and the courts to act in the mentally-impaired individual's best interests. *If*, for the sake of argument, it was granted that liberty, as discussed in this section, protects the right to procreate, Justice La Forest concludes that the counsel's claims went beyond the kind of protection section 7 grants. "All section seven does is to give a remedy to protect individuals against laws or other state action that deprive them of liberty. It has no application here", he states.⁴⁸

The respondent's counsel replied with another argument based on a section of the Charter, this time, section 15 (1) which refers to equality rights. This section states:

15 (1): Every individual is equal before and under the law and has the right to equal protection and equal benefit of the law without discrimination and, in particular, without discrimination based on race, national or ethnic origin, colour, religion, sex, age or mental or physical disability.

The gist of the argument is that to deny the guardian the role of a substitute decision-maker is to discriminate against the ward in the sense that she had been denied equal protection and equal benefit of the law. In the words of the counsel “the most appropriate method of ensuring the mentally incompetent their right to equal protection under section 15(1) is to provide the mentally incompetent with a means to obtain non-therapeutic sterilizations, which adequately protects their interests through appropriate judicial safeguards”.⁴⁹

Although section 15 was not in force at the time of the original court hearing in Prince Edward Island, Justice La Forest allowed the argument to be put forward. He then stated that the arguments were inadequate, because they are based on the incorrect assumption that the court’s decision in response to an application (to consent to a non-therapeutic intervention for an incompetent person) is, in some construed way, the decision of the incompetent individual. The Justice comments that “More troubling is that the issue is, of course, not raised by the incompetent but by a third party”⁵⁰. Furthermore, in response to the section fifteen argument, Justice La Forest states that the court has a duty to protect mentally incompetent individuals and has wide discretion to do what it considers to be in the best interests of mentally incompetent individuals.

In his closing remarks, Justice La Forest emphasizes the seriousness of the court's duty to protect the mentally incompetent by stating that, excluding emergency situations, a surgical procedure without consent is battery. The burden of proof for justifying such interventions rests with the party seeking consent to have the procedure performed. The burden of proof, a civil one, needs to be commensurate with the seriousness and risks associated with the intervention. The judge also warned that the courts must be very cautious when hearing applications to receive consent to perform non-therapeutic interventions, because it would lead to the abuse of this vulnerable population. In addition, he advised that it was essential that in any proceedings involving interventions for a mentally incompetent individual, that the individual have independent representation.⁵¹

Although the case did not deal with non-therapeutic research, it is probable that the same line of legal reasoning would prevail if consent was sought from the courts to recruit a mentally incompetent individual for participation in non-therapeutic research. Non-therapeutic research and non-essential therapy share the characteristic of being elective interventions, not necessary for the patient or subject's well-being. Therapy is expected to directly benefit the patient. In contrast, non-therapeutic research has the promise of benefitting indirectly other parties, and, only coincidentally, may benefit the subject directly. Considering there is not a

stronger case for providing consent for participation in non-therapeutic research, it is reasonable to conclude that the courts would take the Eve case as a precedent. Thus, the courts would probably decide to exclude mentally-impaired individuals from involvement in non-therapeutic research.

Furthermore, considering that the Eve case deals with the question of third-party consent for an individual who was never mentally competent, the decision has major implications for SDAT research. Alzheimer's Disease patients differ from the profoundly retarded because, at an earlier stage in their lives, they were independent and capable of stating their wishes. Thus, the SDAT patient could be in one of the following situations: (i) could have made known his wishes when he was competent, regarding research participation, or (ii) did not make known his wishes when he was competent, regarding research participation.

In the second situation, the SDAT patient is in a similar position to Eve, because knowledge of the patient's preferences is unobtainable. The guardian in both cases, has the responsibility to act in the patient's best interest. However, when the patient's wishes are known, the surrogate faces two choices:

- (i) respect the patient's previously stated wishes, and consent to his participation in non-therapeutic research

- (ii) act in the patient's best interests, and consent or refuse depending on the research's protocol and knowledge of the patient's wishes.

Current guidelines supported by the Eve decision, would prohibit the surrogate from consenting to the patient's involvement in any non-therapeutic research, regardless of the patient's previously stated wishes. Currently, although the mentally-impaired patient can leave clear instructions regarding his association with non-therapeutic research, the guidelines prohibit the surrogate from honouring these wishes because the research is non-therapeutic, that is, not in the patient's best interests. The responsibilities of the surrogate will be studied in chapters four and five. However, at this time it can be said that the surrogate's priority is to protect the weak and vulnerable subject from harm. In other words, the surrogate should not consent for the patient to be in a non-therapeutic project that exposes the subject to more than minimum risk. Consenting to exposure to more-than-minimal risk is an altruistic act of self-sacrifice that can only be done by the competent subject himself, and not delegated to a third party.

It will be argued, in chapter four, that it is possible for a third party to honour the patient's previously stated wishes, with the caveat that he not expose the patient to more-than-minimal risk. Permitting a vulnerable subject to be exposed to more-than-minimal risk is a violation of

the responsibilities of a surrogate to act in the vulnerable individual's best interest.

If the MRC is correct in its assumption, and if the Courts did take a protectionist position and prohibit surrogates from providing consent for non-therapeutic research, then there are serious consequences for society and its members. In the words of the Law Reform Commission, "With respect to ethical principles, the legal problem is therefore complex. An absolute ban on experimentation involving the mentally deficient can be objected to on the same grounds that we discussed in connection with children: it precludes certain kinds of desirable progress in the treatment of mental illnesses".⁵² However, the pendulum cannot swing to permitting research without regulations and to abandoning the request for a valid consent when the prospective subject is incapable of assessing the risks and benefits attendant upon his participation. The Commission correctly advises that a laissez-faire position may not be taken on the matter of protecting research subjects with impaired competency. Also, the Commission makes an important point that adults with mental deficiencies are more vulnerable than children, because they are a more heterogeneous group. Therefore, concludes the Commission, "If law and ethics are to allow experimentation on the mentally deficient, strict requirements must therefore be laid down".⁵³ Thus, on utilitarian grounds, the Law

Commission recommends that individuals with mental deficiencies, which would include patients with Alzheimer's Disease, should be allowed to be research subjects in non-therapeutic research if certain ethical and legal requirements are met. In their working paper, the Commission makes the following recommendation regarding the use of mentally-impaired individuals in non-therapeutic research:

The legality of non-therapeutic biomedical experimentation on mentally deficient persons should be recognized, in a general federal statute on experimentation provided that the following conditions are met:

- (a) the research is of major scientific importance and it is not possible to properly conduct it using adult subjects capable of giving consent;
- (b) the research is in close, direct relation to the subject's mental illness or deficiency;
- (c) the research does not involve any serious risks for the subject;
- (d) the consent of the incompetent person's representative and of an independent third-party (a judge, an ombudsman or the incompetent person's lawyer) is obtained; and
- (e) where possible, the incompetent person's consent is obtained, and his refusal is always to be respected.⁵⁴

These recommendations demonstrate that the Commission respects the requirement that fundamental interests of a mentally incompetent individual should be protected from harm. Also, to the Commission's credit,

it accepts a subject's refusal as final, regardless of his mental status. This is an important point, because it would mean that researchers and surrogates would have to accept dissent (as opposed to assent) and uncooperative behaviour as sufficient reason to halt the subject's participation immediately. Also, the requirement that an independent third party provide consent in addition to the surrogate is commendable. The independent party would serve to diminish the impact of coercion, and would be a check on the surrogate's decision and the experiment's design. The additional safety check enhances the protection of the vulnerable individual's fundamental interests.

However, there are some difficulties with the recommendations. The Commission criticised the MRC for not answering the question whether the mentally incompetent individual's right to integrity can be waived by third-party consent to non-therapeutic research. Yet, the Commission fails to answer this very question in its own recommendations. Also, the Commission provides little guidance on what is meant by serious risk to the subject, a concern which is central to determining whether the risk-benefit ratio is acceptable. In addition, their last recommendation is confusing, at best, and contradictory, at worst. How can an incompetent person provide consent? Presumably, the Commission is supporting the acceptance of the concept of factual versus global incompetency which would be a progressive

move. However, if that is the direction that the Commission is heading, the recommendation should have been phrased to indicate that the prospective subject's competency to provide consent should be determined before the decision-making is transferred to a surrogate.

A more important difficulty with the last recommendation is not that the incompetent person is to be assessed to determine if he has sufficient understanding to make a decision, but that it is implied that a low standard of competency is acceptable. In the following section, it will be argued that competency to provide consent requires a high level of autonomy and mental competency, and therefore it is highly unlikely that any individual who is mentally deficient would have the capacity to provide consent for research. The Commission is suggesting a low standard for this important decision when, as will be seen, it is morally and legally preferable to make the requirements for competency more stringent to consent to research. Heightening the standard of competency will have two consequences: fewer competent subjects, and more reliance on surrogate consent. Admittedly, the latter course of action has serious problems, but in the following chapters it will be argued that it is the better option.

Another major issue raised by the Law Reform Commission's paper is whether the traditional approach of the MRC of making recommendations should be replaced by introduction of legal statutes to deal specifically with

issues related to biomedical research. The paper is being reviewed by health-care researchers and other interested parties across Canada and a final decision not been made yet. In the fifth chapter, a case will be made for supporting the Law Reform Commission's recommendations.

In summary, current research codes and legal rules do not address adequately the ethical issues raised when mentally incompetent individuals are associated with therapeutic and non-therapeutic research. These sources focus on protecting individual autonomy, but provide little guidance regarding the consent process and design of SDAT research. Also, the MRC Guidelines present a dilemma. On the basis of a social utility argument, the MRC agrees that patients, with health problems needing to be investigated, have to be recruited to be subjects in investigations studying the specific problems that they have. However, to protect these vulnerable individuals, they state that strict rules regarding design and consent process must be followed. Yet, in respect to the mentally and physically impaired individuals, their recommendations in effect prevent any non-therapeutic SDAT research.

2.5 Summary

Although health sciences research endorses the noble end of promoting health, as Fasella and Bertazzoni stated at the International Summit on Bioethics regarding research ethics, society is not prepared to give investigators free rein to conduct investigations. Society places limits on the price to be paid for research's advances. Hence, depending on the design of the experiment, some investigators who wish to conduct SDAT research are frustrated in their efforts to reduce the suffering and the high economic costs associated with SDAT.

There is a conflict of interests which current legal statutes and research guidelines do not resolve. On one hand, there is the interest of vulnerable research subjects to have their dignity and integrity respected. On the other hand, the research community has an interest in learning more about the etiology, prevention and management of the disease. Society wants research to adhere to established rules but at the same time, wants research to contribute to reducing the micro and macro costs of SDAT. If the rights language were to be used, it would be a conflict between the rights of vulnerable research subjects to be respected and the right of other individuals to have good health. In the following three chapters, a way to resolve these ethical dilemmas and issues will be proposed which takes into consideration the respective interests of all parties.

Notes

1. Toulmin, S. "Can Science and Ethics Be Reconnected?", The Hastings Centre Report, June, 1979, p.32.
2. Fasella, P., Bertazzoni, U. "Who Sets Standards for What and How?". Towards an International Ethic for Research With Human Subjects. International Summit Conference on Bioethics, April, 1987, Ottawa, Canada. p. 67.
3. Barber, B. Science and the Social Order. Collier Books, New York, 1970, p. 31.
4. Medical Research Council of Canada Guidelines on Research Involving Human Subjects, 1987. p. 7.
5. Thomas, J.E., Waluchow, W. Well and Good. Broadview Press Ltd., First Edition, 1987, p. 104.
6. Mill, J.S. Utilitarianism. Collins, Fontana Library, 1962, p. 290.
7. Guidelines, p. 15.
8. It is interesting to note that the incidence of SDAT is considerably higher than the incidence of Acquired Immune Deficiency Syndrome (AIDS) but the advocates for AIDS research had done a more effective job than the SDAT community in publicising the need to conduct research and thus, placing AIDS research high on society's agenda. Competition for health research funding leads charities to be competing with each other for assistance. In the end, the group that can best marshal the media and afford lobbyists often "wins the day" as opposed to funds being distributed more equitably.
9. Dunstan, G. "The Role of the Public". Towards an International Ethic for Research with Human Beings. International Summit Conference on Bioethics, Ottawa, April, 1987, p. 92.
10. Ibid., p. 93.

11. Guidelines, p. 9.
12. The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, Washington, DHEW Publication. No. (OS) 78-0012, 1978. pp.2-3. Quoted in R. Levine's article "Clarifying the Concepts of Research Ethics". Reprinted in J. E. Thomas, Medical Ethics at the Edge of Life, Samuel Stevens. Toronto 1983, p. 199.
13. Guidelines, p. 9.
14. Levine, R. Ethics and the Regulation of Clinical Research. Urban and Schwarzenberg, Baltimore and Munich, 1986, p.3.
15. Ibid., p.3.
16. Guidelines, p. 9.
17. Guidelines, p. 9.
18. Guidelines, p. 7.
19. Law Reform Commission of Canada, Biomedical Experimentation Involving Human Subjects. Working Paper 61, Ottawa, 1989, p. 1. Hereafter referred to as LRC Working Paper 61.
20. U.N.T.s., 172, (1976), p.999.
21. Rec. No. r-83 (1983).
22. LRC Working Paper 61, p. 44.
23. Guidelines, p. 28
24. Guidelines, p. 28.
25. Ibid., p. 31.
26. LRC Working Paper 61, p. 44.
27. LRC Working Paper 61, p. 11. In this quotation, the LRC is referring to the publication LRC, Behaviour Alteration and the Criminal Law, Working Paper 43, Ottawa, 1985.
28. Ibid., p. 29.

29. Ibid., p. 29.

30. Medical Research Council of Canada, Ethics in Human Experimentation. Report 6, 1978, Ottawa, 1978.

Supreme Court Report, volume 2, 1986, re. Eve. Citation as follows:
2 S.C.R. page 327.

31. Medical Research Council of Canada. Ethics in Human Experimentation. Working Group on Human Experimentation, Report no. 6, 1978, p. 30.

32. Ibid., p.30-31.

33. Ibid., p. 31.

34. Ibid., p. 31.

35. Canada Supreme Court Reports, 1986, volume 2, part 1, pp. 388-438. Judgement of Judge La Forest.

36. Statement made by Judge Marshall at the conference, Legal and Ethical Issues in Alzheimer's Disease Research, held in Toronto, January 20, 1989.

37. {1986} 2 S.C.R., pp. 395-6.

38. Ibid., p. 400. These issues are numbered 4, 5 and 6 respectively in the text.

39. Ibid., p. 415.

40. Ibid., p. 416.

41. Ibid., p. 422. Cases referred to are P.S. by Harbin v. W.S., supra, (Ind.); Matter of Terwilliger, supra, (Pa.); In re Penny N., 414 A. 2d 541 (N.H. 1980); Matter of C.D.M., supra, (Alaska); In re. Eberhardy, supra, (Wis.).

42. As will be seen after the status of SDAT patients is discussed in the following chapter, the judge's decision is compatible with the position advanced that SDAT patients have fundamental needs and society has a responsibility to act in ways that will protect these vulnerable individuals.

43. Ibid., p. 435.
44. Ibid., p. 426.
45. Ibid., p. 427.
46. Ibid., p. 427.
47. Ibid., p. 434.
48. Ibid., p. 436.
49. [1986] 2 S.C.R., p. 436.
50. Ibid., p. 437.
51. Ibid., p. 438.
52. LRC, Working Paper 61, Ottawa, 1989. p. 45.
53. Ibid., p. 45.
54. Ibid., p. 45.

Chapter III

The Alzheimer's Disease Patient as a Research Subject

The language of human needs is a basic way of speaking about this idea of a natural human identity. We want to know what we have in common with each other beneath the infinity of our differences. We want to know what it means to be human, and we want to know what that knowledge commits us to in terms of duty. What distinguishes the language of needs is its claim that human beings actually feel a common shared identity in the basic fraternity of hunger, thirst The possibility of human solidarity rests on this idea of a natural human identity. A society in which strangers would feel common belonging and mutual responsibility to each other depends on trust, and trust reposes in turn on the idea that beneath difference there is identity.

Michael Ignatieff ¹

3.1 Introduction:

Thus far the ethical difficulties associated with the use of human subjects in Alzheimer's Disease research have been presented and the role and value of the health sciences research have been outlined. Health sciences research has the noble and beneficent goal of alleviating suffering and improving the health status of individuals, groups and large sectors of the population. However, in respect to SDAT (Senile Dementia of the Alzheimer Type) research involving human subjects, a number of ethical,

clinical and legal problems prevent SDAT researchers from conducting some types of SDAT research. As discussed in the previous chapter, non-therapeutic research involving mentally incompetent patients (the majority of SDAT research) presents serious moral problems and is prohibited by law in most jurisdictions.

Considering the social and economic costs associated with caring for SDAT patients, research advances hold the promise of immense social and economic benefits on the micro and macro level. Thus, it is not the goals of medical research, but the process of achieving these ends that can present ethical problems.

The next step in the investigation is to look at what Ignatieff, in his book The Needs of Strangers, calls the identity of strangers. The purpose of this chapter is to study the moral status and moral worth of SDAT patients. In the course of this chapter, it will be argued that the weak and vulnerable in our society continue to have moral worth and have fundamental needs as opposed to rights. Therefore, the position advanced is that society has a responsibility to respond to these strangers who may no longer even know themselves.

The examination, in the two previous chapters, of the social consequences of the prevalence of Alzheimer's Disease, a disease having the cardinal features of loss of autonomy, rationality and moral agency and, of

the ways that health sciences research is frustrated in its efforts to achieve its goals, has set the stage for chapters three and four which constitute the theoretical heart of the thesis. The fundamental question to be considered is how clinical research, in its pursuit of knowledge, can balance the interests of subjects and the community while ensuring that neither side is harmed. Research codes express the western, liberal tradition of respect for individual autonomy and are based on the ethical principles of justice, beneficence, non-maleficence and respect for persons. However, research codes are of limited value. They serve to guide researchers but they do not and are not intended to prescribe ways of resolving conflicts between ethical principles. Furthermore, research codes contain the very problem troubling Alzheimer's Disease research: how to balance respect for individuals and at the same time serve the interests of the community.

Before responding to global question about balancing the needs of research subjects and society, it is necessary to:

- (i) examine the status of the SDAT research subjects to determine what rights, interests and needs if any they have, and
- (ii) study the obligations of society and researchers to prospective SDAT research subjects.

The major legal restraint on conducting research is the rights of the research subject. However, if the prospective subjects are Alzheimer patients, a number of questions arise: do they have rights, and if so what

rights? If they do not have rights, how are they to be protected from being harmed when they are research subjects? The first of these questions sets the agenda for the present chapter which focuses on the status or the identity of SDAT patients and their needs. The second question will be the concern of chapter four when the focus will shift to determining the responsibilities of society, caregivers and researchers to this specific population given their status established in chapter three.

This chapter focuses upon constituents of a moral world:-rights, moral subjects and agents, claims and interests. Hence, the discussion of the philosophical foundations of the thesis will be prefaced by some remarks about the thesis' working assumptions and terminology.

One assumption grounded in the consequentialist tradition is that morality is a study of what constitutes a good life and morality has a social face. Thus, essential to the notion of the moral realm is the existence of inter-personal relations between individuals or parties who are called moral agents and moral subjects. How we choose to treat others in the community involves an appeal to moral underpinnings. Thus, I agree with Peter Miller in assuming that morality should be characterized "as the articulation of the legitimate responsibilities, particularly the more fundamental and overriding of these, that ought to appeal to, guide, or be enforced upon moral agents" and that an important aspect of our moral

responsibility is the construction, maintenance, and improvement of the social order.²

Another assumption is that a moral agent is an autonomous and rational individual, acts independently and is responsible for his decisions. In contrast, a moral subject lacks autonomy and rationality and is dependent on others for his well-being and protection. The dependent moral subject being weak and vulnerable is not capable of independently nor competently meeting his welfare needs.

The majority of SDAT patients are dependent moral subjects (welfare subjects) because of their cognitive deficits. The terms dependent moral subject, moral subject, welfare subject and the weak and vulnerable will be used interchangeably throughout the thesis. The relationship between moral subjects and agents occurs in a dynamic moral realm where many variables influence both the agent, the subject and the environment. The complexity of the moral realm should not be minimized. The relationship of the two parties and the realm they occupy was well described by Miller, who wrote that the “two distinguishable aspects of an agent’s responsibilities are (a) to the moral patients’ (read dependent moral subjects) (singly or collectively) to which the agent is responsible, and (b) the values for which the agent is responsible”.³

Another assumption is that a moral agent ought to support the good or welfare of individuals and in so doing, promote general well-being. In the case of moral agents, the priority is support and maintenance of individual autonomy, however, for dependent moral subjects it is protection of their positive and negative welfare needs. Supporting these global, fundamental needs requires promoting the instrumental and basic goods of health, education, nutrition and a safe environment. The mirror image of the goal of promoting autonomy is responding to the welfare needs of moral subjects in a respectful manner. Supporting these global, basic values requires promotion of the instrumental goods of health, education, nutrition and a safe environment. Hence, it is a good to protect welfare subjects from exposure to the threat of serious harm in any context, including those associated with health sciences research.

In a dynamic, interactive society composed of moral agents and subjects, the moral agent will receive positive and negative feedback for his efforts to respect obligations to moral subjects. Furthermore, in the deontological tradition, good or goal-based arguments must be the foundation of the conduct and social policies which the moral agents support. (This point will become more important as the chapter unfolds and the defence of protecting the weak and vulnerable moves beyond bald consequentialist arguments of social utility).

On account of a moral agent being autonomous and rational, he is capable of supporting society's values and accepting responsibility for welfare subjects. Also, moral agents can influence social policies in order that the basic, global value of autonomy and respect for all individuals is realized. In other words, he is a moral agent who can act independently, evaluate options, execute decisions, and take responsibility for his actions.

In linking morality and autonomy with rationality I acknowledge a Kantian insight about the moral realm. It is assumed that rationality is a necessary corollary of being autonomous, permitting consistent and informed choices and secondly, autonomy is constitutive of the individual who is a moral agent. In making this assumption, I am in the good company of T. Engelhardt who conceptualizes Kant's ethical theory as a way of demonstrating that to act morally "is to act rationally in the sense of acting in ways that are not self-contradictory".⁴ In order to formulate maxims that can be universalized without self-contradiction, it is necessary that the moral agent be rational and autonomous. Furthermore, this concept of self-respect involves extending the same respect to both rational and autonomous beings and also, individuals with diminishing and depleted autonomy and impaired rationality. Hence, the coherence of the moral realm depends on rational, moral agency.⁵

There are two short answers to the question about the moral status of individuals with SDAT. One answer is that they are no longer autonomous, are mentally incompetent and consequently have no rights, interests, claims, or responsibilities. The second answer, probably more popular, is that they have certain rights conferred by society (and perhaps inviolable), such as the right to dignity, respect and protection from harm. These short answers will be challenged by the longer answer that individuals with diminishing or depleted autonomy have fundamental needs (welfare needs) and are dependent on moral agents and society who have an obligation to protect these vulnerable individuals from harm. Although they lack autonomy and moral agency and therefore rights, they continue to have moral importance because they continue to have fundamental needs. It is acknowledged that concurrently vulnerable individuals (that is individuals with impaired autonomy) can have legal and conventional rights, (and do so, in Canada) depending on the social values, social policies and political climate of the given society.

The analysis of the status of SDAT patients will be in four steps, each step corresponding to a section in the chapter.

- (i) Present the philosophical foundations of this thesis.
- (ii) Discuss the loss of moral agency by SDAT patients and its consequences for affected patients.

- (iii) Propose a response to the question: "What rights if any, do SDAT patients have?"
- (iv) Discuss the claim that mentally incompetent individuals have the right to integrity and dignity.

In the conclusion, the work regarding the loss of moral agency and the obligation of society to protect the welfare needs of dependent moral subjects (i.e. SDAT patients) will be integrated and thereby pave the way for chapter four which examines society's response to the weak and vulnerable.

3.2 Philosophical Foundations:

The philosophical orientation of the thesis combines elements of deontology and consequentialism. Following strictly either approach will not lead to a resolution of the ethical problems troubling SDAT research. However, elements from both routes and a recognition of the points of convergence between both theoretical approaches can provide a way out of the either-or grid-lock. Before the proposed alternative philosophical approach is presented and justified, the limitations of both the deontological and consequentialist routes in the context of SDAT research ethics must be discussed.

Neither approach provides sufficient protection for the SDAT patient, who by his very nature, is vulnerable and depends on others to ensure that he is not harmed when involved with research. According to the Kantian perspective, moral subjects unlike moral agents, do not meet the criteria of being a human being and thus do not benefit from the protection accorded autonomous, rational moral agents who are ends in themselves. Given that they do not fall under the protective umbrella of the second formulation of the categorical imperative, they may be treated as means rather than ends, as experimental data rather than persons.

The principal limitation of the Kantian deontological approach is that it does not go far enough. This is the case because the Kantian notions of autonomy and moral agency which are constitutive of human nature, do not embrace individuals with diminishing and depleted autonomy. The concept of autonomy is central to human nature and supports the position that the individual's integrity is inviolable and that individual autonomy should be promoted and maintained. However, strictly speaking, this line of protection is not extended to the weak and vulnerable members of society lacking moral agency. Given that autonomy is constitutive of human nature and moral subjects are not autonomous individuals (hence not human beings) they are at risk of being treated as means rather than ends.

But if the Kantian approach can only go so far, the same observation can be made regarding the consequentialist route. The limitation of the consequentialist approach is that it does not protect SDAT patients from harm, should society's values change. Of course, it is true, that some societies do accept the obligation to protect the vulnerable members of its community and in turn, support this duty by social policies and legal statutes implementing or enforcing this accepted social value. However, there is no guarantee that this situation will remain constant. Society can change its priorities and consequently, the vulnerable could be viewed differently and become a convenient and passive pool of subjects for all types of SDAT research. Should there be a shift in social values and priorities, it is unlikely that appeals to the intrinsic worth of persons would stand up against social utility arguments. This lack of guarantee of protection for the weak and vulnerable is the main weakness of the consequentialist approach.

An example will clarify this point. One argument given by the Nazis in favour of establishing ghettos, was that the concentration of Jewish population and other specific populations would increase war productivity because factories and workers would be in close proximity. The Jews themselves co-operated because they reasoned that re-location would halt their being seized at random to work. While the action did maximize

productivity and minimized random selection of workers, it failed to protect their inviolable right to integrity and dignity, both of which evaporated in the face of social utility arguments justifying establishing labour camps and ghettos. Thus, the problem with consequentialism is not that it will not be properly implemented. Instead, the worry is that social utility arguments determined by social mores and prejudices properly applied will undermine general well-being.

Having shown that the Kantian and the consequentialist routes fail to provide a guarantee of protection to SDAT patients, I will propose an alternative approach to the problem. I propose to modify the Kantian concept of the realm of ends to include moral subjects. This modification is, however, consistent with the spirit of Kant's thought. In addition, points of convergence between deontological and consequentialism ethical theories, which focus on respecting the obligation to treat the disadvantaged in a beneficent and non-maleficent manner, are drawn together to provide a foundation for protecting weak and vulnerable individuals, especially in the research context.

The proposed enrichment or expansion of the Kantian concept of the realm of ends to include moral subjects takes into account individuals not considered by Kant, that is, the mentally impaired lacking moral agency and rationality. According to Kant, a rational, autonomous moral agent has

the capacity to make universal laws to which the agent is also subject. The agent belongs to the realm of ends and when "legislating, is subject to the will of no other. The rational being must regard himself always as legislating in the realm of ends possible through the freedom of the will, whether he belongs to it as member or as sovereign".⁶ Dependent, moral subjects lack practical reason or will and autonomy and thus, are not capable of formulating their personal ends. Nevertheless, as sentient beings, they can be harmed and if assisted, can perform some tasks and can respond in a limited way to their surroundings. Even when their autonomy is diminished and replaced by dependency, moral subjects nonetheless are related to agents and remain members of the moral realm. Thus, although they have severely limited capacities they continue to have fundamental needs (read interests, welfare needs or rights) and have moral worth. The first consequence, of expanding the Kantian concept of the realm of ends to include affected patients, is that they should be treated as ends in themselves having intrinsic worth. Secondly, the scope of the categorical imperative is likewise expanded to include the weak and vulnerable.

On the view I am developing, society's role is to promote the development of autonomous individuals and to protect those with diminishing or depleted autonomy. Therefore society's social policies should be supportive of these goals. However, in order to achieve these goals,

society has an obligation to provide the instrumental goods necessary for the attainment and maintenance of general well-being. Promoting autonomy and respecting dependent members of the community are two related aspects of the fundamental good of respecting all members of the community.

By contrast with the deontological approach which starts with obligations and moves to the good, consequentialism begins with the good, for instance, of protecting the weak and the vulnerable members of the community and later arrives at the obligations owed to affected individuals. Referring to consequentialism's starting point of a good or value accepted by society, Sumner states in The Moral Foundations of Rights, "A non-relative conception of value thus enables us to make sense of saying that there are ultimate goods - life, health, knowledge, pleasure or whatever - which all of us have reason to promote, wherever they may be found and whomever they belong to".⁷ These goals are desired by all reasonable, rational individuals and are worth pursuing for their own sake. Not to support these global values would be considered irrational and contradictory. In short, most individuals would agree that these goods are valuable and society should have social policies and a legal system to ensure that these goods are maximized. In addition, the instrumental goods, or infrastructure required to achieve these general values should be secured and maintained. These

goods are valuable for all individuals and hence are neither relative nor subjective. These values can be integrated with the basic, global value of supporting individual autonomy. Indeed, the fact that these separate yet related goods can be combined presupposes their commensurability.⁸

Thus, supporting and maintaining individual autonomy is consistent with the provision of the prerequisites of welfare for all members of the community which includes protecting dependent moral subjects from harm.

Consequentialists, like Sumner and Hare, can develop a set of values grounded in rationality and claim that the global goals and constituent values of these goals are not dependent on the vagaries of individual moral agents. However, there will be jurisdictions that will not accept this set of values and the vulnerable will be at the mercy of public pressure. To be more precise, the market place and cost-containment policies could dictate, not only the type of research that will be funded, but also the manner in which SDAT patients will be associated with research.

The alternative approach also proposes that moral agents have an obligation to respect and protect the weak and vulnerable. The first point of convergence between deontological and consequentialism ethical approaches is that they both agree that moral agents have an obligation to protect the weak and vulnerable. For the deontologist, accepting the moral obligation to treat affected patients as ends in themselves can occur if the concept of

the realm of ends is appropriately enriched. Then, it becomes possible to will consistently maxims promoting the well-being of the disadvantaged. The consequentialist can recognize that individuals and society have obligations to affected patients and defend these obligations to the weak and vulnerable without accepting the premise that the mentally impaired have intrinsic worth. Furthermore, the second point of convergence for deontologists and consequentialists is their appeal to prudential and self-interest reasons to justify their acting in a non-maleficent and beneficent manner to the weak and vulnerable. Kant's imperfect duties to others are based on a realization that the moral agent wants to receive "love and sympathy" when he is in need.⁹ Similarly, the consequentialist justifies actions and rules in terms of what will best serve the needs of the community and its members.

Thus, in my alternative approach, there is an intersection of the deontological and consequentialist routes when moral agents turn their attention to "putting into action". For consequentialists the good to be promoted is the well-being of the weak and vulnerable which is consistent with the ideal of individual autonomy. Even in Kant we have the intersection of deontological and consequentialist approaches. Although Kant did not consider the situation of mentally impaired individuals, the discussion of imperfect duties to others demonstrates that Kant would

support treating moral subjects in a beneficent and respectful manner. Men would not will as a universal law “let each one be as happy as heaven wills, or as he can make himself; I will not take anything from him or even envy him; but to his welfare or to his assistance in time of need I have no desire to contribute”.¹⁰ Rational men would not support this law of nature because to do so is logically inconsistent “since instances can often arise in which he would need the love and sympathy of others, and in which he would have robbed himself, by such a law of nature springing from his own will, of all hope of the aid he desires”.¹¹ Kant allowed for moral subjects to be the ends of principles generated by moral agents and thus, they are treated as ends in themselves having intrinsic worth. Kant’s imperfect duties extend protection from moral harm to moral subjects (for instance, SDAT patients). There is an element of self-interest in the formulation of imperfect duties which is echoed in the consequentialist’s approach to protecting the weak and vulnerable. However, the Kantian approach grants intrinsic worth to those requiring “the love and sympathy of others”.¹²

The Kantian moral agent’s prudential and self-interest argument for assisting the less fortunate is of limited value if the moral agents only assist other moral agents. Hence, the expansion of the concept of the realm of ends is logically consistent with the notion of imperfect duties. A moral agent treats moral subjects with respect because of their intrinsic worth. In

addition, Kant recognized that a moral agent's actions are influenced by the desire to be treated in a respectful manner if he becomes a moral subject. Hence, the moral agent wants the realm of ends to include moral subjects in order to guarantee that if he should become a moral subject, he will be treated as an end, not exclusively as a means. It would be logically inconsistent for the moral agent to restrict the realm of ends to rational moral agents because, under these conditions, he could not expect to be treated in a respectful, beneficent and non-maleficent manner in the event he becomes mentally impaired. More regarding this point is in chapter five.

The alternative approach proposed can be stated in a maxim referring to the manner in which weak and vulnerable members of humanity should be treated by autonomous moral agents. The maxim is "Autonomous, moral agents ought to protect dependent moral subjects and respect their welfare needs". The moral subject has the negative welfare need to be protected from harm which is a broad term referring to anything that threatens his physical and/or mental health. Welfare needs also include positive assistance in the areas of shelter, food, clothing, safe environment adequate health care and access to legal services. Could this maxim be universalized and be the basis of planning, providing and evaluating society's treatment of SDAT patients? To answer this question, I propose that we subject the maxim to some kind of a test recommended by

Drs. Thomas and Waluchow in Well and Good. They recommend criteria based on three formulations of the categorical imperative. The criterion consists of three questions and they state that a wrong answer to any of the questions would mean that the moral agent has a moral obligation to refrain from acting on his personal maxim.¹³ The “right” answers to the three questions are:

- (i) yes
- (ii) no
- (iii) no

Thus, the “wrong” answers are:

- (i) no
- (ii) yes
- (iii) yes

These are the three questions:

- (i) Could I consistently will, as a universal law, the personal maxim upon which I propose to act?
- (ii) Would my actions degrade other rational agents or myself by treating them or myself as a mere means?
- (iii) Would my action violate the autonomy of some rational agent, possibly myself?

Given my reformulation of the Kantian concept of the realm of ends, the questions should be modified as follows.

- (i) Could I consistently will, as a universal law, the personal maxim protective of moral agents and subjects, upon which I propose to act?

- (ii) Would my actions degrade other rational agents, dependent moral subjects, and/or myself by treating them or myself as a mere means?
- (iii) Would my action protect the integrity of rational agents and/or moral subjects, including myself?

Before turning our attention to the proposed maxim to determine if all the revised questions can be answered positively, some clarification of the reformulated questions is necessary. Regarding the reformulated first question, the modification specifies that maxims, when generalized, apply to a wider class composed of those who are autonomous and also those who lack sufficient autonomy to be moral agents. In respect to the second question, the amended question strikes at the central issue: once the concept of humanity is reformulated, then both moral subjects and agents have intrinsic worth which is to be respected. Also, moral agents have an obligation to respect the dignity of both agents and subjects. To do otherwise degrades not only the moral agent initiating the maxim but also the object of the maxim which can be a moral agent and/or subject. In the third question, autonomy of some rational agent has been changed to integrity of the agent and subject to capture the fact that the realm of ends has been expanded to include both autonomous and non-autonomous individuals. Both agents and subjects have integrity, that is they are ends

in themselves, and hence violation of this common characteristic replaces autonomy which is only possessed by agents.

If the answer to the first question is “yes” and “no” is the answer to questions two and three (as I believe it should be), this confirms that my proposed maxim “Autonomous, moral agents ought to protect dependent moral subjects and respect their welfare needs” could be universalized. In respect to the first question, the answer is “yes” because the maxim can consistently be willed to be a universal law because competent autonomous moral agents would agree that they would benefit from the protection afforded by this maxim in the event that they became weak and vulnerable. Regarding the second question, the answer is “no” because the maxim would prevent a moral agent from degrading himself or others whether they be agents or subjects. Also, the maxim would not condone the action of an agent who undermined his own autonomy by treating either moral subjects or agents merely as an instrument to realizing an end. When the Kantian notion of the realm of ends is expanded, failure to respect the integrity of other (subjects and agents) undermines the agent’s autonomous nature. Hence, the maxim should protect vulnerable individuals from association with research treating research subjects as experimental data.

Regarding the third question, again the answer is “no”. There is a moral obligation to act on the maxim and if moral agents elect not to protect

the integrity of the mentally impaired, they fail to respect the intrinsic worth of dependent members of the community. Having shown that the proposed maxim is universalizable, let us now consider the primary consequences of adopting this maxim. The direct consequence would be that the freedom of some moral agents would have to be restrained in order to achieve the good of protecting the vulnerable from harm and respecting their welfare needs. Restraining individual freedom is called justice by Kant because the rationale for limiting freedom and moral agency encompasses preventing individuals from being treated unjustly, that is, from being treated merely as a means. Kant sanctioned limiting the actions of moral agents on the grounds that their interventions would promote the essential ends of humanity. "The fundamental rule, in terms of which I ought to restrain my freedom, is the conformity of free behaviour to the essential ends of humanity. I shall not then follow inclinations, but shall bring them under a rule.....and being a free agent, I must have a rule, which is the essential end of humanity".¹⁴ Later in the same text, Kant stated, "The conditions under which alone the fullest use of freedom is possible, and can be in harmony with itself are the essential ends of humanity. It must conform with these. The principle of all duties is that the use of freedom must be in keeping with the essential ends of humanity".¹⁵

Under ideal circumstances, limitations on moral agency would not be needed. Moral agents being autonomous would realize their goals when their particular ends are compatible with other moral agents exercising their will to pursue their personal goals. Simultaneously, moral subjects are respected and their welfare needs are met by moral agents. Thus, rational, moral agents would not need to interfere with other agents engaged in achieving their goals. Unfortunately, ideal conditions seldom prevail. Rules and social policies are required to restrain some individuals from interfering with the freedom of others and to ensure that subjects are respected. Agreeing to laws restricting the freedom of researchers and protecting the vulnerable only makes sense in a society having the infrastructure to apply, explain and enforce these maxims.

Having considered the major consequence of universalizing the proposed maxim, the next issue to be addressed is the question of justification. Why should individuals and society subscribe to a rule which protects the vulnerable from harm and ensures that their welfare needs are met? There are several basic reasons why moral agents and society would adopt universal rules to promote general well-being of all members of the community, including those who are autonomous and those with diminishing and depleted autonomy.

First, most reasonable individuals, if placed behind a Rawlsian veil of ignorance and asked whether they prefer a society which respects or neglects the needs of all members including autonomous and non-autonomous individuals, would choose to live in the former society. In other words, the majority of autonomous, rational individuals would choose a society that is committed to providing the "basic goods" or fundamental needs of its members. Also, they would agree for prudential and self-serving reasons, that the vulnerable members of the community should be respected and not be exploited. Hence, interventions, rules and legal statutes designed to protect the weak and vulnerable are justified because the majority of rational, reasonable moral agents agree that protective measures are needed at the macro and micro level to promote the well-being of themselves and others. Appropriate self-interest or self-love is consistent with the Kantian notion of imperfect duties despite its apparent incompatibility with Kantian disclaimers about self-interest detracting from pure motivation.

There are two senses of self-interest relevant to this discussion. First, there is self-interest which operates like an insurance policy. As a moral agent, I am interested in doing what is necessary to promote my autonomy and well-being. This is the sense in which Kant used the notion of self-interest. Secondly, self-interest can be understood more generally as

referring to a beneficent attitude grounded in justice. For example, a rational, moral agent behind Rawls' veil of ignorance evaluates actions in terms of what would be in the best interests of all, including himself. Thus, principles and actions are supported not because they will always work in my favour, but because the decision is a fair one. In the realm of SDAT research, both senses of this notion play a role. As a moral agent, I treat the weak and vulnerable in the fashion I would prefer to be treated, if I were an SDAT patient. On another level, I acknowledge that for the best interests of society, the weak and vulnerable should be treated in a respectful, humane manner which in turn will have benefits at the micro level.

Secondly, as mentioned earlier, from the Kantian perspective, competent moral agents would choose in advance not to be harmed in the event that they became moral subjects. To do otherwise, would be logically inconsistent. When discussing imperfect duties to others, Kant stated that it would be illogical for a prosperous individual not to assist someone less fortunate because he can acknowledge that it is possible that his circumstances could deteriorate and if so, he would prefer to be treated in a respectful and helpful manner.

The decision not to be responsible for protecting the vulnerable and meeting their welfare needs carries serious risks. A moral agent would

have to accept that if he became vulnerable, there is a strong possibility that he might not receive beneficent care and he runs the risk of being harmed. Thus, he could be responsible for his own welfare, and hence will need to “purchase” the protection and treatment required for his safety and well-being and not be dependent on individuals and society. Considering that most moral agents are not prepared and/or can not afford to take these risks, the majority would prefer the establishment of universal rules of conduct in respect to the vulnerable individuals, for instance, SDAT patients. Provision of protective measures can be supported by most individuals on self-interest and prudential reasons because, barring an early death, anyone who lives long enough to become elderly is a member of a weak and vulnerable population and his position would be exacerbated if he was elderly and had SDAT.

When a moral agent fails to consider the possibility that he could partially or fully be dependent on others because of a loss of moral agency, he is cutting himself off from the very assistance he wants to receive if his fortunes declines. Hence, it would be illogical for the autonomous moral agent not to recognize the need for imperfect duties of respect and beneficence to moral subjects. In addition, these rules respect the intrinsic worth of both moral agents and subjects by expressing respect for the nature of man as an autonomous moral agent who could be a dependent

moral subject. Therefore, the possibility of moral subjects being treated as merely a means to an end is minimized.

Thus, Kant's justification of restrictive rules and laws is compatible with the consequentialist's utility argument favouring judicious government interventions. However, the deontological approach is on firmer ground because it recognizes the intrinsic worth of the mentally impaired, immune to fluctuations in social values and public opinion pressures. Again, the major concern with consequentialism is that when it is properly applied, in some cases, the weak and vulnerable could be denied adequate protection from harm.

Thirdly, the consequentialist can justify having general rules applicable to all regarding treating the weak and vulnerable in a protective, respectful manner. The consequences at the macro level and micro level justify the consequentialist's position that the fundamental needs of the disadvantaged should be met. Society's primary goal is promoting general well-being and respect for all its members. To be more specific, it is a good to promote general well-being and protect the weak and vulnerable. These goods are realized by means of implementing and evaluating social, health and research policies designed to promote these primary goods. Hence, the interventions are justified if they maximize the realization of society's fundamental, global values. Constraints on individual autonomy are

justified when they are required to promote individual autonomy and the maintenance of instrumental goods.

Now the objection can be raised that my alternative approach is fundamentally a consequentialist position because a moral agent considers what rules and actions would best serve his needs if he became a moral subject and acts accordingly. Undeniably self-interest and prudential thinking underpin the veil of ignorance line of reasoning, and also the expansion of the Kantian position in respect to the realm of ends. However, from the perspective of a moral agent, it is reasonable for him to think in terms of maximizing his security and it is hard for him to escape consequentialist thinking especially when we are all facing growing older and becoming vulnerable. Kant admits that the rationale for imperfect duties is self-interest. Hence, the point is well taken.

The difference between the deontological and consequentialism approaches and my proposed alternative position is that my account recognizes the intrinsic value of the affected patient. Thus, it attempts to guarantee that the vulnerable will be treated in a respectful manner because of their moral worth and not because it is socially acceptable and/or demanded by legal statutes. Thus, the expansion of the concept of the realm of ends, should serve to protect the mentally impaired from the mere exercise of society's discretionary powers. The similarity between the

proposed alternative approach and the deontological and consequentialism position lies in the recognition of the role of self-interest in determining how moral agents treat moral subjects.

To conclude, what are the implications of this approach for SDAT research? The proposed alternative approach supports the position that research regulations are necessary to ensure that autonomous moral agents honour their obligations to respect and protect moral subjects. Hence, the establishment of research rules and legal statutes, concerning the involvement of mentally impaired individuals in research, would be in keeping with realizing the good of protecting weak and vulnerable individuals.

Moral agents have the moral title or authorization to interfere with another's exercise of unbridled freedom by developing research codes of ethics. However, research recommendations and legal rules must be based on a recognition of the moral worth of moral agents and subjects and therefore, should protect all concerned parties from association with SDAT research threatening the well-being of mentally impaired individuals. In other words, the research guidelines should reduce the incidence of disrespecting a moral agent's autonomy and failing to adequately protect a dependent moral subject. Constraints on the researcher's freedom and society's discretion are sanctioned because they serve to protect both moral

agents and subjects from harm. For Kant, the freedom of rational moral agents can be limited by justice and legal constraints belonging to the domain of enforceable obligations.

An implication in respect to the use of affected individuals in SDAT research, is that the researcher is not exempted from the obligation to respect and protect vulnerable individuals. Meeting the welfare needs of the mentally impaired subjects to be protected from harm is a non-negotiable good, which should not be compromised when affected patients become research subjects. If vulnerable subjects are not respected, one possible negative consequence is that the community could develop a mistrust of the research and retaliate by reducing public support for research. In addition, caregivers could refuse to consent to research and thus deprive researchers of a sufficient number of research subjects to yield statistically significant results. Thus, SDAT research would be effectively frozen.

Statements calling for a relaxation of research codes because they are too restrictive and costly are persuasive. Counter arguments must be on firmer ground than social utility arguments exclusively. The proposed alternative approach should provide a sound foundation for replying to this pragmatic position because it does consider the costs and benefits of research policies. At the same time, the intrinsic worth, or in other words,

the integrity and dignity, of all research subjects, is valued and respected. If the vulnerable subject's intrinsic worth and fundamental needs are not honoured, then these individuals are being used merely as a means which is not morally acceptable.

There are elements of consequentialist and deontological thinking in the proposed philosophical approach. As discussed both routes have limitations and hence I can not commit myself fully to one or the other approach when addressing the ethical issues in SDAT research. Thus, I have brought together elements from both approaches in order to find a way to understand the moral status of moral subjects and how we should respond to these weak and vulnerable individuals.

3.3 The Developmental and Dynamic Theory of Autonomy

It is necessary to start by looking at the capacity for autonomy because much of the debate about the rights of SDAT patients hinges on whether or not they have autonomy, or to be more precise, the ability to act autonomously. Autonomous individuals are rational, able to make decisions, exercise control over their lives and act independently. An autonomous moral agent has the capacity to retain and evaluate information, make a decision based on sound reasons and at the same time resist coercion from other individuals, groups and institutions. They are

the masters of their own lives which is to say that they are autonomous agents.

The developmental theory of autonomy is based upon the work of Lawrence Haworth. In his book Autonomy,¹⁶ Haworth presents a comprehensive analysis of autonomy incorporating two understandings of autonomy: (i) as a psychological and, (ii) as a normative idea. Central to Haworth's theory of autonomy is the notion that the capacity to be autonomous develops and secondly, that there are degrees of autonomy.

I propose now to extend his concept of autonomy and then use this modified theory, called developmental or dynamic, to explain the demise of autonomy, moral agency and competency characteristic of SDAT. Haworth's conception of autonomy supports the argument that autonomy is a matter of degrees and is not an absolute term. Depending upon the situation, a different degree of autonomy is required. Also, depending upon the situation, a different degree of autonomy is permitted to be exercised by the agent.

A great deal of the discussion whether SDAT patients have rights hinges on whether they are autonomous, or to be more precise, have the capacity to act autonomously. It will be argued in this chapter that strictly speaking, they lack rights because they lack autonomy. Later in the fifth chapter it will be proposed that the specific task of consenting to research

requires a high degree of competency that excludes the majority of SDAT patients. However, before discussing the notion of diminishing moral agency, the salient features of Haworth's theory will be presented

The developmental theory is in the Kantian tradition but differs from Kantian theory of rationality because it allows for degrees of autonomy and rationality (and therefore, for degrees of mental competency). In other important ways, the two theories converge. Both the Kantian and the developmental theories are based upon two necessary conditions: the individual must be an autonomous, rational agent and have freedom to exercise his options.

Haworth proposes that autonomy as a psychological concept has two levels called minimal and normal. The development of the capacity to be autonomous and degrees of autonomy are central to Haworth's theory and his concept of autonomy provides an account of the development of an autonomous, competent individual (whom I have called a moral agent). Normal autonomy or what I call full autonomy requires self-control, independence, competency and the ability to reflect critically. The child has minimum autonomy when he has the capacity to complete a range of tasks competently but lacks higher reasoning abilities required to have normal autonomy. As he states succinctly, "An advantage to relating autonomy to competence is that it points to the necessity of conceiving autonomy

psychogenetically. Further, it suggests clues concerning the main stages in the psychogenesis. One obviously is not born autonomous; one only has a capacity and a native impulse to become so. And although becoming autonomous is an achievement, it doesn't happen all at once but can be in stages".¹⁷

So according to Haworth, in the normal course of human development it is natural for autonomy to develop. Granted that an individual is not born autonomous, the development of the capacity is a function of his environment and development pattern supervised by his parents or guardians. The parent's task is to assist the child develop the traits of an autonomous individual: independence, self-control and competence. The long term goals are to prepare the child to be critically competent, make sound and moral choices, be autonomous and accept what Haworth terms the autonomist position. For Haworth, minimum and normal autonomy are related because normal autonomy builds on the skills and knowledge attained at the level of minimum autonomy. At the higher level, the individual has more competence, independence, and self-control.¹⁸ The ability to act on the basis of reasons distinguishes the higher of these two levels of autonomy. In addition, the degree of self-control, discipline and the level of competence in executing a skill are a function of the individual's development. The crucial difference between minimum and

normal autonomy is that when the individual has normal autonomy he has the ability to give sound reasons for actions and to reflect critically upon data presented. The use of critical reflection to evaluate which path to choose distinguishes the two categories of autonomy. No rites of passage identify that an individual has attained normal autonomy. States Haworth "... there is no magical moment when from being non-autonomous one becomes autonomous or from being minimally autonomous one becomes autonomous in the full sense. No more than there is a time when a callow youth becomes a mature adult".¹⁹ Some individuals with minimum autonomy do not have sufficient autonomy and rationality to meet the criteria of a Kantian rational agent.

In the normal course of development Haworth thinks it is natural for autonomy to develop. Responsible parents structure the child's environment in order for autonomy to be nurtured and respected. The parent's task is to assist the child to develop the traits of an autonomous individual: independence, self-control and competence. The long term goals are to prepare the child to be critically competent, make choices, be autonomous and accept what Haworth terms the autonomist position. An individual is not born autonomous and the development of the capacity is a function of his environment and development pattern. The individual with minimum or simple autonomy is capable of completing tasks competently

but lacks higher reasoning abilities required to have normal or full autonomy.

Competence, self-control and independence are the three requirements for normal autonomy and a deficiency in any of these three traits, as Haworth calls them, prevents an individual from being autonomous.²⁰ The notion of competency, for Haworth refers to the capacity to reflect, deliberate and make a decision. The transition from minimum to normal autonomy can occur only if the individual has mastered “a measure of deliberation or critical reflection” which is an expression of the individual’s rationality.²¹ A rational, competent individual has the capacity to think through issues and to appraise information critically. His decisions and conduct are based on reasons as opposed to being reactions. Thus, one result of critical reflection is “to cause the activity it guides to come out from under the control of other people”.²²

Both types of autonomy require some degree of self control but the ways in which one has self-control become more complex as one becomes fully autonomous. Self-rule or self-mastery is required for an individual to be autonomous. There is a relationship between the degree of autonomy and the degree of self-control. The fully autonomous individual is not ruled by emotions, desires or biases. In contrast, minimum autonomy requires self-control in respect to simple skills and decisions. Full or normal

autonomy requires self-control in respect to sophisticated decision-making which requires a comprehension of and reflection upon data, sometimes complex and contradictory.

Thus, the ability to be critically reflective and reach decisions on the basis of reason distinguishes these two levels of autonomy. The degree of self-control, discipline and the level of competence displayed when critically evaluating options are a function of an individual's physiological and psychological development. To follow up on Haworth's claim that no rites of passage identify that an individual has attained normal autonomy, consider for example, the reasons for decisions made by children. A child may select a preferable option of playing in his garden and not on the street because of habit and fear of punishment, and not because of his ability to make a sound decision after evaluating options. As he matures, the individual is capable of making decisions about where he will and will not go, based upon reasons. Later, if he has the misfortune to develop SDAT, he will depend on others to control his environment to prevent him from wandering and getting lost because he can not decide nor recognize where he is located and how to retrace his steps.

An autonomous moral agent should not be influenced by coercion. Having attained normal (full) autonomy, the agent has achieved separation and distinction from others, or to use Haworth's term, "individuation" from

others has occurred. Unless individuals separate from others, they do not have the “ability to make projects their own”, and “this individuation is incomplete in that they remain creatures of others or of their own impulses”.²³ Autonomy is present when there is independence of thought, will and action. Like autonomy, independence is on a scale but the optimum condition of complete independence in all three categories is achieved by few. The thoughts, wishes and movements of all are constrained and influenced by many factors beyond one’s control.

However, given that we are enmeshed in a society and are bombarded with information (often biased), the ideal of complete independence is achieved by few. Hence, it is necessary to evaluate critically these influences and minimize their impact in order to be as independent as possible. In the fifth chapter, ways of managing and reducing coercion are proposed.

The independence Haworth focuses on, he calls procedural independence which refers to independence in thought. The ability to think critically, appraise information and make judgements is essential to being autonomous. Having this critical facility which could be termed critical appraisal, advances the individual from minimal to normal autonomy. When the ability “to reflect critically on one’s own conduct has been developed, then by exercising the ability one gains a measure of control over

one's life which those who continue to be guided by others and their own impulses forego".²⁴

The integration of the three essential traits (self-control, independence and competence) is critical competence which is constitutive of normal autonomy. Critical competence differs from competence because it embraces more than competency to complete certain tasks (for instance, activities of daily living) and more than mental competency. To have critical competency is to have the ability to analyze options without coercion, in terms of their value and consequences and choose an option based on reasons. This level of reasoning takes into account intentions, biases, overt and covert pressures. Thus, critical competence incorporates the three characteristics of full autonomy (self-control, independence and competency) and expresses their inter-relationship. Writes Haworth "Having critical competence, a person is first of all active and in his activity succeeds in giving effect to his intentions. Having critical competence, the active person is sensitive to the results of his own deliberations; his activity is guided by purposes he has thought through and found reasons of his own for pursuing. Normal autonomy is critical competence. As a complex character trait or habit, the signs of its possession are found in the way a person meets the challenges of day-to-day living and, beyond this, creatively seizes the opportunities that come his way".²⁵

We now move from the psychological notion of autonomy to consider its normative force. There is a normative component to autonomy because the autonomous individual is also a responsible moral agent and ought to consider the impact of his actions upon others and himself. Also, he should strive to maintain his status as a fully autonomous individual, accepting his responsibilities to others and society in general. Because autonomy is the principal value, a fully autonomous individual should promote and/or maintain conditions in his community that support the development of autonomy.

Thus, being responsible is also a necessary condition of being autonomous. Those who have crossed the threshold to normal autonomy “are thought of as responsible for their acts and lives. For this a measure of critical competence is necessary”.²⁶ Haworth’s fully autonomous individual is a moral agent: he makes and executes decisions using his critical competence in situations of choice that will affect others. To be autonomous, the moral agent must have a high degree of critical competence. Being autonomous demands that one is responsible for one’s decisions and the results of the decisions. In other words, being autonomous is a social activity. An autonomous individual at the normal level is responsible for his behaviour and the consequences of his decisions. Recalling the individuals’ enmeshment in a task environment or social

milieu, Haworth considers that individuals have a generalized responsibility for the activities of their community. There is item specific responsibility and generalized responsibility for the values and behaviours supported by the society's legal and conventional rules and supported by their social policies. A responsible, critically competent individual has accepted some responsibility for the community's actions and, in Haworth's words, has "a standing bias against becoming irresponsible".²⁷ With this moral stance, comes a responsibility to protect the community's disadvantaged.

Having discussed Haworth's concept of normal autonomy, the relationship of full autonomy to the concept of moral agency is evident. A moral, rational agent is required to have what Haworth calls normal autonomy. The requirements for both moral agency and normal autonomy are the same: self-discipline, responsibility and critical competence.

Moral agency or normal autonomy can only develop and be sustained in a society having an infrastructure providing the constituents of well-being: education, health care, legal services and a safe environment.²⁸

A similar point was made by J. Raz in his recent work The Morality of Freedom in which he argues that liberalism should have a commitment to promoting the conditions and the infrastructure required for promoting autonomy.²⁹

Recalling that valuing autonomy is accompanied by protecting the weak and vulnerable, the same infrastructure should serve the needs of those with diminishing and depleted autonomy. Thus, not only the development, nurturing and support of autonomy, but the protection of the vulnerable, require that the society be committed to the value of autonomy.

The extension of Haworth's developmental approach to autonomy and competency admitting of degrees is applicable to the clinical experience with SDAT patients. Competence to perform certain tasks is not always equivalent to being fully autonomous. Consider the case of a child who as he matures, becomes more competent in executing certain skills and builds on these abilities to complete competently, more complex tasks. Thus, as the child moves along the continuum of autonomy, he moves from less than minimum to minimum autonomy and, then to normal (full) autonomy. However, as a SDAT patient deteriorates, the process is reversed. When he loses full autonomy he loses the capacity to perform competently tasks associated with critical competency. As he continues to be more dependent, he moves along the continuum to minimum and finally to depleted autonomy.

The degree of autonomy an individual has can remain constant, increase or decrease. As a child matures and becomes independent, gains self-control and is able to critically reflect, he develops normal or full

autonomy. As a moral agent, his status can be constant for a long period, and then for a variety of reasons, the same traits can diminish and an individual's degree of autonomy can deteriorate to the level of minimum or depleted autonomy. Haworth only discusses progression along the continuum from simple to normal autonomy but an individual can deteriorate and move from normal to minimum and then depleted autonomy. The theory is extended to explain the process in reverse, that is when a moral agent's autonomy diminishes and/or is depleted. Not only can an individual mature and move along the continuum of autonomy, moving to minimum and then normal autonomy, but he can deteriorate and have diminished or depleted autonomy. The ravages of the SDAT, lead to a deterioration in judgements, insights, memory, and cognitive abilities and therefore, the ability to be an autonomous, rational moral agent deteriorates. This decline is a mirror image of their progress on the continuum of autonomy during their youth. Unfortunately, the decline can occur in much less time than it took to acquire normal autonomy. Considering that the degree of autonomy can increase or diminish to the point of depletion, I have called the theory dynamic or developmental.

Before proceeding further, a few words about diminishing and depleted autonomy are necessary. Individuals below full autonomy may not have the possibility nor the capacity to attain full autonomy or critical

competency. The possibility is denied by social and environmental factors. For instance, parents may neglect raising their children to be responsible and independent, or society may not support a universally accessible education and health care system. An individual lacks the capacity to develop full autonomy when health problems impede his psychological, physiological and normative development, for instance, being developmentally delayed and having serious learning problems. An SDAT patient has diminished autonomy because there is no possibility that he will recover his lost moral agency. In contrast, a child at the same threshold of minimum autonomy does not have diminished autonomy because he has the possibility to be a moral agent.

Where do Alzheimer's Disease patients fall on this continuum?

The individual who develops SDAT has diminishing autonomy and therefore moves downward on the continuum as the disease progresses. Between these three markers (full, minimum and depleted) which roughly correspond to the three broad stages of early, middle and end stage SDAT, there are grey areas which moral philosophers and clinicians find hard to assess. Considering that diagnosis is based primarily on identification of symptoms (for instance, failing memory, poor judgement and insight), a few, newly diagnosed patients could be at the level of full autonomy but as cognitive functioning deteriorates they will have minimum autonomy. Lacking

sufficient autonomy to be a moral agent, they have become dependent moral subjects. Usually by the time the disease has been diagnosed, the patient with significant deficits would be located at the level of minimum autonomy. Thus, while able to perform some functions he is unable to manage effectively important aspects of his life. As the disease advances, the patient (now a dependent moral subject) becomes more impaired because of his failing capacity to be autonomous (accompanied by deteriorating cognitive functioning). Then as his dependency on others increases, he moves to the level of depleted autonomy and eventually is fully dependent on autonomous individuals and society to ensure that their welfare needs are met. In the following chapter, it will be proposed that the majority of SDAT patients are at the level of minimum autonomy or below and therefore, do not have the capacity to consent to research. For the present, suffice it to say that the consent process requires that the prospective subject have the capacity to consent to an important decision freely, which involves remembering and assessing information given by the researcher, evaluating the probability of being harmed, and appreciating the consequences. Thus, the capacity to consent requires critical competence (or full autonomy). The fact that the behaviour is initiated by the individual and that he is responsible for his behaviour, in a sense makes the behaviour the individual's own behaviour.

The decisions made by those with normal autonomy and critical competence can be complicated. Autonomous individuals often are faced with a number of options with different consequences that in turn require more decisions to be made. The agent must be capable of ranking options and evaluating consequences which again underscores the need for critical competence when assessing options and making important decisions.

Individuals at the level of minimum autonomy or below need to be protected first from their own actions and secondly, the behaviour of others. For instance, unless supervised, an individual with SDAT can take a walk unaccompanied and being unable to recognize his surroundings, get lost, wander and can die from exposure before found.

For the autonomous agent, life is a series of decisions and these decisions can be ranked. There are discrete, momentous decisions which can impact immensely on the course of our lives and/or the lives of others. Consenting to be a research subject and deciding to refuse life-saving treatment are examples of discrete and important decisions. At the other extreme, there are everyday decisions which we make so often that after a period of time, a habit has been established and we are unaware of our making a decision. Then, in the middle there are discrete decisions which will have important consequences but not on the same scale as momentous decisions. In the process of making pivotal, discrete decisions, an

autonomous agent at the same time is “simultaneously making a life, and that what is finally important is the degree to which that life is his own, under his control”.³⁰ An autonomous moral agent is in control of his life and exercises critical competence to make sound decisions for which he is accountable. However, as SDAT progresses, the patient first loses the capacity to make important, pivotal decisions followed by an inability to make less important ones. Progressively, he loses moral agency, independence, self-discipline and is not responsible for his well-being. The persistency of competency in some domains may give the false impression that critical competence is intact. Hence the need for careful assessments of SDAT patients before they are asked to consent to research and make other important decisions.

The important distinction between freedom to deliberate and freedom to act must be emphasized when assessing individuals with physical and external constraints on their activities. This distinction is an important one in the realm of geriatric care. It is a common mistake to make, but it should not be assumed that because an individual can not execute a decision requiring critical competence to make, he is incompetent to make the decision. For instance, an elderly individual who decides to make a new will disinheriting all his children and leaving his fortune to the Humane Society can be competent to decide how to disperse

his assets but unable because of problems with hearing and some paralysis following a stroke, to write the will, make an appointment with a lawyer or travel alone to the lawyer's office. Unless he is assisted he is not able to execute his decision. Also, the environment can restrain both the freedom to make and execute a decision. Institutionalized individuals frequently are deprived of the means of executing their decisions, even sound ones and are coerced to make decisions that do not disturb the status quo.

Haworth acknowledges the important role of the environment in decision-making. He states that the individual's life is organized into structures or systems, such as families, neighbourhoods and a society which are interdependent and interacting with each other. What he terms the task environment (the task being to be autonomous) is ordered into categories and structures which permit us to function. The so-called task environment for autonomy is multi-dimensional and the individual interacts with many individuals, groups and institutions concurrently. For instance, when consenting to research, the prospective subject may have to consider the impact of participating on his family, health care team and community, and also, whether participation conflicts with his goals and values. With a SDAT patient, the capacity to weigh all these factors deteriorates and hence, it becomes increasingly difficult to evaluate the consequences of consenting or refusing. The capacity to interact with other individuals,

specifically moral agents wanes and concurrently the ability to respond to feedback deteriorates as the affected patient becomes more dependent on moral agents and society.

Also society has the power to nurture or prevent the development of critical competence. In Haworth's words, society can have two faces, "One is the face of opportunity, the other is the face of constraint".³¹ In so far as the environment is flexible, controllable and accessible, it forms a domain for autonomy. When these conditions are threatened, the extent to which an individual can live his life on his own terms is diminished and "there is little chance to act in accordance with behaviour motivated by his critical competence".³² The power of institutions to coerce has been well documented by social scientists, most notably by Goffman.³³ The term "institutionalized" has become shorthand for the stifling of autonomy in institutions, such as residences for the elderly. One of the most powerful institutions is the health care system where the distribution of power between researcher and subject and also, between physician and patient is unequal. Hence, there are risks associated with challenging the rules or, to use Haworth's terms, the opportunities and constraints. In short, institutions are strong systems which are not value-neutral and can present a threat to autonomy which has to be reckoned with. In chapter five, ways of minimizing coercion will be proposed.

Haworth, however, has over simplified society's role in supporting the growth of autonomy by making it either for or against autonomy. Herein lies a problem that has troubled most liberal, democratic countries: how much freedom can be permitted before constraints are imposed? The same problem lies at the heart of this thesis: to what extent can the freedom of the researcher be constrained by the rights of the research subjects, if in fact they have rights? If they do not have rights, on what basis is research controlled? It is this balance between freedom and constraint that must be found if we are to prevent both harm to the individual and society. There will be more discussion of this balance in the following chapter.

Haworth considers autonomy to be society's primary value. However, this statement must be put in a context. After basic survival needs are met, individuals can move on to examine interpersonal issues and their relations with others and society in general. At this stage, individuals will value autonomy as a fundamental value and strive to promote and maintain individual autonomy and the infrastructure required, not only to facilitate basic needs, but also the promotion of a society valuing autonomy. A society will determine the level of autonomy it deems desirable and is prepared to underwrite: providing the constituents of autonomy can be costly. Some communities could decide that society can not promote

developing a high level of individual autonomy because the social policies and infrastructure, required to realize this end, are too costly. Should that be considered to be the case, then some compromises have to be made on the level of autonomy to be realistically realized.

Although Haworth does not discuss specifically the status of those with diminishing and depleted autonomy, his theory can be developed further to assist in understanding the moral status of SDAT patients. Specifically, the theory presents an explanation of autonomy's growth which also can be expanded to explain the decline of the same capacity. Although Haworth does not talk in terms of moral agency, his theory of autonomy has been extended to connect it with the notion of moral agency. When the correspondence between moral agency and normal autonomy is made, the ground has been established for the development of a criterion of competency to consent to research, requiring a high level of autonomy and moral agency. In chapter five, the capacity to consent to participate in research which has the prerequisites of critical competency (normal autonomy) will be discussed. Also, in chapter five, it will be argued that consenting to be a research subject is beyond the capabilities of the majority of SDAT patients.

Furthermore, when Haworth's theory of autonomy is developed and applied to the problem at hand, it is seen that SDAT patients lack

autonomy, moral agency and critical competency. Hence, in the event that they do have rights, they will not be able to exercise nor defend these rights. In the following section, the question of whether dependent moral subjects can be right-holders will be answered.

3.4 The Moral Status of Individuals with Alzheimer's Disease

According to Haworth, when an individual is autonomous or has the potential to be autonomous he has rights and can claim certain "modes of treatment" from others. The position proposed in this section, is based on an integration of aspects of L. Haworth's notion of autonomy and W. Sumner's work on moral rights. The wedding of elements of their work is then expanded or "nudged" further and brought to bear on the questions at hand, regarding the moral status of those with SDAT and how they should be treated.

The position advanced is that although dependent moral subjects lack autonomy and therefore can not be right-holders, they are nevertheless, moral or welfare subjects who can have claims on moral agents and society who, in turn, have an obligation to respect their fundamental (welfare) needs. (In the next chapter, the nature of this obligation and why the obligation should be honoured will be examined). The argument rests on a theory of rights which requires a right-holder to be a moral agent and, on

society's obligation to promote autonomy and protection of the vulnerable. These are two values essential to general well-being. An Alzheimer patient with diminishing or depleted autonomy has lost the possibility of having moral rights because they lack the capacity to be agents. Autonomy is a necessary condition of having rights and therefore, lack of autonomy is incompatible with moral agency. This position regarding whether SDAT patients have rights, is based on W. Sumner's insights in his recent book, The Moral Foundations of Rights. However, in this section it will be proposed that the position that vulnerable and weak individuals should be protected by society, can be reached by taking a consequentialist approach as Sumner does, or the deontological route.

The organization of the argument will be as follows:

- (i) discuss Sumner's theory of rights as choices
- (ii) apply Sumner's theory to the study of the moral status of (SDAT) patients
- (iii) examine the question whether SDAT patients are right-holders or non right-holders.

Each step will correspond to a separate sub-section. However, before proceeding further a brief discussion about the nature of rights is necessary.

Recently, rights have become ubiquitous. For instance, the mentally disabled, the fetus and also animals are all claimed to have rights. Most recently, protectors of our threatened planet have even ascribed rights

to the environment. Certainly, some of the above named vulnerable groups have been granted rights by the legal system, but this is not my primary concern. That positive legal and conventional rights exist to protect vulnerable individuals and research subjects is not the issue. We know that different societies have had different rules and policies about the treatment of the weak and vulnerable, specifically the elderly and mentally incompetent. Also, we know that different societies at different times have chosen to respect or not to respect these rights. It is important to emphasize the difference between the moral and legal status of the mentally incompetent. For instance, the MRC Guidelines supports its statement that mentally and physically disabled have rights to integrity and dignity referring specifically to the Canadian Charter of Rights and Freedoms.³⁴ In brief, there are three types of rights: moral, legal and conventional.

On one level, the need or interest of the weak and vulnerable members of the society to be protected because of the intrinsic nature of the weak and vulnerable can be recognized. Then if they wish, societies can have, or strive to develop legal statutes reflecting the society's social values and confer rights on these individuals. Alternatively, society could decide that it is too costly to respect the fundamental needs of dependent members of the community and hence, provide no legal protection, or perhaps only limited protection. It is possible for moral rights, conventional, and legal

rights to be in agreement or in conflict. For instance, many societies state that they value protecting and respecting children, the mentally ill, and the mentally and physically impaired but the society does not have legal statutes conferring legal rights on these individuals.³⁵ The focus of this investigation is on the moral rights of affected patients. Granted that there are three types of rights and each type can be recognized or not, there are several scenarios that can be played out in society, for instance:

- (i) moral status recognized but lacks legal or conventional backing
- (ii) moral status recognized but lacks legal backing
- (iii) moral status recognized but lacks conventional backing
- (iv) moral status recognized with legal and conventional backing
- (v) legal rights without moral backing
- (vi) conventional rights without moral backing
- (vii) legal and conventional rights without moral backing
- (viii) no moral, legal and conventional backing for the position of the weak and vulnerable.

The purpose of this section is not to analyze these possibilities but instead to establish the SDAT patient's moral status in order that the legal and conventional rules can be supported, rejected and/or be reformed when they do not back the affected patient's moral position. When the moral status of SDAT patients is not clarified, and the legal and conventional

rules do not support their moral claims, there is not a basis for criticizing these legal and/or conventional rules.

Legal rules have several valuable purposes even when in disagreement with conventional rules and social practices. Positive laws can serve the interests of morality by protecting vulnerable individuals and contribute to improving their circumstances. They can also play an important educational role when conventional rules condone discrimination and exploitation. Also, in the long run, legal regulations regarding treatment of the disadvantaged, can contribute to changing attitudes and behaviours. Hence, in the fifth chapter, recommendations regarding the protection of SDAT research subjects which could be used to amend current research regulations to render them more sensitive to the needs of SDAT patients, will be proposed.

Only recently have the weak and vulnerable (including the mentally ill and incompetent, and also children) been granted rights and certain protection in most western, liberal societies. In other societies, they lack legal protection and even where there are legal mechanisms to protect the vulnerable, the shield of protection is fragile.

Frequently, ethical and clinical problems arise because legal statutes do not respect moral rights. The example of the legal rights conferred on children illustrates the differences between legal, conventional

and moral rights. It is widely recognized that children are vulnerable and have fundamental welfare needs. Although most societies recognize the moral rights of children, only some societies have conventional rules respecting the claims of children. Fewer jurisdictions provide children with legal protection from harm. The United Nations adopted a Charter of Rights for Children (regarding their rights to shelter, food, education, health care and protection from exploitation) in 1989. This Charter has been universally hailed as a noble and important document but few countries adopted it or respect the rights identified in the document. In certain societies there are conventional rules regarding the protection of children and in a limited number of jurisdictions, these conventional rules coexist with legal rules offering some degree of legal protection. Laws regarding child labour, free public education, and public health programmes are a recent phenomenon in western countries but do not exist in the majority of countries. Legal rules or the lack of rules are a response, in most cases, to society's priorities. For instance, laws regarding child labour were changed in nineteenth century England in response to growing public pressure to change these practices yet in many countries today, child labour continues. Similarly, recent changes in Canada regarding child protection are in response to growing concern about child abuse.

There is a great similarity between the position of children and SDAT patients in our society. Both populations are vulnerable for the same

reasons which include: lack of full autonomy and moral agency, dependence on others for their care and safety, inability to defend themselves effectively from harm, inadequate physical and emotional resources to endure being harmed, and welfare needs that they can not meet effectively.

The persistent worry is that if society's priorities and legal statutes changed, these shifts could harm weak and vulnerable members of the society. Certainly the domain of law is not exhausted by the study of statutes. However, in the context of this examination of the status of SDAT patients, the emphasis will not be on legal rules. Respecting autonomous agents and protecting dependent subjects can be interpreted and implemented in a number of ways by different societies. Thus, the focus of this section is to go beyond what rights societies confer on the weak and vulnerable because if the moral status of SDAT patients is not established a critique of certain legal and conventional rules will fail to get a grip. Thus, it is necessary to go beyond the demands of "positive rights" to find support for the diminished autonomy and protection of the vulnerable SDAT patient.

a) Sumner's Theory of Rights as Protected Choices:

Sumner's theory of moral rights serves as the basis for claiming that the majority of SDAT patients cannot be right-holders. It will be

argued that moral subjects, lacking rights have welfare needs and should be protected from harm and that moral agents have an obligation to respect and protect welfare subjects' fundamental needs including the need not to be harmed.

In The Moral Foundation of Rights, Sumner presents a theory of moral rights by choice as opposed to rights based on interests. This theory of moral rights as choices leads to a way of understanding the status of both parties (moral agents and subjects) and the relationship of agents and society to the subjects. The distinction between these two theories is crucial because the theory chosen will determine whether rights are held by SDAT patients and justify protecting affected patients. As we shall see, rights as choices go hand in glove with the developmental theory of autonomy because it presupposes that a rights-holder is autonomous at the level of normal autonomy and has moral agency. In contrast, for the rights as interests approach, it is not necessary to be a moral agent or be at the level of normal autonomy. The choice model preferred by Sumner not only promotes the primacy of moral agency in society but also allows the moral agent to choose to support ends and thus reinforces the central role of autonomy in society.

Sumner's work is a response to Hohfeld's classification of fundamental legal concepts.³⁶ Hohfeld distinguished four concepts of rights and each type had an appropriate jural correlative.³⁷ The four correlatives are:

First order:

- (i) claim-right - duty
- (ii) liberty or privilege - no right or duty (as basis of claim)

Second order:

- (i) power - liability
- (ii) immunity - disability

A claim-right refers specifically to the situation in which one says X has a right (or claim or demand-right) to Z from Y. The correlative is a duty (or an obligation) of Y to X to do or refrain from something. The second notion is of right as a privilege or liberty (the opposite of a duty) which does not have the correlative of a duty. The third type is a power or legal capacity for addressing the jural relations between individuals. The correlative of a power is a liability because an individual's jural relations are being controlled by another party. The fourth type of right is an immunity or the lack of liability which occurs when the other party has no power over the individual's jural relations.

The fundamental concepts of a relational duty and full liberty proposed by Hohfeld are adopted by Sumner.³⁸ A relational duty is a duty owed by Y to X. The relational duty corresponds to the claim held by X against Y. A liberty is the opposite of a duty. Thus, a full liberty is an unconstrained choice.

Hohfeld considered first order rights to be claims but in addition, the second order normative categories could incorporate full liberties into the concept of a right. Sumner's goal is a purer concept and, therefore, he removes rights associated or justified because of powers and full liberties from the category of rights. He contends that there is an unfortunate proliferation of rights that must be halted and argues that on examination, many of the so-called rights are what Sumner calls "packages of Hohfeldian normative advantages"³⁹. By this term he means that liberties, claims, immunities and powers can be combined in many ways and to the benefit of the right-holder. Hence, in Sumner's opinion, it is foolish to attempt to "embark on an exhaustive inventory of the possible structures of a right".⁴⁰

Instead, he analyzes two models of the nature of claims by investigating their analogues for rights. First, the theory of rights as interests has the analogue of the benefit account of claims. According to this model of rights, the right-holder is the beneficiary of duties he imposes on others who have an obligation to honour his claim. Hence, the right-

holder with the claim does not have to be a moral agent; all that is required is he have an interest to be honoured. The respondent or object of the claim is active, and hence he should be a moral agent able to respond in a responsible and competent manner and fulfil his obligation to the rights-holder who benefits from having the interest and hence, a right. The claim-right imposes an obligation on others to honour this right. A right grounded in an interest is a claim-right.

For Sumner, the claims account which he calls a control account of rights, is the notion of rights as protected choices, that is backed by obligations imposed on others and also, legal and conventional rules.⁴¹ “Central to this conception is the idea that the right-holder having the freedom to choose among a set of options, and of this freedom being protected by a set of duties imposed on others”.⁴² Its protection is based on a claim for non-interference against other moral agents.

The choice theory of rights is preferred by Sumner because according to this theory, the right-holder is free and therefore, capable of making certain decisions and is a moral agent. Thus, at the micro level the model supports developing and maintaining normal autonomy and moral agency and recognizes that autonomy is the principal constituent of well-being. At the macro level, the theory supports developing a society that

values individual autonomy and considers development of autonomy an essential function of society.

Both approaches agree that rights serve to restrain the pursuit of individual and social goals and impose claims on others. According to the choice and interests models rights "... must protect their holders by imposing normative constraints on others and that these constraints must include duties borne by others. Thus, whatever else rights may consist of, they must consist of claims".⁴³ Although both models have the same understanding of the purpose of rights, each model proposes that rights serve a different function. The interest model considers rights to be "devices for promoting individual welfare".⁴⁴ The device promotes individual welfare or interests, and autonomy could be one of these interests. In contrast, the choice model considers rights to be "devices for promoting freedom or autonomy" and thus this model gives prominence to promoting autonomy.⁴⁵ Hence, to be a right-holder according to the choice model, it is necessary that the right-holder be an autonomous moral agent. However, a right-holder according to the interest model does not have to be autonomous.

The freedom to choose is protected by duties imposed on others and all claims involve the power to demand or waive certain behaviour on the part of the duty-bearer. An important difference between the two models is

that the choice model restricts the conferring of rights to those who are autonomous. Therefore, concludes Sumner “the conception of rights as protected interests is likely to distribute rights more widely than the conception of rights as protected choices.”⁴⁶ Having rights of choice is a dynamic function requiring a right-holder who is an agent, not a passive beneficiary of others fulfilling their duties in respect to passive right-holders. Also, the theory of rights based on choice which “treats rights as devices for promoting freedom or autonomy” is a dynamic model.⁴⁷ Hence, the right-holder as stated earlier is required to evaluate and co-ordinate a network of normative relations binding him to other individuals.

Sumner proposes that there are two types of moral rights: specific and universal. Rights which “respond to invariant features of the human condition and a further set of rights which are relativized to the peculiar social, economic and cultural circumstances of a particular society”.⁴⁸ However, in both cases a right is conferred on agents because the given right with its specific content has the potential “to strike the most favourable overall balance among competing interests”.⁴⁹ Without universal moral rights, the conditions or pre-requisites of individual well-being could not be sought nor maintained. The constituents of welfare such as education, health, autonomy and liberty are incorporated into this universal value. What Sumner calls universal moral rights are what was

referred to earlier as non-negotiable: the universal value of well-being and its constituents which most reasonable people would agree are goods that society should strive to achieve, maintain and support. For instance, given that most individuals can agree that universal access to education is preferable or desirable this moral right is universal, although not all will benefit from having some form of education and some will only benefit indirectly.⁵⁰

For Sumner, in the consequentialist tradition, universal moral rights are not natural rights because they are based upon conventional rules. These moral rights place limits on the interactions of moral agents with both moral agents and subjects. All rights impose on the agent a bundle of duties, liberties, claims, powers and immunities. The composition of the bundle is determined by the content of the right, that is by what the right says. When a prerequisite of being a right-holder is being a moral agent, the right-holder has the capacity to respect normative limits and protect the interests of the moral subjects. The network of normative constraints that a moral agent co-ordinates includes constraints designed to prohibit harming individuals and groups. To do otherwise would be to sabotage the global value of the promotion of general welfare.

The theory of rights as choices favours both individual and collective rights. Rights can be held by a group on condition that all

members of the collective are responsible and capable individuals, have a process for seeking consensus and for behaving in concert. If each member is able to comply with normative constraints and exercise normative powers, then the group has moral rights. Thus, on the choice model “collectivities will qualify as the subjects of rights as long as they possess the requisite capacity to act on behalf of their members”.⁵¹ For instance, a union of investigators or a patient advocacy group could have rights. Therefore, concerns about consequentialism concentrating on benefits and burdens and running the risk of short-changing the rights, claims, and interests of individuals, and in particular vulnerable individuals have been addressed by the theory of rights as choices. This is the case because the choice model assigns a central role to agency. In contrast, the interests model does not require that the right-holder have moral agency and the right-holder can be passive. The choice model demands that the right-holder always be active and respond by honouring his obligations to respect the claims of welfare subjects.

Both models of rights support moral agency being wedded to social responsibility and adopting a protective position towards the vulnerable members of a community. According to the interests model, the right-holder can be passive but in contrast, the rights as protected choices model requires the right-holder to be interactive and dynamic. The interest

model's right-holder is the beneficiary of a set of protective duties held by moral agents. In contrast, the right-holder according to the choice model is required to be an active manager of a network of normative relations connecting him to others, from which it follows that a being is a right-holder only if it possesses what Sumner calls "these managerial skills".⁵² In short, the rights-holder must be independent, competent and responsible. Only an autonomous agent can be independent and be capable of controlling what Sumner termed "a network of normative relations connecting her to others".⁵³

For Sumner, a right, that is a moral right, has the function of conferring upon its holders a degree of autonomy over a specific aspect of their lives and rights function to support and protect autonomy or moral agency. Hence, to be a moral right-holder, an individual must be a moral agent. Any constraints associated with the right, function to protect autonomy. Although Sumner does not use the term agent, the right-holder by definition is a moral agent because he is required to have full autonomy or critical competence.

Of interest is the subsequent distribution of rights attendant upon acceptance of either theory. The interest conception ranks autonomy as a high order interest and therefore will accept any right recognized by the choice conception of rights. Also, the interest theory will extend rights to

“any being capable of (the requisite sort of) autonomy” if the being has interests. The required level of autonomy can be lower because having autonomy is not a prerequisite of having an interest. Hence, by effectively lowering the minimum requirement for being a right-holder, the theory of rights, as protected interests, will lead to a wider distribution of rights than would be permitted by the theory of rights as protected choices, which requires that the right-holder have full autonomy and be a moral agent. The interests model of rights includes the possibility that one of the fundamental interests to be protected is autonomy. In contrast, the choice model ranks promotion of autonomy higher than other interests. On the interests theory, rights are claimed or conferred. All human beings will have rights and also, animals can have rights.

Whether one chooses the choice or interest model, depends in Sumner’s words on “the importance you attach to defining clear theoretical boundaries, and to reserving rights as special purpose devices whose primary function is to safeguard one central ingredient of well-being, namely autonomy”.⁵⁴ The choice model is preferable because it has the advantage that it gives more prominence to moral agency. Also, the model clarifies and emphasizes the special role that rights can play in promoting autonomy and protecting the weak and vulnerable. Sumner states that whatever model is selected will only determine how you characterize “the

moral protection to be afforded welfare subjects".⁵⁵ Similarly, whichever model is chosen, it will only determine the way that we characterize the promotion of autonomy in society and will not weaken the commitment to promoting autonomy just as it will not weaken the commitment to being protective of moral subjects.

One of the "clear theoretical boundaries" of the choice model is that rights-holders and non-right-holders are clearly identified which facilitates understanding the status of non-right-holders. Granted that rights according to the choice model are special-purpose devices for promoting autonomy, only moral agents are right-holders and consequently, certain individuals and objects, such as fetuses, infants, the mentally impaired and the environment do not have rights. Being human is not a sufficient requirement of having rights. Rights are reserved for those capable of exercising autonomy, critical competence and the rights they hold. Thus, only certain individuals can be rights-holders and given the criteria, many with SDAT will be ineligible. In other words, the choice model is based on the premise that rights can only be held by autonomous moral agents. According to Haworth's standard, the level of autonomy is normal autonomy because critical competence is required to make moral choices. Individuals lacking the capacity for moral agency can not have rights according to the choice model. However, those lacking moral agency, such as young children

and the mentally impaired do have rights according to the interests conception. The principal reason that rights according to the choice model can not be granted to those lacking full autonomy is that a right-holder needs to be a moral agent.

Merging Sumner and Haworth, one arrives at the position that rights (as choices) can only be held by moral agents having critical competence. This active approach can only be undertaken by an individual who is fully autonomous and critically competent. The threshold of autonomy required to be a right-holder according to the choice model can not be lowered to depleted autonomy because the right-holders have to be moral agents.

A moral right has the function of securing a degree of autonomy for its holders. Therefore, moral rights are justified because they protect and/or promote the autonomy of the individual and justify imposing constraints on others because the constraints safeguard the agent's autonomy. Furthermore, on consequentialist grounds, a moral right is justified because it promotes the general well-being and its constituents. Sumner considers autonomy to be the primary constituent, but I have expanded this notion to include protection of the vulnerable whose autonomy is diminished or depleted. Other constituents are the instrumental goods of education, health care, shelter, access to legal services

and a safe environment. The notion of a moral right in an appropriate rule system is the most advantageous way of promoting this general well-being in a manner based upon the principles of beneficence and non-maleficence.

Within the consequentialism framework, Sumner argues that agents have moral justification for taking conventional rights seriously, if they are morally justified. The existence of a moral right is linked with the justification for a conventional right but conventional and moral rights are not “species of a common genus”.⁵⁶ Some moral rights are distinct from conventional rights because they are not derived from positive social morality. “A moral right with a determinate scope and content is genuine just in case the policy of conferring a right with the same scope and content in some conventional rule system is strongly justified in the actual circumstances under which the system in question would operate”.⁵⁷ In the next sentence Sumner admits that this formulation is “unwieldy” and that it is more convenient to say that “a moral right exists whenever the corresponding conventional right is morally justified, or simply that moral rights are morally justified conventional rights.”⁵⁸ The requirement that a conventional right be justified depends on the context. “The existence of some moral rights may thus be a matter of the justifiability of their recognition in a complex network of conventional rule system”.⁵⁹

A conventional rule system confers rights only if it has rules which in turn, confer relational duties or claims and, also, normative powers. Both legal and conventional institutions can confer rights on those to whom they apply. The agent possesses a right under either rule system “when rules which are valid within that system confer upon me the appropriate bundle of liberties, claims, powers, and immunities, and when the system as a whole is efficacious”.⁶⁰ Conventional rights can not create moral rights. Rejecting a parallel account of moral rights, Sumner prefers “... an analysis of moral rights which refers only to conventional rules plus the notion of a moral justification. On this account, very roughly, we have a moral right whenever the assignment to us of a conventional right is, or would be, morally justified”.⁶¹ A parallel theory of conventional and moral rights is refuted because each set of rights has a different justification. A conventional right is justified because it is supported by the society’s social policy and mores, rewarded by social approval and is demonstrated to be efficacious.

It is possible to have a legal and/or a conventional rule without a corresponding moral right and vice versa. When legal and conventional rules do not have moral backing, moral agents recognizing this discrepancy should be socially active and work to modify or change social policy to express moral rights. For instance, human rights activists in South Africa

and throughout the world continue to work on behalf of blacks and coloureds in South Africa against apartheid policies. In this case, conventional and legal rules lack moral support.

To emphasize the difference in content and practice of different categories of rights, Sumner distinguishes between non-institutional and institutional rights. Institutional rights are stated in the Charter of Freedoms and Rights, the MRC Guidelines and comparable documents. Legal rights can be valid and at the same time rejected by the society. Regarding rules conferred by social morality, the only rules recognized are those that receive allegiance by the population in general. "The validity of a particular rule is thus a direct, though also complex, function of its efficacy. This feature is, of course, shared by all non-institutional rule systems."⁶²

The non-institutional system lacks sanctions of an established legal system to enforce its rules. However, non-institutional rights have powerful sanctions in the form of social pressures and rewards. Ultimately, the establishment and adherence to the attendant duties hinges on the rights being accepted by the society. For instance, there can be disagreement between conventional, moral and legal rules regarding the question of whether or not SDAT patients can be subjects in invasive, non-therapeutic research procedures. Take the example of family members agreeing to donate the brain tissue of their deceased relative who has SDAT, to a SDAT

research centre. Conventional wisdom values highly participation in clinical research and to refuse, is often viewed as a selfish act. Currently, there are no legal rules requiring that the donation be made or that the tissue automatically be taken. However, conventional rules strongly support the next of kin consenting to this invasive procedure for research purposes, shortly after the affected patient dies. (In chapter four the question of whether there is a moral imperative to be a research subject will be studied).

Non-institutional rights also differ in the content of their rules. The main concern of the legal system is to impose duties. However, social morality will include standards for “noble and meritorious behaviour”.⁶³ Thus, duties grounded in beneficence and non-maleficence can be incorporated into moral rights. Legal, conventional and moral rights have force for different reasons. Legal rights have force because they are warrant particular actions under the rules of the given legal system. The normative force conventional rights have, occurs because they receive widespread compliance and allegiance. Moral rights have normative force because they operate within a positive morality or accepted social code. Conventional and moral rights (as opposed to legal rights) are based upon the conventional morality of the given society. Society’s conventional morality or moral code can constitute a non-institutional system of rules and thereby be able to confer conventional rights and usually does so.

These rights, states Sumner “may display all of the articulation demanded by the conception of rights as protected choices”.⁶⁴

A society may or may not recognize a particular moral right. A moral right is recognized when existing social policies express and implement public support for the right. If the system is neutral or opposed to the moral right, then the relevant social policy needs to be reformed. Establishing that a moral right is recognized by the given society demands social policy evaluation. The concept of a moral right places limits and constraints on the right-holder in addition to duties and responsibilities.

Sumner argues against the position that consequentialism is incompatible with recognizing rights (nihilism) by arguing that a right is genuine when the social policy, recognizing the right in the appropriate rule system, is the most effective way of promoting a selected goal. The basis for selected goals “will be the inventory of ultimate goods. Whatever other goods this inventory might include, it seems reasonable to suppose that in some way or another it will acknowledge the value of those states which are the standard sources or components of individual well-being: life, health, liberty, autonomy, sociality, the development and exercise of powers and abilities, and so on. These goods must be collated into some global value”.⁶⁵ In summary, moral rights are grounded in goals that promote well-being.

b) The Significance of the Choice Model of Rights For Alzheimer Disease Patients:

Sumner's theory of moral rights has important implications for the question of the status of non-autonomous individuals and the responsibility of right-holders to non right-holders. According to the choice model, the necessary condition of being a right-holder is being a moral agent, that is a rational agent with normal autonomy. Hence, with the choice model, the majority of SDAT patients who are moral subjects lack sufficient autonomy to be moral right-holders.

This point is made clearly by Sumner, when he states "On the choice model all non-humans beings will lack rights if they lack agency, but so will many human beings (fetuses, infants, and the severely mentally handicapped)". By contrast, according to the interests model, the orthodox position, "all human beings will have rights if they have interests, but so will many non-humans (at least some animals). On both models it is quite inconceivable that the extension of any right should coincide exactly with the boundaries of our species. It is thus quite inconceivable that we have any rights simply because we are human".⁶⁶

Thus, the question arises, given that the majority of SDAT patients are not right-holders, what are the consequences of not holding rights? According to Sumner, non-rights-holders have interests, can make claims on

moral agents and society and society has an obligation to protect these moral subjects. Hence, their interests continue to attract the attention of responsible moral agents. In this section, I expand Sumner's account of the moral position of non-right-holders according to the choice model of rights and propose that the mentally impaired have needs as opposed to interests. As we shall see presently, the notion of "needs" is preferable to "interests" when the non rights-holders are mentally impaired individuals. Affected patients continue to have fundamental, welfare needs and dependency relationships with moral agents and society. Hence, they are the beneficiaries of what Sumner calls moral protection provided when moral agents honour their obligation to their moral dependents. Thus, moral status is not the exclusive privilege of those capable of being right-holders. In Sumner's words, "Having moral rights is not the same as having moral standing: to think otherwise is to assume that rights exhaust the moral domain". Furthermore, continues Sumner, "Restricting rights to agents is therefore compatible with extending moral standing to a much wider class of creatures - perhaps to all those who have interests, or a welfare, which can be protected by the imposition of moral constraints".⁶⁷ Rights are only one component of the moral domain and therefore, to be deprived of rights is not to lose all moral status and importance.

Sumner states that to have a claim, it is necessary to have an interest to be protected. An interest-holder can be a moral subject or agent. Thus, interests can be divided into two classes:

Class I: interests that can be actively claimed by moral agents and

Class II: interests or needs that are passively "claimed" by moral subjects.

I am proposing that the needs versus interests language be used when discussing class II interests for reasons given shortly below. In respect to the SDAT population and other mentally incompetent individuals the term "need" is preferable because it better captures the essence of the SDAT patient's posture: he is a dependent individual unable to articulate, assert or defend his interests and only capable of exhibiting through his diminished autonomy that he still has fundamental needs.

The notion of "need" is preferable to interests because the population in question have lost the capacity for a dynamic relationship with society and/or moral agents. An interests-holder is able to receive and integrate feedback and adjust his conduct accordingly. Thus, the principal difference between the first and second class of interests (needs) is that the first class of interests carries overtones of activity as in the phrase, takes an interest, and is closer to the notion of moral agency than is the passivity of needs. "Needs" do not require activity on the part of the needs-holder. Furthermore, interests involve a two way purposeful interaction between

the individual with interests and moral agents. By purposeful it is meant that the interest-holder can plan and execute interactions with individuals, groups and organizations, in order to achieve specific ends. Also, he can understand the responses or feedback from others and after critically reflecting on this information, he is capable of responding appropriately which could include modifying his conduct. However, the passive individual with needs is not expected to initiate, nor is capable of initiating purposeful, interactive relationships with moral agents.

Needs are a sub-class of interests. In proposing that a need is a fundamental requirement for survival that the needs-holder can not secure, I am indebted to Dr. Simpson for his clarification of the concept of a need in his paper "The Priority of Needs over Wants". Simpson's work not only provides a valuable insight into the dependency of needs-holders and the objective nature of their needs but also provides a view that promises to have relevance for the SDAT patient. He defines a need as an end that is essential for the individual's security and thus it is both a rational and objective end. Furthermore, an individual has a need when he lacks the means and/or the ability to secure the ends necessary for their safety and survival. In Simpson words, "we do not each happen to want security, we need it".⁶⁸ The fundamental need of SDAT patients is to be protected from harm and have their other basic welfare needs met. Alzheimer patients are

in a state of dependency and unless these needs (class II interests) are recognized and acted on by moral agents, they are in danger of being seriously harmed, and even dying. Hence, to paraphrase Simpson, they do not “happen to want security”, they need it.

An individual who has fundamental needs but lacks autonomy has a claim to be respected even though he does not have the capacity for interactive relationships. The claim made by a needs-holder is more akin to a statement that can not be asserted or defended. Whether the need is respected hinges on the response of moral agents to the dependency of the SDAT patient. In the case of SDAT patients, the clarification of the notion of interests by introducing the sub-class of needs agrees with the symptomatology associated with the progress of SDAT. Also, the notion of needs serves to clarify how we conceptualize the relationship between moral agents and subjects. In addition, the moral agent and society have an interest in maintaining and promoting the well-being of those lacking autonomy because in so doing, society is promoting general well-being. Furthermore, society's promotion of the well-being of those lacking autonomy is simply a species of its promotion of well-being in general. The concept of needs provides an avenue to understanding more profoundly and discussing what Ignatieff calls “a natural human identity”. All men share these fundamental needs but we differ in our capacity to meet them. Hence,

the notion of “human solidarity” referred to by Ignatieff is based on the recognition of this common bond which provides a foundation for honouring the claims of the weak and vulnerable.

Sumner acknowledges that it is “conceptually possible for us to owe duties to any creature capable of being harmed or benefited, and for such creatures to have claims against us”. Furthermore, there is no logical barrier to acknowledging the moral force of these duties and claims or conceding that the acknowledgement or imposition would serve to promote our well-being and the main constituents of this “global value”.⁶⁹ Granted that society’s well-being is constituted by the well-being of all its members, Sumner concludes that there is a “prima facie case” to protect the well-being of non-autonomous, dependent subjects and therefore, the actions of moral agents in respect to the moral subjects should be assessed in terms of harm, versus benefits, for the general population. Actions in which the potential for harm is not out-weighed by the potential for equally substantial benefits should be avoided. Protecting dependent subjects includes meeting their positive and negative needs which promotes the global value of well-being and its constituents. In short, the “moral protection” of vulnerable subjects is based on the principles of beneficence or non-maleficence.

Sumner's model of rights as choices differs from the traditional theory that rights are claims. Both approaches admit that rights are claims but according to the choice model the right-holder must be able actively to claim his rights. According to the theory of rights as choices, the right-holder has a duty to act responsibly and respect the claims of moral subjects. To be more precise, Sumner states that right-holders have a relational duty to protect the claims of those lacking autonomy and rights.⁷⁰ The moral subject's interests (according to my account, needs) determine his claims. Then, needs define the status of the weak and vulnerable by conferring moral value on them.

Sumner proposes that a society which has chosen the basic goal of promoting general well-being will have also elected to protect the welfare of all its members. The promotion of human well-being involves meeting human needs of all members of the community, the weak and the vulnerable, the strong and the able. The "relational duty" referred to by Sumner, becomes a duty to protect the weak and vulnerable in the context of SDAT research. "It would be quite astounding", remarks Sumner, "if the best policy for pursuing our consequentialism goal involved imposing duties which forbid us to interfere with the liberty of others but no duties requiring us to promote their well-being, regardless of how badly off they might be".⁷¹ The nagging problem with the consequentialist position

adopted by Sumner is that society may decide to weaken or abandon social policies protecting the weak and vulnerable (as many have) and offer social utility arguments in defence of a different set of priorities. For example, society could decide that it is too expensive to care for SDAT patients' needs and drastically reduce or even withdraw all health services to this population and re-allocate the resources to paediatric care, or to an entirely different priority, such as fighting a war overseas.

Sumner's theory of moral rights by choice "fits" well with Haworth's theory of autonomy as a psychological and normative idea. The major point of convergence is moral agency or autonomy. Sumner refers to agency and Haworth to autonomy but the theories are complementary. The right-holder is a moral agent who is fully autonomous (has autonomy at the normal level). To function at the autonomous level, according to Haworth's theory, the individual has to be a moral agent. The managerial skills required by right-holders are so sophisticated as to require that the moral agent have critical competence, that is, have full autonomy, or in Sumner's terms, be a moral agent and a right-holder.

Agency and autonomy are synonymous in the context of rights by choice. Hence, the agent having critical competence is capable of selecting options and therefore his rights are based on choices. In contrast, those less than fully autonomous, lacking critical competence, are incapable of

exercising rights based on choices. Therefore, states Sumner, "On any plausible analysis of agency the choice model will deny rights, on logical grounds, to inanimate objects, plants, non-human animals, fetuses, young children and the severely mentally handicapped".⁷² Given that agency and autonomy develop as one matures psychologically, autonomous agency is a facility that rational, critically competent individuals have attained. Sumner grants that older children and mildly mentally handicapped can qualify for some rights. These individuals have achieved what Haworth termed minimal autonomy but lack critical competence.

Moral rights (based on the choice model) can only be held by those with a high degree of autonomy, agency and critical competency. Thus, if older children and the mildly mentally handicapped were granted moral rights they would be very near or at the threshold required to be accorded "normal" autonomy. Thus, in response to Sumner's statement that older children and some mildly retarded children can qualify for rights, if they do qualify to be rights-holders, then mildly retarded individuals and the older children who are exceptional adolescents have been wrongly classified.

It is true, of course that if we grant that autonomy and agency are on a continuum, inevitably there will be grey areas because of the nature of the disease process (competency may fluctuate during the day and, also vary in respect to different tasks). Nevertheless these grey areas do not

invalidate the view that there are clear cases of autonomy. This conception of autonomy admits that assessing competency is frequently complex and challenging and that some cases will require regular, on-going assessments. The importance of adopting the approach that autonomy and competency are on a continuum as opposed to the bi-polar model of competency (one is or is not competent in all aspects of one's life) will be dealt with again in chapter five when the concept of competency to consent to research participation is discussed.

c) Alzheimer's Disease Patients as Rights-holders versus Non-rights-holders:

At the beginning of this section, it was proposed that there were two short answers to the question of whether mentally incompetent SDAT patients can have rights: "No" because they lack autonomy and "Yes" because they have rights to dignity and integrity (whether conferred by society or perhaps inviolable natural rights). The longer answer requires that it be acknowledged that they do not have rights even though they lack autonomy. However, they do have fundamental needs on the basis of which they may claim protection from society.

However, the denial of rights to dependent welfare subjects needs to be addressed. Again the short answer is that mentally incompetent

individuals do have rights because society confers certain rights on them. For instance, the mentally impaired have the right to social assistance and health care. Here again, however, there is a longer answer. Whether the consequentialist interest or choice model of rights or a deontological approach is taken, a line has to be drawn between moral and legal rights. Sumner, a consequentialist and positivist, also acknowledges that there are global or universal rights which all reasonable individuals would agree to support even if they would not benefit directly from supporting these rights which should be valued constantly, regardless of public opinion. Hence, the positive morality, legal statutes and social policies of a humanist community are open to criticism if they fail to promote autonomy and protect the interests (needs or rights) of vulnerable, dependent welfare subjects like mentally impaired SDAT patients. Thus, both consequentialists and deontologists may agree that the weak and vulnerable have a need or right to be protected from harm and have their welfare needs (rights) met. Regardless of whether society has decided to confer welfare rights on the vulnerable, they have welfare needs.

From the consequentialist perspective, there are two ways of answering the central question of what rights mentally incompetent patients have:

- (i) They have certain rights by virtue of being members of a given community with interests that they can claim (e.g. welfare rights).
- (ii) Dependent moral subjects have fundamental needs (e.g. welfare needs) which should translate into protective obligations.

Whether we take the choice or interests approach to understanding rights, the mentally impaired (moral subjects) are the beneficiaries of protective duties held by moral agents (right-holders). Therefore, they should be protected from harm when associated with health sciences research.

The second approach is favoured because Alzheimer's Disease is characterized by a loss of autonomy and a need for protection and care. A modified choice model of rights geared to a developmental theory of autonomy facilitates the recognition of the moral status of SDAT patients who can not themselves exercise rights, or *actively* defend their interests. In addition, the merging of aspects of these respective positions requires of moral agents that they recognize their moral obligations to the weak and vulnerable who lack rights but do have basic needs. The choice model of rights promotes right-holders taking a protective stance and honouring their relational duties to moral subjects. The passive claims of affected patients need to be grounded in needs, which a human society has an obligation to honour, since they can not actively claim these welfare needs from society. Underlying this approach is the assumption that the moral agent as a member of a society that has adopted the basic good of promoting general

well-being has a general obligation to respect the claims of moral subjects to have welfare needs met. If an autonomous individual refuses to recognize an affected patient's rights or needs, the affected patient whether a right-holder or need-holder is impotent. It is not within his power to assert his own rights. However, his passive needs-claim imposes an obligation on the moral agent to ensure that his fundamental needs are met, especially the need to be protected from harm. The moral agent's obligation to respond is derived from the advantages he enjoys as an autonomous moral agent. As an agent he is capable of:

- (i) self-directed rational conduct, and
- (ii) changing rules and obstacles preventing the claim being honoured.

Hence, the strength of the agent's claim is dependent on the capacity of the moral agent, as Sumner states "to conform one's conduct to normative constraints and the capacity to alter such constraints". In addition, society must have the same capacities to respond responsibly to the right-holder's claim.

Assuming that agents and society have the capacity to respond to the right-holder's claims, whether they will respond is another matter influenced by several factors including public pressure and economic variables. If society is responsive and responsible, the claim-right is respected.

There are three ways of describing the relationship between the welfare subject and the moral agent.

(i) Interest Model:

Both moral agents and subjects can have interests and rights. When a moral subject has an interest, he has a claim to basic goods. Moral agents have a corresponding relational duty to respond.

(ii) Choice Model:

Both moral agents and subjects can have interests but only moral agents can have rights. Moral subjects have an interest in having their fundamental interests met and thus have a passive claim on moral agents in respect to these basic interests. Moral agents have a corresponding relational duty to respond.

(iii) Modified Choice Model or Needs Model:

Both moral agents and subjects can have interests but only agents can have rights. Subjects have fundamental needs and passive moral claims on moral agents to have these needs met. Moral agents have a corresponding relational duty to protect welfare subjects.

The third model is preferable because the notion of “needs” more explicitly captures the dependency of the mentally impaired individual lacking moral agency. Being dependent on others and lacking moral agency he is passive. According to the choice and interest model, the affected patient has interests. The difficulty with the concept of interests, as discussed earlier, is that interests is not precise enough, because interests can be held actively by moral subjects or passively by agents. The former sense requires the agent to have “two way” relations with others which is beyond the capabilities of the majority of mentally impaired individuals. Only the choice model modified to take into account needs, accurately reflects the dependency on others of those incapable of asserting, exercising or defending rights or interests for themselves. Thus, the third approach more accurately expresses the passive nature of the subject’s relationship with the moral agent(s): the subject is totally dependent on the agent and society for his welfare and is unable to contribute significantly to the relationship.

In terms of Haworth’s extended theory of autonomy, the moral subject has regressed from full autonomy to a lower degree of autonomy or to depleted autonomy. When this happens at this stage, the affected patient’s next of kin or a surrogate is required to act on their behalf to prevent them from being harmed. This protective relationship is based on

the recognition of the individual's vulnerability, dependency and lack of moral agency.

The model preferred indicates a commitment to promoting and protecting autonomy as the prime contributing factor in promoting well-being. I have added that promotion of autonomy has the corollary of protecting those lacking autonomy, the weak and vulnerable. With the choice model, rights become a "special-purpose device" to protect agents and the vulnerable. In Sumner's opinion, whichever model is preferred, "it will determine only the way in which you characterize the moral protection to be afforded welfare subjects who do not qualify as agents; it will not weaken your commitment to providing them with that protection".⁷³

The choice model and also, the modified model (needs model) are preferred because they acknowledge more profoundly the nature of the needs-holder as a dependent individual unable to meet his own welfare needs unassisted. Their dependency and need first generate a claim and then impose an obligation on moral agents to promote human well-being, a notion that enhances the weak as well as the strong. When individuals are acknowledged to be non-autonomous, dependent subjects in need of protection, moral agents have an obligation to meet those needs. A similar claim is made by the SDAT patient "claiming" a right. The fundamental need for security is stated starkly and clearly. Therefore, when the claim is

conceptualized as a need rooted in full dependency of the moral agent on the moral subject, the needs-claim could be stronger than the rights-claim.

Metaphorically speaking, the modified choice model turns the traditional understanding of the rights of the mentally incompetent and children inside out. The focus is shifted from dependent individuals having rights to autonomous, responsible, rational individuals having rights and being capable of responding to obligations. Thus, moral agents can make choices about how to promote and maintain the general well-being of moral subjects. Right-holders have relational duties or a duty to protect non-right-holders (moral and welfare subjects). Moral agents honour their obligations to moral subjects when the needs of the weak and vulnerable are brought under the protective umbrella of moral responsibility to promote their well-being. Granting a right to an individual who is mentally impaired provides him with no protection because he is incapable of exercising the right. The shift to needs places the onus on agents to be morally responsible and honour their obligations to the weak and vulnerable, whose inability to meet their basic needs, jeopardizes the realization of their well-being as dictated by the limits of their handicap.

Sumner acknowledged that both models of rights provide the moral subject with protection and that the approach preferred hinges on the importance attached to what constitutes a clarification of the boundaries for the preservation and promotion of “the one central ingredient of well-being,

namely autonomy".⁷⁴ In the realm of SDAT research, the modified choice model is preferable because a careful analysis of the relationship of moral agents and subjects based on theoretical distinctions between rights, interest and needs reveals not only the unequivocal dependency of moral subjects but also the need for acknowledgement of an obligation to compensate for the dependency. This is the case not only because rights are conceived as special purpose devices promoting autonomy but, in addition, because needs are conceived as special purpose devices having the primary function of promoting the other central ingredient of well-being, that is the protection of the weak and vulnerable who lack autonomy, from harm.

Although Sumner concludes that both models afford the same degree of protection to those lacking autonomy,⁷⁵ it would be plausible to suppose that the modified choice model geared to needs could strengthen the needs-holders claim when the dependency of the moral subjects is presented in a more stark, precise manner.

However, whether this difference in models will "translate" into moral agents being more disposed to honour their duties or even if it more disposes them to honour their duties, whether they will exercise this capacity is moot. It does however, provide a more favourable context for that "translation". Problems for the right or need holder who is vulnerable arise when: (i) society refuses to recognize the right or need, (ii) society accepts the validity of the claim-right but fails to fulfil its obligations to

right or needs-holders. In the next chapter, both situations will be examined when the obligations of society and researchers to SDAT research subjects are discussed.

Suffice it to say at this stage that if a consequentialist approach is taken, the welfare of the vulnerable hinges on society adopting the basic good of general well-being and then implementing social policies and legal rules which protect and promote well-being encompassing the vulnerable. The major problem with consequentialism committed to promoting the general good is that the moral agenda may shift in ways that are detrimental to SDAT patients.

Within the consequentialist framework, it is permissible to critique a given society when the appraisal of society's conduct is made along the lines proposed by Hart in Law, Liberty and Morality, where he distinguishes between positive and critical morality. He suggests that this distinction favoured by utilitarians in the last century be revitalised. According to Hart, positive morality is "the morality actually accepted and shared by a given social group, from the general moral principles used in the criticism of actual social institutions including positive morality. We may dub a system that employs such general principles "critical morality".⁷⁶ When questioning whether society has a "right" to enforce morality, Hart states that this critical stance can only be taken if an appeal

is made to *some* acknowledged general principles of critical morality as the basis for criticizing others. "And it is surely clear that anyone who holds the question whether a society has the "right" to enforce morality, or whether it is morally permissible for any society to enforce its morality by law, to be discussable at all, must be prepared to deploy some such general principles of critical morality. In asking the question, we are assuming the legitimacy of a standpoint which permits criticism of the institutions of any society, in light of general principles and knowledge of the facts".⁷⁷

It can not be disputed that the vulnerable are better protected in some societies than others and secondly, that a great deal of work has to be done to protect the mentally impaired and/or the elderly from being harmed and neglected, even in our own society. If societies offering protection to vulnerable populations are to be praised and others failing to protect the same populations are to be criticized, there must be an appeal to a common moral tenet or to be more specific, to a moral principle. For instance, Hart considered the principle of equality to be a principle of critical morality (and also the one natural right he acknowledged), the principle of critical morality which is appealed to in this investigation is the principle of autonomy and respect for persons. Different societies can interpret and apply this principle in different ways but there remains the fact that this

general principle can be used to criticize social policies, legal statutes, individual conduct and positive morality.

To conclude, Sumner's choice theory of rights as choices when appropriately extended provides an understanding of the moral status of SDAT patients, as passive need-holders having moral worth. Recalling that Haworth's theory of autonomy when "pushed further" explained the loss of autonomy and moral agency accompanying SDAT, when these aspects of their respective work are merged, we have a way to understand the moral and clinical changes associated with the SDAT and also, a justification for moral agents being protective of these weak and vulnerable individuals.

3.5. Conclusion:

This study is entrenched in the western, liberal tradition of respecting individual autonomy and respect for persons including the weak and vulnerable which crosses the boundaries of both deontological and consequentialism ethical theories. Most reasonable individuals would choose to treat the vulnerable in a respectful, non-maleficent manner because they would elect to be treated in this fashion if they had the misfortune to become dependent on others for their welfare. Thus, to make laws that threaten the safety of the vulnerable, contradicts the commitments and ideals of liberal, democratic countries. Also, when there

is a lack of respect for dependent moral subjects, this group is at risk of being used as a means to an end exclusively. This action would be a violation of the nature of man, as understood in the western, liberal tradition, albeit, a dependent, vulnerable individual.

There is an overlap between these ethical theories because the second version of the categorical imperative requires that the autonomous individual ask whether the proposed conduct would be disrespectful to the moral agent and/or the others. Similarly, a consequentialist would evaluate an act or rule by evaluating if the results maximized utility, in this case respect for persons, or to be more precise, protecting the vulnerable.

A point of convergence between deontologists and consequentialists is agreement about the importance of autonomy, justice and rights in terms of developing a society that respects general welfare and more specifically respects the needs of the weak and vulnerable. Social policies and legal statutes should be designed to protect and promote individual autonomy and its constituents and, also respect all individuals. However, when the individual lacks full autonomy, society's infrastructure needs to be arranged so as to protect vulnerable subjects in research projects from harm (non-maleficence).

Sumner's consequentialist theory of rights provides a way of understanding why dependent moral subjects, who previously were moral

agents, can have moral status and should be respected. The choice model accommodates and justifies moral agents responding in a beneficent and non-maleficent manner to the needs of moral subjects. The serious difficulty with consequentialism is that it is possible for protection of the weak to rank low on society's list of priorities. Hence, part of the proposed resolution to the ethical problems of SDAT research is grounded in the integration of a developmental theory of autonomy and a judicious choice of a model of rights (the choice model in its modified form being preferred).

Also, Sumner's consequentialism approach meshes with Haworth's fundamentally deontological theory of autonomy in respect to the issue of moral agency. Both Sumner and Haworth consider autonomy to be the most important and necessary characteristic of moral agency. Also, both the theory of rights as choices and Haworth's psychogenetic (I preferred to call it developmental or dynamic) theory of autonomy restrict being autonomous to high functioning moral agents and rank autonomy and moral agency as the most important constituent of man's essence and well-being. Integrating and developing Haworth and Sumner's work on moral agency serves to accommodate conceptually the decline in moral agency characterizing Alzheimer's Disease. When extended, their work leads to the conclusion that moral subjects lack sufficient autonomy to be right-holders but have moral worth as needs-holders and welfare subjects.

Although Haworth does not describe autonomous behaviour in terms of agency, the conception of agency is essential to his work. The individual at the normal or full level of autonomy is a responsible agent by virtue of being independent and in control of his own life. Haworth's idea of autonomy as a psychological and normative idea includes the concept of degrees of autonomy and specifies the necessary conditions of being a master of one's life. The criterion for full autonomy, proposed by Haworth, is a high standard: with full autonomy, the individual must have attained critical competence. In other words, the fully autonomous individual is rational, independent, competent and in control of his life. His behaviours are uncoerced and the result of careful reflection of his options. Haworth only considers progression up the continuum of autonomy and, hence, I expanded his notion of autonomy to account for the decline of moral agency and autonomy.

There is an overlap between consequentialism and deontological ethical theories regarding restricting freedom when the goal is to promote autonomy. For Kant, justice has the narrow meaning of restraining freedom in order to remove obstacles or interferences with individual freedom. Kant justified limiting freedom on the grounds that rational men would agree to the proposed restrictions and submit themselves to the same constraints. Similarly, Mill approved restricting individual freedom when

its exercise harmed others and he thought that these limits would benefit society. Hence, according to both ethical approaches, rights can function as protective mechanisms, limiting individual and society's freedom when the welfare of the vulnerable is at risk.

Both Sumner and Haworth qualified the notion of human rights in a way that was consistent with the promotion and maintenance of autonomy and its prerequisites. If the choice model is adopted, rights are restricted to independent, autonomous agents who have what would be termed full autonomy according to Haworth. The theory of rights as choices provides a foundation for thinking about what rights, if any, individuals with depleted agency and autonomy have. Whichever model is chosen, and despite their differences they are "still conceptions of the same concept". "They have a commitment to the root idea that the function of rights is to serve as one kind of constraint on the pursuit of social goals. Thus, they share the conviction that real rights - standard, normal rights - must protect their holders by imposing normative constraints on others, and that these constraints must include duties borne by these others".⁷⁸ Recalling that morality assumes the notion of responsibility for one's own actions, the autonomous agent exercises moral responsibility when protecting the needs of moral subjects.

The integration of these elements forms a mixed theory which incorporates a deontological insight with a consequentialism component. This conceptual approach permits a critique of positive morality based on references to the general moral principle of respect for persons and autonomy. Moral agents according to both the deontological and consequentialism approaches must evaluate the impact of their maxims or social policies. Thus, there is an overlap between both approaches. According to the second categorical imperative, the moral agent must ask whether the proposed conduct would degrade himself or others if someone was treated as a mere means (e.g. if a human being were to be treated as experimental data). In short, the consequences in terms of respecting the research subject are evaluated. Similarly when a consequentialist inquires whether research policy X is beneficial, he asks if the proposal will maximize utility, in this case, protect the vulnerable.

If the specific research protocol does not respect the fundamental needs of SDAT research subjects to such an extent that they are at risk of being seriously and/or permanently harmed both the deontologist and consequentialist would agree that the protocol is unacceptable. The former would argue that the basic nature of the subject was not respected. On the other hand, the consequentialist would argue that the conduct fails to maximize protection of the weak and vulnerable and also that there will be

costs to society at the micro and macro levels not justified by placing vulnerable SDAT patients at risk.

Furthermore, checks on the research enterprise are costly in terms of human and economic resources. To trivialize or dismiss these costs is a disservice to the SDAT patients and indicates a lack of appreciation of the expertise required to care for affected patients. Unless the costs at the macro and micro levels are taken into account, the serious and valid questions raised by Daniel Callahan about setting limits in the health care system can not be answered.⁷⁹

It is preferable for moral and political reasons to acknowledge that social policies offering protection to affected patients are costly and can put the brakes on SDAT research than to deny the consequences of honouring the needs of welfare subjects. Then, the next step is to justify the choice to recognize the needs of the weak and vulnerable. The argument should be based on a recognition of the nature of the individuals but also must take into account the consequences of these policies. To do so is in agreement, as stated earlier with the second categorical imperative which relies on an assessment of whether the maxim treats an individual merely as a means. Similarly, defenders of protecting mentally impaired research subjects can not rely on social utility arguments alone because in some cases, consequentialism can violate justice. In both cases, the main defence of the

vulnerable will be based on respecting their fundamental needs as moral subjects.

The moral duty to protect the needs (interests) of dependent moral subjects (welfare subjects) agrees with the MRC's recommendation that research should honour the right to integrity and dignity granted to the mentally incompetent by the Canadian Charter of Rights and Freedoms.⁸⁰

The terms right to dignity and integrity are used frequently in bioethics and it is important to clarify the meaning of these rights in respect to SDAT patients who are prospective research subjects.

First, according to the choice model of rights (and also the modified version) when the right-holder lacks autonomy, the individual can not have a right to integrity or dignity. What then can be made of the MRC's claim that the mentally and physically disabled have these rights? The answer lies in clarifying the distinction between moral, legal and conventional rights and also welfare needs (interests).

The MRC acknowledges a conventional right to be respected which is to say, an individual's dignity and integrity should be respected. In most Western, liberal countries this right is held by all individuals, including its vulnerable members. In addition, some jurisdictions have legal rights corresponding to this conventional right. For instance, the Canadian

Charter of Rights and Freedoms confers these rights on all members of the society.

Unfortunately, the term right to integrity and dignity has been bandied about indiscriminately, and in the process has become a cliché used as a rallying point for many special interest groups. Hence, caregivers argue that to defend the dignity and integrity of the affected patients, more research has to be done despite the costs to the subjects. Also, they can argue that to preserve their own integrity as they struggle with the burden of the illness, more research is needed. Furthermore, other caregivers argue that their relatives' dignity and integrity would be violated if they were to be used as research subjects in projects offering no benefits to the subject because they would be reduced to "guinea pigs". Similarly, the emotionally laden expression "guinea pigs" has entered the vocabulary of research ethics and contributes to inflaming issues as opposed to promoting analysis of the key questions, particularly, how to respect research subjects.

What is meant by integrity and dignity? In part, integrity and dignity refer to the physical and mental well-being of an individual. This goal or end of well-being is achieved by members of the community being given the opportunity to have their welfare rights (or needs) met. Thus, the constituents of education, health care, legal system, shelter and food in

addition to protection from harm, all contribute to attaining or maintaining integrity and dignity.

In the case of the right to integrity and dignity conferred on all by the Charter, the legal and moral rights do not correspond to distribution of rights according to the choice model of rights. Although an individual lacking autonomy by definition is not a moral right-holder, certainly he can have legal rights and conventional rights conferred upon him (and does have them conferred in Canada). If the interest model were to be preferred, then he would be a right-holder in the sense previously discussed. Also, the dependent moral subject can lose these conventional and legal rights but his status as moral right-holder or a needs-holder would not change. Thus, it is possible for a moral and legal right to be in conflict. For instance, if the recommendations of the Belmont Report which favour relaxing the protection currently provided to potential research SDAT subjects were adopted by the legal system, there would be a conflict between the moral and legal realms. The investigator would have the legal right to expose incompetent human subjects to the potential for harm above the level of minimum risk if the potential for obtaining information justified the subject's participation in the research project (making sense of this equation will be discussed in chapter five). Given that a moral agent and society has

an obligation to protect the welfare subject, there would be a conflict between what is permitted legally and the agent's moral responsibilities.

According to Sumner, moral rights are conventional rules that are morally justified, therefore it follows that there are some conventional rules at odds with the legal rules which accounts for the conflict between moral and legal rights. These conflicts arise because the scope of legal rights is broader than the scope of moral rights and tensions occur because there are moral rights which fall outside what we are legally mandated to do.

When there is a conflict between the moral and legal rights, social policy must be reviewed and reformed to agree with the moral rights or rights, advises Sumner.⁸¹ The present thesis proposes that if there was agreement between moral, conventional and legal rules, and social policies implement and support these rules, then the conflicts would be resolved and SDAT patients would be beneficiaries of moral agents' protective duties.

A beneficial and practical consequence of acknowledging that welfare subjects have needs which they passively claim is that society has an obligation to provide a minimum standard of care which ensures that positive and negative welfare needs of the vulnerable are met.⁸² Thus social policies should be designed, implemented and evaluated in respect to honouring the obligation to protect the needs or, if preferred, rights claimed.

Research is one possible activity for the vulnerable SDAT patients occurring within a wider context. Let us imagine that a Rawlsian “veil of ignorance” is placed in front of fully autonomous agents and competent individuals in the prime of their lives. If they were asked “How would you like to be treated if you became mentally impaired and dependent on others for your safety and welfare?” it is reasonable to hypothesize that the majority would request that the minimum standard of care meet their physical and emotional needs. Thus, they would want to be in as safe and comfortable setting as possible, and be treated with sensitivity and intelligence as opposed to being harmed, exploited or ridiculed. The manner in which care is provided can render a service harmful and degrading when psychological as well as physical needs are not met. Therefore, prudential reasons and empathy can motivate individuals and the community to exercise the duties of beneficence and/or non-maleficence in respect to dependent subjects.

Research policies should respect this minimum standard of care. When designing research involving SDAT patients the primary goal should be protecting vulnerable research subjects from harm (the negative welfare needs-rights). In the realm of care and treatment attention should be focused on both negative and positive welfare rights or needs (although more frequently, only the negative ones receive attention to some extent).

However, when we move to the context of research, the focus is on protection from harm and hence, negative welfare needs or rights must be the priority. There will be further discussion in chapter five on the ensuring that the specific needs of SDAT research subjects are respected.

To conclude, both Haworth's and Sumner's work supports the position proposed in section one of this chapter, that the essence of man is to be an autonomous, moral agent. Thus, rights exist to promote, support and protect autonomy. When moral agency is diminished significantly or is depleted, moral agents have become dependent moral subjects unable to have rights, but are capable of having claims based on their fundamental (welfare) needs. Hence, rights function to promote autonomy and claims in respect to needs function to protect the welfare of vulnerable subjects.

In the western, liberal tradition respect for individual autonomy is highly valued and both Kant and Mill acknowledge the importance of this capacity. Whether a deontological or consequentialism approach is taken, the same conclusions regarding the use of vulnerable subjects will be reached. However, an exclusively positivist approach places the vulnerable research subject at the mercy of the vagaries of society's priorities. Both Sumner and Haworth's work provided a basis for answering the questions about are the rights, claims and interests of Alzheimer patients. The weak and vulnerable, the strangers in our society, have their identity defined in

terms of their needs which they can only articulate through their presence. Thus, they have been defined in terms of what they lack: autonomy and a will to care for themselves.

Examining their fundamental needs only makes sense in a community which has accepted that autonomy and respect for all are goods which society should strive to develop and maintain. Also, the probing behind the language sheds light on, in Ignatieff's words "...what we have in common with each other beneath the infinity of our differences".⁸³ The language of needs as Ignatieff remarked has the advantage of striking home at shared identity or common bond and in so doing paves the way for the next chapter which will examine the obligations of moral agents and society to Alzheimer patients.

Notes

1. Ignatieff, M. The Needs of Strangers. Penguin Books, Chatto and Windus, London, 1984, p. 28.
2. Miller, P. "On Justifying Morality." in Ethics and Justification, edited by D. Odegard. Academic Printing and Publishing Co., Edmonton, 1982, p. 200.
3. Ibid., p. 201.
4. Engelhardt, T. The Foundations of Bioethics. Oxford University Press, Oxford, 1986, p. 68.
5. According to the Kantian position, a rational agent is autonomous and has the capacity to act in accordance with his conception of laws, which is to say to act in agreement with principles. Thus, the rational moral agent has a will or what Kant calls a practical reason. The actions of rational agents have a subjective principle or maxim and also, objective principles which a rational agent would necessarily act if full reason was dominant over emotions and other influences. When the rational agent does act on the basis of objective principles, his will and conduct are described as good or right. For Kant, acting from self-interest and passion does not make a man morally good. Instead, acting in accordance with impersonal, objective principles valid for all men (that is moral agents) in addition to himself can make a man morally good.

Imperatives are objective principles considered necessary and when complying with these imperatives is a right action, all imperatives commanding moral agents to do good. A rational and good agent would act on objective principles or imperatives and thereby demonstrate goodness or rightness. In Kant's words, "Only a rational being has the power to act in accordance with his idea of laws - that is, in accordance with principles - and only so has he a will. Since reason is required in order to derive actions from law, the will is nothing but pure reason" (Groundwork 401).

Furthermore, only rational agents can be ends in themselves states Kant, and thus only they can have an unconditioned and absolute value. Hence, it is morally wrong to use them exclusively as a means to an end whose value is only relative. Unless there were ends in themselves, there would not be unconditioned good nor any categorical imperatives. Given that rational agents are all subject to universal laws they constitute the realm of ends. The ends refer not only to rational agents as ends in themselves but in addition, their personal ends.

Hence, the rational agent must be free, have a will, be autonomous and morally responsible. Also, the agent must be able to enter into relations with other rational agents all being ends in themselves and hence having intrinsic worth.

6. Foundations, 434.
7. Sumner, L. W. The Moral Foundations of Right. University of Oxford Press, Oxford, 1987, p. 169.
8. Ibid., p. 170.
9. Ibid., p. 434.
10. Ibid. p. 434.
11. Ibid., p. 434.
12. Ibid., p. 434.
13. Thomas, J. E., Waluchow, W. Well and Good, Second Edition, p. 26. In addition, Dr. Waluchow had advised me that a negative answer to the first question or a positive answer to the second and third question would have the same effect.
14. Kant I. Lectures on Ethics, p. 122.
15. Ibid., p. 124.
16. Haworth, L. Autonomy. Yale University Press, New Haven. 1986.
17. Ibid., p. 2.
18. Ibid., p. 17
19. Ibid.,p. 45.
20. Ibid., p. 32.
21. Ibid, p. 26.
22. Ibid., p. 28.

23. Ibid., p. 46.
24. Ibid. p. 45.
25. Ibid., p. 46.
26. Ibid., p. 184.
27. Ibid., p. 189.
28. Ibid., p. 168.
29. Raz, J. The Morality of Freedom. Oxford University Press, 1986.
30. Howarth, L. Autonomy, p. 105.
31. Ibid., p. 111.
32. Ibid., p. 111.
33. Goffman, E. Asylums: Essays on the Social Situation of the Mental Patients and Other Inmates. Doubleday, New York, 1961.
34. Medical Research Council of Canada, Guidelines on Research Involving Human Subjects. p. 31. Quotation refers to Section 7 of The Charter of Rights and Freedoms.
35. Another relevant and important example of the fragility of legal protection offered by rights and laws occurred in 1990, in the U.S.A. penal system. In the case of Harper vs. the State of Washington, the prisoner was forced to take psychiatric medication against his will although he was mentally competent. Legal experts and psychiatrists in the U.S.A. consider this is the thin edge of the wedge and this case will herald an erosion of rights won for institutionalized individuals over the past 40 years.
36. Hohfeld, W.N. "Rights and Jural Relations" from Fundamental Legal Conceptions. Reprinted in Philosophy of Law. Edited by Joel Fineberg and Hyman Gross. Wadsworth Publishing Company, Belmont, California, 1980, p. 259. (article is pp. 259-269)
37. Hohfeld, W. N. Fundamental Legal Concepts. Yale University Press, New Haven, 1964, p. 5.

38. Hohfeld, W.N. "Rights and Jural Relations". Philosophy of Law. Editors: J. Feinberg and H. Gross. Wadsworth Publishing Company, Belmont, California. pp. 252-269.
39. Ibid., p. 45.
40. Ibid., p. 45.
41. Ibid., p. 46.
42. Ibid., p. 46.
43. Ibid., p. 47.
44. Ibid., p. 47.
45. Ibid., p. 47.
46. Ibid., p. 47.
47. Ibid., p. 47.
48. Ibid., p. 211.
49. Ibid., p. 211.
50. This example was given by Professor Sumner, during a meeting with him, December 11, 1989.
51. Ibid., p. 209.
52. Ibid., p. 47.
53. Ibid., p.47.
54. Ibid., p. 205.
55. Ibid., p. 205.
56. Ibid., p. 141.
57. Ibid., p. 148.
58. Ibid., p. 148

59. Ibid., p. 142.
60. Ibid., p. 75.
61. Sumner, L. W. "Reply to Hurka and Copp". Dialogue, XXXVIII (1989), 149-155, p. 152.
62. Ibid., p. 88-89.
63. Ibid., p.89.
64. Ibid., p. 87-88.
65. Ibid., p. 202.
66. Ibid., pp.205-206.
67. Ibid., p. 204.
68. Simpson, E. "The Priority of Needs over Wants". Social Theory and Practice, volume 8, no. 1, (spring 1982), pp. 95-112.
69. Ibid., p.204.
70. Communication with Dr. L.W. Sumner, Dec. 11, 1989.
71. Ibid., p. 212.
72. Ibid., p. 203.
73. Ibid., p. 205.
74. Ibid., p. 205.
75. Ibid., p. 205.
76. Hart, H.L.A., Law, Liberty and Morality. Oxford University Press, London, 1963, p. 21.
77. Ibid., pp. 19-20.
78. Ibid., p. 47.
79. Callahan, D. Setting Limits. Simon-Shuster Press, 1976.

80. Medical Research Council of Canada, Guidelines Regarding the Use of Human Subjects. p. 31.

81. Sumner, L. W. see note 7, p. 201.

82. Admittedly, the positive welfare needs will be harder to negotiate and attain. Traditionally, society responds to problems as opposed to taking preventative measures. Thus, there are programmes to prevent wandering instituted before programmes to enrich the life of the SDAT patient are established.

83. Ignatieff, M. The Needs of Strangers. Penguin Books, Chatto and Windus, London, 1984, p. 28.

Chapter IV

The Obligations of Society and Researchers to Alzheimer's Disease Research Subjects

Questions about human needs are questions about human obligations. To ask what our needs are is to ask not just which of our desires are the strongest and most urgent, but which of our desires gives us an entitlement to the resources of another. This natural pairing of the idea of need with the idea of duty and obligation is what distinguishes need from desire. Need is bounded by the idea of the necessary or the essential. Desire is unbounded even by the idea of utility. It is possible to specify the duties which would follow from an obligation to meet someone's needs. But the duty would be boundless, and therefore meaningless, if it extended to a person's desires.

M. Ignatieff ¹

4:1 Introduction:

The purpose of this chapter is to examine the nature of society's and the researcher's obligations to vulnerable research subjects, specifically subjects with SDAT. The chapter builds on chapter three which dealt with the moral standing of those lacking autonomy and together they constitute the heart of the thesis. In addition, tensions between various duties and how to accommodate different obligations will be examined. Finally, it will be proposed that society should take a protective stance towards vulnerable research subjects which in turn, should be expressed in social, health and

research policies designed to respect and protect weak and vulnerable members of the community.

Specifically, there are four objectives:

- (i) Study society's obligations to vulnerable research subjects and society in general.
- (ii) Similarly, examine the health sciences researchers' obligations to vulnerable research subjects and society.
- (iii) Evaluate the proposal that all members of a community have an obligation to be research subjects.
- (iv) Evaluate consequences of society and researcher's honouring their obligations to society and research subjects.

We shall look at each of these in turn.

4.2. Society's Obligations:

The goal of this section is to analyze society's obligations to the community in general, clinical investigators and research subjects. In addition, the tensions that arise when society strives to honour its obligations to these different parties will be examined. Again, the philosophical orientation is a mix of deontology and consequentialism enriched further by the addition of social contract theory.

The overall approach continues to be in the western, liberal tradition of respecting and promoting individual autonomy. The analysis of what obligations society has to various parties is undertaken within a

framework that values individual autonomy and rights. In this liberal tradition, difficulties arise when individual is asked or required to sacrifice some degree of personal freedom for the community's good. When these tensions and conflicts develop, trade-offs and compromises are necessary to preserve individual human well-being and social order. In the realm of SDAT research, the key players are the investigator, subject and society, each having their respective needs and goals. The purpose of this section is to clarify their respective needs and/or obligations and then to propose a way to meet the needs of all concerned. It will be recommended that protecting vulnerable individuals should rank higher than promoting the social good but that under certain conditions, there will not be unnecessary roadblocks thrown in the way of SDAT research.

The view being developed here is consistent with the social contract theory. It is assumed that society is based on a social contract and the nature of the contract can vary from jurisdiction to jurisdiction. In western, liberal societies which value highly the individual as opposed to the common good, society is composed of individuals prepared to sacrifice a degree of personal autonomy and contribute to the community in a number of ways. In return, society provides an infrastructure, security and basic goods (i.e safe environment, education and health care, judicial system). Members of a community are fully or partially dependent on society to assist them, to

varying degrees to meet their welfare needs. In turn, society should have welfare policies designed to assist individuals, to the degree necessary, to maintain and protect their well-being.

Also, it is assumed that the society has endorsed principles of justice similar to Rawls's two principles of justice which are concerned with the assignment of rights and duties and also the regulation of social and economic advantages. The two principles are:

- (i) Each person is to have equal right to the most extensive basic liberty compatible with a similar liberty for others.
- (ii) Social and economic inequalities are to be arranged so that they are both (a) reasonably expected to be to everyone's advantage, and (b) attached to positions and offices open to all.²

Thus, society has accepted the concept of justice as fairness.

According to the difference-principle each member of society does not receive the same proportion of basic goods. Explains Rawls, "Assuming the framework of institutions required by equal liberty and fair equality of opportunity, the higher expectations of those better situated are just if and only if they work as part of a scheme which improves the expectations of the least advantaged members of society".³ Therefore, dependent moral subjects (i.e. SDAT patients) receiving proportionally more basic goods from society than independent moral agents is a just practice in a society that values the concept of justice as fairness.

Another assumption is that individuals join in a social contract for the purpose of establishing and maintaining a social system to improve their chances of having a safe, stable environment for all members. Hence, the fortunate of today find it logical to respond to the needs the disadvantaged because in time, they assume that the same protective umbrella of fairness may be needed to protect them. As autonomous, competent individuals move down the continuum of autonomy and their needs increase, in a society that has just social policies, these needs will be addressed.

Society's principal goal is to promote safety and general welfare and treat all its members with respect. To achieve these ends it is necessary to have an infrastructure and social policies supporting individual autonomy, and promoting the protection of welfare subjects. There is an obligation to provide what Rawls calls the "basic goods" which are the necessary preconditions for human well-being. Hence, the constituents of well-being, such as health, education, knowledge and a legal system should be provided by the social system.

Thus, the starting point for the discussion is the assumption that society's purpose is to provide a social system which permits individuals to live as safely and freely as possible. At the same time society can restrain individual freedom only to the degree needed to permit development of

society's overall goals. Also, individual freedom can be restrained to prevent an individual harming himself or others.⁴ Furthermore, society can limit freedom when it is more beneficial for the individual that an outside party intervene to remove, what Kant would call, an obstacle to freedom. Individuals agree to sacrifice some freedom and comply with legal and conventional rules in order to receive basic and instrumental goods, notably education, health care, protection from harm and a legal system.

In chapter three, it was proposed that the weak and vulnerable population, which includes the majority of Alzheimer's Disease patients, have needs as opposed to rights because they lack moral agency or autonomy, the pre-requisite of being a rights-holder. Individuals with diminishing or depleted autonomy are dependent moral subjects who continue to have fundamental welfare needs although they are unable to make choices and protect their interests. These dependent moral subjects rely on moral agents and society for their safety and welfare needs. Their needs-claims are correlated with obligations held by moral agents and society.

Questions about human needs are questions about human obligations, as Ignatieff claims.⁵ To have a need is to have a commonality with other members of the community because all individuals, regardless of their level of autonomy, have welfare needs. The difference between them

is the degree to which they depend on others to have their needs met. The needs of strangers correlate with moral agents and with society's acknowledged obligation to respect and meet their fundamental welfare needs. Whether or not the rights or needs approach is taken, dependent moral subjects, by virtue of their dependency on moral agents, have a claim to have their needs or rights respected. Moral agents in turn have an obligation to honour the welfare needs (rights) of these dependent individuals, often strangers to them. Through social welfare policies, these obligations can be honoured and on an individual basis, individuals assist in various ways, dependent people whom they know.

All members of a society draw on the resources of society to meet their welfare needs. It is all a question of degree. As an individual's autonomy diminishes, or to use clinical terms, as cognitive functioning and mental competency declines, welfare needs are met less effectively, the more dependent that individual is on moral agents and, at the collective level, society. It is not sufficient that society recognizes the entitlement of the weak to society's resources and its obligation to protect dependent members of the community. In addition, at the individual and collective level, this obligation should be honoured by instituting, implementing and evaluating social policies designed to promote the well-being of each individual and hence, the collective good. Required by all is an infrastructure that

facilitates the provision of basic goods and an organizational framework to distribute goods fairly, and permit individuals to strive to fulfil their goals and meet their interests. Moral agents and subjects are enmeshed in society's infrastructure which ideally, should function to support individual autonomy and protect the vulnerable. Thus, the infrastructure should permit a society to enact just social policies.

The obligation to provide the required services and structures springs from the nature of the social contract. In a liberal society, society exists to promote autonomy and respect for all and hence the laws and structures should represent and promote these values. Individuals have needs because of a loss or lack of a basic good. These include positive and negative welfare needs which all individuals share: food, clothing, shelter, safe environment, social stimulation, adequate medical care, access to legal services and an educational system. As one moves along the autonomy continuum, the individual becomes more or less capable of satisfying these needs independently. Nevertheless, all individuals belonging to a given society depend to some extent on its social infrastructure which permits its members, who are autonomous, to lead more independent lives.

In addition to concrete needs needed for survival, there are emotional and social needs which are equally necessary for well-being: for instance, respect and acknowledgement. Ignatieff calls these needs

intangible and states that they include love, respect, solidarity and dignity.⁶ These intangible needs confirm respect for the individual and his membership in society. Unless both concrete and intangible fundamental needs are met, individuals are not being treated as ends in themselves. Of interest and importance to this investigation are the needs for respect and dignity which constitute individual integrity. Although intangible needs are harder to define, measure and evaluate than “hard” or “concrete” needs both are essential for well-being. The *soma* and *psyche* are interdependent and influence each other. Thus, the dichotomy between physical and mental health is artificial and, hence, it is inaccurate and unhelpful to ignore the importance of intangible needs as well as concrete or “hard” needs. Deprivation of either type of basic needs can impact on an individual’s health (psychological and physical or both) and constitute harm.

Within either the consequentialist or deontological framework, individuals can make claims to have welfare needs met. Thus the origin of society’s obligation to respect its members’ needs is the claim made by individuals to have their welfare needs met. Whether a rights-claim by a moral agent or a needs-claim by a moral subject, there is a correlative obligation on the object of the claim to respond.

From the deontological perspective, the answer again lies in respect for man as an end in himself. In Part II of The Doctrine of Virtue, Kant

discusses the duties of virtue to others and his work sheds important light on why moral agents should be protective of the weak and vulnerable. These duties are fulfilled or observed. The virtue of love accompanies fulfilling a duty and the virtue of respect is present when we observe duties to others.

By love, Kant means the maxim of benevolence (practical love). A moral agent acting benevolently, that is having a good will can perform acts that lead to good being done. Hence, there is a distinction between wanting or willing to do good and the consequence of the action. Respect is “to be taken in a practical sense (*observantia aliis praestanda*), as a maxim of limiting our self-esteem by the dignity of humanity in another person.”⁷ The duty of love to others is manifested in the duty of making another individual’s end the ends of the moral agent and society. In Kant’s words “The duty of respect for my neighbour is contained in the maxim of not abasing any other man to a mere end (not demanding that the other degrade himself in order to slave for my end).”⁸ There is a difference between the two virtues. Love is meritorious and demands of its object a response but respect is a duty of observance which does not make the same demand. When a duty of love to another is honoured, “I obligate the other as well: I make him indebted to me” In contrast, when fulfilling the duty of respect “I obligate only myself, contain within certain limits in order to

detract nothing from the worth that the other man, as a man, is entitled to posit in himself".⁹ In Kant's words, active, practical benevolence (beneficence) is "making another's well-being and happiness my end". The duty of practical love is present only when moral agents are interacting because they are capable of responding to each other. However, when the moral agent interacts with the dependent moral subject's claims, the duty of respect dominates because the dependent welfare subject can not respond. The relationship is asymmetrical.

The claims of others should be heeded because every moral agent has a duty to be beneficent, "that is, to promote, according to his means, the happiness of others who are in need, and without hope of gaining anything by it", stated Kant. Why is the duty of beneficence a duty for all agents? Most reasonable individuals appreciate the reasonableness of behaving beneficently to the needy because they recognize the possibility of their own vulnerability to being dependent on others in the future. "Consequently, the maxim of common interest - of beneficence toward the needy - is a universal duty of men, and indeed for this reason: that men are to be considered fellow-men, that is, rational beings with needs, united by nature in one dwelling place for the purpose of helping one another".¹⁰

In the previous chapter, it was proposed that the realm of ends be expanded and thus the above quotation by Kant should be amended in the

following manner. The maxim of common interest, that is, of beneficence toward the needy, is a universal duty of men, and indeed for this reason: that men are to be considered fellow men. That is to say, that all men including rational moral agents and dependent moral subjects with their respective needs, are united by nature in the realm of ends, in one dwelling place for the purpose of helping one another when able to do so and assisting our fellow-men when they become dependent on others, for their welfare. Again, the motivation of self-interest and prudential planning is present.

But what if the individual making the claim is not rational nor a moral agent? In Engelhardt's words the principle of beneficence "reminds one of what the moral life can be about - fashioning webs of sympathy through a commitment to providing goods to Fellow persons in need".¹¹ Then the duty of respect comes to the fore. "Every man has a rightful claim to respect from his fellow-men and is reciprocally obligated to show respect for every other man" states Kant. When the realm of ends includes moral agents, all individuals have a claim to be respected and this claim should be respected by fellow-men. Furthermore, in agreement with the second formulation of the categorical imperative, because all men (moral agents and subjects) have dignity, none can be used exclusively as a means by another, no matter how noble the cause, but must always be treated at the

same time, as an end in himself. The respect with which a moral agent should hold himself is the standard to be applied to his fellow-men. Likewise, a moral agent should not have double standard when interacting with others. "...in other words, he is obligated to acknowledge, in a practical way, the dignity of humanity in every other man. Hence, he is subject to a duty based on the respect which he must show every other man".¹²

Thus, from the Kantian perspective, society and moral agents respond to the claims of others because of the nature of man and also, because it would be contradictory and self-defeating not to respond in the manner that you would want to be treated. When moral subjects claim welfare needs, society and moral agents have an obligation to act in accord with the duties of love and respect. The duty of practical, active love is beneficence. Society responds to the needs of others in a beneficent fashion if the initiator of the claim is an autonomous moral agent. As discussed in the previous chapter, the mentally impaired have certain fundamental needs (or if preferred, inviolable rights) and society has an obligation based on the duty of respect to honour their claims. When the realm of ends is expanded as proposed, and the passive originator of the claim is a dependent moral subject, the agent again should respond in a respectful manner. In this case, his actions are also grounded in the principle of non-

maleficence because his ethical priority is to protect the vulnerable moral subject from harm.

Also, the utilitarian approach can justify society's obligation to respond to the claims of moral subjects (welfare subjects). Whether those lacking competence and autonomy are needs-holders or right-holders they make claims which society has a correlative obligation to honour. The content of these needs, interests or rights is the same as the content of the inviolable rights to dignity and integrity. The mentally incompetent have a claim to be protected from harm and have their welfare needs met. When society's global value is promotion of general well-being and protection of the weak and vulnerable, society responds in a non-maleficent fashion because it is in society's interest to honour these claims.

The difference between the two approaches is that according to consequentialism, society's response is determined by the expected benefits to society. In both cases the moral agent's action is motivated by a duty to assist dependent moral subjects. Thus, duty or obligation plays a major role in consequentialism and deontological moral thinking. In deontology, duty is primary. However, in consequentialism, we come to duty later because it is a derivative of the good or end that the duty promotes.

The healthy population, for self-interest reasons, support non-maleficent social welfare policies. The consequentialist would justify

responding to the claim in terms of the social utility of promoting a society that respects the weak and vulnerable: a position which will be harder to defend as it becomes less “cost effective” to care for the disadvantaged at the expense of the stronger. Again, the difficulty with the consequentialist route is that society can change its agenda, and caring for the weak and vulnerable could be ranked less important, or even of no importance. Thus, the value of promoting general welfare and protecting the weak and vulnerable could be eclipsed by other values: for instance, if the good of the majority would be enhanced if certain SDAT studies were permitted although the cost could be serious harm to SDAT research subjects. The cost can be justified when respecting the weak and vulnerable is a negotiable value, and cost effectiveness is valued more than general well-being. However, if the global value or good of respect for all members is a non-negotiable, then the costs must be weighed in the context of that non-negotiable good.

A common element in both approaches is the recognition of moral reciprocity across time. Kant’s discussion of imperfect duties recognizes the importance of considering how one would prefer to be treated in the future. Also, consequentialists consider the impact of their actions in the short and long term. Hence, they both consider how they should be treated now and

in the future, and conclude that they have a duty to respect the needs of the weak and vulnerable (or if preferred, their rights, and their dignity).

Society has responsibilities to the general population and also, to specific sub-groups. When responding to all its obligations, conflicts can arise or certain duties place too large a drain on society's resources. Thus, some obligations can not be met adequately. Of interest to this study, are society's obligations to:

- (i) individuals without SDAT (general population),
- (ii) SDAT patients, and
- (iii) researchers.

Society has a responsibility to:

- (i) provide consistently good quality care for all members of the community.
- (ii) support research which is expected to reduce social and economic costs of SDAT at, both the micro and macro levels, because the knowledge acquired will lead to:
 - (a) improving the quality of life of SDAT patients and their caregivers, and
 - (b) learning more about the disease process and thereby contributing to a reduction in incidence, improvement in management and prevention strategies.

The global obligation is to promote general welfare. This includes the responsibility to provide the instrumental goods of health care, knowledge and security for all members of the community, the weak and

vulnerable and the strong and able. Moral agents and collectively, society have an obligation or duty to assist individuals with diminishing or depleted autonomy because they lack sufficient moral agency and critical competency to meet these needs effectively. Thus, society has an obligation to honour the passive claims, of dependent individuals, to have welfare needs met and also, to support caregivers in their efforts to provide care for affected patients.

An interest in having welfare needs met and being protected from harm is also shared by competent individuals who work co-operatively in their society to establish social policies designed to maintain or secure individual and general well-being. The crucial difference between the two groups is that rational moral agents are able to exercise some control over their lives but those with SDAT are incapable of protecting themselves or promoting their own welfare needs.

Even though the majority in society do not suffer from SDAT, rarely does anyone escape some degree of dependency on the health care system. Also, given the incidence of SDAT, many of us know someone who has SDAT or is a caregiver for an affected patient. Thus, most individuals have an interest in acquiring more information about the prevention and management of SDAT in order to reduce their chances of developing SDAT or having the heavy responsibility of caring for a SDAT patient. In

addition, they have an interest in a society providing a health-care system which meets these particular kinds of health needs. Having said this, society also has a duty to prevent the costs of caring for SDAT patients from draining the health care system of resources and depriving others of effective health care.

Why should society respond to the claims of the general community and the SDAT patients to have their welfare needs honoured? Again the conclusion, that society has an obligation to respond to the claims of the weak and vulnerable and also the stronger members, may be supported by a mix of deontological and consequentialist insights, though the former approach is preferable for reasons yet to be given.

Granted that both competent and incompetent individuals have needs, generally society's response to competent moral agents is a positive one based on the principle of beneficence. However, when the welfare subjects are vulnerable (e.g. SDAT patients) their claims are respected in a negative fashion grounded in the principle of non-maleficence.

The price for providing "basic goods" as they are called by Rawls, is high and is rising. Health care costs are escalating but contrary to popular opinion the major reason is not the shift in demographics related to more people living longer. "Although the average annual health care costs rises sharply with age, it accounts for only a minor proportion of the 651 percent

growth of real personal health-care outlays between 1950 and 1987", states the health economists Aaron and Schwartz regarding the U.S.A. health care system.¹³ Nevertheless, if more people live to be in the old-old category, and more effective ways of preventing or managing SDAT are not found, providing chronic care for the elderly SDAT population will become a large drain on the social-welfare budget. This is the case because the average life expectancy after being diagnosed with SDAT is six years and during the course of the disease the individual will deteriorate from being independent to requiring community support to, in almost all cases, residing in an institution providing total care.

The prediction that SDAT will be the major public health problem of the next century because of the high social and economic costs raises the issue of allocating scarce resources. As the costs of caring for SDAT patients rise and the ability of society to provide for the health care needs of all its members is threatened, one way to defuse the tension is for society to support SDAT research investigating ways to reduce the incidence and enhance management of SDAT. It is in society's interest to reduce the incidence of SDAT because the costs associated with the loss of capable, independent members of the community is a drain on scarce resources. With the onset of SDAT an individual changes from being independent and productive to being dependent partially or fully on others for their welfare

and safety. Thus in response to the individual desire not to have SDAT and society's wish to reduce the incidence of the debilitating disease, society has an obligation to support health sciences research which strives to reduce the morbidity and mortality associated with SDAT. Also, in order that health care professionals can provide effective therapies and fulfil their first duty to do no harm, society has an obligation to support health sciences research.

Society expresses its support for research by providing public funds, supporting educational and health care facilities where research is conducted, and also by making recommendations through appropriate bodies regarding how health sciences research should be conducted. After societies accept their duties the next step is to implement policies and actions in response to the claim. In addition, it is imperative that the effectiveness of programmes be evaluated.

To conclude this section, the origin of society's obligations to respect the welfare needs of all members of society lies in the claims made by agents and welfare subjects. Their claims correspond to society's obligation and duty to meet their welfare needs. Society is obligated to respond because the relationship with others is grounded in duties of virtue to others, specifically practical love and respect. In turn, society and individuals should shape their response in terms of these duties because to

do so is based on a respect for man's dignity as an end in himself (not merely a means) and in the recognition that it is morally contradictory not to act in the manner that one would want to be treated in the event that he fell upon unfortunate times.

A society which could be described as humane and responsible, has different obligations to different groups but a common element is the duty to meet the welfare needs of all members of the community realizing that some need more assistance than others. The obligations to the weak and vulnerable are universal. Thus, when an SDAT patient becomes a research subject, society not only continues to have an obligation to ensure that his welfare needs are met but that adequate protection of human subjects is instituted. Granted that society should not condone exposing SDAT patients to excessive risks in any context, a researcher should not recruit SDAT patients to be research subjects when their involvement would pose a serious threat to their well-being. If their association with high risk research was sanctioned, then society would have failed to honour its obligation to protect the vulnerable members of the community. Although research provides a way to reduce the costs of caring for SDAT patients releasing scarce resources for other research must be restrained by obligations to vulnerable research subjects.

4.3 Researcher's Obligations:

Research plays a major role in society. Research's goal is to acquire knowledge, an instrumental good used to promote the good of health and general well-being. Conducting research is a good because it is necessary for the development of effective therapies. Research is morally right when it is conducted in accordance with regulations respecting the worth of research subjects and designed to gain knowledge that will alleviate and cure health problems and also, promote the general well-being of the community.

In the previous section, it was seen that health sciences research may be conducted in a way that defuses the tension between meeting the health and social needs of the Alzheimer population and other members of society. The purpose of this section is to examine the responsibilities of researchers to society and to human subjects.

The goals of SDAT research are:

- (i) to acquire new information that has the promise of discovering or improving interventions that will prevent the disease and/or retard its progress.
- (ii) to acquire information that holds the promise of developing more effective ways to care for Alzheimer patients and their care-givers, and thus improve the quality of their lives.

In conceptual terms, the overall goal of SDAT research is to maintain, preserve and promote the autonomy and well-being of aging individuals and

their caregivers. This research can be classified into two broad categories with the caveat that the categories can overlap. First, there is research investigating the disease process to learn more about the etiology, prevention and management of SDAT which can be referred to as “hard” research. Second, there is research which studies ways of improving the status of chronically and terminally ill patients and their caregivers which can be called quality of life research. For instance, investigations study ways to maximum independence in performing the activities of daily living (for instance, cooking and shopping). Success in achieving the goal will yield benefits at the macro level for all members of the community.

There is a moral imperative to conduct research. The health care professional’s first duty is to do no harm and secondly to do good. Neither of these duties can be fulfilled unless his interventions have a reasonable chance of assisting the patient. To fulfil the first obligation of not harming the patient it is necessary that the health care professional use therapeutic interventions that have been found to be effective and reliable under similar conditions. To determine that an intervention is effective and reliable, the intervention must have been evaluated by researchers using a well designed study producing valid evidence.

The researcher has responsibilities to society in general and also to specific research subjects. To society they have an obligation to conduct

research that has the promise of benefiting SDAT patients. The results of their work will contribute to developing validated, effective therapeutic interventions for SDAT patients and/or their caregivers and in addition, their work could lead to reducing the incidence of SDAT. Thus, society as a whole benefits. On the other hand, researchers have an obligation to respect the vulnerable subject's claim to have his welfare needs met. The regulations regarding experimental design and the consent process restrict the freedom of the investigator to seek new knowledge. Also, they guide the researcher and if followed, these regulations assist him to fulfil his respective obligations to the society in general and the research subject.

To the community, he has an obligation to conduct research that is scientifically valuable and thus, act in a beneficent fashion. This obligation to do good is fulfilled when the protocol meets the requirement for an ethical design. The obligation to subjects to do no harm is met when the researcher proceeds only when a valid consent from a subject or a surrogate for participation in a scientifically valuable study having an ethical design, is obtained.

In the following sub-sections, how these obligations can be met will be examined.

a) Obligations to Society:

Research can not work in a vacuum. It is influenced and regulated by conventional and legal rules and, also society's priorities. Society's interest is to have researchers conduct investigations that are scientifically valuable. In layman's terms the research should have the potential directly or indirectly to benefit affected patients and/or their caregivers, and also indirectly benefit society. Thus, SDAT research should address the interests and needs of the following groups:

- (i) individuals who do not have SDAT and want to reduce the probability of their having SDAT
- (ii) SDAT patients whose quality of life could be improved
- (iii) caregivers of SDAT patients who want to improve the quality of their lives
- (iv) society which wants to reduce the costs of caring for SDAT patients.

These needs and interests correspond to the researcher's obligation to plan research which meets the ethical requirements of experimental design. By designing research which is scientifically valuable and ethically sound the investigator can fulfil his obligation to do good for all of the above listed parties. Furthermore, when research involves human subjects, the investigator has to consider the consent process, no small feat when the cardinal feature of the prospective subjects is diminishing or depleted

autonomy. In the next section regarding obligations to the subject, the requirements for a valid consent will be examined.

The essential requirements for an experimental design to qualify as ethical, listed by Drs. Thomas and Waluchow, are as follows:¹⁴

- (i) Either genuine promise of treatment where none presently exists or genuine doubt about the efficacy of present treatment where it does not exist.
- (ii) a clearly formulated hypothesis of the form: "If we wish result x, procedure y is a means to its probable achievement."
- (iii) a protocol calculated to confirm/confute the hypothesis.
- (iv) favourable risk-benefit ratio.
- (v) monitoring of research.
- (vi) researcher should not be the person recruiting subjects.
- (vii) evaluation.

The requirements are self-explanatory but a few brief comments are needed. A major requirement for research to have scientific merit is balancing the degree of risk to the subject and the possibility of benefit to others. On one hand, "The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study...", states the Nuremberg Code.¹⁵ Concurrently, the investigator is required to compare the degree of risk to the subject versus possible benefits. The degree of risk "should never exceed that determined by the

humanitarian importance of the problem to be solved by the experiment” advises the Code, in respect to the risk-benefit ratio.¹⁶ There are two ways of evaluating the risk-benefit ratio and the assessment involves a minimum of two parties but depending on the circumstances, more individuals can be involved. The assessments are:

- (i) objective evaluation conducted by
 - (a) research team, and on most occasions by,
 - (b) Research Ethics Board ¹⁷
- (ii) subjective evaluation conducted by
 - (a) prospective subject or
 - (b) surrogate

The first assessment is completed by the researcher and an REB is called “objective” because epidemiological data and clinical experience are the basis of the prediction. The second type of assessment is completed by the prospective subject or the surrogate who brings to the evaluation all his “baggage”. His values, circumstances, goals and health status all impact on his assessment of the costs and benefits of being a subject and hence the assessment is called “subjective”. Thus, different conclusions can be reached. The subjective evaluation occurs after the research has been designed and approved by an REB. In other words, the subjective evaluation

is integral to the consent process. Therefore, when referring to risk-benefit ratio, it has been at the objective level.

The fourth requirement for an ethical design is that the risk-benefit ratio be favourable, that is favourable according to the objective assessment process. Unless otherwise indicated, whenever the risk-benefit ratio is mentioned, the objective assessment of this ratio is being referred to, as opposed to the subjective assessment. In the next chapter, these two ways of evaluating the risk-benefit equation will be discussed further.

The fifth requirement regarding monitoring of research serves as an additional check on the research project. It is not sufficient for a study to be approved by an REB. The project should be reviewed on an ongoing basis by the investigators, REB and other interested parties. Their attention should focus on evaluating the research's design, consent process and subject selection. In some cases, it may be learnt there is sufficient evidence to justify halting the study because it had been demonstrated already that the intervention is an effective therapeutic intervention.

The sixth requirement is controversial because it addresses the point that in recent times, frequently the roles of health care professional and researcher have been combined and consequently when these roles are mixed, the roles of patient and subject become merged. Thus, when a researcher recruits subjects, there is a strong possibility that he will also be

involved in the patient's health care management. Therefore, the subject has a conflict of interests and is exposed to coercion. Ways of reducing the possibility of coercion will be discussed in the following chapters.

Lacking in the criteria listed is a requirement in respect to subject selection. When the subjects are chronically and terminally ill, as is the case with SDAT patients, subject selection is an important ethical issue. The guidelines regarding other chronically and terminally ill patients should apply in the case of SDAT research. Subjects should be selected from this vulnerable pool only when there is no other available source for the information sought by the researcher. As mentioned earlier, the value of using animal subjects in SDAT research is limited. Thus, it is necessary to involve human subjects in SDAT research in order to learn more about SDAT's causes, prevention and management. Similarly, only schizophrenia patients can be asked to be subjects in research projects investigating schizophrenia. Although the SDAT population could be a convenient pool of subjects for many studies, they should be employed in experiments that can only occur if they are subjects and/or in studies that do not pose a threat to their well-being. Also, there should be a limit on the number of times an affected patient can be selected to be a research subject, in order to prevent the vulnerable patient being exploited and harmed through over-exposure to research interventions, some of which can be mentally and/or physically

exhausting. Thus, the requirement regarding subject selection should protect a vulnerable individual from being associated with activities that can pose a threat to his fragile health status and, therefore, serve to ensure that his fundamental needs are respected. However, because SDAT patients are chronically and terminally ill, their health status should not be jeopardized. Thus, strict rules should be followed when these vulnerable individuals are subjects. In chapter five, specific recommendations regarding the association of affected patients in SDAT research will be proposed.

When the research has met the criteria of an ethical design and the subject or their surrogate has given a valid consent, then the researcher has fulfilled his obligations to society.

(b) Obligations to Research Subjects

When SDAT patients are research subjects, stringent regulations regarding the experimental design and consent process are imperative. The major way to protect the research subject is by means of the consent process. The requirement that a research subject's consent be informed and that the consent be freely given by the subject is the opening statement of the Nuremberg Code and echoed in subsequent research codes.

To the research subject who is autonomous and competent to consent, the researcher has an obligation to respect the subject's autonomy.

However, the obligation changes when the SDAT patient moves downward on the autonomy continuum and is not capable of consent to be a subject. The researcher's obligation is to do no harm to the subject, or in other words, to act in a non-maleficent manner. In the former case, the researcher fulfils this obligations by securing a direct, valid consent and in the latter case, a valid indirect consent. The criteria for a valid consent from a subject (direct consent) and a surrogate (indirect consent) are similar and were given in the first chapter. What if the affected patient had expressed his wishes earlier regarding research participation and/or the surrogate knows what actions would be consistent with the long standing wishes of the patient? The surrogate should honour the previously stated wishes and values on condition that the surrogate does not give indirect consent for the affected patient to be a subject in a research project classified as above minimum risk. Thus, acting in the affected patient's best interest can put the brakes on respecting the patient's autonomy when the patient is no longer able to consent directly.

The competent subject is autonomous and therefore has an interest in having his autonomy respected. To use the rights language, he has a right to consent or refuse to participate and the researcher is obligated to respect this right. When the subject has diminishing or depleted autonomy and is not sufficiently competent to consent, decision making is transferred

to a surrogate who has the responsibility to honour previously indicated wishes of the subject if known (with the caveat mentioned above regarding research ranked higher than minimum risk) or act in the subject's best interests.

Both competent and incompetent subjects have welfare needs or interests and differ in their capacities to meet these needs. The dependent mora! subject (vulnerable, incompetent subject) depends on society, researchers, and their next of kin to protect him from harm and to meet his other basic needs. The researcher has an obligation to consider the impact of a research intervention on a subject who is vulnerable and be cognisant of the fact that these defenceless, prospective subjects depend on others to be protected from exposure to excessive risk.

Also, by means of the consent process the surrogate has the opportunity to evaluate the proposed research and decide if research participation would be in the patient's best interests. Evaluating the risk-benefit ratio is crucial to deciding if the patient should be associated with the research. For both the subject and the surrogate, the consent process gives them the opportunity to conduct what has been termed the subjective assessment of the risk-benefit ratio. The values, circumstances and priorities of the subject are taken into account when the protocol is assessed.

Although all subjects are exposed to some degree of harm, the degree of risk must be appropriate in light of the expected benefits. Nevertheless, the vulnerable SDAT patient should not be exposed to research carrying the risk of serious and/or permanent harm (physical and/or psychological). Hence, SDAT patients should not be involved in research classified (at the objective level of assessment) as above minimum risk, regardless of the expectation of benefits.

The criteria for a valid consent from either a subject or his surrogate are difficult to meet for a number of reasons. The nature of the information given to the subject, the status of the subject or surrogate and the manner in which the consent is sought, can all be obstacles to securing a valid consent. Frequently, the prospective subject can not evaluate adequately the scientific data related to the experiment which often requires a facility with abstract concepts, such as appreciation of the probabilities of benefits and risks. The prospective SDAT subject could be unable to recall, concentrate or evaluate information relevant to the protocol. The next of kin could be unable to appreciate the consequences of consenting because his insight and judgement are impaired on account of fatigue and anxiety. The consent could be sought in a hurried fashion, allowing little time for questions and clarification in a busy setting, lacking privacy. Also, a member of the treatment team could be recruiting subjects

which puts pressure on the patient or family to co-operate and consent. Although the possibility of coercion is always present, because of the unequal nature of the relationships, ways to minimize coercion will be presented in chapter five.

To the MRC's credit, they acknowledge that the criterion of a valid consent is demanding but nevertheless, recommend that this standard be sought. The MRC does an admirable job of trying to match the theory and practice of obtaining a consent mechanism frequently from an institutionalized, ill patient with poor concentration. The Guidelines offers the investigator the following advice: "Put simply, prospective subjects must receive, in a language which they understand, enough information about the proposed study and their prospective role, to enable them to decide whether or not to participate".¹⁸

The investigator should adopt an educational approach because he is required to assess what information is important and match this assessment with his estimation of how much information the subject can appreciate. Then, he should "be guided by tailoring the disclosure to a reasonable person in the circumstances of the prospective subject".¹⁹ Also, "the level of disclosure should be proportionate to the likelihood and the scale of possible harm, but even the remote possibility of injury should be disclosed", cautions the Guidelines.²⁰

Thus the Guidelines do not provide a clear answer to the important question of how much autonomy or competency is required. Also, the test and definition of competency which should be used when assessing competency to consent to research activity is not discussed. What is said is that the prospective subject must understand information supplied by the investigator and be capable of making a decision with respect to the question of whether he wants to be associated with the research. Thus, it is implied that the depth of understanding required is a function of the complexity of the information regarding the protocol. Later this sliding scale approach to competency will be criticized and a standard based on the task of consenting will be proposed.

The MRC does give explicit directions regarding information that the subjects should be told which they state should include:²¹

- (i) reason for the study
- (ii) research techniques involving the subject (for instance, randomization)
- (iii) reason for inviting prospective subject to participate
- (iv) the reasonable expected benefits and consequences of the study
- (v) foreseeable risks, discomforts and inconveniences for the subject
- (vi) complete details about confidentiality
- (vii) expected time commitment from subject

- (viii) plans to have a follow-up study and information about retention of data
- (ix) rules regarding halting the study and withdrawing a subject from the study
- (x) the right of the subject to withdraw from the study at any time and without penalty.

In addition, the researcher has the responsibility when the prospective subject is concurrently a patient to provide additional information. The patient must be informed of other therapeutic options and how the experimental intervention could affect his current status. Thus, the required information includes:²²

- (i) the patient's prognosis without intervention
- (ii) alternative interventions available
- (iii) experimental aspects of proposed intervention
- (iv) interventions available to patient who becomes a research subject for the sake of the research
- (v) an estimate of the likely success and failure of all interventions that may be offered and withheld
- (vi) an estimate of the risks and possible adverse effects of offered interventions
- (vii) clear distinction between procedures that are part of the usual patient care and the research interventions.

The information requirements are listed to make the point that the prospective subject is required to have a high level of cognitive functioning

and competency. Otherwise, he would be unable to evaluate the required information, distinguish between standard and experimental treatments and appreciate the probability of risk associated with the intervention. On some occasions, there is a good deal of information given over a period of time which will require the capacity to recall the information correctly and a facility in manipulating a wealth of data. Then the crucial step of evaluating the information and making a decision is based on an appreciation of the consequences of the decision. In philosophical terms, the prospective subject must have full autonomy, rationality and critical competence to give a valid consent.

In the MRC's Guidelines, discussed in the section "Informed Decision-Making" is the level of disclosure required from the investigators. Continuing a point referred to earlier in this section regarding the level of disclosure by the investigator to the prospective subject, the Council recommends that "The level of disclosure should be proportionate to the likelihood and scale of possibility of harm, but even remote possibility of injury should be disclosed".²³ The higher the probability of risk and harm, the more information should be provided to the prospective subject.

The investigator has an unenviable and in some situations untenable task. Trying to tailor information to suit the prospective subject's level of comprehension and the requirement to have total disclosure

regarding the associated risks can give the researcher two responsibilities at odds with each other. The complexity of the information and/or the limited abilities of the prospective subject can prevent even a researcher with excellent communication skills from obtaining a valid consent from a subject. If the researcher does provide the prospective subject with as much information as he can comprehend, the prospective subject may lack sufficient data to appreciate the probability of risk and be unable to give a valid consent. On the other hand, if the researcher gives the subject basic relevant information, knowing that the prospective subject will not appreciate all he is being told, the researcher is no further ahead. This is the case because a necessary qualification for providing consent to research carrying "even the remote possibility of harm" is a high level of competence and cognitive functioning. The capacity to consent to research participation will be discussed further in the next chapter. Suffice it to say, at this point, that full autonomy and critical competence are the necessary requirements to meet the criteria of being competent to consent to research. Hence, the prospective subject is required to be functioning cognitively at the level expected of a responsible moral agent.

Returning to the Guidelines, the MRC is giving a mixed message. The Council states that the goal is a valid consent. However, the Council also states that when the prospective subject is having difficulty

comprehending the information provided, then the amount of information provided can be scaled down to meet the subject's capabilities. When the information to be given is analyzed, the information that the investigator can delete or simplify is limited. The minimum information would include a number of concrete details regarding the experiment, some discussion of the probability of risk and expected benefits to the subject and/or society. To critically analyze the information, the prospective subject needs to remember the relevant information, have a good understanding and command of the information, be able to manipulate the facts and probabilities, and marshal reasons why he should or should not participate and reach a conclusion based on the information provided. If these criteria are not met, a valid consent has not been given.

In summary, the investigator is obligated to conduct research which has an ethical design and a consent mechanism which ensures that a valid consent is secured from the subject or his surrogate. When designing an ethical protocol the researcher is acting in a beneficent manner towards members of society: he is trying to reduce mortality and morbidity through health sciences research. The investigator is respecting the autonomy and/or needs of the prospective subject when following rules regarding obtaining a valid consent. Researchers have an obligation to respect their human subjects because of their intrinsic value as dependent moral subjects

and also because it is beneficial for society. A social utility and self-interest argument can be offered for respecting the weak and vulnerable research subjects because most western countries value protecting the defenceless and do not prize social gains won at the cost of exploiting the incompetent and the aged, especially when the prospect of growing old looms more immediate. Whether the subject is autonomous or not, the investigator should act in a non-maleficent manner to the subject. In addition, when the subject is autonomous and competent he has an obligation to respect the subject's right to self-determination. The rights and needs of research subjects manifested in the requirement for a valid consent are a constraint on the researcher's desire to acquire knowledge.

When the subject shifts from being autonomous to dependent, there is a corresponding shift in the ethical priority for both the researcher and the community. When individuals are autonomous, both society and the research community have an obligation to support the subject's autonomy, but in the case of a dependent subject, the need to protect the subject from harm becomes the ethical priority. This change in priorities has consequences for the design of research requiring incompetent subjects which will be discussed in detail in the following chapter.

4.4 Is there a Moral Imperative to be a Research Subject?

The tension between freedom and coercion runs through health sciences research. However, the conflict between these two forces takes on a different dimension when society demands that individuals return the favour, so to speak, by being research subjects. In brief, the argument based on consequentialism and social contract theory is as follows.

- (i) Members of a community have entered into an agreement that accepts restrictions on freedom in return for certain benefits, notably, meeting of welfare needs, protection from harm and the opportunity to exercise freedom within certain constraints.
- (ii) Members of a community benefit either directly or indirectly from knowledge gained through health sciences research.

Thus, it is concluded:

- (i) members of a community have an obligation to participate in research that promises to benefit their community, and in some cases, the subjects themselves.
- (ii) the community can demand that its members honour their obligation to be subjects.

The purpose of this section is to refute the second conclusion. It is assumed that members of a society have a moral responsibility to be

subjects in health sciences research but not that society can coerce individuals to honour this obligation.

Granted that health sciences research is necessary and a good, it does not follow that there is a moral imperative to be a research subject. Subject selection should follow stringent regulations designed to protect subjects from harm and coercion, and also to respect the subject's self-determination and/or their fundamental needs. In the paper, "Medical Research on Human Subjects as a Moral Imperative", Visscher clarifies this point, stating "The use of human subjects in biomedical research is considered by scientists to be indispensable to progress in medical science and to consequent improvement in the art of medical practice, but the protection of the rights and welfare of every human being is equally a first priority of a civilized society. So long as these two basic precepts are not in conflict there are no major ethical problems in connection with scientific study on human subjects".²⁴ Ethical problems arise when these two objectives are in conflict as is the case, it will be seen, when there is an obligation to be a research subject. Although health sciences research and the use of human subjects are necessary for the practice of effective health care we should not be subject to a moral imperative to participate.

The reasons for opposing this conscription of subjects are:

- (i) Requiring members of a community to honour the obligation to be a subject overrules respect for individual autonomy and is contrary to the fundamental values of western, liberal societies valuing self-determinism.
- (ii) Conscriptio of subjects can have an unfavourable cost-benefit ratio when the costs to society as a whole are considered.

These reasons will be examined in turn.

a) The Limits of Coercion:

The position that individuals have a duty to be research subjects is based on the premise that as members of a society, each individual has certain obligations and duties. Specifically, because individuals are the recipients of advances made in health care they should contribute to further gains being made by health sciences research by being research subjects.

In western, liberal societies, the terms of a social contract, permit individual liberty being restricted for the benefit of all, or for certain parties, under specific conditions. A delicate balance is sought among restricting individual autonomy, fairly distributing goods, promoting society's goals and preserving social order.

In order to maintain a given social system promoting a number of common goals, constraints on liberty are necessary and duties are imposed.

Society imposes an obligation on its members to respect legal rules in respect to many aspects of our lives (e.g. business, driving, employment, unions, freedom of expression and worship, access to medical and legal services).

Research is a valuable activity, but not important enough to demand that all members of the community be a pool of research subjects to be drawn from at society's or the researcher's discretion. Also, the obligation to be a research subject is an unenforceable obligation. I am in the good company of Hart when I take the position that society should not force individuals to be moral. In Law, Liberty and Morality, Hart explained why he opposes Lord Devlin's position in favour of enforcement. Hart stated:

It is perhaps misleading to say with Lord Devlin that social morality, so far as it secures these things [universal values of individual freedom, safety of life, and protection from deliberately inflicted harm], is of value because they are required for the preservation of society; on the contrary, the preservation of any particular society is of value because among other things it secures for human beings some measure of these universal values.²⁵

When society enforces morality it is jeopardizing the securing of the universal values necessary for society's "preservation". Hence, to coerce subjects is counter-productive because of the negative impact of enforcement

on society when the universal values listed by Hart are not appropriately respected.

The question could arise: should the obligation to be a subject should be enforced, when there is an insufficient number volunteering to be subjects in a study considered to be valuable because, for instance, the proposed research promises to acquire information about the cause of a terminal illness? Similarly, can elderly patients be conscripted to be in clinical trials of medications to prevent memory loss? The answer is “No” because while the research is important and valuable, the benefits of the research do not justify overruling respect for individual autonomy.

Individuals enter social contracts to gain some protection and benefits and are prepared to accept the cost in terms of restrictions on individual self-determination. They sacrifice some degree of personal liberty when joining others who have agreed to make the same or similar “trade-offs” to have their fundamental needs met and protected. Given this reason for entering a social contract, it is illogical and unlikely, that individuals would agree to a subject conscription and surrender self-determinism.

Jonas makes a similar point, by bringing to our attention that social contracts are usually founded on the concept of the primacy of the individual. Therefore, regulations demanding that the common good be ranked above the good of the individual is not compatible with the society’s

values. In Jonas' words, "This primacy is itself a metaphysical axiom or option peculiar to our western tradition, and the whittling away of its force would threaten the tradition's whole foundation".²⁶ Therefore, being a research subject falls beyond the scope of transactions that can be demanded of moral subjects and agents and thus, neither competent nor incompetent individuals should be coerced by society to be research subjects and thereby, "return the compliment".

b) The Costs of Conscripting Research Subjects:

Social policies requiring that individuals be research subjects would be costly for health sciences research and for the community as a whole. This position against conscription is based on consequentialist arguments examining the costs and benefits of voluntary or compulsory recruitment of subjects. Also, it is inconsistent with the deontological arguments regarding the inviolability of moral agents and subjects. Conscription of subjects is not desirable because the practice could undermine a social system which values individual autonomy and be a violation of individual integrity.

To understand why the policy would be costly, it is necessary to examine the consequences of conscripting subjects. On one hand, there may be benefits in terms of research findings which can be used to improve the

health status of specific individuals others and society's welfare. However, the costs for these advances are high: self-determination has been squashed by conscription. The costs for society and individuals are too high because the gains in health care have been made at the expense of undermining respect for individual autonomy and society's values. When the social system is threatened, many functions of a stable society including conducting research are also jeopardized.

It is a mistake to isolate the benefits of health sciences research from the benefits and costs of conducting research for society. Benefits in the realm of research can have a negative impact on society. This cost at the macro level can outweigh the specific benefits of research. The distinction between benefits specific to research and the community and the dependency of research on the community's support was made by Dyck and Richardson in their paper "The Moral Justification of Research Using Human Subjects". They point out that there are two criteria which should be satisfied when human research subjects are associated with research exposing them to risk.²⁷ These criteria are:

- (i) The research should hold promise of benefits determined by the estimation of the relative harms and benefits. Benefits increase pleasure by supporting and improving the health status, and therefore the quality of life of individuals.
- (ii) The research should reinforce structural values which are maintained by satisfying the requirements of informed consent.

The benefits of research influence society's structure, values and stability. These benefits can only occur and be appreciated within a social order or system because these "benefits are for the sake of increasing happiness by sustaining and improving the quality of human life", according to Dyck and Richardson.²⁸ Society and its members will decide what constitutes a benefit and the social systems should be designed so as to be supportive of society's values and maximize these benefits. Society not only supports maximizing benefits but also supports restraining conduct which threatens to harm any of its members.

The second type of benefit is structural and impacts on society's general well-being and infrastructure. This type of benefit is distinct and more valuable than specific ones gained through clinical research because the costs associated with the diminution or loss of fundamental social values outweigh benefits won by research. As Dyck and Richardson state, what meaning would "benefits" have for those who have no freedom, or for those who were victims of extreme injustice, or for those who lived in a society where no one could be trusted and where no contract was honoured? ²⁹ I would add, that the "benefits" would be questionable when the knowledge gained is at the cost of conscripting subjects, conducting research which is not ethically sound (for instance, has an unfavourable risk-benefit ratio)

and/or abandons the consent process when mentally impaired subjects are needed for research that has an ethical design.

In the realm of health sciences research, the underlying social values are autonomy, justice, beneficence and non-maleficence. Thus, when researchers conduct their investigations in a fashion that violates these structural values then the very conditions that “make benefits possible and meaningful” are violated.³⁰ Dyck and Richardson point out that in the realm of research, these underlying or foundational values are protected by the requirement of informed consent.

According to the second criterion, there is a limit to the costs a society can sustain to receive benefits. There is a point beyond which the costs can threaten the social order and no benefits would justify jeopardizing the social system to this extent. This is the case because a violation of structural values strikes a blow to the means to their achievement. “To violate a structural value, therefore, is to violate the very condition that makes benefits possible and meaningful” state Dyck and Richardson. They consider harm to the social structure is too high a price to pay for any benefits gained by violating the ethical canons of research. They continue, “There is a certain type of harm that cannot be outweighed by any benefit, no matter how great the benefit may be. This harm is to the

second type of moral value we have mentioned above, that is, violation of a structural value".³¹

A research policy permitting conscription of subjects renders redundant the consent process. Both the investigator and society have the authority to decide who should be subjects, and presumably when and how they would be associated with research. This action would sound a death knell to the goal of supporting and promoting the development of individual autonomy and protecting vulnerable members of the community. Research involving subjects who did not give a valid consent threatens to undermine the values supporting society's very existence and this is too high a price to attain improved health and attendant social benefits at the micro level.

Furthermore, abandoning the consent process removes the second line of defence protecting the subject from harm. Therefore, both competent and vulnerable subjects could be involved in research they may have not chosen to be associated with, for a variety of reasons. Conscription places the full assessment of the risk-benefit ratio in the hands of society and the research community and hence, the subjects could be "drafted" to participate in risky protocols against their wishes, and in the case of SDAT subjects, without subjects appreciating the consequences of the action. The temptation to take advantage of the mentally impaired would be considerable. Considering that a policy of subject conscription has wide

ranging consequences which undermine the society's values, it is recommended that a valid consent continue to be a non-negotiable requirement for conducting research involving human subjects.

Once again, this consequentialist line of reasoning depends on society valuing autonomy, justice and protection of the vulnerable. As discussed in the previous chapter, society's moral and social agendas can change with the result that dependent individuals can become more vulnerable. When society no longer respects autonomy, then the consent process is viewed as meaningless and an obstacle to conducting research.

According to Mill, a sacrifice which does not increase the sum total of happiness or the means to happiness is a waste. Happiness is not what the individual considers necessary for his pleasure alone but also includes that which is for the happiness or well-being of all. It is consistent with Mill's view, that for the common good, the consent mechanism remain intact and furthermore, be strengthened. It is not in the individual's interest to support a policy of conscription not only because they may suffer from the policy but also because the policy would undermine the liberal social system.

The cost of abolishing the consent process and giving society or the researcher the authority to recruit subjects against their will would be very high, even if the requirement of an ethical design was met. The western

tradition of respecting the individual would be replaced by valuing society's collective good over the individual's freedom. This reversal of values could be chosen by a society or be imposed. Under ideal circumstances, the reversal of values would occur after a thorough analysis of actual and predicted consequences throughout society.

From a deontological perspective, there are also good reasons to prohibit conscription of subjects no matter how promising the benefits. To require individuals to be research subjects and deny them the opportunity freely to decide, is to treat subjects as means. Reducing individuals to cogs in the research machine, used regardless of their desires, demonstrates lack of respect for individual dignity and therefore, is morally unacceptable. As advocated in chapter three, regardless of the mental status of the subject, their fundamental interest, or need to be protected from harm, has to be respected.

In summary, conscription of research subjects can only occur if the consent process is eliminated. The consent mechanism serves the valuable purpose of supporting and promoting individual autonomy, and in addition, respects individual inviolability. To abolish the cornerstone of research involving human subjects, removes a structure designed to protect all subjects, both autonomous and vulnerable from harm and ensure that their fundamental needs, or if preferred, their inviolable rights to dignity and

integrity, are protected. Furthermore, the consent process has the function of ensuring that the needs of vulnerable individuals are not overlooked or sacrificed in the pursuit of social benefits.

4.5 Conclusion:

After examining the respective obligations of society, researchers and research subjects, two conclusions can be reached:

- (i) a minimum humane standard of care for Alzheimer patients is mandatory,
- (ii) the ethical priority in SDAT research is the protection of welfare needs, in particular the need to protect vulnerable subjects from harm.

This shift in ethical priorities requires modification to research regulations regarding the use of SDAT patients.

The recognition that society has an obligation to respect the claims of the weak and vulnerable to protection from harm and to have their basic needs met leads to the conclusion that society should establish a policy of a minimum standard of decent or humane treatment for the SDAT population and other mentally and physically impaired individuals. The purpose of the policy would be to ensure that all dependent and vulnerable members of the society have their welfare needs met and are not exposed to excessive harm.

Therefore, the standard would stipulate clearly that vulnerable individuals should be protected from psychological and physical harm and have their welfare needs met. In terms of the SDAT population, this would include providing a safe and comfortable environment, good nutrition, nursing and medical attention, maximizing ways to communicate, access to legal services and being treated in a respectful manner. Lack of efficient supervision, inappropriate or inadequate housing, poor diet, lack of structure and routine, isolating the patient, changes in the environment, poly-pharmacology or lack of health care services are a few of the many variables that can harm a SDAT patient, exacerbate his status and could lead to death. Researchers would be required to respect this standard when planning and conducting research involving mentally impaired research subjects.

The case for a minimum standard of care is consistent with consequentialist and deontological arguments. The majority of moral agents (or reasonable individuals) will appreciate the benefits of establishing a standard of care below which vulnerable, dependent individuals should not slip because it is morally and socially preferable for Alzheimer patients to have their welfare needs met and be protected from harm. The duty to treat others as ends in themselves expresses the virtue of respect which supports establishing policies and rules that promote honouring the

intrinsic worth of others (including mentally incompetent individuals). In addition, it is in one's self-interest and logically consistent to act in a non-maleficent manner to the vulnerable. Both consequentialist and deontologists can appreciate that social policies and actions should be based on their reasoning about how they would want to be treated if they developed SDAT.

An identification with affected patients is easy to make because the only confirmed risk factor is growing old. No matter whether rich or poor, and regardless of whether one is prepared to take risks, everyone who reaches the age of sixty-five is at risk of developing SDAT. Therefore, what Engelhardt called "the web of sympathy"³² or what others might call wise planning, can justify developing and supporting social policies guaranteeing SDAT patients and other vulnerable populations with a minimum, humane standard of care.

Predicting the social and financial costs of providing a minimum standard of care versus not protecting the mentally impaired and meeting their welfare needs, falls beyond the scope of this investigation. However, it is reasonable to suppose that there are high costs at the micro and macro level when the weak and vulnerable are not protected. The cost of caring for Alzheimer's Disease patients in a comfortable, safe and pleasant residence, whether their home or an institution and also, meeting their

welfare needs is expensive. The alternative is to have mentally incompetent individuals inadequately cared for or left to fend for themselves. For example, a policy of neglect would condone housing affected patients in Bedlam-like institutions (or more precisely, warehousing) and have serious, harmful consequences for the residents. Such patients could lack adequate supervision, food, medical and nursing attention. The lives of these residents are physically and mentally distressful and are frequently shortened. Without this minimum decent standard of care, a society can not consider itself humane, responsible or moral.

Another option is increased privatization of care for the chronically and terminally ill which transfers more responsibility to their families who in most cases, lack the human and financial resources to care effectively for their family member during the entire term of the illness. More specifically, in most cases the major responsibility for care is transferred to an elderly spouse if alive and/or a female relative. In the U.S.A. and other countries lacking a universally accessible health care system, this option is the norm. Hence, the burden of illness is borne nearly in full if not entirely, by the family at great emotional and financial cost.

A minimum standard of care policy would have universal application and important implications for society. All individuals and groups having association with the weak and vulnerable would be required

to respect the policy. Thus, investigators in addition to health care professionals, public officials and the legal system would be required to respect the policy of a humane standard of care. With respect to the field of SDAT research, adoption of the standard would require the development of additional research guidelines addressing specific issues raised when weak and vulnerable individuals are research subjects. In chapter five, some recommendations will be proposed. A consequence of investigators failing to respect the minimum standard of treatment could be an erosion of trust between the subject and investigator. Consequently, it would be more difficult to conduct research because of lack of sufficient subjects and a reduction in public support.

When the research subjects are mentally impaired (moral subjects), the second consequence is a change in ethical priorities for SDAT research: the priority is protection of the vulnerable subject from harm. Considering that the majority of prospective subjects for SDAT research are not autonomous nor competent, the traditional ethical priority of respecting the subject's autonomy is not relevant. In western, liberal countries researchers are guided by research codes and legal statutes that emphasize respect for individual rights and autonomy. Thus, it is necessary to modify current research codes to address the ethical priority in SDAT research.

When ethical priorities are changed, the traditional research codes do not “work well” with the majority of SDAT research. To be specific, these codes do not adequately assist investigators facing ethical issues when designing SDAT research and trying to recruit subjects, because the Nuremberg Code and its descendants are based on an autonomy model and have two goals:

- (i) protect individual autonomy, and
- (ii) protect the subject from association with research that is not scientifically nor ethically acceptable.

The first goal is not appropriate for the majority of SDAT research protocols because they have failing cognitive functioning and depleted or diminished autonomy. Thus, the second goal rises in importance as the first goal loses relevance. The combination of being unable to provide consent and at the same time, trying to avoid participation in protocols which expose the subject to excessive harm, places prospective subjects in a highly vulnerable situation. Society, researchers and SDAT patients’ next of kin have an obligation to protect prospective subjects from harm because affected patients lack sufficient autonomy and the capacity to provide a valid consent.

There are two sources of protection: the design of the research and then the consent mechanism. When the research protocol is scientifically

and ethically sound and has been reviewed by an Ethics Review Board, it is not expected that subjects will be seriously harmed. Secondly, the consent mechanism provides the subject or his surrogate the opportunity to evaluate the risk-benefit ratio and decide whether they want to be associated with the study. When the subject is not autonomous, the consent mechanism's major function has changed, from respecting patient autonomy, to providing a mechanism for protecting the subject from harm and acting in his best interests. In a few cases, the mentally impaired research subject has stated his wishes beforehand and thus, the surrogate when honouring these wishes, is respecting the subject's autonomy, after the fact. Thus, the consent mechanism serves as a second line of defence. The priority should be protecting vulnerable subjects from participation in research that threatens their integrity and well-being. This protection is sought through continuing to require a valid consent not from the subject, but from a third party (guardian). This is the case because even though the subject has lost his autonomy he continues to have moral worth and dignity, and the dependent moral (welfare) subject has the fundamental need to be protected from serious harm associated with being a research subject. Thus, respecting the potential subject's claim to have his welfare needs respected, replaces respecting his autonomy.

The surrogate's responsibility remains the provision of a valid consent. Whenever possible, he should honour his ward's previously stated wishes if known and always, act in the dependent person's best interests. When the surrogate follows the directions stated when the patient was competent, he is respecting the subject's autonomy after the fact, so to speak. Regarding determining what are the prospective subject's best interests, the surrogate's priority is to protect the subject from exposure to excessive harm (that is, harm rated objectively at above minimum risk). Thus, the surrogate has the onerous responsibility of deciding if the protocol respects the established standard of care. When a surrogate decides to consent or not he must give careful consideration to the risk-benefit ratio and consider how the intervention will affect the subject in terms of both concrete and intangible fundamental needs.

Research regulations and legal statutes in Canada and most western jurisdictions prohibit the use of mentally incompetent subjects in non-therapeutic research. Hence, the scope of research that the surrogate can provide consent for is limited to therapeutic research. From the researchers and society's perspective, are these regulations too restrictive? Do legal statutes and research guidelines discussed in chapter two prevent researchers and society from fulfilling their obligations to society?

Society, researchers, subjects, caregivers and surrogates have to consider the needs of prospective SDAT research subjects and the interests of society. The prospective subject's interest is to be protected, and to be treated as an end in itself. The community has an interest in reducing the incidence of SDAT and the attendant social and economic costs associated with the caring for SDAT patients. Also, members of the society want to reduce their own chances of having SDAT and, in an increasing number of cases, are dependent on the health care system to provide effective management interventions to assist them as caregivers. At the same time, members of the community want to institute policies and standards that they could reasonably support and accept if their circumstances changed.

On one hand, there is the concern that the goal of acquiring more knowledge and proceeding more aggressively with SDAT research is hampered by research regulations posing obstacles to conducting non-therapeutic research and some instances of therapeutic research. Less restrictions would widen the scope of research and allow researchers to conduct therapeutic and non-therapeutic research with a higher possibility of risk because it has the promise of indirect, and perhaps direct benefits. Thus, it is thought that it is to society's advantage to be less restrictive regarding the use of vulnerable subjects. Presumably, this research would lead to more new information which would lead to reducing the incidence

and improving management of SDAT at a quicker pace. However, at the same time, individuals do not want to establish expedient rules that they cannot accept at all times. Furthermore, non-therapeutic research and high-risk therapeutic research require that the subjects be associated with research not offering them direct benefits (that is objective benefits). In the judgement of the MRC, involving mentally impaired individuals with non-beneficial research poses a threat to the subjects' inviolable rights to dignity and integrity.

When the ethical priority is switched from respecting autonomy to protecting the subject from harm, a new tension emerges: protecting society from harm attributed to the costs associated with caring for SDAT patients and protecting SDAT patients from harm when associated with SDAT research. Therefore, there is a tension between acting in a beneficent manner towards society and a non-maleficently to vulnerable subjects.

In order for research codes to assist researchers in the field of SDAT research, additional guidelines are required to take into account that, the priority in most cases is not respecting autonomy but protecting weak and vulnerable subjects. Modifications to research regulations have commenced already. According to the Nuremberg Code, only subjects who give their own consent can be research subjects and only therapeutic research was to be permitted. Thus, Alzheimer's Disease and paediatric

research were prohibited. Subsequently, the Helsinki Accord responded by permitting surrogates to consent for those unable to provide their own consent and permitted both therapeutic and non-therapeutic research under certain circumstances. The use of mentally impaired subjects has not been adequately addressed by current codes and legal statutes. Also, there is lack of consensus regarding what constitutes competency. Hence, in the next chapter there will be an analysis of the concept of competency and also, recommendations regarding the use of SDAT patients as research subjects will be proposed.

In conclusion, the ethical priority is protection of weak and vulnerable research subjects. However, when this priority is grafted on to current research guidelines, society and researchers are stymied in their efforts to reduce the suffering associated with SDAT in addition to, reducing the economic and wide-ranging social costs of SDAT. Thus, the question arises: are the research regulations prohibiting the use of mentally incompetent subjects in non-therapeutic research too restrictive and costly?

In the next chapter the issue of how to mesh the need to respect the fundamental needs of vulnerable research subjects with current research regulations will be examined. A resolution to this problem will be proposed that would permit society and researchers to fulfil their respective

obligations with some constraints, under conditions designed to protect weak and vulnerable subjects.

Notes

1. Ignatieff, M. The Needs of Strangers. Penguin Book, New York, 1985, p. 27.
2. Rawls, J. The Principles of Justice. Harvard University Press, Cambridge, Mass., 1971, p. 60.
3. Ibid., p. 75.
4. Also, individuals can be restrained in some jurisdictions for harming the organizations and the environment.
5. Ignatieff, M. see note 1, p. 27.
6. Ibid., p. 27.
7. Kant, I. The Doctrine of Virtue. Edited by H.J. Paton, p. 116 (448).
8. Ibid. p. 117 (449).
9. Ibid., p. 117, (449).
10. Ibid., p. 121, (453).
11. Englehardt, H.,T., Jr. The Foundations of Bioethics, Oxford University Press, New York, 1986, p. 71
12. Ibid., p. 132, (462).
13. Aaron, R. Schwartz, D. "Rationing Health Care". Across the Board, summer, 1990, p. 35.
14. Thomas, J.E., Waluchow, W. Well and Good. First Edition Broadview Press Ltd., 1987, p. 105.
15. Nuremberg Code, section 2.
16. Nuremberg Code, section 6.

17. The MRC recommends that all clinical research involving human subjects be reviewed by an REB. All research receiving public funding and/or being conducted at an educational institution must be approved by an REB. However, privately funded research conducted outside educational facilities (for instance in the community) can be conducted without the approval of an REB.
18. Guidelines, p.23.
19. Guidelines, p. 21.
20. Ibid., p. 23.
21. Ibid., p. 22.
22. Ibid., p. 22.
23. Ibid., p. 23.
24. Visscher, M. "Medical Research on Human Subjects as a Moral Imperative". In Biomedical Ethics, edited by T. Mappes and J. Zembaty. McGraw Hill Book Co., New York, 1986, p. 183. From M. Visscher's book Ethical Constraints and Imperatives in Medical Research, Charles C. Thomas, Publisher, Springfield, Illinois, 1975.
25. Hart, H. L. A. Law, Liberty and Morality. Oxford University Press, London, 1963, p. 70.
26. Ibid., p. 70.
27. Dyck A, Richardson H. "The Moral Justification for Research Using Human Subjects". In Biomedical Ethics and the Law, see note 1. Originally published in Use of Human Subjects in Safety Evaluation of Food Chemicals - Proceedings of a Conference. National Academy of Sciences and National Research Council, Pub. 1491, (Wash., D.C., 1967), pp. 217-227.
28. Ibid., p. 220.
29. Ibid., p. 222.
30. Ibid., p. 245.
31. Ibid., p. 245.

32. Engelhardt, H. T., Jr. The Foundations of Bioethics, Oxford University Press, New York, 1986, p. 71.

Chapter V

From Theory to Practice

5.1 Ethical Problems Associated with Alzheimer's Disease Research:

Human experimentation since World War II has created some difficult problems with the increasing employment of patients as experimental subjects when it must be apparent that they would not have been available if they had been truly aware of the uses that would have been made of them....There is a belief in some sophisticated circles that attention to these matters would "block progress".

Henry Beecher, M.D., 1966¹

...Perhaps we have erred on the side of over-protection. In the name of respect for persons, we are not allowing them (elderly subjects) the full participation in the human endeavour of experimentation, that could give meaning to a life of suffering and chronic disease and disability. Especially for institutionalized persons, by protection we do not allow the choices and freedoms that we would allow other people, constricting their life experiences unnecessarily.

C. K. Cassell, M.D., 1987²

In the previous chapter, the obligations of society and researchers were examined and thus the foundation was laid for studying how the needs of Alzheimer patients might be met, and at the same time, society and researchers fulfil their respective duties. The objective of this chapter is to

discuss the complex problems associated involving SDAT patients in research and propose a resolution of the ethical dilemma: whether promoting the social good should take precedence to respecting the needs of vulnerable subjects.

The position to be advanced is that society's and the research community's obligation to respect the needs (or if preferred inviolable rights) of the vulnerable SDAT patients ranks higher than conducting health sciences research carrying the risk of harming the dignity and integrity of the weak and vulnerable. However, there remains room to manoeuvre and find a resolution to the question of whether mentally impaired or incompetent individuals can be associated with non-therapeutic research.

The main focus of this chapter will be studying the hard case of whether mentally impaired SDAT patients who can not consent to be subjects, may be research subjects in non-therapeutic research. In chapter two, the current regulations were discussed and it was seen that such research excludes the use of mentally impaired subjects. It will be proposed that under certain conditions, mentally impaired SDAT patients can be associated with non-therapeutic research.

Another goal is to link moral theory and the research field. The statements of Beecher and Cassell, separated by 20 years, capture the

ethical tension between the theoretical and clinical realms: can the researcher's obligations to conduct research having the potential to promote general well-being be compatible with respecting the welfare needs of vulnerable subjects? Also, these quotations were selected because they illustrate that research continues to struggle with implementing research guidelines in the clinical field. In his important paper "Ethics and Clinical Research" published in the New England Journal of Medicine (1966), Beecher revealed that in the U.S.A., codes of research ethics were not followed in many instances by medical researchers. Beecher cited twenty-two examples funded by government agencies and conducted in public institutions (hospitals, prisons, mental institutions, military departments including National Institutes of Health, Veterans Administration Hospitals) which did not follow the accepted codes of ethics, especially in respect to the requirement for a valid consent. Beecher initiated an examination of the relationship between the research's ideals and researcher's methodology.³

The reasons for the chasm between rules and conduct were discussed twenty-one years later by David Rothman in "Ethics and Human Experimentation: Henry Beecher Revisited".⁴ Rothman commented that what was more surprising than the violations of research guidelines was the public objections to research practices based on an unbridled utilitarian approach. The urgency to do research during World War II, which

sanctioned waiving the requirement for an informed consent, is a habit that has continued in the post-war years. The impact of Beecher's paper, widely reprinted in the lay press, in concert with a growing general wariness about the benefits of science and what Rothman terms "a general hostility toward authority", led to a rise in "rights-oriented movements on behalf of prisoners, mental patients, women and of course, human subjects".⁵ Another result was the increase of moral philosophers, lawyers, social scientists and policy makers entering the realm of medical research and raising ethical questions. Thus, decisions which had been, in most cases, under the exclusive control of researchers were subject to appraisal by other interested parties who could have a different set of priorities.

During the sixties, when the social climate was sympathetic to the needs of vulnerable subjects and the rights of minorities, the Canadian Medical Research Council developed guidelines regarding medical research and the DHEW in the U.S.A. established a Presidential Commission to study the ethics of medical research and the use of human subjects.

Has the pendulum swung too much in favour of research subject's rights? Twenty years after Beecher's landmark paper, Cassell states that the emphasis upon respect for persons could be "blocking progress" at great cost at the macro and micro level.⁶ Her charge has to be taken seriously

and thus, in proposing a way to integrate theory and practice, Cassell's concerns will be addressed.

As discussed in the previous chapter, when planning medical research involving human subjects, the investigator has to consider the two pillars of health sciences research, the consent mechanism and the design of the study.⁷ The investigator has the following responsibilities:

- (i) respect the vulnerable subject's fundamental needs, and
- (ii) design scientifically valid research which has the potential to benefit the subject and/or society.

Trying to meet both obligations can lead to an ethical dilemma when mentally impaired individuals are needed for non-therapeutic research and, in some instances for therapeutic research depending on the risk-benefit ratio. This is the case because the research does not offer any promise of direct benefits or if there are direct benefits, the risk-benefit ratio is unacceptable (i.e. the risk of harm is not justified because the expectation of benefits is low and the benefits are of limited value, or the risk is too high regardless of the nature of the benefits expected). Secondly, the use of mentally impaired subjects in non-therapeutic research is prohibited by current research guidelines and in most jurisdictions by legal statutes. Furthermore, the researcher's difficulties are compounded because

there is no widely accepted definition of the concept of competency to consent to research.

The resolution of these problems, and in particular the hard case of how the mentally impaired and incompetent can be associated with non-therapeutic research, is built on a two pronged approach that (i) modifies the classification of research and (ii) strengthens the consent process.

The organization of the chapter will be:

- (i) identify the ethical problems associated with SDAT research in respect to
 - (a) the consent mechanism, and
 - (b) the experimental design.
- (ii) propose a resolution to ethical problems with SDAT research based on:
 - (a) conjunctive definition of competency to consent to research
 - (b) modification of classifications of research.
- (iii) present recommendations for conducting SDAT research.

Unless attempts are made to find a balance between respecting the needs of SDAT subjects and the interests of society in conducting all types of SDAT research, and in the process incorporate ethics into the realm of Alzheimer's Disease research, Alzheimer patients will be at increasing risk of being harmed and exploited as society and researchers work to reduce the spiralling costs of dementia.

5.2 Resolution of Ethical Dilemma:

The resolution of the ethical problems facing investigators, society, subjects and surrogates will be built on:

- (i) a tightening of the consent mechanism, and
- (ii) changes in the criteria for an ethical experimental design.

These proposed changes are grounded in a recognition of the nature of Alzheimer's Disease and the obligation of society to respect the fundamental needs (inviolable rights) of the mentally impaired and incompetent which include the majority of Alzheimer's Disease patients.

The position to be advanced is that individuals with Alzheimer's Disease who are mentally impaired should be allowed to participate in non-therapeutic and invasive research studies, on condition that current research codes and guidelines are modified to ensure that vulnerable subjects are protected effectively. This position challenges the MRC's recommendations that what they call mentally-incompetent (read mentally impaired) individuals can not be associated with non-therapeutic research and that secondly, surrogates can not consent for these individuals to be subjects in non-therapeutic research. The concepts of competency and incompetency, and therapeutic and non-therapeutic are crucial and the proposed resolution of the dilemma is grounded in a re-evaluation of these concepts.

This section will be divided into three sections. First modifications to the classification of research and modifications to the requirements for an ethical experimental design with the SDAT population will be presented. Then the concept of competency to consent to research participation will be analyzed before the resolution is presented.

There are three responses to the question of whether incompetent SDAT patients should be associated with non-therapeutic research.

- (i) There should be an absolute ban because the subjects are being exposed to some risk and will receive no benefits.
- (ii) Research should be permitted with no restrictions or minimal ones. For instance, the requirement for a valid consent can be waived when the risk is categorized as mere inconvenience or when the subject is incompetent and the research meets the criteria of the ethics of an experimental design.
- (iii) Permit mentally incompetent individuals to be involved in therapeutic and non-therapeutic research if certain strict ethical rules are followed. These rules are designed to ensure that the subject's fundamental needs are met and not threatened. Thus, the subject's dignity and integrity is not be threatened and the subject is not exposed to excessive risk (e.g. above minimum risk).

The first and second options are unacceptable on consequentialist grounds because of the immense costs on the macro and micro levels. A halt to research undermines the practice of health care professionals who rely on research to discover and improve therapeutic interventions. Unregulated research would expose subjects to harm and contribute to research being jeopardized.

Subject selection is a difficult issue in SDAT research. Choosing only competent or incompetent subjects is attractive but neither option is morally acceptable and both options are also clinically troubling. First, to recruit only competent or incompetent patients and target a sub-section of the SDAT population to bear all the risks or burdens of research, especially “non-therapeutic” research is an unfair distribution of the burdens of research.

Furthermore, there are specific problems associated with drawing from the sub-section of competent SDAT patients because of diagnostic issues, respect for patient’s defence mechanisms and predicting harm.

Diagnosis of SDAT is not confirmed with absolute certainty until an autopsy is done. However, diagnostic tests can assist the physician make a diagnosis as the disease progresses. However, in the early stage of the disease, diagnosis is difficult to make with confidence. Dr. A. Ropper, a neurologist, remarks “Because of the gradual onset of dementia, its

complexity and the assumption that senescence and deterioration are untreatable, dementia is probably often undiagnosed in its early stage and its symptoms go untreated".⁸ By the time diagnosis is confirmed, there is a strong possibility that the patient would not meet the standard of competency to consent to research to be advanced later in this chapter. Also, in the early stage, mis-diagnosis can occur because there are a number of co-existing health problems. In addition, over-medication can result in a cluster of symptoms resembling dementia. Hence, it is estimated that 35% of those diagnosed as suffering from senile dementia have other health problems which are treatable.⁹

Another problem with focusing on those who can consent directly is that being involved with SDAT research can cause serious psychological harm to the patient. This is the case because during all stages of the disease, and in particular during the first stage, patients can be unaware of their disabilities and may respond by denying the seriousness of their condition. Reisberg *et al* in the paper "Insight and Denial Accompanying Progressive Cognitive Decline in Normal Aging and Alzheimer's Disease", state that there are a cluster of problems associated with the patient's denial of his deterioration. "Clinicians, in particular, need to be sensitive to the magnitude and course of the denial in the syndrome of age-associated cognitive decline and Alzheimer's Disease. In the early stages of

Alzheimer's Disease, in particular, denial may result in under-recognition of symptomatology, not only by the patient, but by the diagnostician, as well".¹⁰ Denial can result in mis-diagnosing of the disease and the stage of SDAT. The denial occurs in the areas of cognition and emotional functioning that are most affected by SDAT (for example, in respect to memory loss). Therefore, clinicians, investigator and caregivers should learn to recognize and respect the patient's denial as a defence mechanism used to cope with a terminal and chronic disease. Asking an affected patient in the early stage to be a subject in SDAT research could be distressful and pose a serious risk for the patient because it threatens to remove his defence mechanism. For instance, if the intervention is self-revealing (testing mental functioning and memory) participation can confirm what the patient has been denying and exacerbate his status.¹¹

There are different problems with only relying on mentally impaired patients which were well described by Schwartz in his paper "Informed Consent to Participation in Medical Research Employing Elderly Subjects". Referring to institutionalized SDAT patients, he writes: "Because researchers may attribute a low value to the lives and health of these subjects, it may be especially important that we be vigilant in protecting their autonomy from intended or unintended abuse".¹² I would prefer to say that their fundamental needs have to be protected, but agree

with Schwartz that the lives of SDAT patients are not highly valued by some and hence they are at risk of being exploited. Considering that misdiagnosis can occur during the early stages of the disease, recruiting only from non-institutionalized, competent patients who are in the first stage of SDAT (as recommended by the N.J A.'s report) would be to unjustly target a sub-section of the SDAT population who may not even have SDAT and if the patient has SDAT, asking him to be a subject can be very harmful. Therefore, what is needed is a way of permitting non-therapeutic research with both competent and incompetent Alzheimer's patients which respects the subject's dignity and integrity (e.g. fundamental needs and interests or inviolable rights).

Therapeutic research presents fewer ethical problems but is restricted (at this time) to investigating palliative interventions for patients and caregivers. Investigations to improve the quality of life of the Alzheimer community is essential research but not sufficient as long as the causes and preventive measures are not known. Research investigating the etiology, risks and prevention methods is required to reduce the need for palliative measures in the first instance. There are complex ethical decisions to be made when non-therapeutic research is undertaken but the alternative of only permitting therapeutic research poses other difficult ethical questions. Not to investigate the causes and prevention of

Alzheimer's Disease has profound moral, clinical and social consequences. In philosophical terms, the development of SDAT is an erosion of autonomy, critical competency and moral agency. Hence, the progression of the disease is a morally regressive phenomenon. The social consequences of failing to reduce the incidence in society falls outside the scope of this study but must be acknowledged. There is general agreement that SDAT will be a major public health problem. The failure to address the rising incidence of Alzheimer's Disease (and the number of dependent moral subjects) by searching for effective interventions to reduce the human, social and economic costs associated with SDAT, is socially and morally irresponsible. There would be grave consequences at the micro level and also, macro level in terms of promoting and supporting autonomy and well-being.

Given that mentally impaired research subjects can not participate in non-therapeutic research, the classification of research is a crucial issue. The question to be explored is: "May the mentally impaired be subjects in research offering them no promise of direct benefits?" The short answer is "Yes". It will be argued that SDAT patients may participate in non-therapeutic and intrusive research on condition that the research design:

- (i) includes a consent mechanism, and
- (ii) respects the proposed standard of care for Alzheimer's patients (therefore, research should not be classified as above minimum risk).

The Medical Research Council states that mentally (and physically) impaired individuals should not be associated with non-therapeutic research because this action would be a violation of their integrity and dignity. The goal of this section is to demonstrate that vulnerable individuals can be subjects in non-therapeutic research without having their integrity threatened. The position to be advanced is based on the following points:

- (i) the distinction between therapeutic and non-therapeutic research is inappropriate and irrelevant for the SDAT population
- (ii) the priority for SDAT research should be the protection of the SDAT population from the risk of harm classified as above minimum risk.

The first step is to show that in the realm of SDAT research, the traditional terminology and classification of research is irrelevant and needs to be replaced by a conception of health sciences research which fits the clinical realities of SDAT.

Research is classified as therapeutic or non-therapeutic research. Therapeutic research advances knowledge and holds promise of benefit for the subject (directly) and others (indirectly). Non-therapeutic research advances knowledge, benefits others (indirectly) and is not expected to be of direct benefit to subjects.

The distinction between the categories of therapeutic and non-therapeutic should be replaced by the general category of clinical or health

sciences research which provides a better way of handling the intricacies of research involving SDAT patients. The traditional classification of therapeutic or non-therapeutic Alzheimer's Disease research is not appropriate nor helpful because the notions of benefit and quality of life are ambiguous for the SDAT patient who has a terminal and chronic illness. The majority of SDAT subjects can not benefit directly from research participation because the research is not expected to ameliorate their condition nor reverse the disease's progress. The only exemption is quality of life research which investigates management strategies for assisting SDAT patients and their caregivers. For example, research projects investigating the effectiveness of different day hospital programmes hold the promise of improving or maintaining SDAT patients' quality of life.

A direct benefit offers therapeutic value to the subject and at the same time, contributes to the progress of health sciences' work. At this time in the history of SDAT research, there is no expectation of remission or cure. After developing Alzheimer's Disease the patient's life expectancy varies from a short period of time to twenty years. However, the average life span is six years during which period, the individual deteriorates progressively. Considering the present knowledge about the etiology, treatment and prevention of Alzheimer's Disease, there is no promise of direct benefits for SDAT subjects in terms of the disease's progress. In the

future, when more is known about the disease process, it is expected that some SDAT research will offer direct benefits to the subjects. Alzheimer's patients are not unique in this situation. Other terminally ill patients, such as some cancer and AIDS patients may be subjects in research offering no promise of direct therapeutic benefits.

Also, the decision whether the research is therapeutic or not is made by the researcher. The subject, if given the opportunity to review the protocol, could disagree. For instance, the subject may find it psychologically and spiritually therapeutic to be a research subject and contribute the advancement of knowledge about SDAT. For others, the benefit of participating in a research project can be more concrete: an opportunity to get away from the busy hospital ward or to give his overworked spouse a free afternoon.

The distinction between therapeutic and non-therapeutic research was first made by the Helsinki Declaration. Levine studied in the important article "Clarifying the Concepts of Research Ethics", the distinction and made two telling points which demonstrate that these distinctions are neither helpful nor practical.

First, he argues, many types of research can not be classified as either therapeutic or non-therapeutic. For instance, the double-blind and placebo-controlled drug trials are neither therapeutic nor non-therapeutic as

defined by the Declaration. In both cases neither the physician nor the subject- patient knows if the drug will benefit the participant. The activity can not be deemed therapeutic because it is uncertain if the activity will have any therapeutic value for the patient. The activity is not non-therapeutic because non-therapeutic research requires subjects who are healthy or “for whom the experiment design is not related to the patient’s illness”. This difficulty can be overcome by allowing therapeutic research to have the potential to benefit the subject directly or indirectly, not exclusively directly.

Secondly, Levine makes the point that research designed to study a disease process is not permitted according to the regulations regarding clinical research. Again the requirement that the clinical research, combined with professional care, must be justified by its therapeutic value for the participant disqualifies many research studies that would not benefit the participant directly. Again, the requirements, for pure, clinical research which prevent the protocol from using subjects who suffer from the health problem, need to be revised in order that the inclusion criteria would permit these individuals to be subjects given that the requirements of a good study design were met.

Secondary gains associated with research participation are coincidental and should be distinguished from direct objective benefits. It is

possible for non-therapeutic research to have secondary gains which contribute to an amelioration in the subjects, although the research intervention has no impact on the progress of the disease. This is the case because frequently the patient has a number of social and health problems in addition to his Alzheimer's Disease, for instance, depression, lack of family supports, coronary artery disease, visual and hearing problems. The research intervention could improve the patient's condition because it impacts upon one of the other co-existing health problems. An example will clarify the point. An Alzheimer's Disease patient enters a clinical trial investigating a new medication to improve memory. The subject's memory continues to deteriorate during the trial but he is more co-operative at home. A secondary gain for the subject was the weekly trips to the local SDAT clinic where he socialized with other patients and the patient, sensitive staff. Although his memory continued to fail, his mood improved because of the increased social stimulation.¹³

The Medical Research Council, when recommending that Alzheimer patients only be involved with therapeutic research, is not giving relevant or helpful advice because they are using a classification system that does not "fit" the SDAT population. The bi-polar classification system when applied to SDAT research is fraught with problems and also the classification system fails to do what it is supposed to do: distinguish

research that will or will not benefit the subject. Hence, the classification system should be replaced by the general classification of health sciences research which investigates causes, prevention and management of the disease and hence incorporates research studying the disease process and ways to improve the quality of life of SDAT patients and their support network.

Adoption of the new general category is not a verbal sleight of hand to make the problem of whether SDAT patients can be involved in non-therapeutic research disappear. Instead the general term simply recognizes the fact that therapeutic and non-therapeutic research overlap and that the notion of benefit is not a relevant concept for many terminally and chronically ill SDAT patients. Also, a general term is preferable because it is difficult to predict what will or will not be a benefit for the subject and this problem is exacerbated when the subject has difficulties understanding information about the risk-benefit ratio and communicating any concerns.

Having a general category of health sciences research is not a green light for research to use SDAT patients in any SDAT research proposed. The therapeutic and non-therapeutic categories served the useful purpose of identifying research that offered no promise of direct benefits (from the researcher's perspective) to the subject and if the SDAT patient was excluded from such research, his welfare needs would not be threatened.

The same protection can be given the vulnerable subject if health sciences research is evaluated in terms of whether or not it will respect the vulnerable subject's welfare needs. Thus, the principle of non-maleficence should be dominant: the research should be evaluated in terms of whether or not it will harm the subject.

For independent, autonomous subjects the autonomy model expressed by the Nuremberg Code was appropriate. Now with a growing population characterized by a loss of autonomy and moral agency, the ethical priority of protecting the subject from harm is to be ranked higher than the prospective subject's benefits. Hence, the central issue is the degree of risk that the subject will be exposed to and to what extent the subject's fundamental interests are protected. In short, when protecting autonomy and directly benefiting the subject are not ethical priorities, the crucial factor is the other side of the harm-benefit ratio: harm to the subject. Thus, the MRC's recommendation should be amended to ensure that mentally impaired and incompetent individuals not be involved in health sciences research which has the potential for serious and permanent harm to the subject. This recommendation incorporates the minimum standard of care for Alzheimer Disease patients proposed in the previous chapter. Then, clinical research and social policies would both respect the

dependent moral subjects' fundamental interests, with special attention being paid to the need to be protected from harm.

To avoid doing harm to the vulnerable subject, the investigator must assess the cost of the research in terms of the level of risk to the prospective subject, and protect the subject from exposure to experiments with an unacceptable degree of risk, no matter how valuable the expected social benefits. When direct benefits are not expected, then the degree of harm that the subject can be exposed to must be low. Also, a low degree of risk is required in order to respect the vulnerable individual's welfare needs. Thus, the level of risk associated with research participation or in other words, the probability of doing harm to the subject becomes the standard used to decide if vulnerable subjects should be associated with health sciences research.

The U.S. Federal regulations has defined three categories of risk which are used widely by researchers: mere inconvenience, minimal risk and above minimum risk. The median of minimum risk is the reference point for defining the other two categories.

Minimal Risk:

the risks of harm associated with the proposed research are not greater, considering probability and magnitude, than those

ordinarily encountered in daily life or during the performance of routine physical or psychological tests.¹⁴

Mere Inconvenience: lower than minimal risk.

Higher than Minimal Risk:

risk higher than minimal risk but only by a “minor increase”.¹⁵

These categories are of major importance in evaluating the ethical design of SDAT research. For instance, the MRC Guidelines highlights the role of these classifications in determining which subjects should be associated with what types of research when it states that “research into Alzheimer’s Disease, for instance, may require the affected subjects to be exposed to uncomfortable and above minimum risk procedures”.¹⁶ The N.I.A. offers a cautionary note regarding the use of these categories, stating that in applying these definitions “to SDAT patient subjects, it should be remembered that many elderly individuals are especially averse to risks or discomforts which may be taken for granted by other members of the population, and these special sensitivities, when they exist should be respected”.¹⁷ It is proposed that the standard of minimum risk or risk associated with daily living be the maximum degree of risk with which SDAT subjects are associated. Thus, the mentally impaired subject should

not be involved in research classified as above minimum risk regardless of the expected benefits for others.

Admittedly, there are problems with the concept of risk and estimating degrees of risk. The Law Reform Commission wisely advises that to protect the subject, the term risk should be given “the broadest possible legal content” and include risks to life, physical and mental health and also, mere inconvenience.¹⁸ Hence, the investigator has a moral responsibility to design protocols that avoid exposure by the subject to unnecessary risks and also, to eliminate any risks not strictly necessary to completing the research study.

Risk has to be judged in terms of its objective seriousness, and secondly, the probability of harm occurring. The objective seriousness of the risk is defined by the Law Reform Commission to mean “the measure of its consequences were it to come about. Thus, a risk would be considered serious if the possible consequence is serious”.¹⁹ However, there is a threshold beyond which risk must never pass regardless of the expected probability of occurring, which is when the research could lead to death or permanent physical or psychological damage.

The first step is to determine the seriousness of the risk when designing the protocol and also, to determine the probability of the harm occurring. Evaluation of risk is a complex process and requires several

steps. When designing his protocol, the investigator needs to rely upon his clinical experience, the reported findings of other investigators regarding the considered research intervention and epidemiological evidence. However, the estimation of the general statistical risk is only one step of the assessment of risk. Also, the researcher considers how the proposed intervention will impact upon members of the target population, in this case, Alzheimer patients. The seriousness and probability of risk associated with the intervention can be predicted by the investigator with varying degrees of confidence depending on the reliability of the information he has to draw on and his clinical experience. The last step is to describe the risk as being below, at, or above minimum level of risk, or in some circles as high or low risk research.

It must be emphasized as discussed in the previous chapter, that the assessment of risk and benefit occurs on two levels, the objective and subjective. The prospective subject has an opportunity to express his evaluation of the protocol during the subjective assessment that occurs during the consent process. If the prospective subject is competent, then he is able to freely consent or refuse. However, when incompetent, the chances of his preferences being respected diminish. If he has left explicit instructions with a next of kin or durable power of attorney, then his wishes should be respected. However, in the majority of cases, the decision is

transferred to a surrogate lacking instructions and often what is in the best interest of the subject becomes what the surrogate would prefer in similar circumstances. The recommendations given later in this chapter regarding conducting SDAT research, address this problem and should enhance the possibility of preferences being respected after the patient is incompetent.

The research protocols that pass the level of objective assessment should not be rated higher than minimum risk. When the subject reviews the risk-benefit ratio of a so-called non-therapeutic research proposal classified as minimum risk, the prospective subject can disagree with the researcher in the following ways:

- (i) decide the research is riskier or more inconvenient than the researcher stated and/or,
- (ii) decide that the research has benefits because it meets his need while making a contribution to society and enhances his fragile self-esteem.

The fact that the subjective and objective assessments can differ is true of all types of research. However, SDAT researchers are at a disadvantage when predicting risk and benefits because of the lack of empirical research about the types and levels of risks associated with growing old and also, about how the elderly perceive risk associated with

daily living. Hence, researchers should be conservative and cautious when assessing the level of risk for SDAT subjects.

The investigator draws from his own clinical experience with the research population and also the reported findings of other researchers using the proposed intervention with the same population. Furthermore, he has to consider individual risk which varies from person to person, depending upon the variables of, for instance, age, sex, social class and health status. Then, the investigator can decide if the risk is acceptable and whether the research design is sound ethically. To this end, the guiding principle as stated by the Law Reform Commission is that "Everything must be done to protect the life and integrity of the human subject even at the expense of increased knowledge".²⁰

In the realm of SDAT research, the emphasis is on predicting the risk of harm because, as discussed, the concept of benefit is ambiguous in the context of SDAT research. Whether the risk is justified is first decided by the investigator designing the protocol. If at this level it is deemed too risky, the research should be halted or revised. The second objective assessment is completed by a Research Ethics Board (REB's). Currently, review by an REB is not obligatory and hence, there are many research projects not reviewed (e.g. research funded by the private sector, hospitals unaffiliated with a university, and private research institutions). If a

proposed study is deemed ethically and scientifically acceptable by the research team and a REB, individuals can be invited to be subjects. If the REB considers the risk too high, they recommend that changes be made to reduce the risk associated with participation for vulnerable subjects.

During the process of recruiting subjects, the subject or surrogate has the opportunity to evaluate the research's design and therefore, the objective assessment of the harm-benefit ratio. There are many variables which can influence an individual's decision, including age, social status, health, place of residence, family responsibilities, attitude towards science, values and mental status. A research intervention which the researcher and a REB consider to be at the level of mere inconvenience could be rated as above minimum risk by the subject. For example, an SDAT patient could disagree with the researcher's prediction that having a CT scan in the local hospital is only a mere inconvenience. He knows from past experience that after a CT scan, he is confused and anxious for several days afterwards and thus he ranks the experiment as being above minimum risk and refuses to consent. In another situation, the researcher predicts the research poses minimum risk because the intervention requires that the subject do some physical exercises. For a patient who has always been involved in a fitness programme, the required exercises are a pleasure which he thinks do not expose him to minimum risk of harm. Hence, he is pleased to be a subject.

However, his spouse who is also asked to be a subject, always has found exercise to be boring and unpleasant and now tires easily after little exertion. Thus, this prospective subject thinks that the intervention poses more than minimum risk but nevertheless agrees to be a subject in order to keep her spouse company.

Admittedly, harm and risk are free-floating at this stage and the proposal that the vulnerable subject should not be exposed to more than minimum risk (as determined by the objective assessment), is made at the abstract level. Now, is the time for researchers and clinicians to put flesh on this criterion in order that the concept can be used consistently. Hence, research is required into the meaning of risk for vulnerable and elderly individuals. Specifically, we need to know more about the influence of age on the perception of risk. What is the impact of the probability of death occurring sooner, for an elderly population rather than for the younger population, on attitudes and behaviours? Does growing old, and in some cases learning that you have SDAT, make prospective subjects more or less cautious in taking risks?

Furthermore, if the subject's assessment of the research is above minimum risk, he can be a subject if certain conditions are met, including the requirement that the subject be competent to consent. A competent prospective subject is capable of volunteering to be associated with higher

risk research, with the caveat that the research has a sound ethical design. However, mentally impaired subjects should not consent directly to research participation (regardless of the level of risk) and as will be discussed, the surrogate should not consent indirectly for the affected patient's association with above minimum risk research.

Physician Richard Ratzan who has a particular interest in geriatric ethics has taken an initial look at why elderly research subjects are different. His observations although based only on anecdotal evidence are interesting and valuable.²¹ Ratzan comments that the criterion of minimal risk meaning risks associated with daily living can not have the same meaning for all age groups because many elderly individuals reduce the risks of daily living. For instance, daily risks such as icy streets, hot weather and motor vehicle accidents are eliminated from their schedules by the elderly "who have consciously and unconsciously minimized their risks while maximizing their comforts. Those who live long enough to become elderly often do so by decreasing the number of risks in their lives, for they know they have little or no control over the magnitude of these risks".²² Furthermore, the objective costs associated with risks are higher for elderly individuals. A striking example, is a the difference between the consequences of falling on an icy path for an elderly rather than a younger individual. As many elderly patients (frequently women) in orthopaedic

units in acute care hospital can testify, for an elderly person, a slip can initiate a chain of events leading to the loss of independence for some elderly individuals and their waiting for months in an acute care hospital for a bed in a nursing home or home for the aged. After the fall which breaks her hip, the elderly woman is in a hospital and socially isolated. She may become confused, sad, depressed and poorly motivated. Thus, the patient is unable to return to her own home because of her poor mental status and reduced mobility. By contrast, for a younger person, the same fall might only result in a bruises or a few days at home resting.

In addition, Ratzan found that the desire for comfort is a greater motivator than fear of dying for many elderly individuals. Interestingly, seeking comfort can involve taking risks but presumably, risks associated with maintaining comfort are ones that some elderly individuals are prepared to take. The ranking of comfort over safety is one explanation of the frequent refusal of some elderly people to leave their home where they are unable to live safely and move into a nursing home despite urging from their treatment team, family and friends to accept living in a safer setting. Hence, when assessing a proposed intervention, the prospective subject could be using a different criterion than the researcher to assess the risk associated with the research intervention: will this intervention disturb my daily routine? In summary, Ratzan's pioneering clinical work

demonstrates that further research is needed to learn more about the increased risks associated with old age and also, the impact of aging on the perception of risk.

Also, the MRC recommends that mentally impaired individuals be exempted from invasive research for the same reason that they should not be associated with non-therapeutic research (failure to respect their inviolable right to dignity and integrity). The legal definition of invasive research is that the intervention breaks or punctures the skin, for example, a venipuncture, and the legal offence is defined as battery by the courts. However, interventions which invade an individual's privacy, are embarrassing and degrading but fall outside the legal definition of invasive interventions. Hence, the legal definition of "invasive" is of a limited value and the distinction between the invasive and non-invasive research fails to identify precisely other kinds of intrusive research likely to pose a threat to the subject's well-being. A venipuncture for an SDAT patient completed using sterile technique would be classified as invasive according to the legal definition. In contrast, observation of an Alzheimer patient trying to perform activities of daily living, which for some subjects can be humiliating, would be not be classified as invasive. Like the terms therapeutic and non-therapeutic, invasive or non-invasive fails to provide an effective mechanism for assessing the level of risk for the subject.

The principle of doing no harm (non-maleficence) should be the basis of assessing research protocols involving vulnerable individuals. A benefit of changing the measuring stick to the level of risk in place of therapeutic or non-therapeutic, and invasive or non-invasive is that the focus of the assessment will be protection of the prospective subject. Thus, “non-invasive” and “therapeutic” research which nevertheless threatens the subject’s well-being would be identified. Therefore, it is in the subject’s interests for the researcher and an REB to use the criterion of to what extent the intervention threatens to harm the subject regardless of whether the research intervention is therapeutic or not, and also, invasive or non-invasive.

To summarize the discussion of research design, the classification of research into therapeutic or non-therapeutic, or invasive or non-invasive is not appropriate for the SDAT population and should be replaced by the one general category of health sciences research. The case of weak and vulnerable patients should respect the proposed minimum standard of treatment policy advocated in chapter three. Thus, SDAT patients should not be associated with any health sciences research that fails to respect their fundamental needs (inviolable rights). They should not, therefore, be associated with any health sciences research classified as above minimum risk at the level of objective assessment. Thus, it is possible for mentally

impaired and incompetent patients to be associated with research classified as non-therapeutic and invasive without threatening their integrity or well-being. The subject will not benefit directly but also, he is not expected to be exposed to more than minimal risk.

5.3 Competency to Consent to Research:

Many of the same factors that have led to profound interest in informed consent - a growing mistrust of professionals in general, a rising consumerist and self-help orientation, and the exposure of some startling examples of the misuse of trust by medical experimenters - have led in turn to an examination of the presumed prerequisites to effective informed consent, competence among them. Despite its recent prominence, however, the issue of competence (sometimes referred to as capacity) to consent to research is of relatively recent derivation and awaits generally acceptable attempts at definition.

P. Appelbaum and L. Roth, 1982.²³

a) Introduction

The remarks regarding the concept of competency made by the psychiatrists Appelbaum and Roth in their paper "Competency to Consent to Research", are as relevant today as they were in 1982. However, with the increased incidence of Alzheimer's Disease, the need to understand the concept of competency to consent to research participation and have a universally accepted definition of the concept, has intensified.

An extensive literature review of competency, competency in relation to consent to research, and consent from Alzheimer patients produced a number of papers on the topic of consent. However, there were very few papers addressing competency to consent to research and the ability of Alzheimer patients to provide consent for any interventions. The large majority of papers were written by physicians (usually psychiatrists), lawyers and a very few by philosophers. The strong association between the law and psychiatry is practical. However, it is regrettable that moral philosophy has not had a more influential role in clarifying the concept of competency.

Roth and Appelbaum commented that despite widespread acceptance of the notion that you must be competent in order to consent to be a subject, there is a lack of consensus about what it means to be competent. In their words, "Despite its recent prominence, however, the issue of competence (sometimes referred to as capacity) to consent to research is of relatively recent derivation and awaits generally acceptable attempts at definition".²⁴ Linking philosophy with health sciences and the law should shed light on the thorny issue of when an individual with diminishing autonomy is competent to perform the important task of consenting to research.

The great importance of an individual's mental capacity in providing consent to participate in a research study was recognized for the first time formally by the Nuremberg Code in 1947. The opening sentences of the Code state:

The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent: should be situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision...²⁵

Furthermore, the Code states that the responsibility for determining the quality of the consent, that is to say whether the prospective subject was competent to provide a consent and that the circumstances did not render the consent void, rests "upon each individual who initiates, directs, or engages in the experiment. It is the personal duty and responsibility which may not be delegated to another without impunity".²⁶

Two comments about this landmark statement need to be made. The Code makes it an absolute requirement that the consent process not be compromised in any way: the competence of the subject is absolutely essential. Lacking is any provision of guidelines to be followed when the

subject is deemed unable to provide his own consent. Secondly, the Code refers only to non-therapeutic research.

Thus, stated Appelbaum and Roth “For minimal risk research, mere “assent” was required constituting a lower standard for competency, for that particular situation.”²⁷ The Belmont Report also allowed “Participation by incompetents in research posing higher degrees of risk was permitted only with a variety of types of substituted consent and supervision of the process.”²⁸ Thus, the Belmont Report approved:

- (i) a sliding scale of competency
- (ii) the involvement of the mentally impaired in research classified as higher than minimal risk.

When a sliding scale of tests of competency is used, the more risky the research, the higher the standard of competency. The position to be advanced is that both of these recommendations pose serious threats to the well-being of SDAT patients and should not be followed. Alternative recommendations will be proposed later in the chapter.

As discussed in the previous section, in the mid sixties, there was a cluster of events that contributed to rules about informed consent being taken more seriously and being reinforced by government regulations. The well- publicized research involving injecting live cancer cells into patients without the consent of the patients or caregivers and the publication of the

Beecher paper led to the widespread recognition of the need for regulations governing research involving human subjects. The codes, regulations and guidelines that emerged stated that the person providing consent must be legally competent. Thus, lawyers and judges were accorded the pivotal role of deciding that a prospective subject was unfit for providing consent.

Lacking accepted criteria of incompetence, the courts had a difficult task.

In Canada, there is a strong commitment to the goal of informed consent from a competent subject and the courts have the unenviable job of declaring an individual incompetent to provide consent. Thus, the very population needed by SDAT researchers, the mentally incompetent, would be excluded from research studies if the Nuremberg Code's recommendation about informed consent was followed. However, the MRC agrees with the position of the World Medical Association that mentally impaired individuals can be subjects under strict conditions, including obtaining a valid indirect consent for their involvement from a third party.

The Helsinki Declaration of the World Medical Association identified two types of research: clinical research combined with professional care and non-therapeutic clinical research. The Declaration permits surrogate decision-making in both cases. In respect of therapeutic research, the Declaration states "In cases of legal incapacity, consent should also be procured from the legal guardian".²⁹ Regarding non-therapeutic

research, the recommendation is the same: "if he (the subject) is legally incompetent, the consent of the legal guardian should be procured".³⁰

To set the stage for the discussion of competency, it is useful to repeat the requirements for a valid (direct) consent.³¹

- (i) responsibleness
- (ii) competence
 - (a) legally
 - (b) mental status
- (iii) comprehension
- (iv) voluntariness
- (v) free to withdraw without penalty.

The existing criteria for a valid direct and indirect consent are satisfactory. However, when the prospective subject has SDAT and is losing his autonomy and control over his life, deciding which SDAT patients are capable of consenting to research is a crucial issue and a difficult task. Assessing the level of autonomy and competency is entwined with the diagnosis of SDAT. We know that one loses the right to consent to research participation in addition to medical treatment when one is not autonomous and declared mentally incompetent. Yet there is no clear understanding of what is meant by loss of competency nor is there a widely accepted standard used to determine levels of competency. The lack of consistent standards of

competency can expose vulnerable subjects to the risk of harm. The first line of defence is the requirement for a sound ethical design. If this criterion is met, then there are three possibilities:

- (i) the prospective subject is competent to consent to research that could be classified above minimal risk (and continue to have a favourable risk-benefit ratio). He assesses the level of risk (subjective assessment) and can agree or refuse.
- (ii) the prospective subject is mentally impaired and indirect consent is sought from a surrogate. In this case, the level of risk should not be above minimal (objective assessment) and hence, the subject should not be exposed to excessive risk if the surrogate consents.
- (iii) the prospective subject is mentally impaired and permitted to consent to research. Because he is deemed to be competent to consent to research, he can consent to research classified as higher than minimal risk (objective assessment). The prospective subject lacks the capacity to assess the consequences of participating given his particular circumstances.

The third situation illustrates the need for a high standard of competency to consent to research. The combination of the higher standard with the proposed changes to SDAT research's experimental design should

prevent mentally impaired SDAT patients from being in the position of having to make decisions beyond their mental capacity and unwittingly exposing themselves to situations that could be harmful for them, even if the protocol is ethically sound. The merging of the recommendations regarding competency and research design is designed to respect the fundamental need of the weak and vulnerable to be protected from harm.

Recent clinical research by psychologists Drs. Witherspoon and Dyman of Brock University into the phenomenon of memory loss would support the conclusion reached at the conceptual level.³² Learning new information has a minimum of three steps. New information is coded and stored, then decoded and retrieved to be used in concert with other information when needed. Dyman and Witherspoon have found that in the early stages of SDAT, the ability to learn new information is lost in most individuals. Providing a consent to participate in research requires learning new information. The nature of the research, the risks and benefits, details regarding the intervention are all new pieces of information or familiar information organized in a new form. However, implicit knowledge (learning acquired usually early in life and reinforced by years of practice, for instance, playing a musical instrument, playing bridge and social manners) is the last of the cognitive skills to be lost. Thus, an individual who is seriously cognitively impaired could be at risk of complying with an

authority figure (for instance, a physician or researcher) because of entrenched early social conditioning and learning.

The pioneering work of these two psychologists in the field of memory loss in the SDAT population demonstrates that the majority of affected patients lack the cognitive skills to be autonomous moral agents capable of making a valid consent. Considering that SDAT patients lose the ability to learn new information during the early stages of the disease, then the capacity to consent is also lost because appreciating the consequences of consenting occurs after the subject has recalled and evaluated the information. In brief, consenting requires learning new information, a capacity lost early in the disease process. Thus, consenting to research is a capacity that is lost early. There are other definitions and criteria of competency which permit more SDAT patients to consent directly for research participation but as will soon be seen, these standards are morally unacceptable.

Currently most SDAT patients can not consent to research because they are declared mentally incompetent and hence, the decision is transferred to a surrogate. Thus, determining what criteria should be used to determine whether an SDAT patient can consent to research can increase, maintain or decrease in the number of patients eligible to consent. A proposed conjunctive definition promises to reduce the number of SDAT

patients who may be solicited to participate in research since this involves inviting them to perform tasks beyond their capacities. However, a conjunctive definition promises to halt the practice of SDAT patients automatically losing the chance to consent to research. Instead, an individual assessment is required to determine if patients in the early stage still have the capacity to perform the specific task of consenting to research as opposed to being mentally incompetent or competent. The task of consenting to research requires appreciation of new information, ability to engage in a dynamic relationship with the researcher, and complete the steps involved in making a sound decision which is beyond the capabilities of most Alzheimer patients but not all. It is necessary that those with the capacity to consent be identified in order that they are allowed to consent and thus, their autonomy is maintained and respected. It will be seen that the more rigorous definition of competency will be a service to SDAT patients and also researchers.

Examination of the concept of competency and competency to consent to research will be organized as follows:

- (i) discussion of mental incompetency and task-specific competency
- (ii) review various standards of competency
- (iii) present criteria of competency to consent to research.

The objective is to demonstrate the weaknesses of the bi-polar model of competency and to point out that the task of consenting to research is a specific and sophisticated function, distinct from competency to perform other specific tasks (such as, consent to medical care, make a will, changes residences, take a holiday, shop, drive a car). In philosophical terms, competency to consent to research requires *full* autonomy or *critical competence* and is based upon the developmental theory of autonomy discussed in chapter three. It will be seen that the concept of competency and a standard of competency to consent best serves the needs of the weak and vulnerable and does not undermine their diminishing or depleted autonomy.

The proposed conjunctive definition of competency to consent is more demanding and specific than the standard for mental incompetency currently used to decide if an individual is capable of consenting to research. The capacity for consent requires a high level of autonomy and rationality. As the following section unfolds, it will be argued that only moral agents (that is autonomous individuals) have the capacity to provide a valid consent to participate in health sciences research.

b) Global versus Specific competency:

Before presenting the concept of competency to consent to research, some discussion of terminology is necessary. Mental incompetency is a legal term and an individual is declared mentally incompetent when it is found that the individual can not provide for his own needs and protection. The legal definition of mental incompetency states that for the mentally incompetent individual “aspects of intellectual functioning such as comprehension of, or the ability to discharge required duties is inadequate”.

The Ontario Mental Health Act states that an individual can be considered mentally incompetent when the patient is suffering from a mental disorder of a nature or quality that can result in:

- (i) serious bodily harm to the patient,
- (ii) serious bodily harm to another
- (iii) imminent and serious physical impairment of the patient.³³

When deemed mentally incompetent, the individual loses the right to manage most aspects of his personal life. Hence, the impact is global as opposed to task specific.

Mental incompetency can be associated with physical and mental illness and also age (being a child or young adolescent). For instance, a young child, a heavily sedated patient, or a psychotic patient wearing

summer clothes outside during the winter might be declared mentally incompetent.

With adults, competency is assumed until incompetency is proven. At present legal and the medical professions work together to determining legal competency. An individual assessment of all suspected mentally incompetent individuals must be made and a judge must make a decision after studying evidence provided by physicians and other interested parties. A major problem is the lack of established guidelines for determining competency and thus the quality of the evidence can vary widely. The status of mental incompetency must be proved in a special court hearing with evidence provided, in most cases, by physicians. There are serious consequences when one is found to be mentally incompetent: the individual can have all his legal and civil rights removed and be at great risk of having his inviolable rights (to dignity and integrity) disrespected. At set times, in most jurisdictions, the mentally incompetent individual has the opportunity to appeal the decision at a review board or its equivalent.³⁴

To be competent means having the skills and knowledge required to execute a task in a capable manner. In addition, to be competent means that the individual is in control of his life, is autonomous, and is able to make decisions based on an appreciation of the costs and benefits of his

choice. The concept of competency is central to understanding man as an independent, responsible, moral agent.

There are two models of competency, global and specific. The global model is bi-polar: an individual is or is not competent to perform most functions. The assessment examines whether the individual can meet their basic needs and/or is a threat to the welfare and safety of themselves or others. Given that mental incompetency is based on the bi-polar model of competency when an individual is declared mentally incompetent, he loses most civil rights and is deemed incapable of performing many functions including consent to research, consent to medical treatment and to manage one's personal affairs.

The legal and medical definition of competency requires that the individual has the capacity to understand the risks and benefits of the proposed intervention and therefore, can appreciate the consequences of his behaviour. The standard way to make an assessment of the mental status of the individual is in terms of the progress of the disease. When the individual reaches a certain stage in the disease process, he is declared globally incompetent. He is then unable to consent to research participation and receiving or refusing medical treatment, in addition to losing other legal rights. An individual clinical assessment is required to determine if the individual (i) understood the information and (ii) understood the

consequences of his decision. Frequently, the investigator informs the prospective subject of (i) and (ii) and if the subject can make an “either” “or” decision or defer his decision to a third party he has demonstrated the ability to make a choice and is deemed competent to provide consent for research participation.

The major problem with linking competency with the progress of the disease is that the presumed test of competency is not a for specific tests and, therefore the individual’s ability to perform some tasks and not others will not be acknowledged. Thus, it is possible for a prospective research subject to consent without appreciating the nature of the research and its attendant risks and benefits.

There are serious consequences in terms of the individual’s legal and moral rights when he is declared mentally incompetent. Competency means having the capacity to exercise self-determination and make responsible and sound decisions in respect to one’s welfare. Hence, the notion of competency is based on an understanding of the nature of man as an autonomous and moral agency. Yet there is a scarcity of philosophical literature on the concept. Unless moral philosophy contributes to the discussion of competency and assists in the development of criteria of competency, the concept is at risk of being primarily a reflection of conventional wisdom or prejudices.

Whether a patient is found to be incompetent or not depends on a number of variables including: social values, place of residence, availability of legal aid services, standards of assessment, and the experience of the physician and judge involved with the case. To varying degrees, judges will be influenced by their judicial experiences, in addition to personal experiences and values. The legal definitions fall short of guiding judges and physicians dealing with many individual cases. It is difficult for decisions not to be made at the reflective as opposed to reflexive level because of the lack of an objective standard of mental competency.

The speciousness of the bi-polar model is known to caregivers and health professionals who have worked with Alzheimer patients and other mentally impaired individuals. From their clinical experience, they know that competency is task specific and, hence, an Alzheimer patient can be competent to perform some tasks but unable to perform others. The loss of competency in different domains is gradual, rapid, fluctuating and/or can be sporadic. What is known is that in all domains, the decline in functioning is progressive and competency, with respect to specific tasks, is on a continuum. In short, the bi-polar model does not match clinical realities. There are some serious consequences if this either-or approach is used.

- (i) Some mentally impaired individuals could be unjustifiably deprived of control over certain aspects of their lives. Thus, the abilities remaining are compromised when they should be maximized.

- (ii) Some mentally impaired individuals deemed competent may continue to make important decisions when they are incapable of doing so, and thereby, expose themselves to harm.

In both cases, the well-being, integrity and fundamental needs of the individual are threatened because the either-or model fails to address the clinical fact that the abilities of patients with deteriorating cognition do not fit the all-or-nothing approach.

In contrast, specific competency refers to the cognitive capacity to understand the nature and consequences of the specific decision to be taken. Competency or the capacity to perform a specific function effectively or competently should be qualified. For instance, a SDAT patient may be competent to live independently but unable to travel outside his neighbourhood. The concept of competency as a specific ability to perform a certain task overcomes the problems of the all-inclusiveness or exclusiveness of the global concept of competency. Furthermore, the concept of specific competency has therapeutic value because individual strengths are identified and supported and measures are introduced to maximize the patient's abilities and compensate for his losses. Hence, it is in the patient's best interest to be assessed in terms of being competent or incompetent to perform a specific task. When competency is linked with a specific tasks, competency should be assessed in terms of competency to perform the task in question. In order to declare an individual mentally incompetent (to

perform task X), the criteria of competency to perform task X have to be determined and each task will have separate criteria. If the individual does not have the capacity to perform the task according to the standard expected, the individual is deemed incompetent to perform that specific task.

Competency and incompetency to consent to research is a specific capacity distinct from mental competency and incompetency which are global terms. Required is a different approach to competency that takes into account the cognitive capacity of the individual to perform specific tasks, in this case consent to participate in research. This is to say, a way is needed to ground competency in a theory of autonomy that incorporates moral agency, full autonomy and critical competency. The general global term of competency refers to an overall ability to perform major tasks adequately but when the capacity to perform specific tasks deteriorates, the general term fails to explain or describe the individual's unique pattern of deterioration or to identify the remaining capacities. In addition to the general terms of "competence" and "incompetence" there is a vast expanse of the human condition that does not fall into these general categories. When differentiation of abilities is addressed, the interests (and inviolable rights) of the moral agent or dependent moral subject are more likely to be highly respected.

Thus, it is imperative that philosophical, medical and legal discussions of competency move from the concept of global competency to specific competency because the global concept fails to characterize the individual's specific losses and to recognize the capacities that remain. Thus in recent times, law and health sciences are moving away from the global concept of competency and incompetency to specific competency and incompetency:- a progressive move based on respect for the individual and requiring careful, individual assessments by trained staff.

c) Competency to Consent to Research Participation:

In order to develop criteria for the specific task of competency to consent to research, it is necessary to look at what is specifically required to give a valid consent. The principal skills are:

- (i) ability to retain and evaluate information relevant to the proposed research
- (ii) ability to make a sound decision
- (iii) ability to make an independent decision
- (iv) ability to maintain an interactive relationship with researcher

Hence, the capacity to make an informed decision regarding being a research subject requires certain skills and the capacity to maintain an interactive relationship.

The first requirement of evaluating relevant information can be an obstacle when the prospective subject is unable to retain and comprehend sufficient information to make a reasoned decision. Depending upon the progress of the disease, the prospective subject can understand some information but in most cases will lack the judgment, insight and reasoning abilities (mental competency) required to make a decision based on the information provided.

Consenting is decision-making, a complex process with a number of steps. To give a valid consent, the subject must have the capacity to evaluate relevant information given by the researcher and also the capacity to make a decision. An analysis of the decision-making process which incorporates elements of psychology, neurology, sociology and other social and health sciences falls beyond the scope of this work. However, what is of importance is the acknowledgement that consent or refusal to be associated with a research study is a specific task calling for the decision of whether or not to be a research subject.

The process of deciding is distinct from the information given. The decision to consent to be a subject is different from the decision to take a philosophy course, take a cruise, watch a comedy or drama programme on television. Information is received, stored, recalled, thought about, analyzed and evaluated. When deciding to consent, the information not only must be

understood but the prospective subject should put the information in a context and appreciate the consequences of consenting (or refusing) in terms of his circumstances. The decision to consent or refuse impacts on the subject, the research team, the society and in turn these interactions influence him and thus the system-like relationship continues. The researcher and prospective subject are enmeshed in an interactive relationship when a valid consent is given.

When the prospective subject evaluates information and decides, he also considers the meaning of the research intervention for him given his history, status and expectations. The prospective subject should not be coerced to consent and if this occurs, the consent is not valid. Ways of minimizing and managing coercion will be presented later in the chapter.

In philosophical terms, the prospective subject giving a valid consent is a responsible moral agent capable of making decisions that reflect his intentions, goals and values. The decision may not be the choice expected by the researcher. However, research subjects are allowed to refuse and make wrong decisions from the researcher's perspective without their mental status automatically being questioned. When the choice made reflects the subject's life-long values and attitudes, the choice can be described as an authentic decision. Thus giving or refusing consent to

research is a highly demanding task requiring sophisticated cognitive skills matched by a high degree of autonomy.

In recent times, both law and psychiatry are moving away from the global concept of competency and incompetency to specific competency or incompetency:- a progressive move which is based upon respect for the individual and requiring careful, individual assessments. During the past twenty years, Drs. Roth, Lidz and Appelbaum sometimes with Meisel, (a law professor) have been working on more stringent standards for assessing “competency” and their work is valuable for moral philosophers and SDAT researchers. They reviewed work in the field of competency and admitted there was little to be found regarding the issue of consent to treatment and research. Roth, Lidz and Meisel studied the decisions of judges deliberating competency cases and found that several standards of competency were used. They stated, “the various standards that have been proposed appear generally to cluster into four groups. While the relationship among these groups requires further empirical study, our clinical experience plus the literature we have reviewed suggest that these four groups may be arranged hierarchically to furnish a progressively more stringent standard for assessing a subject’s competency”.³⁵

Roth and Appelbaum’s landmark paper entitled “Competency to Consent to Research”,³⁶ narrowed the scope of an earlier paper “Tests of

Competency to Treatment”, written by Roth, Meisel and Lidz.³⁷ Although their work presents a psychiatric overview of competency to consent to research, their work is valuable and deserves analysis. By looking at their descriptive and functional approach, a basis for developing a conjunctive definition and understanding of competency to consent will be presented. As they explained, psychiatry’s dependency on the law is necessary because “The entire edifice of involuntary treatment is erected on the supposed incompetency of some people to voluntarily seek consent to needed treatment”.

In the paper “Tests of Competency to Consent to Treatment” Appelbaum and Roth stated that “There is a dearth of legal guidance illuminating the concept of competency to consent to medical treatment”.³⁸ Nevertheless, they turned their attention to the specific task of competency to consent to research and stated that their research revealed that there were four categories of competency on a continuum, each requiring more sophisticated cognitive functioning.³⁹ The four stages are:

1. Evidence of a choice:

This lowest test of competency considers a “yes” or “no” answer to be sufficient for consent or refusal. To be deemed incompetent, the individual must fail to indicate a preference either verbally or by means of

his behaviour. Thus, as Roth (who does not favour this test) states succinctly “ This test focuses not on the quality of the patient’s decision but on the presence or absence of a decision”.⁴⁰ Evidence of a choice is the least demanding standard and solely behavioural in orientation because all that is required is a yes-or-no answer. Agreement or refusal to participate can be verbal or non-verbal.

Given the simplicity of the test, who would not qualify to provide evidence of a choice? There are a few categories of individuals who are unable to respond verbally or non-verbally. Certain psychiatric disorders interfere with the ability to demonstrate a preference, for example, mutism, catatonic states, mania and severe psychosis. Also, individuals who are seriously ill, in a coma or a delirium and/or heavily sedated are incapable of meeting this primitive standard.

Roth identified the main weaknesses of this low test of competency is its failure to confirm individual understanding of the nature and consequences of the research intervention. Given that the test is a behavioural one, a mere yes-or-no or transferring the decision to another will suffice as evidence of competence. Advocates of this minimal standard argue that this test offers maximum protection to the mentally disabled and psychiatric patients because by co-operating they have voted “with their feet”. The contrary is the case. This standard offers minimum protection to

vulnerable subjects needing maximum protection from harm. Regarding Alzheimer patients, during the last stages of the disease, some patients who do not want to participate may not have the capacity to refuse verbally or non-verbally.

2. Factual understanding of the information:

This standard requires that the prospective subject understand the facts relevant to his participation. The usual formulation of this standard is “the subject have the cognitive capacity to consider the relevant issues”. The MRC Guidelines provide specific recommendations about the information to be given to and understood by the prospective subject. These were dealt with in the previous chapter. The basic requirement of this test of competency is that the individual indicate a comprehension of the meaning of the information about the proposed research. This test is deficient because merely understanding the data is only part of the decision-making process. The information has to be analyzed and appraised which requires more sophisticated cognitive functioning and more independence than is required to merely comprehend the facts presented. The prospective subject can have a grasp of certain concrete facts but this is only the first stage in understanding the nuances and implications of a decision based on this information.

There are a number of medical and psychiatric health problems that may prevent a prospective subject from meeting this standard: organic brain damage, being comatose or having fluctuating levels of consciousness and failing cognitive functioning. Also, problems with recalling information and poor attention span which occur with SDAT, can prevent the prospective subject from having a factual understanding of the information provided.

The individual's competency is tested by asking him to demonstrate his understanding of the issues. The standard way is to ask the prospective subject to repeat the information provided, in his own words, including the risks and benefits of participation. The weakness of this test of competency is that the researcher's and the prospective subject's perception of risks and benefits can differ and his reasons for agreeing or refusing may appear unsound to the researcher when they "make sense" for the prospective subject. Secondly, this test could be only a test of the prospective subject's recall of information and not of any appreciation of the consequences of consenting.

3. Rational manipulation of the information:

Rational manipulation of information is based upon the ability to factually understand information presented by the investigator. When the prospective subject has, what Roth terms, the ability to understand the information and weigh the pros and cons of participation he has the ability to manipulate the information. This test of competency to consent requires that the prospective subject deliberate and decide whether to participate or not. Thus, this standard requires a higher degree of autonomy and cognitive functioning than the previous standard.

The standard builds on the previous one because the objective is “to determine how the information that the subject assimilated is utilized in the decision-making process”.⁴¹ The test focuses on the prospective subject’s judgment, rationality, weighing of risks and benefits, and decision-making capacity. Appelbaum and Roth have a long list of psychiatric signs and symptoms that would interfere with rational manipulation of the information which include: delusions, hallucinations, anxiety, euphoria, anger, agitation, excessive dependency, passivity and unwarranted trust. The rigor of the requirement of understanding, state Appelbaum and Roth “obviously increases with the amount and complexity of material that is required to be understood”.⁴²

This test can be the reasonable answer test disguised. That is, the prospective subject demonstrates a rational manipulation of the information by giving an answer that the researcher considers to be reasonable: consent. Although they acknowledge this problem, Appelbaum and Roth comment that a greater difficulty lies with estimating the impact of impaired rationality because rationality is not impaired equally in all aspects of decision-making. They state that most experts agree that impaired rationality does not affect decision-making in all realms but the impact can be restricted to a discrete area of mental functioning. In other words, the ability to make decisions regarding one aspect of an individual's life can persist when the individual is incapable of making other decisions. This observation is supported by clinical practice, and emphasizes the need for a task-specific conception of competency.

4. Appreciation of the nature of the situation (actual understanding):

The most stringent standard requires (i) factual understanding, and (ii) rational manipulation to occur "in the context of the subject's appreciation of the nature of the situation".⁴³ Unlike factual understanding, this standard requires that the prospective subject consider the importance of the situation at hand (e.g. providing consent) to the information presented. In addition, the standard differs from rational

manipulation of data because the expectation is that the prospective subject will be able to recognize and take into account relevant data as opposed to all the information at hand or presented. Evidence of meeting this standard has been described as appreciating the consequences of providing or refusing consent, recognizing “in mature fashion, the implications of alternative courses of action and appreciate both cognitively and affectively the nature of the thing to be decided”⁴⁴ or “appreciate what is relevant to forming a judgement of the issue in question, i.e. ...consider relevant information”.⁴⁵ This demanding standard could not be attained by the majority of SDAT patients.

Again the emphasis is on the result of the decision-making process. Appelbaum and Roth apply this standard to the research context and state that the prospective subject who met this standard would understand the nature of the proposed procedures and “evaluate rationally their risks and benefits”.⁴⁶ In order to meet this standard, the individual must have the capacity to think abstractly, evaluate information and set priorities. The central issue is deciding if the prospective subject has evaluated the information in a manner that has resulted in a decision based on an appreciation of the information presented.

This conception of competency which will be called full competency is present when the subject is a moral agent with full autonomy and critical

competence. The major problem with the actual understanding test, in Roth's opinion, is the determination of what constitutes appreciation of the request. How do you really know that the prospective subject has understood and evaluated the information? In Roth's words "What constitutes adequate understanding is vague, and deficient understanding may be attributable in whole or in part to physician behaviour as well as to the patient's behaviour or character".⁴⁷ Certainly the litmus test of "yea" or "nay" associated with the first test of competency is not vague but this type of certainty is of little value. However, during the consent process, the investigator has the duty to ascertain whether the prospective subject has critically appraised relevant information and has sound reasons for his decision given his circumstances, values and goals. Appelbaum and Roth state that "...of necessity the subject's view (e.g. on the presence or absence of illness or the results of accepting or refusing participation) ultimately must be measured by their correspondence with the consensus of knowledgeable (usually professional) opinion on those issues".⁴⁸ Thus, a danger with this standard, which can be avoided, is the equation of a sound or rational decision with the decision that the researcher desires, that is a consent. In other words, again it is possible that highest standard is met when the prospective subject's appreciation of the situation is deemed to be a reasonable response by the researchers and thus, deviant decisions

indicate lack of competency. This issue will be addressed by the conjunctive definition of competency which allows for competent individuals to refuse to be a research subject and to make a wrong decision.

Appelbaum and Roth conclude their paper by recommending that before a standard of competency to consent to research can be established, selected empirical data and further clarification of the requisite moral imperatives are required.⁴⁹ With this information, they propose, the various interests involved in human experimentation can be protected.⁵⁰

When the four conceptions and tests of competency are reviewed, the most demanding or highest standard is preferable because whoever meets this standard can meet the criteria of a valid consent. That is to say he has the capacity to give a free, fully informed valid consent. In the U.S.A., the DHEW has implicitly adopted this test for individuals who are not mentally impaired or mentally ill and has recommended the creation of consent committees to evaluate the decisions of research subjects.

To the MRC's credit they have one standard of competency for all research subjects, that of understanding the proposed research and appreciating the consequences of consenting which is the highest standard of actual understanding. The highest test is morally preferable for two reasons. It protects prospective subjects from being involved in research activities without giving valid consent. Also, the test is morally preferable

because implicitly, the inclusion criterion for providing consent includes being a moral agent which in turn entails that the agent be autonomous, have critical competence and be morally responsible and, does not include dependent moral subjects.

Therefore, in addition to the obvious groups of Alzheimer patients and young children who would be excluded from providing a valid consent, there are those who fall somewhere between having full and minimum autonomy. To repeat the point made in the previous chapter, individual assessments are necessary to determine if the prospective subject can provide a valid consent. When a demanding test of competency is used, it is predictable that the pool of prospective subjects capable of providing a valid consent will be drastically reduced because individuals who could pass the tests for factual understanding and manipulation of the information would not be deemed competent enough to provide a valid consent for research. This high standard of actual understanding described by Roth and his associates is not likely to have universal appeal. Commenting on his fourth standard of competency, Roth summarized the problems associated with demanding a high standard of competency to consent to research when he stated that he did not support adoption of the test because if this sophisticated level of understanding is accepted, "this test delineates a

potentially high level of competency, one that may be difficult to achieve.”⁵¹

A cautionary note should be added, however. Regardless of the standard preferred, when clinical investigators, clinicians and next of kin are working with elderly and SDAT patients, they must bear in mind that sensory and language problems are more common with this population. Difficulties in hearing and speech, and/or little or no command of the languages of the country can prevent an elderly individual from giving a valid consent when they are capable of doing so. Also, these deficits can contribute to the patient being mis-diagnosed.

Currently, in Canada there are no legal rules regarding the level of competency required to consent to research participation. The Eve case focused on providing surrogate consent for non-therapeutic medical intervention but did indicate that the Canadian judiciary probably would take a strong position in favour of protecting vulnerable subjects. Protecting vulnerable subjects goes hand in hand with requiring a high level of competency. Granted that the Supreme court made protection of the patient its main concern, it is reasonable to assume that the protection of prospective research subjects would also be a priority. If this was the case, the highest test of competency which affords the prospective subject the highest degree of protection would likely favoured by the courts.

The standards described by Roth and Appelbaum have laid the foundation for proposing a conjunctive definition of competency to consent to research. To be considered competent to consent, the subject must meet *all* the following conditions.

- (i) understands the risks, benefits and consequences of his decision and behaviour
- (ii) appreciates his particular circumstances including the state of his health, prognosis and treatment options
- (iii) understands the significance of the risks, benefits and consequences in respect to his values, goals and particular circumstances
- (iv) is capable of critically evaluating information provided
- (v) is capable of making a sound decision based on information provided and of appreciating his circumstances and particular values
- (vi) accepts responsibility for his decisions, his behaviour and the consequences of his actions on himself, his family and others
- (vii) resists pressure (overt or covert) to make a particular decision

The term comprehensive understanding or Roth's term of actual understanding defines the level of understanding required to provide a valid consent. Comprehensive because the critical appraisal of the proposed research should include:

- (i) information provided by the researcher
- (ii) appreciation of one's health status
- (iii) appreciation of the potential for harm or benefits to the subject

Thus, the subject must be able to evaluate the meaning of being a research subject in terms of his particular circumstances. In order to function at this high level it is necessary that the subject have critical competence which incorporates factual understanding of information given, rational manipulation of data and also, actual understanding.

Analysis of each condition will indicate that all requirements are essential. The first condition of understanding the consequences of the decision, is not surprising. An accepted requirement of providing a valid consent is that the individual understand the risks, benefits and consequences of the decision. This level of understanding may take some time to reach, hence the subject and researcher need to have a dynamic relationship fostering the subject's appreciation of the information presented. In turn, as mentioned earlier, the researcher has a responsibility to explain all the relevant information to the prospective subject. Simplifying the information is allowed but eliminating vital information is unacceptable. If the prospective subject is unable to understand the necessary information, then his competency should be questioned.

The second condition recognizes that the prospective subject must have an appreciation of his particular circumstances, including his health status and therefore, have the knowledge base to proceed to the next step. Thus, a patient who has not been informed of his status and prognosis

would be unable to provide a valid consent. When an individual is informed about the research intervention and his particular circumstances, he can evaluate the impact of the intervention upon his life and decide whether he wishes to be associated with the study. The individual's values and goals also influence the decision. For instance, an individual with a strong altruistic streak would probably be favourably disposed to volunteering but an individual distrustful of the medical profession might be inclined to refuse. Similarly, a newly diagnosed SDAT patient who has had the life-long dream to have a trip around the world probably could be expected to refuse entering a longitudinal study requiring weekly tests in favour of making a trip as soon as possible, while still able to travel. Thus, the subjective evaluation done by the subject (or surrogate) is integral to the consent process. The objective assessment is a filter and should prevent any research posing more than minimum risk to the subject when assessed in terms of objective evidence and clinical experience. The subject's assessment can differ from the objective evaluation and he may acquiesce or decline the request. The fact that the subjective and objective assessments can differ is true in all types of research. However, SDAT researchers are in a new field and do not have as large a body of epidemiological evidence, as other areas of clinical investigation can draw on, when determining the level of risk for SDAT subjects. Hence, as mentioned earlier, researchers should be

conservative and cautious when assessing the level of risk for SDAT subjects.

The consent process gives the prospective subject or his surrogate the last word on the level of risk associated with the intervention. The prospective subject's assessment of the risk may disagree with the researcher's for a number of reasons including: age, health status, social class, geographical location, ethnic background, quality of caregiver support and institutional care. The important point is that the subject's evaluation of the risk be respected and not over-ruled by the researcher. For example, if the prospective subject considers testing of his mental status to be invasive and potentially very harmful, his assessment is to be respected, despite the researcher's prediction that the intervention is at the level of minimum risk.

The next two conditions refer to the decision-making process. The first two characteristics referred to the ability of the individual to receive information from others and reflect upon his particular situation. The next two characteristics refer to the processes that an individual must be capable of executing in order to make a sound decision. The prospective subject must have a dynamic relationship with the researcher, learn and retain relevant information regarding the research study, evaluate this information taking into consideration his particular circumstances, and also,

evaluate and appreciate the risks and benefits of his participation. In clinical terms, competency to consent requires sophisticated cognitive skills, memory, the ability to think abstractly, set priorities and make a decision. In philosophical terms, consenting or refusing to be a research subject requires critical competence, which is to say the individual is fully competent, can act independently and be responsible for his decision. In other words, the prospective subject is fully autonomous and has comprehensive understanding. The essential feature is the ability to make a decision that is sound and respects one's welfare needs.

Decision-making is a complex process, and as stated earlier, an analysis of decision-making is a hybrid study falling outside the bounds of this study. Suffice it to say that there are three general steps:

- (i) the individual evaluates the information given, asks further questions, engages in a dynamic relationship with the physician to learn more about the proposed intervention.
- (ii) the individual takes the information and considers what the intervention will mean for him. Are the costs too high considering his values, goals and lifestyle? Unless the second step is taken, the information remains at an abstract level.
- (iii) the individual making a decision and accepts responsibility for the consequences.

Haworth discussed in detail the decision-making process and required that an autonomous (critically competent) individual not only reach a sound decision but also execute the decision. However, this requirement is

not essential and with elderly and chronically ill populations, it is imperative that the task of making a decision be separated from executing the decision. The latter task is a distinct step requiring other characteristics which an autonomous and mentally competent person can lack, such as physical strength, mobility, financial resources and human resources. For instance, deciding where to live and how to move are two distinct tasks. An elderly individual could be unable to organize moving himself from the family home into a smaller condominium, yet this does not mean he is incompetent to make the prudent decision to move to a smaller residence with less responsibilities. Individuals with impaired physical abilities but competent cognitive abilities who have access to financial and human resources to assist them, often escape being "labelled" incompetent: a benefit that the competent but less fortunate in our society often do not enjoy.

When the information is less complex, can less competency, so to speak, be sufficient to consent to research participation? In other words, can a sliding scale of competency be accepted? The answer is "No" because to give consent is the result of a decision-making process which, as discussed earlier, requires a high level of cognitive functioning and full autonomy. Yet what about consent for simple research studies that only ask, for instance, if a chart can be reviewed or whether a blood sample can be taken? Only to look at the information relevant to the specific intervention

is to overlook that consenting is a process. It is required that there be an assessment and appreciation of the costs and benefits and that the prospective subject make a sound decision based on the information given. The decision-making process is distinct from the information given; regardless of how apparently simple the experiment, the subject has to complete the decision-making process in order to give a valid consent. Also, it is arrogant for a researcher to presume that any intervention is simple and harmless from the subject's perspective. For example, if the research protocol included reviewing the patient's chart, the prospective subject could find the intervention embarrassing or distressing. The chart to be reviewed could contain sensitive information to which the prospective subject does not want the researcher to have access.

What is meant by a sound and rational decision? Moral subjects and agents have, respectively, welfare (fundamental) needs and interests which include not being harmed. These basic, fundamental welfare needs (for moral subjects) and rights (for moral agents) are: protection from harm, and the basic goods of education, health service, safe environment and access to legal services. When an individual can not ensure that his fundamental interests are met adequately, then a moral subject depends on moral agents who have an obligation to protect the weak and vulnerable. Actions which hinder or block their meeting, or having their welfare needs

or interests met, jeopardize their well-being. Thus, there is an objective criterion against which decisions and actions of moral subjects and agents can be measured. If their actions promote or maintain well-being and/or do not expose the subject to harm, then their actions and decisions are sound and rational. A competent individual is able to provide for his own needs and protection. Thus, if the decision taken does not interfere with the subject performing these tasks permanently or seriously, then the decision is compatible with ensuring one's welfare interests are met. In the case of a mentally impaired subject, when the decision is transferred to a surrogate, then the substitute decision-maker must be guided by the same criteria.

When respecting the stated wishes of dependent subjects or making a decision that protects the subject's welfare need to be protected from harm, the surrogate is acting in the subject's best interests. A sound and a rational decision is one that can be explained by reasons based upon correct information and an appreciation of the impact of the intervention upon one's lifestyle. Thus, a sound and rational decision can be contrary to the physician's, family's and society's wishes. It is recommended that the answer be based on a correct understanding of relevant information given and an appreciation of the consequences, and also express the subject's values. The decision could be termed authentic, sound or rational. The term authentic is preferred because of its emphasis on expressing the subject's

consistently held values and goals. Also, authentic is preferred because the terms sound and rational imply agreement with socially approved notions about what is rational, that is, to consent to be a subject.

Under ideal circumstances, an individual should make a free decision, uncoerced by others. Coercion takes many forms and, despite the efforts of conscientious health care professionals, it may not be possible to remove completely overt and covert coercion. For instance, research is valued in our society and thus there is a bias throughout society favouring consenting and refusal is regarded as a deviant behaviour. A competent individual can refuse to participate in a well designed study and continue to be deemed competent when the individual bases his decision on correct information and his own particular values and wishes.

It should be recognized that abolishing coercion is not possible but that reducing and managing coercion is a reasonable goal that should be pursued. Coercion occurs on two levels:

(i) General:

Society values certain attitudes and behaviours and rewards individuals conforming to these norms. This type of systemic coercion reflects society's values and reinforces the status quo. For example, the current climate supports health sciences research and encourages individuals to be research subjects. Hence, it is

controversial, if not deviant behaviour to refuse to be a subject.

This type of coercion is usually covert but can be very strong.

(ii) Specific:

This type of coercion that is based on an unequal relationship between prospective subject and the researcher or his representative which preys on the vulnerability of the individual being asked to comply.

Ways of managing systemic coercion fall outside the realm of this study. Suffice it to say that the first line of defence is to be aware of social covert coercion and that the pressure to conform to societal expectations can be challenged. For instance, the aboriginal peoples of Canada are working to change the public's attitude to their demand that native rights be respected and their land claims be settled as soon as possible.

The second type of coercion is also difficult to manage because the vulnerable patient and his caregivers are dependent on the health care system and under such conditions, it is difficult for a prospective subject to refuse to be a subject. For instance, a patient or his family could be asked before the patient's death, to donate some of the patient's brain tissue after he has died, for research purposes. Knowing full well that they will be dependent on the health care system for an extended period of time, it could

be difficult for those patients and family members to refuse. Hence, this type of coercion is incompatible with giving a valid consent.

Also, when information about the risk-benefit ratio is given to the prospective subjects, it is possible that the information given will be biased: this also is a covert form of coercion. If the researcher thinks that the intervention is a mere inconvenience, then it requires a discerning, critical individual to critically appraise the information, sifting out biases.

The requirement that a subject give consent free of coercion was not included in the conjunctive definition because some types of coercion are endemic to society. Thus, the prospective subject can not eliminate coercion but he can learn to recognize and minimize the influence of others. Also, researchers and society have an important role in controlling the second type of coercion. In the next section, guidelines regarding minimizing overt and covert coercion will be proposed.

In summary, the functional approach taken by psychiatrists and lawyers is valuable, but in addition the moral dimension provided by the conjunctive definition of competency to consent to research participation is needed. Consenting to research is an activity having the prerequisite of full autonomy, which is to say critical competency. Thus only individuals with a high degree of autonomy (normal or full autonomy) are eligible for providing consent to participation in research activity. The conclusions that

the prospective subject must have full autonomy and have critical competence to be considered sufficiently competent to provide consent, mirror each other. It was established earlier that full autonomy was required to provide an informed (valid) consent. Therefore, the conclusion, that competency to provide consent requires autonomy and critical competence, is a logical development of chapter three. Also, having deteriorating or diminished autonomy indicates a diminution of critical competency and, therefore the prospective subject is not capable of giving a valid consent.

Both competence and autonomy are on a continuum. To be eligible to provide consent to research requires that the individual have full competence which would exclude individuals with failing and depleted competency. If the conjunctive definition was classified according to the four standards of competency to consent put forth by Roth and associates, it would be compatible with the highest level of actual understanding. Thus, providing consent to participate in a research study is a task that the majority of AD patients can not competently complete.

That the conjunctive criterion protective of prospective subjects is a high standard of competency is admitted. The current trend is to promote the autonomy of vulnerable subjects (Stanley,⁵² Cassell,⁵³ Dubler,⁵⁴

Lynn,⁵⁵). Both the more demanding standard and the trend to favour a less demanding standard share the same goal of promoting autonomy.

Depending on the definition of competency and the standard accepted (constant or sliding) the decision to intervene and switch the ethical priority from protecting autonomy to protecting the vulnerable subject is made at different stages on the continuum of autonomy. The trend is to accept a low standard of competency which is justified by some clinicians and lawyers on the grounds that the remnants of autonomy should be maximized because it is considered therapeutic to maximize the independence of patients losing control over aspects of their lives. Another approach, and the one proposed, is to defend the Alzheimer patient's autonomy and capacity to make certain decisions when he is able to competently make these decisions and to provide aids to maximize his capacity to consent. However, when the prospective subject can not understand the information given and is unable to give a valid consent, caregivers, researchers and health professionals have a responsibility to transfer the decision-making to a surrogate. At this point the risks of permitting the subject to determine what risks he wants to take are too high. To protect the best interests of the subject, a substitute decision maker should be appointed when the subject has less than full autonomy

because if society or researchers wait longer, they fail in their obligation to honour the vulnerable individual's need to be protected from harm.

Surrogate consent is fraught with problems, most notably, how does the surrogate fulfil his duty to honour the mentally impaired patient's previously stated wishes or act in his best interests, as opposed to choosing what he would prefer for himself if in the same circumstances? Another major problem with dependence on surrogate consent is that the MRC recommends that a third party not consent for mentally impaired subjects to be associated with "non-therapeutic" research.

As discussed in chapter two, under current guidelines, a surrogate can not consent for a mentally impaired individual to be a subject in non-therapeutic research because this is considered not to be in the subject's best interests. Only a competent individual is permitted to consent for his own participation in non-therapeutic research. Thus, the conjunctive definition of competency to consent to research would prevent mentally impaired individuals from being asked to make decisions beyond their capacity. However, there remains the problem of how to include mentally impaired individuals in non-therapeutic research. One consequence is that prospective subjects not capable of consenting are prevented from making decisions beyond their capacity. Thus, they should not be asked to run the risk of harming themselves. Another consequence is that the pool of

subjects depending on a third party to give an indirect, valid consent has increased.

Despite these important problems with turning to a surrogate decision-maker, this option is preferable to permitting subjects vicariously to remain in control of aspects of their lives which they are no longer capable of managing. In the following section, recommendations will be made which should minimize some of the problems associated with surrogate consent, and hence make this bitter pill easier to swallow.

5.4: A Proposal for Involving Alzheimer Disease Patients with Non-therapeutic Research:

The purpose of this section is to bring together the insights of the previous sections and present a possible way to overcome the major dilemma facing SDAT research: Can mentally impaired individuals be associated with non-therapeutic research and if so, under what conditions?

The resolution to the dilemma is based on two focal concerns arising in conjunction with experimental design and competency to consent to research. The resolution is built on two inter-related pillars.

(i) Regarding the Ethics of the Experimental Design:

The distinction between therapeutic and non-therapeutic is to be replaced by the general category of health sciences research which

reflects the clinical realities of conducting research on terminal illnesses. Also the regulations regarding the risk side of the risk-benefit ratio are to be made more stringent: mentally impaired subjects should not be associated with any research that exposes them to more than minimum risk associated with daily living.

(ii) **Regarding Consent Mechanism:**

The consent process remains unchanged but the standard of competency is strengthened. The global and bi-polar concept of mentally competency could exclude individuals able to consent to research participation and therefore deprive them of the opportunity to be autonomous. However, more frequently, individuals unable to consent to research are permitted to do so because they have not been deemed mentally incompetent and would not be deemed mentally incompetent if assessed according to the bi-polar model of competency. Competency to consent to research is a high functioning activity requiring a high level of autonomy. Thus, it is proposed that an individual would lose this capacity before being considered to be globally mentally incompetent.

The consequence of having a high standard for competency to consent to research is that fewer prospective subjects will be asked to

consent to participate when this task is beyond their capacities. A related consequence is that subjects still considered competent can be asked to be subjects in “non-therapeutic” research and research classified as above minimum risk. Thus, mentally impaired patients could be in “double jeopardy”. Not only are they asked to perform a task they lack the capacity to perform but the range of activities they are asked to consent to includes both “therapeutic” and “non-therapeutic” research and the level of risk could be high. In contrast, prospective subjects unable to consent to research are only considered eligible (under the strict regulations to be proposed) for clinical research classified as minimum risk. When mentally impaired individuals are asked to consent to research participation, and perhaps also to be a subject in a more than minimum risk study, there is a possibility of harmful consequences. In addition, another consequence is that surrogate consent will be sought more frequently.

The pressing question is whether society and the research community are prepared to adopt a high standard. The high standard, in terms of critical competence, autonomy, responsibility and independence characteristic of a moral agent, will exclude many who have not been declared mentally incompetent. In other words, the general, global classification of mental incompetency is lower than the standard of competency required to consent to research. Abandoning the specific model

and/or accepting a lower standard of competency are an abdication of responsibility to the weak and vulnerable. However, a test should not be chosen because it yields the largest pool of prospective subjects. To do so would be an invitation to use the mentally ill, senile and young children, prisoners and other vulnerable human subjects because they failed to object.

Relying so heavily on surrogates is not the ideal solution. On the negative side, surrogates often do not know the prospective subject's wishes. Knowing what is in the subject's best interest's often translates into choosing what the surrogate would want under similar circumstances. The positive consequence is that the surrogate should be mentally competent and be an advocate for a weak and vulnerable individual.

However there is an ethical and legal problem. Can a surrogate nominate a mentally impaired individual to be a subject in a study offering the subject no promise of direct benefits? The MRC refers to the Charter to support its protectionist position that mentally impaired patients not be involved with non-therapeutic and invasive research and, also that a third party cannot consent for mentally impaired individuals to be a subjects in research offering no promise of benefits to the subjects. Also, we have seen that the MRC supports its recommendations by a reference to the Eve case (discussed in chapter II).

First, the problems about the scope of the surrogate's power with respect to mentally impaired subjects are overcome when it is accepted that

the distinction between therapeutic and non-therapeutic SDAT research is inappropriate and the general category of SDAT clinical research is preferable. As discussed earlier, putting aside this traditional classification system is not a verbal sleight of hand. Instead, having a general category recognizes the fact that SDAT research studying the disease process is not therapeutic for SDAT patients, just as cancer research investigating the etiology and prevention will not impact on the progress of the subject's terminal illness. Also, the distinction should be dropped because it is difficult to know what will be therapeutic from the subject's perspective. A so called non-therapeutic study could be therapeutic to some subjects because they have the opportunity to contribute to society which they value highly. Thus, the notion of therapeutic is ambiguous in the realm of SDAT research, as it is for any research investigating a terminal illness.

If this distinction is replaced by the general one of health sciences or clinical research, surrogates can provide consent for their mentally incompetent wards to participate in research (whether "therapeutic" or "non-therapeutic") on condition that certain strict regulations regarding the design of the experiment and the consent process are followed. Specifically, it is necessary that:

- (i) a valid direct or indirect consent is obtained
- (ii) the risk-benefit ratio be no higher than minimum risk.

The surrogate has the responsibility for respecting the prospective subject's fundamental needs and to protect the individual in question from exposure to excessive harm (i.e. above minimum risk) if consent is given. Thus, when the surrogate evaluates the proposed research protocol he must determine whether the research's design promotes the society's established minimum standard of treatment for the mentally impaired (proposed in chapter four) and protects the weak and vulnerable from risk of serious harm. Therefore, the proposed changes in experimental design and the consent mechanism and, also the established standard of care for mentally incompetent individuals are interrelated and interdependent factors which shape the surrogate's responsibilities.

This resolution of the ethical problem of the role of the surrogate in SDAT research contradicts the MRC's recommendation regarding the use of mentally impaired subjects. If the MRC and the courts decide that the distinction between therapeutic and non-therapeutic research for SDAT patients is inappropriate, a significant first step would be taken to resolving the legal and ethical problems associated with SDAT research. Then, there would be no necessity for the Supreme Court to rule on a precedent-setting case requiring that a surrogate ask for permission to volunteer a ward for "non-therapeutic" research. However, as will be seen, the court's consent

should be sought if the research is classified as above minimum risk (regardless of whether it is “therapeutic” or “non-therapeutic”).

The MRC recommends that the surrogate should not be permitted to grant consent for his ward to participate in non-therapeutic research in order to protect the vulnerable subject from harm and exploitation. Their goals, which should not be sacrificed, are met by the position developed in this chapter. The research subject can be associated with research which offers no promise of benefits (according to the researcher’s objective assessment) on condition that the research does not present a serious risk of harm to the subject’s well-being. In a phrase: no benefits nor costs are anticipated. Thus, the subject’s welfare needs are not jeopardized , or if one prefers to use the language of rights, his inviolable rights to dignity and integrity are not violated.

The MRC supports its protectionist stand by stating in, the liberal tradition, that individual inviolable rights must not be violated. Also they support their position by stating that the Charter has enhanced support of vulnerable individuals. They do not expand this statement but do refer to the Eve case to support their claim that the Charter enhances the rights of mentally and physically disabled individuals. As the analysis of the Eve case in chapter II indicated, the MRC’s indirect reference to the Charter to support their protectionist position by referring to the Eve case can be

challenged. An analysis of the Eve case reveals that the Supreme Court did not accept the respondent's arguments that non-therapeutic interventions are prohibited under section 7. It is paradoxical that the MRC should cite the Eve case to demonstrate that the Charter enhances protection afforded to the mentally incompetent who are prospective research subjects. The MRC has taken a circuitous route to refer to the Charter but nevertheless, presumably the MRC thinks that sections 7 and 15(1) would have a bearing on the question. Yet close scrutiny of the Eve case reveals that the Court (i) did not accept arguments from either side based on section 7 and, (ii) rejected arguments based on the other sections. Instead, the Supreme Court grounded its protectionist stance in the authority of parens patriae which has a long tradition in English common law. Thus, the MRC's oblique reference to the Charter in the context of the Eve case is unhelpful.

A preferable approach for the MRC would have been to refer directly to sections 7, 12 and 15(1) of the Charter and recommend by direct reference to the Charter that the mentally impaired are exempt from non-therapeutic research. However, when sections 7 and 12 are studied, these sections state standards that deem certain types of experimentation as illegal but do not ban non-therapeutic research. Instead, these sections support a focus on whether the subject will be harmed and not whether the

research will benefit or not benefit the subject. The first provision is in section 7 which states:

Everyone has the right to life, liberty and security of person and the right not to be deprived thereof except in accordance with the principles of fundamental justice.

Therefore, a research intervention which endangered any of these values would be in conflict with the Charter. Both therapeutic and non-therapeutic research may violate or respect this section. If the proposed medical research is to be acceptable legally, the research must respect the right to life, liberty and security of person. Thus, section 7 supports society's adoption of a standard of care which protects the fundamental inviolable rights (which can be read, fundamental interests) of mentally incompetent individuals in all circumstances, including the field of medical research. This section also supports the re-framing of ethical issues in SDAT research to be the protection of the vulnerable subject from excessive harm regardless of whether the research is therapeutic or non-therapeutic. The surrogate who has the responsibility of being the mentally incompetent individual's advocate has the responsibility of protecting the vulnerable individual's security of person. Thus, this section also supports the surrogate having the highest standard of competency, in order that he can fulfil this onerous role.

In addition, section 12 also refers to the type of treatment that all individuals should be protected from, under Canadian law. The section states:

Everyone has the right not to be subjected to any cruel and unusual treatment or punishment.

The Law Reform Commission reports that according to current case law, treatment has been read broadly and can include medical research. Therefore, the Commission considers that section 12 is sufficiently broad in scope to protect the experimental subject.⁵⁶ Again, the Charter is not commenting upon therapeutic or non-therapeutic research but on the importance of protecting subjects from exposure to harmful research studies. A non-therapeutic research intervention is not harmful per se. What makes the intervention cruel or harmful is the effect that the intervention has upon the subject and adverse reactions can be associated with either category of research.

Wisely, the Law Reform Commission has made recommendations that could settle the legal arguments and assist the MRC to take a clear, uncontroversial stand regarding the issue of associating mentally impaired individuals with non-therapeutic research. The merits of the Commission's recommendations, that non-therapeutic biomedical experimentation on

mentally disabled individuals should be recognized as a legal activity in a federal statute, will be discussed in the following section.

Although the MRC was criticized by the Law Reform Commission for being unclear about the use of vulnerable, mentally disabled individuals in non-therapeutic research, the same criticism can not be levelled at its firm commitment to protecting the mentally incompetent individual's right to integrity. Can the inviolable rights, to which the MRC refers, be protected when the mentally incompetent individual is volunteered for non-therapeutic research by a third party? According to the Law Reform Commission, the MRC's questioning of the legality of third party agreements to the participation of a mentally impaired and incompetent individual in non-therapeutic research is based upon their concern that the vulnerable subject's right to integrity can be, in effect, subject to waiver by a third party.⁵⁷

The MRC's fears, that the inviolable right to personal integrity will be waived or overridden by a surrogate, is a legitimate one. It is fitting that the Council act as the prospective subject's advocate and raise the issue of protection of inviolable rights (welfare needs or rights). However, the circumstances under which a third party may waive these rights cries for clarification. The MRC proposed that rights are not respected when the surrogate provides consent for non-therapeutic research but are respected

when consent is provided for other research protocols. The MRC has mistaken the act of volunteering a ward for non-therapeutic research with violating the subject of the right to integrity. On the view advocated in this chapter, it is exposure to research having an unethical design or failure to obtain a consent from a competent surrogate which violates the subject's interests. As discussed, particular attention must be paid to the degree of risk associated with the research. Thus, it is formally recommended that the mentally impaired subject not be a subject in research classified (objectively) as higher than minimum risk regardless of the promise of direct or indirect benefits. If the research project fails to respect the subject's fundamental interests, then the surrogate has waived the subject's integrity. If the surrogate fails to take his responsibilities seriously and does not act in the subject's best interests, or is not competent enough to review the protocol, then there is a good chance that the subject's right to integrity is infringed because of a break-down in the consent mechanism.

It is not the act of providing indirect consent for non-therapeutic research per se that violates the right to integrity, but rather the nature of the research with which the ward will be associated. If the distinction between therapeutic and non-therapeutic research is dropped, the ethical priority of protecting the subject would be more clear. To use the language of rights (as does the MRC) the subject's right to integrity will be protected

when the dependent moral (and research) subject's right to integrity is understood to mean he has a fundamental interest in being protected from harm, and having his welfare needs met. Thus, this proposal emphasizes the primacy of non-maleficence when dealing with SDAT patients. Also, the notion of harm has been broadened and thus, research included under minimum risk can be considered appropriate for SDAT patients but would have been excluded according to the bi-polar "therapeutic" and "non-therapeutic" classification system.

This resolution honours the prospective subject's need to be protected from harm and underlines the deontological emphasis on the mentally impaired individual as end-in-itself. For Kant, "man and generally any rational being *exists* as an end in himself, *not merely as a means* to be arbitrarily used by this or that will, but in all his actions....must be always regarded at the same time as an end".⁵⁸ In chapter two, it was proposed that the realm of ends or humanity be expanded to include subjects who even though they lack rationality, continue to have fundamental needs (or if preferred interests). Thus, Kant's practical imperative "So act as to treat humanity, whether in thine own person or in that of any other, in every case as an end withal, never as a means only" would extend to vulnerable and weak individuals. Therefore, all research subjects, regardless of their mental status who are a means to the end of acquiring new knowledge,

should not be treated *merely* as a means. On this view then, rational and non-rational individuals can be used as a means, on condition that they are still respected as ends in themselves. Alzheimer's Disease research which protects the interests of its research subjects respects these individuals as ends-in-themselves. Thus, according to the deontological perspective, it is morally permissible to use mentally incompetent individuals in both therapeutic and non-therapeutic clinical research on condition their needs or if you prefer, inviolable rights are being respected.

Also the notion of respecting has a different character when moral agents are respecting moral subjects lacking rationality. Respect for individuals continues to play a dominant role in determining how rational agents treat moral subjects. Respect is demonstrated in two ways: (i) protect the prospective vulnerable subject from harm by following strict regulations regarding the use of vulnerable individuals as research subjects, and (ii) respond to the subject's indication that he does not want to be a subject, by removing him from the research project. Thus, respect for moral subjects as ends-in-themselves includes acting as a guardian and advocate for the dependent, vulnerable moral subject.

This protective approach grounded in non-maleficence agrees with Kant's understanding of imperfect duties. Kant divided duties into perfect and imperfect (meritorious) duties, and then further divided them into

duties to oneself and to others. A perfect duty could be a universal law but an imperfect duty could not be willed to be a universal law. However, imperfect duties do promote certain goals, for instance, an individual's own development or the happiness and welfare of others. Kant provided two examples of imperfect duties. The first one is cultivating one's abilities which is an imperfect duty to oneself. Kant sees the advantages of a universal law requiring individuals to engage in "enlarging and improving his natural capacities".⁵⁹ The second imperfect duty is benefitting others, which is an imperfect duty to others. It is the latter case which is relevant to this discussion. A man is enjoying a successful life but sees others, whom he could assist, struggling with difficulties. He then asks himself whether their plight matters to him and concludes that "I have no desire to contribute anything to his well-being or to his assistance when in need". He agrees that it would be advantageous if all men agreed to assist the disadvantaged but also admits "it is impossible to *will* that such a principle should have the universal validity of a law of nature".⁶⁰ Nevertheless, in the following passage Kant discusses why the individual should act beneficently towards the needy man. The passage is as follows:

If such a way of thinking were to become a universal law of nature, the human race admittedly could very well subsist and doubtless could subsist even better than when everyone prates about sympathy and benevolence and even

on occasion exerts himself to practice them but, on the other hand, also cheats when he can, betrays the rights of man, or otherwise violates them. But even though it is possible that a universal law of nature could subsist in accordance with that maxim, still it is impossible to will that such a principle should hold everywhere as a law of nature".⁶¹

This is the case because the will would be in the position of contradicting itself "inasmuch as cases might often rise in which one would have need of the love and sympathy of others and in which he would deprive himself, by such a law of nature springing from his own will, of all hope of the aid he wants for himself".⁶²

For Kant, the duty of beneficence is an imperfect duty to others which requires specific actions. More specifically, the duty of beneficence requires an individual to commit himself, through plans and actions to promote the well-being of others. Imperfect duties involve beneficence in the sense that they strive to: (i) remove an evil or danger (ii) prevent harm (iii) provide some benefit(s).

Engelhardt brings to our attention Kant's acknowledgement that arguments for duties of beneficence are based upon the fact that an individual can not consistently will to have no respect for the principle of beneficent. I favour Engelhardt's interpretation that it would be a contradiction in will and not logic.⁶³ Thus, for Kant, duties of beneficence are not perfect but meritorious or imperfect duties.

An imperfect duty is a prudential action in addition to being a meritorious one. When considering the short and long term consequences, the astute individual realizes that assisting the needy is beneficial because at some time he could be in the same position. Thus, the moral individual can will a universal maxim that the disadvantaged should be assisted because the individual does not want to deprive himself of "all hope of the aid he wants for himself" under different circumstances".⁶⁴ To will this maxim is to respect the inviolable rights of man and to treat individuals as ends in themselves, while concurrently acting in a benevolent and beneficent manner towards the needy and vulnerable.

The discussion of imperfect duties which are duties of beneficence can be shown relate directly to Alzheimer's Disease research. First, the work of SDAT researchers to improve the status of Alzheimer patients and to reduce the social costs of SDAT are examples of actions which fulfil imperfect duties to others. Similarly, when society invests resources in supporting SDAT research and the standard of care which protects the fundamental interests (inviolable rights) of Alzheimer patients, this is an example of an imperfect duty. If society was indifferent to the situation of those with Alzheimer's Disease, the door would be open for abuse of mentally incompetent individuals. For instance, these might be treated as research subjects in studies that expose them to excessive harm and fail to

respect their inviolable rights. Or, a society could agree to social policies funding inadequate, unsafe care and, therefore, fail to provide safeguards protecting the dependent individuals from harm. It would be a contradiction in will for researchers and members of the community not to act beneficently to Alzheimer patients in need of assistance which entails protection from harm.

To continue the application of these insights to SDAT research. The majority of reasonable people, if they reflect upon the incidence rates of SDAT and the personal devastation caused by the disease will agree that there is a need to learn more about prevention and management of the disease. To do so has benefits on the micro level and macro level. At the same time, they can appreciate that investigators need to work within limits that respect inviolable rights. Otherwise, under a *laissez-faire* research policy in the future, they or members of their family could end up being research subjects, and treated only as a means to an end or, perhaps, be exposed to excessive harm.

There is a consequentialist element in imperfect duties. The universal maxim to benefit others is meritorious and prudential. When the two alternatives of benefiting or not benefiting others are compared on consequentialist grounds, the former option must offer more benefits than the latter to warrant moral approval. Kant alluded to some of the benefits

and burdens of choosing to act beneficently to others. For instance, the community would have more resources to devote to popular causes.

However, a society would have to bear the consequences of failing to meet the needs of the vulnerable and being an inhumane community if its members do not respond or ignore the probability that one day they may be a vulnerable member of the community. If the pressing needs of the mentally impaired which could be the fate of many moral agents is not responded to, then beneficent social policies designed to protect the welfare of the vulnerable would be in jeopardy if not abolished.

On the micro level, a rise in individualism and a lack of support for respecting welfare needs (or rights) increases the chances that today's prosperous and healthy individuals would be dealt the same hand when it is their turn to be dependent on society. Kant does not discuss in depth the results, on a macro level, of the society failing to adopt a beneficent social policy towards vulnerable members of the society, yet the consequences are predictable. Social policies of neglect or abandonment, as discussed earlier could lead to social disorder and unsafe communities. For example, many health care professionals consider de-institutionalizing mentally ill patients and returning them to the community without a solid community mental health programme was harmful to vulnerable, disadvantaged patients and, also has contributed to the massive social and public health problem of

homelessness in the U.S.A. Social policies paying less attention to how society can assist their citizens, place more value on protecting an individual's positive right to freedom than protecting the weak and vulnerable. It is reasonable to conjecture that in a liberal society, social order would be adversely affected if society's indirect sanctioning of the mistreatment of mentally incompetent individuals became known. The public probably would lose confidence in the research process and the trust established between patients-subjects, health care professional-investigators, caregivers and funding agencies probably would be undermined. Subjects might become scarcer, making it more difficult for researchers to obtain statistically significant results.

If the imperfect duty of benefiting others is practised, then moral agents and society will have a responsibility to respect the fundamental needs of Alzheimer patients. This conduct of individuals and the community, based on the principle of non-maleficence, reinforces the social order and enhances the probability that others who develop SDAT will be treated in a similar, non-maleficent fashion. From the deontological perspective, human subjects whether mentally impaired or not can be a means to an end but not merely a means. Under the proposed guidelines regarding consent and experimental design, mentally impaired subjects would be respected as ends in themselves because the research's design

would ensure that the level of risk is minimal. Thus, the subject is not expected to be exposed to the possibility of being seriously harmed. The consent mechanism which requires comprehensive understanding as the standard of competency, protects the human subject's interests (or inviolable rights according to the Kantian approach). The requirement that the individual who provides the consent must have sufficient competence (comprehensive understanding) to assess the risk-benefit ratio furnishes the feed-back loop between the consent process and the ethics of experimental design.

There are elements of consequentialism and deontology in this account of how the weak and vulnerable should be treated by moral agents, and society in general. These two approaches have in common a respect for the individual and recognize the dependency of moral subjects on agents and the community. Also, both approaches agree that it is in the best interest of moral agents to act in a non-maleficent manner towards the weak and vulnerable. On consequentialist grounds, it can be argued that when SDAT subjects are involved in research that (i) protects their needs, and (ii) has the promise of benefitting others indirectly, then the conduct of the investigator with respect to the society is based on the duty of beneficence, and to the subject, on the principle of non-maleficence. The researcher can not harm the subject without jeopardizing the community's

general well-being to some degree. If the level of protection given to vulnerable individuals were reduced and thus, they were not respected as members of the realm of ends, it would be permissible to expose subjects to a higher level of risk when they are involved in research. However, the cost to society for the promise of benefits would undermine the benefits accrued by the research because the subject's needs (or if preferred inviolable rights) which are inter-related to the society's interests and general well-being, have not been respected.

The combination of a stringent consent mechanism and a change in the ethics of experimental design should protect the subject's needs and assist the researcher and society to meet their respective obligations. Currently, the consent mechanism is tied to respecting the individual autonomy and ensuring that the subject's consent is given freely. In the case of SDAT research, consent should be associated with protecting the interests of the subject, that is protecting the subject from harm. The recommendations regarding design would widen the scope for SDAT research and thereby increase the possibility of more research being conducted that will reduce the morbidity and mortality associated with SDAT. Whether the deontological or consequentialist approach is taken, the conclusion is that those with SDAT who are mentally incompetent can

participate in research if certain strict conditions are met, ensuring that vulnerable subjects are protected from harm.

5.5 Recommendations Regarding Alzheimer's Disease Research:

a) Introduction:

The purpose of this last section is to make recommendations for Alzheimer's research based on proposed resolution of the ethical problem regarding the use of mentally impaired individuals in non-therapeutic research. The analysis of the concept of competency to consent on a theoretical level was the preparation for proposing practical recommendations about how to conduct Alzheimer's Disease research which relies on recruiting vulnerable SDAT patients to be research subjects. It is not proposed that SDAT research should be exempted from the traditional requirements for an ethical design and a valid consent, nor is a special category for SDAT research necessary. Instead, it is recommended that to current regulations there be added amendments addressing the problems associated with using SDAT patients as research subjects.

In the field of SDAT research, so-called non-therapeutic research should be permitted if strict guidelines designed to protect vulnerable research subjects are followed. The proposed strict regulations are designed to protect the welfare needs (or if preferred the inviolable rights) of SDAT

subjects and at the same time, to place a check on the possibility of coercing vulnerable subjects and members of their support network, who are also in a vulnerable position because they are also heavily dependent on the patient's treatment team. It is reasonable to suggest that the pressing need for research will increase as the incidence of SDAT continues to rise, and thus the pressure to co-operate and be a research subject will also increase.

At the beginning of this chapter, three possible responses to the question of whether incompetent SDAT patients may be subjects in non-therapeutic research were proposed: absolute ban, minimal restrictions, and permitting this type of research on condition that strict rules protecting the subject were observed. The option preferred is the third one because this facilitates the participation of SDAT patients in research under the protective umbrella of strict standards. It remains to present and discuss the strict regulations needed to ensure that vulnerable SDAT patients are respected when associated with health sciences research.

My recommendations have a number of objectives based on the work in this chapter regarding changing the classification of SDAT research and adopting a higher standard of competency in respect to consenting to be a research subject. The ethical priority is to protect a vulnerable SDAT research subject. Secondly, the guidelines should assist researchers to design research which respects the vulnerable subject's welfare needs (or if preferred, inviolable rights) and also, to obtain a valid direct or indirect

consent. Also, the guidelines will benefit researchers and society because the scope of research permitted is expanded in tandem with stricter restrictions regarding the risk-benefit ratio. The recommendations regarding the type of research to be permitted should serve to protect the subjects from being harmed when associated with research previously prohibited.

In preparing these recommendations I found it useful to draw upon the Law Reform Commission of Canada's most recent working paper, Biomedical Experimentation Involving Human Subjects, (December, 1989)⁶⁵ and the Ontario Guardianship and Advocacy Review Commission's Report (called the Framm Report after the chairman of the commission, Steven Framm).⁶⁶ The Law Reform Commission's (LRC) reviewed legal statutes and ethical guidelines in Canada and other countries and found that the most difficult ethical and legal problem, for research using mentally incompetent subjects, is whether or not they should be subjects in non-therapeutic research. The LRC Commission stated that legal rules regarding biomedical research are necessary, because on rare occasions human research subjects are hurt and exploited. Thus, to protect the rights of research subjects who are the unequal partner in the subject-investigator relationship, and also to enhance protection of the integrity of vulnerable members of the community the LRC Commission recommended that legal

statutes regarding research practices should be introduced. The

Commission stated in their conclusions:

A multidisciplinary approach involving law, ethics and medical science is required. However, it is for the law, in the form of legislation, regulations and judgments, to set the limits of what is socially acceptable in this area. This is a public responsibility that the state may not evade. Despite the integrity and keen professional sense of Canadian researchers, human experimentation cannot be viewed as a purely medical question in which the law has no role to play.⁶⁷

The low incidence of subject abuse, it stated, is not sufficient reason to refrain from instituting legal protection. In the opinion of the Law Commission, the fact that there have been few cases of research harming subjects is not a good argument for not providing research subjects with legal protection, if for no reason other than that after the damage is done, it is too late to establish laws regarding how subjects are associated with research. As an aside, the incidence of other types of abuse (for example, abuse of the elderly, children and women) is under-reported. Hence, it is reasonable to assume that the incidence of subjects' autonomy not being respected and subjects being harmed is under-reported. Also, the fact that SDAT patients are often located in one location, an institution, without a guardian constantly with them in combination with their health status, makes the SDAT population highly vulnerable to coercion and being harmed. The conclusions of the thesis would support providing the weak

and vulnerable with maximum protection and thus would be in agreement with the Law Reform Commission's recommendations regarding establishing legal protection for research subjects. The Commission argued that it could not afford to ignore the possibility of abuses occurring in Canada. The Commission pointed to the fact that the so-called Cameron affair at McGill University's Allan Memorial Institute continued unreported for a number of years to demonstrate that abuse of mentally impaired research subjects can occur for years before being halted even when there are regulations and monitoring mechanisms in place. Also, there are no data to indicate how many studies do not follow research guidelines. In the Commission's words "Where the integrity of the person can legally be endangered, it seems important that limits and rules be clearly defined. It is up to the law to protect basic values, and it cannot and must not leave this role to ethics....There are also many (researchers) who consider that the rules and the parameters within which they are to work should be defined so as to indicate what the limits are to be observed".⁶⁸ These proposed recommendations to be proposed regarding how to conduct SDAT research are a response to the Commission's remark that guidance is needed regarding the limits to be placed on research, in this case SDAT research. Hence, the guidelines could assist both researchers and the legal community prepare legal statutes to protect weak and vulnerable subjects.

The Law Reform Commission's recommendations that regulations regarding the use of mentally impaired individuals in medical research should be brought under legal jurisdiction (as opposed to being recommended by MRC Guidelines lacking legal force) is still under discussion and it is fair to say that the recommendation is not well received by many in the research community who prefer the MRC's approach and cite that there are not enough cases of research subjects being harmed to warrant the law's intervention.⁶⁹ In reply, the Law Reform Commission takes the position that research like other activities which can cause serious harm to humans, including harm to their dignity, should be under the jurisdiction of the legal system.

b) Recommendations:

These recommendations propose that clinical research (therapeutic and non-therapeutic) and the use of Alzheimer patients (regardless of their mental status) should be done in accordance with the following strict guidelines based on the principles of non-maleficence, beneficence, autonomy and justice.

- (i) The research design does not present any known serious risk for the research subject (i.e. not above minimum risk).

- (ii) Alzheimer's patients involvement in research should be restricted in respect to:
 - (i) the type of research (not above minimum risk) and
 - (ii) frequency of participation.
- (iii) A valid consent is obtained from:
 - (i) a subject who is competent to consent to research, that is understands the consequences of consenting, or,
 - (ii) from a surrogate decision-maker (e.g. next of kin). When surrogate consent is necessary, consent must also be given by an independent third party.
- (iv) Competent patients should be encouraged to appoint a person with durable power of attorney (DPA) to make decisions regarding research participation (in addition to other personal matters and financial affairs). The patient should communicate his preferences and values to the DPA.
- (v) Health care professionals providing care to the affected patient and/or his caregivers should not ask these individuals to be research subjects or to give surrogate consent for research participation.
- (vi) A subject's refusal to participate (e.g. any indication of lack of co-operation) should overrule a previous consent by the subject, surrogate or independent third party.
- (vii) When a substitute decision-maker is unavailable, a Public Trustee or Guardian for personal affairs should be appointed. This specially trained, independent individual has the responsibility of being an advocate for the patient's best interests.
- (viii) All research involving Alzheimer patients should be reviewed by a Research Ethics Board (REB).

The proposed recommendations call for discussion. However, before each recommendation is commented on, some general comments are necessary. The purpose of the above regulations is to insure that society and researchers meet their respective obligations to society in general, SDAT patients and, also SDAT research subjects. Hence, research legally (and morally) seeks to realize its goals of acquiring knowledge that will contribute to improving individual health and the community's welfare. Another goal is to respect the fundamental welfare needs of SDAT patients when they become research subjects. To use the language of rights, the recommendations respect the rights of SDAT patients to respect, dignity and integrity and to be protected from situations carrying an unacceptable level of risk to their well-being. Thus, vulnerable research subjects are protected from being treated exclusively as a means to an end, albeit an end that could benefit society.

The first recommendation is extremely important when for example, the research subjects have Alzheimer's Disease and could be associated with non-therapeutic and therapeutic research. This recommendation has special relevance when the level of risk replaces the standard classification of therapeutic or non-therapeutic research. Recalling that there are a minimum of two levels of assessment, objective and subjective, this recommendation refers to the experiment's design advanced by the researcher.

A brief look at the process for determining the risk-benefit ratio will demonstrate that assessing risk and benefit which is difficult at the best of times, is especially complex in the field of SDAT research. As discussed there are three levels of assessment:

- (i) objective assessment completed by the research team
- (ii) objective assessment by an Research Ethics Board
- (iii) direct subjective assessment by the subject or indirect assessment by surrogates.

If the subject is mentally impaired, there will be four distinct assessments:

- (i) researcher
- (ii) Research Ethics Board
- (iii) surrogate
- (iv) independent third party

The researcher and REB must agree on the ethics of the protocol and the surrogate and the independent third party have to agree to consent. If the REB suspects the proposed research fails to respect the fundamental needs of the SDAT patients, the research may be blocked. At the next level, if the independent third party or the surrogate (usually a next of kin) has reservations about the proposed research, consent is refused.

Regarding benefit, so-called non-therapeutic research offers no promise of indirect benefits to the subject in terms of influencing the progress of SDAT. However, the subject could find a direct benefit (e.g. fulfils his sense of civic duty, allows him to be away from a noisy ward). Given the fact that non-therapeutic research offers no promise of direct, objective benefits to the subject, the degree of risk that the subject can be exposed to is limited, despite the potential of indirect benefits offered by the research. The proposed limit of exposure to risk is minimum risk defined, by the President's Commission, in the U.S.A. to mean "that the risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examination or tests".⁷⁰ (The difficulties with these measurements with the elderly population were discussed in chapter four). The researcher has an obligation to vet protocols and the subject should not be placed in the position of having to evaluate research protocols that are unethical, that is, protocols having an unacceptable level of risk (i.e. above minimum risk). There is a threshold beyond which risk should not transgress. Thus, there is agreement that research that could lead to death, permanent and/or serious physical and/or psychological harm should not be permitted no matter how low the possibility of harm. The surrogate has the difficult task of evaluating the risk-benefit ratio for the vulnerable subject and deciding

what is in the subject's best interests (as distinct from what he would choose for himself under the same circumstances).

In addition, the task of classifying risk is difficult because Alzheimer's research is in its early days and there is not a large body of knowledge to draw upon when assessing risk. For instance, a medication might have been used with success on a young population but there is little known about its effectiveness with a geriatric population. Secondly, classifying risk is difficult because predicting how subjects will respond to an intervention is less certain when the subject has SDAT. For example, the research intervention of a CT scan could be classified as mere inconvenience because it is known that the scan does not contribute to physical harm and there are no known side effects. However, for some SDAT subjects, having a scan is a source of great anxiety and it may take a number of days for the patient to cease being labile and restless. Also, frequently the level of risk for a specific research subject is not be known until the subject receives or after he has received the intervention. The same can be said of other populations but the situation is exacerbated with Alzheimer patients because it may be more difficult to prepare the subject with impaired mental functioning for the research intervention. Also, the subject may be unable to formulate or express questions or his concerns before receiving the intervention. Then, afterwards he can have similar

problems communicating the side effects. An unstable patient who is more confused and anxious after having a CT scan may have a number of co-existing problems that mask the side-effects: he may lack the ability to understand why he has deteriorated or the capacity to communicate his reactions. Anyway, the side effects may be attributable to the normal progress of the disease. In addition, as mentioned previously, coercion can be very strong and the subject or surrogate, although reluctant to consent, can be too intimidated to be unco-operative at any stage in the research.

Thus, individual assessment of patient's responses before, during, and after the intervention should be mandatory. Any indication that the research poses or threatens to pose above minimum risk should be sufficient reason to re-evaluate the involvement of the subject.

There is some evidence, albeit only anecdotal evidence but well presented by R. Ratzan, indicating that elderly individuals do have a different perception of risk. The higher incidence of mortality and morbidity in their age group has led many elderly individuals to lead more protected lives and, therefore reduce the possibility of accidents and illnesses. Ratzan's work emphasized that the subjective assessment must take priority over objective assessment of the risks and benefits.

However, there is another variable which has to be considered and that is the effect on an individual of learning he has a terminal, debilitating

illness such as SDAT. There are many examples of individuals evaluating their values and plans, after learning that they have a terminal illness. Having a terminal illness could prompt a patient to avoid risks and seek to make his life as comfortable life as possible. Or a cautious individual could adopt a cavalier attitude to risk on learning that he has SDAT. For others, the desire to make an altruistic contribution to society could over-rule a life long history of scepticism about the merits of medical research.

The second recommendation should protect the vulnerable subject from being a subject too many times, in addition to protecting them from association with above minimum risk research. Once it is permitted to involve SDAT patients in low risk clinical research, it is permissible for them to be subjects in SDAT and other research projects that have an acceptable ethical design. However, it is necessary to have a check on the number of times SDAT patients are research subjects because the population is a cheap, desirable and convenient pool of subjects. Thus, the recommendation should protect the SDAT patient from being harmed by frequently being a subject. In addition to frequency, the requirements of the research have to be considered. Some low risk projects can be more demanding than others.

This recommendation disagrees with the first recommendation of the Law Reform Commission which recommended that when vulnerable

subjects are employed, the research should be in close direct relation to their illness.⁷¹ The rationale for the LCR's recommendation is to prevent disadvantaged individuals from being subjects frequently, and thus being harmed. Once it is permissible to use SDAT patients in research in low risk research under strict conditions, it is illogical to restrict their involvement in research exclusively to SDAT research. Nevertheless, the issue identified by the Commission is an important one and must be addressed. The proposed second recommendation is meant to prevent the disadvantaged from being exploited by being involved in too many studies.

The third recommendation refers to the standard of competency to consent to research and the procedural constraints required in order to give a valid consent. The subject or surrogate must appreciate the consequences of the decision and volunteer freely. The difference between theory and practice has to be addressed in the application of this recommendation. The preferred standard would be the one of comprehensive competency discussed in a previous sub-section. In philosophical terms, this standard requires that the moral agent have full autonomy and critical competency. In clinical terms, the subject would be an independent, autonomous individual with sophisticated reasoning abilities, comfortable dealing with abstract concepts, competent at decision-making and capable of managing coercion from society, and, some clinicians and researchers.

What would be the consequences of adopting this high standard in the clinical setting? Granted that few would meet this standard, it is reasonable to expect that this high standard would not be well received. Whether society wants to accept this high standard is a social policy decision made after considering the benefits and costs of having a high standard. The reasons for having a strict standard that grants protection to vulnerable research subjects have been presented. However, if society does endorse the conjunctive definition based on the basic tenets that a valid consent is grounded in an appreciation of the consequences of consenting and that the decision reached is ethically sound rather than merely socially beneficial, subjects' interests would be better protected. Thus, if necessary, the third standard of competency (rational manipulation of information) could be accepted as a second best standard on the condition, stated above, that the decision reached was a sound one. The standards of evidence of a choice, not merely knowledge of the facts about the research, are unacceptable because they permit individuals to decide whether to be a research subject when they can not appreciate the consequences of their decision. Hence, if the standard is to be reduced, it should go no lower than the standard of manipulation of the information which is an inadequate description of the consent process.

The goal is that competency will be assessed objectively by clinicians trained to assess competency. It goes without saying that the term “objective” needs to be tempered with the knowledge that the decisions of clinicians, lawyers, judges are influenced by their experiences and values. It is not possible to eliminate the influence of personal experience, biases and values, perhaps operating at an unconscious level. However when consistent assessment criteria are used, it is possible that more decisions will be reflective as opposed to reflexive, and also, that biases will be identified and minimized. In addition, it is recommended that assessments of competency be identified as a special skill and that assessments be conducted only by clinicians with special training.

Another goal is that clinicians will employ consistent standards and base their decisions on sound evidence. The assessment should extend over a period of time as opposed to the “snap-shot” approach which denies many Alzheimer patients a fair and adequate assessment. The mental functioning of SDAT patients can fluctuate from day to day and even during the day. For instance, many affected patients function better in the morning and decline during the day. Frequently, confusion is worse during the evening (this phenomenon is called the “sundown” effect). Hence, a prospective subject could agree to be a subject when asked during the evening, without appreciating the consequences of his decision.

These recommendations governing classification of competency and assessment require changes in health sciences and legal communities. As recommended earlier, research directed at developing assessment tools for specific competencies is required to assist clinicians assessing competency. The result will be greater consistency in testing which in turn, results in a more just assessment process for affected patients. Although not eliminated, the role of reflexive and intuitive decision-making would be significantly reduced. Patients, researchers and clinicians would benefit from the institution of more standardized assessment tools and appeal process. They should function to prevent affected patients incapable of consenting to research, making decisions beyond their abilities and thus, perhaps unwittingly exposing themselves to harm.

The recommendation to use an independent third party to supplement surrogate consent for the participation of mentally impaired individual in non-therapeutic research has been made by the Canadian Law Reform Commission in their recent working paper. The Commission recommended that in this particular circumstance, "the consent of the incompetent person's representative and of an independent third party (a judge, an ombudsman or the incompetent person's lawyer) is obtained".⁷² Both the next of kin and the independent third party must agree. Either

party can veto the other and thus the next of kin can not be over-ruled by the ombudsman.

Advantages accrue to the subject if an independent third party is involved in the consent process. The individual assigned the role of ombudsman would have the advantage of having experience in assessing protocols and should be prepared to intervene to protect the subject's best interests. Hence, the prospective subject enjoys the benefit of a qualified advocate experienced in evaluating the merits of the research protocol and relevant legal issues, and in addition, will intervene to protect the subject from being harmed. Also, the ombudsman's presence should reduce the likelihood of coercion on the next of kin. Furthermore, for some family members finding the role of surrogate to be onerous, the ombudsman may be a source of information and support.

The fourth recommendation proposes a way of assisting prospective research subjects express their wishes known in advance and have them respected should they become incompetent to consent to research. Currently, the Public Trustee only has jurisdiction in respect to financial matters and thus would not be empowered to decide whether a mentally incompetent subject should be associated with medical research. Thus, mentally impaired patients (deemed mentally incompetent) need to appoint a Durable Power of Attorney (DPA) and invest the DPA with a wider range

of powers including personal matters as well as health-care needs, in addition to financial matters. Therefore, it is recommended that the powers of a DPA be extended to personal matters, as well as health care needs and financial affairs. The Framm Commission of Ontario has recommended that such a position be established in the best interest of individuals unable to make sound decisions in respect to some or all personal care decisions.

It is preferable that the individual appoint his own DPA as a public trustee for personal matters and communicate his wishes to the DPA.⁷³

First, the Alzheimer patient chooses whom he wants to act on his behalf when he is competent to make this decision. This individual can be a family member or the responsibilities for decision-making can be shared. When appointing the Durable Power of Attorney, the affected patient should explain to the attorney his wishes in detail but also, his goals and values. There may be circumstances in which the office of DPA and the family should be separated in the best interests of the patient. The decision to appoint a DPA is wise when SDAT patients do not want their next of kin to have durable power of attorney for personal and/or financial matters. The patient may suspect that their next of kin will not be able to make important decisions on his behalf because the next of kin does not understand and/or respect his wishes and values. Or the Alzheimer patient may fear that the spouse is susceptible to being coerced by health-care

providers, other family members, and friends. For example, Mr. Jones has long been sceptical of the merits of research and knows that his wife will have a hard time saying "No" to researchers. Furthermore, his children who are doctors will also pressure her, and she will be unable to resist their coercion. To save his spouse the stress of being in conflict with their children and to ensure that his staunch, albeit socially unpopular wishes, are respected, he may appoint a DPA.

The fifth recommendation also addresses the problem of coercion. The opening statement of the Nuremberg Code and all other research guidelines state that the cornerstone of research is an informed consent freely given. In addition, the subject should be free to withdraw in the future without fear of penalty.

As was discussed earlier, the consent process is inherently an unequal relationship and, therefore, coercion is woven into the process. The researcher and/or whoever seeks consent has the responsibility to moderate the inequality of the relationship and create a situation in which the prospective subject feels confident to refuse. There needs to be a recognition of the pervasive problem of coercion by researcher, patients, caregivers, and clinicians. When the problem is acknowledged, events and situations which reinforce the unequal nature of the relationship can be identified and measures incorporated to modify the discrepancy in roles. A programme to

reduce coercion and to penalize those using coercion should be instituted. Ombudsmen, research ethics review boards, hospital administrators, health care providers and/or the Alzheimer Society could be subject advocates and intervene when coercion is identified or reported.

Regarding who should recruit subjects, there are three choices:

- (i) member of the treatment team
- (ii) member of research team
- (iii) independent third party

As discussed, often the health care professional and the researcher are the same and these roles should be disentangled. It is preferable that neither party seek consent because of the possibility of coercion. However, it is unlikely that resources will stretch to cover the cost of an independent third party. Then, the researcher (wearing his own hat, not the health care professional's hat) should seek consent.

In most cases, when the health care professional or the researcher asks for consent, there is coercion to consent. Thus, it is a case of choosing the more attractive option. When a member of the treatment team seeks subjects, as discussed, the patient and family can easily feel coerced because of their dependency on the health care professional. Also, if they do refuse, they will continue to see the health care professional which could be uncomfortable if a refusal to consent has soured the relationship. If the

researcher or member of the research team seeks consent they could coerce the prospective subject by presenting the relevant information in a biased manner. However, the fact that the researcher is not part of the treatment team, and hence, probably will not have much influence over the patient's life, makes it easier to say no to the researcher than a member of the treatment team. Neither the first nor second option is desirable but the second one is better than the first choice of someone involved with the patient's care.

Thus, it is recommended that the subject's health-care providers not be allowed to ask their patients to participate in research because the patients have a highly dependent relationship on their treatment team and, in most cases subjects would be coerced. Of the two relationships, patient-health care provider and subject-researcher, the former one should be accorded priority and any action which carries a risk of jeopardizing the relationship (e.g. asking a patient to enter a research study) should be avoided. The health professional's primary moral obligation is to provide care for patients based on the principle of beneficence, and this value must dominate when there is a conflict between therapy and research.

The sixth recommendation states that subject's refusal ranks higher than the consent of a surrogate or advocate. The basis for this recommendation is respect for persons. If the prospective subject refuses

(which may be verbal or non verbal, such as refusal to participate), this primitive, clear message should not be ignored or over-ruled. A caveat of this recommendation is that subjects should not be physically nor chemically restrained in order to ensure that they comply with the research protocol. For instance, returning to the CT scan example, if a mentally impaired Alzheimer subject becomes agitated and unco-operative when he sees the CT scanner, he should not be sedated and/or physically restrained to ensure that the scan be taken.

A refusal can be queried but this should be done in a sensitive manner because the overt and covert goal should not be to change the subject's decision, but instead, to ensure that the subject has received relevant and correct information or to learn whether environmental factors, which can be altered, are not the reasons for the refusal (e.g. noise, heat, attitude of research team members). To overrule a refusal, when the subject is mentally incompetent demonstrates a lack of respect for the individual, who although lacking in autonomy and moral agency, is able to express a preference. Also, any doubt about the subject's expressed wishes, should be presumed to be a refusal.

The seventh recommendation addresses the possibility that an Alzheimer patient does not have a next of kin or durable power of attorney and has not appointed a lawyer to act on his behalf. Under such

circumstances, the responsibility for substitute decision-making would fall to a legally appointed guardian, for instance, an administrator of the institution where the patient resides. In jurisdictions where there are Public Trustees for personal affairs, the responsibility would be transferred to this public official.

Here we are operating in the world of second-best. When neither a next of kin nor a durable power of attorney is available, individuals with no prior knowledge or limited knowledge of the patient become substitute decision-makers (SDM). Given these limitations, the goal is to establish guidelines regarding who the SDM can be, in order to protect the prospective subject from having his fundamental needs neglected or ignored. The guardian concerned with personal matters, including whether the ward should be associated with a particular research study, should be an independent third party, not affiliated with the agency or health care providers attending to the patient. Thus, the guardian should be prevented from having a conflict of interest with any member or members of the health care system or the research team.

The Ontario Guardianship and Advocacy Review Commission proposed that an office of guardians be instituted and advocates be appointed in order to protect individuals incapable of making personal care decisions. In the case of Alzheimer's Disease research because the

prospective subject has lost liberty and autonomy, the focus is now on protection from harm. The recommendations of the Framm Commission with respect to guardianship can be of assistance in planning the responsibilities of an advocate for a prospective Alzheimer research subject. The duties of guardians, attorneys for personal care and substitute decision-makers recommended by the Framm Report are:

- (i) to exercise powers diligently, in good faith and for the benefit of the person who is incapable
- (ii) to make decisions that there is reason to believe that would be made by the person who is incapable, if capable based on the intentions expressed when capable, and the present wishes, and where this is not possible, to make decisions that promote the well-being of the person who is incapable
- (iii) to encourage the person who is incapable to participate in decisions to the best of his or her abilities.⁷⁴

The Framm Commission's recommendations regarding the decision-making responsibilities of the Trustee could apply equally well, in the event that the Trustee is making a decision about research consent. The goal of an authentic decision made by a surrogate which is "a decision taking into account the values of the person who is mentally incapable. In some cases, where an individual has never had mental capacity or where the decider has not personally known the individual and there are no family members to assist in an understanding, authenticity will be unattainable. However,

by striving for authentic substitute decisions, the Committee believes that it will be working towards achieving respect for individual differences".⁷⁵

The Framm Commission identified an immediate need for the establishment of an office of guardians and the appointment of public guardians or trustees for personal affairs. The report stated, "There is a critical need for the establishment of a public office to serve as a safety net for persons who are mentally incapable who are without family and friends to act for them when making necessary personal care decisions".⁷⁶

Consenting to research participation is a personal care decision which should be made by a Public Trustee for personal affairs recommended by the Commission. Currently, in many jurisdictions, Alzheimer patients in addition to other mentally incompetent individuals "fall between the cracks" because there is no public trustee or ombudsman to act in their best interest. The report of the Framm Commission was favourably received by health care providers, but to date the recommendation regarding a Public Trustee for personal decisions has not been implemented.

There is a pressing need for legislation instituting this public office of guardianship in order to protect the weak and vulnerable in all aspects of their lives. An advantage of having a Public Trustee is that a surrogate, considered to be neglecting his responsibilities, may be reported by social agencies and private individuals to the Public Trustee office. Thus, for

instance, suspected elder abuse or failing to act in the patient's best interest or follow the patient's stated wishes could be investigated. Thus, more protection is offered to vulnerable individuals. The Framm Commission recommends that evidence be presented to the office of the Public Guardian and Trustee and if an investigation establishes wrong-doing, a court-ordered guardianship would be appointed. Thus, mentally incompetent individuals would be provided with protection from harm. Among other responsibilities, the Public Guardian or Trustee would provide consent for research in place of a next of kin found to be incapable of providing a valid consent.

The difference between the Law Reform Commission's and the Framm Commission's recommendations is that the Public Guardian works independently and does not share the decision-making regarding personal matters with a next of kin. With the appointment of Public Trustee serving the role of an advocate or ombudsman, there is a risk that the government appointee could be biased in favour of research and fail to appreciate the risks associated with the research for the particular individual. In short, the Public Trustee could be an unofficial recruiter for the researchers or miss the input of close family members regarding the values and habits of the prospective subject.

The independence of the Trustee can be protected by regulations regarding the appointment and the terms of reference of the position. The

possibility of problems with appointing an independent Trustee is outweighed by the problems associated with not appointing a Trustee. Safeguards in the form of checks and balances can be instituted to monitor the system in order to ensure that the mentally incompetent person's best interests and/or stated wishes are being respected. Although the plan is not flawless, with adequate safety checks it offers the prospective subject protection from the excesses of researchers or poorly designed research. If the goals are clear, the role is monitored, and changes introduced as necessary to ensure that the Trustee can fulfil his responsibility to act in the best interests of the subject, then this is a better response than not instituting the office for fear of possible problems that may arise. The independent third party, qualified in legal and medical affairs offers the prospective subject protection when he would otherwise have little or none.

When dealing with the question of research consent the Trustee should be guided by the codes of research ethics, the MRC Guidelines and existing government legislation. Thus, in Canada, the Canadian Charter of Rights and Freedoms, should influence both the Trustee's and the next of kin's decisions. The Framm Report advises that "consideration of the value given expression in the Charter must inform any review of the law relating to substitute decision-making".⁷⁷ Specifically, sections 1, 7 and 15 could guide the Trustee because these sections concern equality before the law,

the right to equal protection and benefit of the law and universal rights of right to life, liberty and the security of person. Thus, the next of kin and a Trustee may not consent to any activity, no matter how bountiful the benefits to society, that violates protections provided by the Charter.

The eighth recommendation refers to scrutiny of the design of the study and the consent mechanism. The goal is to protect the prospective subject from involvement with research that has not met the standards of an ethically designed protocol. In addition to protection of the subject, the REB should check the ongoing progress of research projects, and play a role in educating researchers about the requirements for an ethical design and a valid consent. Research guidelines and the society's laws should be observed when designing a research study. When human subjects are involved, research proposals should be checked for their compliance with professional, conventional and legal regulations. In Canada, research not funded by public funds and not conducted at a teaching institution or agency does not have to be reviewed. For instance, a clinical trial of a medication financed by a pharmaceutical company working directly with family physicians could avoid being reviewed. The process of research ethics review offers a mechanism for identifying unsafe and unethical research and provides protection for vulnerable subjects.

This recommendation supports the excellent recommendations made by the MRC regarding the terms of reference and membership of an REB which are designed to ensure that proposed research is reviewed effectively and fairly. Currently there is no quality control of the decisions of REB's. In other words, there are no evaluations of their work and thus, efforts to address significant differences in performance can not be identified or addressed. In particular, I support the MRC's procedural recommendation that REB's have members of the public on their boards. In addition, a patient or care-giver representative and a member of the Alzheimer Society would be an asset when an REB is evaluating SDAT research.

5.6 Summary:

Although Roth, Appelbaum, Meisel and Lidz provided functional definitions and described the behaviour of competent individuals, the normative question persists: Why is a higher or more demanding standard of competency preferable to a lower one, for instance the standard of evidence of a choice? The concept of competency has to capture the *meaning* of "competence" in addition to *describing* the behaviour of a competent

individual. To meet the conjunctive criteria, the individual is required to have full autonomy or the capacity called critical competence by Haworth. Thus, the autonomous, moral agent can evaluate information, consider his circumstances and make sound decisions which reinforce his autonomy and moral agency.

To accept a lower or adjustable standard, is a morally regressive move because it exposes the subject to harm and is not based upon the principles of beneficence nor justice. Contrary to some arguments put forth, having a more relaxed definition of competency does not support autonomy. For a counter argument to the relaxation, the reader is referred back to the view of autonomy based on deontological and consequentialist arguments put forth in chapter three. There it was maintained that independent moral agents have an obligation to protect the interests of dependent moral subjects, particularly vulnerable research subjects.

If one proceeds with the weaker sense of autonomy, a situation may arise when the either-or model will be resorted to, in which a SDAT patient:

- (i) lacks the capacity to consent to research, and
- (ii) is considered mentally competent.

In this case, the patient would be permitted to consent to an activity when he lacks the capacity to appreciate the consequences of consenting. The situation is morally regressive because the patient's welfare needs are more likely to be protected by an individual incapable of giving a valid consent. Thus, the prospective subject is being influenced to consent to research which is not in his best interests. It is important that the "specific" competency of being capable to consent to research participation be delineated to facilitate a separate assessment of the patient's capacity.

Codes of research ethics, standards of care for Alzheimer patients, legal statutes and social policy should be based on the conclusions reached at the theoretical level. If there is a compromise between theory and practice, the reference point for what ought to occur is the moral plane. Throughout this study, it has been seen that each level has a different terminology. For instance, on the theoretical level, it has been proposed that SDAT patients lacking autonomy and critical competency are dependent moral agents having fundamental needs and do not have rights because they no longer are autonomous moral agents. However, in the public and clinical domain, the language of rights embraced in our society is preferable and should be used. Thus, SDAT patients said to be mentally incompetent have inviolable rights to dignity and integrity because these are terms which are part of the lingua franca of our society. To not use the language

of rights on the practical plane is to further compromise the vulnerable status of SDAT patients.

The proposed recommendations could be added to existing regulations regarding medical research involving human subjects and would serve to protect SDAT research subjects. In addition, these regulations will protect caregivers who may find themselves as either research subjects themselves or being asked to be substitute decision-makers. These recommendations also can be used in other fields of research employing research subjects who are vulnerable and/or mentally incompetent, such as paediatric research and research involving terminally-ill patients.

As discussed in chapters two and four, there has not been a hard case of surrogate consent for non-therapeutic research before the Courts and the Eve case decision should deter one from being presented. The resolution proposed would respect individual rights and freedoms guaranteed in the Charter and also, permit researchers and society to fulfil their respective obligations. Thus, if these recommendations were adopted, in addition to current regulations, it would be possible to conduct SDAT research prohibited by current regulations because the proposal does respect a mentally incompetent person's fundamental needs or, if one prefers, honouring universal rights and equality as guaranteed by the Charter.

A number of ethical principles guide conduct in SDAT research and the ranking of these principles varies depending on the stage of the disease. Alzheimer's Disease has three general stages of early, middle and late, with different characteristics. The flux in a patient's clinical status results in a different set of ethical priorities. During all stages, the clinical goal is to maximize abilities and provide a safe environment. Judgement calls have to be made about the number, and level of risks that are permissible ethically, and that the patient will be allowed to take. The dilemmas that ensue are familiar to parents: how much freedom do we give before we intervene to prevent the child from being in a dangerous situation?

On the continuum of autonomy and competency, at some point the patient will be deemed unable to consent to be a research subject. Until this point is reached, the emphasis is on assisting patients to maximize their autonomy. I say assist, because the researcher should allow for aids that will help the prospective subject understand and appreciate the information given. Ratzan and Melnick have made excellent clinical suggestions regarding aids that can help an individual with poor concentration, and visual and hearing problems. For instance, they recommend large print consent forms, consent forms written in layman's terms, two-part consent

forms, allowing a “cooling off” period between consent being asked and given. These aids having the function of maximizing the ability to comprehend and appreciate the information given could be used with other prospective subjects.

At some point on the continuum, the patient will be able neither to comprehend the essential information nor make a decision, and at this time, the goal changes, from maximizing and respecting autonomy, to protecting a vulnerable subject. Also, at this juncture, the ethical priorities change. When the subject is capable of consenting, the priority is respect for autonomy, followed by the principles of beneficence, non-maleficence and justice to which equal importance is assigned. However, when the patient has become dependent on others, the principle of non-maleficence ranks first, with the principles of beneficence, justice and autonomy occupying the second rung. Depending on the standard of competency chosen, the line, so to speak, is drawn in a different place on the autonomy continuum. The conjunctive definition requiring full autonomy is at the high end of the continuum. The global standard of mental incompetency, would be lower on the continuum. Assent or evidence of a choice would be low on the continuum. The recommended conjunctive definition of competency

requiring critical competency is higher, as stated than the general concept of mental incompetency because one loses the capacity to consent before one would be deemed mentally incompetent. Consenting to research is a high-level activity and this capacity is soon lost by an SDAT patient, but competency to perform many activities of daily living could continue. The difficult cases will be the ones near the "line", no matter what standard is used. Although it is hard to decide these borderline cases, this difficulty is not sufficient reason to not use a standard of competency that maximizes autonomy and protection of dependent individuals.

When the stages of SDAT are superimposed on the continuum of autonomy, and the conjunctive definition of autonomy is used, the capacity to consent is lost, in most cases, during the first stage of the disease. Hence, full autonomy and the capacity to consent are lost before the middle stage is reached. During the middle stage of SDAT, probably the patient has minimal autonomy and by now the patient can not consent even with assistance. During the last stage of the disease, the patient has depleted autonomy and is fully dependent on others. Thus, once again, it is seen that the conjunctive definition of competency excludes the majority of SDAT patients from being able to consent to participate in research participation. However, it should be stressed that other capacities continue and these abilities should be supported during the course of the disease. The most

difficult assessments occur in the early stage as the patient moves closer to the middle stage. It is common for patients to try hard to compensate for their losses, which is a healthy reaction, but on the other hand, this response can mask lost capacities. Also, a patient's performance can fluctuate. One day he is functioning very well and the next day he needs help with tasks. Hence, an assessment should be completed by a trained health care professional over a period of time. The family's observations and input are essential.

In summary, when ranking ethical principles, the status of the patient has to be considered and as his level of functioning changes, so do the ranking of both society's and the researcher's ethical priorities in respect to the subject.

When the subject is competent to consent to research, and secondly when not competent to consent to research, the priorities are as follows:

(i) Subject competent to consent to research participation:

(a) Society:

- (i) In respect to the subject, priority is respect for autonomy
- (ii) In respect to society in general, priority is beneficence.

(b) Researcher:

Has the same ethical priorities in respect to society in general and research subject.

(i) Subject not competent to consent to research participation:

(a) Society:

- (i) In respect to the subject, priority is non-maleficence
- (ii) In respect to society in general, priority is beneficence

(b) Researcher:

The same ethical priorities in respect to the subject and society.

As can be seen, when the mentally impaired are research subjects, the ethical dilemma is not between autonomy and beneficence or how to strike a balance between these two principles. In other words, when the subject is not competent to consent to research participation, the ethical tension is not between the needs of the subject and of society. Instead, the tension is between protecting the fundamental needs of incompetent research subjects and meeting the needs of society. Hence, non-maleficence versus beneficence better captures the ethical tension at this stage. Non-maleficence should rank ahead of beneficence in the realm of SDAT

research. It has been argued that the needs of vulnerable subjects should be considered before research is planned and conducted and hence, non-maleficence has trumped beneficence.

NOTES

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17. Melnick et al, see note 13, p. 534.
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Also, private discussion with Drs. Dyman and Witherspoon at the same conference, April, 1989.

33. Mental Health Act, Ontario, 1984, section 14, (5), p.28.

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36. Roth L.H., Meisel A., Lidz, C.W. "Tests of Competency to Treatment". American Journal of Psychiatry. Volume 134, number 3, March, 1977, pp. 279-284.

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49. They recommend that the following is needed:
- (i) testing of the reliability and validity of the various ways of characterizing competency
 - (ii) characterization of the general population and of discrete populations of particular concern according to these standards
 - (iii) comparison of the decisions by those who meet or fail to meet a particular standard.
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65. Law Reform Commission of Canada, Biomedical Experimentation Involving Human Subjects, Working Paper 61, Ottawa, 1989.
66. Ontario Guardianship Commission Report, Ontario Public Service, Toronto, 1989. Hereafter referred to as the Framm Report.
67. LRC Working Paper 61, p. 57.
68. Ibid., p. 59.
69. At a meeting of the Canadian Society of Bioethics (Ontario branch) held in Toronto in September the Law Reform Commission's work was discussed. Although this snapshot of opinion does not constitute a study, it is remarkable that nearly all physicians present objected to the law intruding into the realm of research which they thought could be well served by the MRC which lacks any legal clout.
70. Quoted in V. Melnick, Dubler, N. et al., "Clinical Research in Senile Dementia of the Alzheimer Type," Journal of the American Geriatric Society, Vol. 32, no. 7, p. 534.
71. LRC, Working Paper 61, p. 45.
72. LRC, Working Paper 61, p. 45.

73. The Competency Clinic of Toronto's Baycrest Hospital recommends that competent individuals leave explicit statements with a DPA and/or their family stating their values, goals, likes and aversions. With this information, the DPA or surrogates are better prepared to decide what would be in agreement with the prospective subject's wishes.

74. Ontario Guardianship and Advocacy Review Commission, (Framm Report), Ontario Public Service, 1989. p. 36.

75. Ibid., pp. 48-49.

76. Ibid., p. 42.

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Chapter VI

Conclusion: Non-Maleficence Trumps Beneficence

We clearly need freedom, no less than we need security, knowledge, and justice. This freedom is not, of course, simply a collection of negative rights. It must be understood in terms of justified attitudes of prudent self-interest, self-respect, and respect for others. The convictions of responsibility for one's action and objectives which these attitudes include give us a rational interest in the freedom which is counterpart of responsible agency. An important implication of this need is that a line must be drawn between personal responsibilities and legitimate claims upon social resources, for freedom from constraining social structures coincides with the possibility of full self-development.

E. Simpson¹

6.1 Summary: How to Do Good Without Harming Research Subjects

Alzheimer's Disease research is plagued by several serious ethical problems which also have a clinical and legal dimension. In this thesis so far, some of these ethical problems have been analyzed and ways of resolving them proposed. At the heart of the ethical issues is balancing respect for the weak and vulnerable with the responsibility to promote autonomy, security, knowledge and justice.

In this last chapter, the results and proposals presented in previous chapters will be integrated and summarized. Also, the questions regarding Alzheimer patients' involvement with medical research raised by the Medical Research Council of Canada in their Guidelines will be responded to. In addition, responses will be given to those questions raised by the International Summit Conference on the Use of Human Subjects in Biomedical Research. Although the focus of this thesis is Alzheimer's Disease research, some of the conclusions can be applied in other areas of research involving mentally incompetent or vulnerable subjects, (for instance, paediatric research).

The Globe and Mail's headline "Alzheimer's Disease Research Hindered by Lack of Competent Subjects" (Jan. 23, 1989) succinctly captured the major problem for SDAT research -- an insufficient number of mentally competent subjects. Also, ethical, clinical and legal problems arise because the majority of prospective subjects are vulnerable for a number of reasons, especially that they have failing mental capacities. In addition, they can be vulnerable for one or more of the following reasons: age, financial status, concurrent health problems, being institutionalized, language, and hearing problems. Problems arise because mentally incompetent individuals, specifically Alzheimer patients, are needed for non-

therapeutic Alzheimer's Disease research which has no promise of direct benefits for the subjects.

If we are to provide more effective care for the rapidly burgeoning class of SDAT patients, there is a pressing need for research. Whether this research can be conducted and SDAT subjects be respected is contingent on whether or not the appropriate legal and moral safeguards are forthcoming. Alzheimer's Disease research like all other types of research must abide by codes of research ethics. Throughout the thesis, there has been a sensitivity to the hybrid nature of this investigation drawing from philosophy, health sciences and law. The study occurs on two levels: (i) the philosophical, theoretical or conceptual level, and (ii) practical or clinical. The emphasis has been on the conceptual and philosophical analysis of the problems. On each level is a set of terms corresponding to those on the other level. For instance, on the theoretical level, the dependent moral agent has fundamental needs not to be harmed and to have welfare needs met, on the clinical level, mentally competent individuals have the inviolable right to integrity and dignity. Ways of bridging the gap between theory and practice have been presented. Unless theory can be put into practice, the investigation is for nought.

The constant theme has been protection of vulnerable human research subjects, affected by Alzheimer's Disease, from being harmed and

used merely as a means to an end. At the same time, the pressing need to learn more about this costly and debilitating disease has been incorporated into the proposed resolution of the research issues. Special attention has been paid to the ethical, legal and clinical impasse posed when mentally incompetent patients are asked to be subjects in research which offers them no promise of benefits. Researchers need to involve subjects who are mentally impaired with therapeutic and non-therapeutic research because, although SDAT research investigating the disease process usually offers no direct benefits to the subjects in most cases (these cases), it cannot be conducted without involving mentally impaired SDAT patients. The option of only recruiting competent SDAT patients as subjects in non-therapeutic research is not entirely satisfactory ethically. The rewards and costs of SDAT research should be distributed among the SDAT population. Granted that SDAT patients can be research subjects under strict conditions, it would be unjust to target a section of the population to bear all the costs of research when it is not likely that they can enjoy any benefits from participation. Thus, there is a pressing need to resolve this dead-lock position.

The position advanced ranked protection of vulnerable subjects as the ethical priority in research using human subjects. However, a way to permit society and researchers to fulfil their obligations and at the same

time respect the needs (or family rights) of mentally impaired research subjects was sought and developed. The protection of these vulnerable subjects is provided by the proposed research guidelines which are based on:

- (1) strengthening the consent mechanism and
- (2) modifying the requirements for research design.

The two-pronged resolution is based on:

- (i) understanding mentally incompetent Alzheimer patients to be moral subjects with fundamental needs (also called the right to dignity and inviolable rights),
- (ii) a theory of developmental autonomy according to which an individual with a high degree of autonomy has critical competence and is morally responsible.
- (iii) a theory of competency which recognizes competency to consent to research as a specific capacity requiring a high degree of cognitive functioning and autonomy.

The resolution of the "hard case" in SDAT research would permit conducting ethically sound SDAT research offering some promise of benefiting society. To cease or unnecessarily delay Alzheimer's research would be counter-productive and socially irresponsible.

In a sentence, the position put forth is a mix of deontology and consequentialism. The goal of research (the consequence sought) is the development of more effective therapies. But if the end is not to justify the means (the bad feature of utilitarianism which is to be avoided) there must be an ethical fit between ends and means. This is not only to find more

effective means to new therapeutic interventions, but also the means to square with our deeper moral sentiments (the deontological constraint). In his landmark paper, Beecher demonstrated that the emphasis on promoting the general good in utilitarianism can be used to justify mis-use of subjects for the social good. That is not my intention.² The thesis has a consequentialist strand, because of the emphasis on respecting Alzheimer patients' fundamental needs at all times, including when they are research subjects. The goal is to protect the weak and vulnerable and, indirectly to promote the good of society. Thus, research and social welfare policies respecting the fundamental needs (or if preferred, the right to dignity) of dependent members of the community are likely to benefit all members of the community. Most reasonable people would agree that a research policy designed to acquire knowledge more quickly, is too costly when the consequences include exploiting vulnerable subjects, possibly undermining individual autonomy, and creating a lack of trust in the research community. In contrast, most reasonable individuals are likely to approve of a research policy based on respect for vulnerable research subjects, which allows SDAT research to continue and expand to include non-therapeutic research with appropriate safeguards. However, it is morally impermissible to gain health and social benefits by means of SDAT research when these benefits are secured at the cost of reducing mentally

incompetent individuals to mere research subjects by exposing them to excessive harm.

Knowledge of the atrocities perpetrated by researchers under the Third Reich led to introduction of important research codes. However, research practices did not change immediately after World War II. Beecher's important paper revealed that during and after the Second World War, medical research was conducted in the U.S.A. (and presumably elsewhere) having poor design and/or without an informed consent. During the war, subjects were compared to conscripted soldiers putting their life at risk. Consent was not sought for being drafted into the armed forces which was considered a far riskier activity than being a research subject. Thus, in this context, neglecting to obtain informed consent from research subjects (usually involved in research associated with the war effort) was not unusual. Beecher's paper demonstrated that after the war, not all investigators followed the Nuremberg Code's recommendations. Pragmatic utilitarian arguments justified these actions. However, in the sixties the social and political climate shifted. A constellation of events, including the publication of Beecher's paper, the growth of the civil rights movement, and a greater awareness of human rights contributed to the development of public pressure for restrictions on clinical research. The change in attitude and the decision to follow the research codes are laudable. However, if this

move is only based on utilitarian grounds, the research subject remains in an unsafe position. The clock could turn back and research codes could again become interesting, abstract documents having no influence over how research is actually conducted. Conventional rules alone should not dictate the way that research subjects are associated with clinical research. Unless the recommendations are on firmer ground, potential research subjects will be at the mercy of the vagaries of public opinion.

The deontological arguments put forth regarding the inviolability of human beings provides a moral anchor and should serve to protect those beings from the vagaries of public opinion and political expediencies. In chapters three and four, it was proposed that mentally incompetent Alzheimer patients are more than crypto-cadavers who lack civil and moral rights. Also, it was proposed that SDAT patients lack rights but do have fundamental needs. Mentally impaired SDAT patients are no longer autonomous and thus, according to the preferred conception of rights as protected choices, are not capable of being right-holders because they no longer are moral agents. However, they do have moral standing by virtue of being moral subjects with fundamental needs which they passively claim. More specifically, these needs are: to be protected from harm and to have their welfare needs met (e.g. good housing, food, health care, and social stimulation). These fundamental needs are the inviolable rights to dignity

and integrity referred to by the MRC's Guidelines and other documents. Integrity refers, in part, to physical and psychological well-being which is achieved when fundamental needs are met. When society accepts that protecting the weak and the vulnerable is good, then right-holders have an obligation to assist dependent moral subjects.

Whether the approach is taken that mentally incompetent individuals lacking autonomy have fundamental needs or have rights, the affected patients do continue to have moral significance and importance in our society. No longer moral agents, they are moral subjects. Being dependent moral subjects, they rely on moral agents to ensure that their fundamental needs (welfare maintenance and protection from harm) and their right to dignity are honoured.

In an age when rights are ascribed to fetuses, neonates, and animals and the environment, to deny that the mentally-impaired have rights is "out of step". Abandoning the language of rights in the public domain, when discussing the status of mentally incompetent individuals, renders the mentally incompetent a dis-service. The choice, modified choice and interests model of rights all agree that whether the SDAT patient's moral status is understood in terms of rights, interests or needs, society has a moral obligation to protect the weak and vulnerable from harm. If the goal is to protect Alzheimer patients from being reduced, (to put the case

crassly), to being experimental material, then the language of rights should be used in most circles when the welfare of Alzheimer patients is discussed. The public is accustomed to discussing questions and issues related to the way vulnerable members of society are to be treated, in terms of rights. To state, in the public domain, that Alzheimer patients have no rights but do have fundamental needs would create confusion and jeopardize the status of this vulnerable population.³ The discussion of the ethical problems of the weak and vulnerable in terms of rights, is a pragmatic and political move, and admittedly does not match the proposed philosophical analysis of the moral status of SDAT patients. As Sumer observes, "...from a practical point of view the language of rights is likely to have considerably greater clout in the moral/political market-place than is the more academic language of claims (and their correlative relational duties".⁴

Existing regulations, research codes and laws, which are designed to protect the subjects' autonomy and protect them from harm, are not appropriate when the subjects are no longer autonomous and the research is not therapeutic. This does not mean however that bona fide research should come to a full halt nor that existing regulations be abandoned. Alzheimer's Disease, like all health problems has social, political and health dimensions. Health care professionals, researchers, and society in general share a responsibility to find more effective ways of treating SDAT patients and,

unless SDAT research including non-therapeutic research with mentally impaired individuals is conducted, they will be frustrated in their efforts to do good and no harm. Hence, the problems with the current regulations need to be overcome and the proposed recommendations are calculated to deal more effectively with the ethical issues associated with SDAT research. The specific problems associated with trying to use established regulations in the context of SDAT research have been identified in Canada by the Medical Research Council in their Guidelines. They identified the major ethical issues related to the consent process and the ethics of the experimental design. To be precise, they do not want Alzheimer's Disease patients who are mentally incompetent to be involved in non-therapeutic and invasive research unless consent is granted by a court. Hence, the Alzheimer patients' inviolable rights to integrity and dignity cannot be compromised by the next of kin, a researcher, an REB, a hospital or a teaching institution because they are basic fundamental rights protected by the Charter. The norm of "inviolable right to integrity" is essentially deontological in orientation. It is reminiscent of the Kantian emphasis on the value of individuals as ends in themselves who should never be treated merely or exclusively as a means to an end.

The majority of health sciences research is on the disease process to discover information about its etiology, risk factors, more effective

treatments and preventative measures. At this time in the course of SDAT research, this type of research can not offer any expectation of ameliorating Alzheimer's Disease, or promise of remission or cure. Hence, strictly speaking, any research studying the disease process and its management is non-therapeutic. The pool of affected subjects to draw from is composed of competent and incompetent patients, and others with diminishing competency who straddle a "grey area" because their capacities fluctuate. If global mental incompetency is the standard for losing the ability to consent to research participation, then the majority of prospective subjects can only be subjects if a surrogate consent is given. Given that a surrogate cannot consent to non-therapeutic research, the majority of affected patients can not enter studies classified as non-therapeutic research.

If, as recommended in this thesis, the standard of competency is revised to require the patient's own consent to research, the pool of eligible subjects is likely to shrink further. Manipulating the description of non-therapeutic research to include vague, abstract benefits is unacceptable. It is one thing for the subject to contribute to society because he believes that, he will benefit in some way. However, it is unacceptable for a researcher to appeal to such a potential benefit in order to induce a subject to participate in research, or to ensure that the research is classified as "therapeutic". Not every prospective subject values contributing to the body of knowledge

about SDAT; he may deem participation in research an unacceptable inconvenience in light of his particular circumstances and preferences.

Furthermore, having a sliding scale of competency or lowering the standard of mental competency are not morally acceptable resolutions of the ethical impasse. This route ignores what is meant by competency to consent, and, in fact, is an expedient way to get approval or assent as opposed to consent. Furthermore, this approach is based on a fundamental disrespect for the mentally impaired patient's fundamental needs. When they are asked to make decisions beyond their capacities, their safety and well-being is jeopardized for the sake of recruiting research subjects.

The MRC's recommendations for absolving mentally impaired individuals from participation in non-therapeutic research are supported in law. However, to date, there has not been a test case in Canada in the post-Charter years. The Eve case was a precedent-setting case, seeking a judgement from the court on the hard case of consent to participation of mentally impaired individuals in non-therapeutic medical interventions. The Supreme Court of Canada took a strong protectionist position in favour of the mentally impaired and refused the request for consent. The decision refrained from using the language of rights and chose instead to decide the case using the best interests model, which also is the approach favoured in this thesis. Considering the decision reached in the Eve case, it is unlikely

that the research community would force the courts to show and make a decision on the involvement of mentally impaired individuals in non-therapeutic research. Chief Justice Marshall commented that, if a case was presented, he would expect the courts to use the Eve case as a precedent and deliver a decision refusing consent for a mentally incompetent individual to be a subject in non-therapeutic research, regardless of the promise of benefits to others.⁵

To understand the position of the MRC and the Supreme Court, it is necessary to reflect on the responsibilities of the guardian who is the substitute decision-maker (SDM). The onerous role of the SDM requires that a decision be made primarily based on the previously stated wishes of the mentally incompetent individual. When the subject's wishes are unknown, or the subject was never competent (as was the situation in the Eve case), then the surrogate must act in the subject's best interests.

Why is the guardian forbidden from consenting to his mentally incompetent ward being involved in non-therapeutic research? In the majority of cases, the prospective subject's wishes are unknown. Thus the surrogate must act in the best interests of the mentally incompetent individual. The MRC considers that volunteering an Alzheimer patient (or any other incompetent individual) to be a subject in non-therapeutic

research offering him no direct therapeutic benefits is not acting in the subject's best interests.

Furthermore, the Law Reform Commission of Canada, in its most recent working paper, reviewed codes of research ethics and legal statutes in Canada and other jurisdictions. The Commission found that non-therapeutic research involving mentally incompetent research subjects is not sanctioned ethically or legally either in Canada, or in other jurisdictions.⁶ The question of what is meant by mental incompetency, and more specifically competency to consent to research, intensifies in the realm of SDAT research. The cardinal feature of the disease is loss of autonomy and mental competency, including the ability to consent to research. Thus, researchers find themselves in the position of asking people with the very problem they want to investigate to be research subjects in studies investigating loss of competency and autonomy. The prospective subjects may not be able to consent, because they have the very symptoms that the researchers want to study.

What is lacking is an established understanding in philosophical, clinical, or legal circles about what constitutes mental competency and a way to assess this universal capacity. The concept of the specific capacity to consent to research is a new concept in the field of mental competency, which Roth and his colleagues have studied. The lack of standardization

regarding the meaning of the concepts, terms, and assessment standards contributes to confusion and unfair treatment for patients and their families. Decisions from judges and/or physicians can vary considerably. Thus with careful doctor-shopping, an astute patient or family can increase their chances of receiving the decision they prefer. For example, the child could manoeuvre to get an assessment from a physician who will be more sympathetic to his case than his parent's, and thus the child can gain control of their parent's estate. Another patient not as experienced with the health care system, could accept passively the decision of a judge who gives him an unsympathetic hearing and declares him incompetent in personal and financial matters, though most judges would have found him mentally competent. The patient can lose many or all legal and moral rights when declared incompetent. In some jurisdictions there is no appeal process, or the process is difficult to access. Thus, it is imperative that these decisions be less subjective and intuitive, and that they be guided by objective standards.

Current research regulations influence SDAT research in two ways. They are strict regarding the ethics of experimental design, because non-therapeutic research is prohibited in theory. Second, given there is no standard for competency to consent to research, the regulations are lenient regarding the requirement for a valid consent. The result is that protection

of the subject from harm is weak, and, at the same time, the freedom of researchers to conduct investigations beneficial to society (potentially reducing the future incidence of SDAT) is restricted. Thus, the status quo is what I have described as a lose-lose-lose situation for the subject, society and researchers. There is an imbalance between the ethics of experimental design and the consent process, resulting in losses for the subject, researcher and society in general.

Throughout the thesis, questions and issues regarding the consent process, design of the experiment, assessing competency and seeking an indirect consent were studied. The resolution of the ethical problems is built on:

- (i) the modification of the ethics of experimental design, to reflect current clinical realities in the field of SDAT research
- (ii) the consent process being made effective and consistent, because it is based on a standard of competency to consent to research.

The result is extension of the types of research projects that can be conducted, though not at the expense of exploiting vulnerable subjects.

The traditional codes of research ethics are not appropriate for Alzheimer's Disease research, because the Nuremberg Code and its descendants promote supporting and protecting the subject's autonomy. However, for SDAT research, in most cases, protecting autonomy is

problematic, and the priority is switched to protecting the subject's fundamental needs.

The ethical priority in the realm of SDAT research is to protect mentally incompetent subjects' fundamental needs, which is to say, protect them from harm and have their welfare needs met. Benefiting society, while still important ethically, is ranked below acting in a non-maleficent manner toward mentally incompetent research subjects. Thus, the focus turns from determining a favourable risk-benefit ratio for the SDAT subject, to determining an acceptable level of risk to which the vulnerable subject is to be exposed. Although it is expected that in the course of conducting SDAT research, there will be benefits on the micro and macro level, this goal is ranked below protecting SDAT subjects. In short, the principle of non-maleficence has trumped promoting autonomy and beneficence.

Regarding the classification of research, it is recommended that the distinction between therapeutic and non-therapeutic be suspended, and the general term of "clinical research" replace the dual classification system.⁷ Removal of the therapeutic and non-therapeutic classification system of research codes is not the green light for what is termed "non-therapeutic" research. Instead, it is intended as a safeguard to ensure that all clinical research will follow strict guidelines designed to protect mentally incompetent subjects.

The other half of the resolution of the ethical problems is the development of a concept of competency to consent to research. "Mental incompetency" is a universal or global term, used by clinicians and the legal community to describe a state of an individual that could threaten his well-being, safety and the safety of others, on account his physical or psychological disabilities. This medical and legal term fails to match the clinical realities of the progress of SDAT. Patients lose specific capacities at different times and at a different rate.

A more just approach for the patient would be to adopt the concept of factual competency, that is, competency in respect to a specific capacity or task. This approach maximizes patient independence, autonomy and abilities, and at the same time, reduces the demand that patients manage aspects of their lives which are beyond their abilities. For instance, in respect to financial matters, this approach would permit the affected individual to manage a monthly allowance but leave management of his entire estate to an individual having power of attorney. If global incompetency were used, the individual would lose all control over his finances, and this could hasten his decline. Similarly, while the individual's capacities to make higher order decisions will deteriorate, he may retain the ability to make less demanding ones. Careful assessments should monitor deficits and assist health care professionals and caregivers to permit the

affected individual to control as many aspects of his life as he can. The assessments should identify areas of competency, weaknesses and incompetency. Thus, appropriate measures can be instituted which may include permitting the individual to perform some tasks, providing assistance to do other tasks, and finally, transferring still other tasks to another. In this way the SDAT patient's autonomy is maximized, and the balance of allowing patients to take risks and setting appropriate limits is based on evidence of the patient's abilities. Thus, the individual may not be able to consent to research, which is a demanding task, but be able to live independently with some assistance. Adopting the specific versus global concept of competency is based on respect for persons and non-maleficence, and serves to maintain the residue of autonomy enjoyed by the patient.

As mentioned, consenting to research is a high level activity requiring a number of prerequisites: abstract thinking, judgement, autonomy, memory, critical appraisal of information, and the capacity to make a consistent independent decision. Also, the prospective subject must be capable of establishing a relationship and communicating with the researcher or research team. On the other side of the coin, the researcher must enter into an interactive relationship with the subject. The investigator has an obligation to give adequate and relevant information, and to respond to queries and concerns raised by the prospective subject. If

necessary, the researcher may have to question the individual's ability to consent. This consent mechanism (or more accurately, consent process) should allow the subject or substitute decision-maker (SDM) to give a valid consent. For his part, the prospective subject is required to be legally and mentally competent, that is, globally competent.

The standard for mental incompetency generally is wider and less precise than the standard for competency to consent to research. Thus, it is possible that an Alzheimer patient could be: (i) incompetent (or lack the capacity) to consent to research and (ii) be mentally competent.

It is proposed that the global concept be replaced by the more precise, task specific standard, in order to protect the prospective subject from demands to make decisions beyond his capacities.

The standard of competency to consent to research requires meeting all six requirements of the conjunctive definition of competency to consent to research (given in chapter five). In brief it is required that the prospective subject be capable of understanding all of the relevant information, critical evaluation of the request to be a subject, the capacity to appreciate consequences of the decision and proceed to make an authentic, sound decision and, in addition, to manage coercion. If the subject meets this standard it would constitute completion of the consent process, and should result in a valid consent for participating in research. It is

noteworthy that it is necessary for the prospective subject first to retain and evaluate relevant information, and to then reach a sound decision. It is crucial that the prospective subject's critical assessment take into consideration his particular situation and desires, and that he reach a decision that takes these factors into consideration. The distinction permits a decision to be made that does not conform with society's or the researcher's wishes. In short, the focus is on the process of reaching a valid consent, and not just the result.

The standard for competency required to consent to research is more demanding and specific than the threshold for global mental competency. The subject is required to retain and learn new information. The cognitive impairments, which start early in SDAT, limit the capacity to consent to research. This conclusion is supported by the empirical research which revealed that, in the first stage of SDAT, one of the first cognitive abilities lost is the capacity to learn new information.⁸ Thus, in the majority of cases, the capacity of SDAT patients to consent to research is lost before the patient would be deemed mentally incompetent. Hence, clinicians need to develop sensitive diagnostic tools to assess specific capacities, in order to separate different competencies and provide the clinical back-up for the conclusions reached at a theoretical level.

There are serious consequences if a protectionist approach were to be taken. First, there would be fewer competent SDAT subjects. Second, the responsibility for consenting to research would be transferred to substitute decision-makers, and this poses its own set of ethical problems. However, this route is preferable to having a less demanding standard of competency to consent to research, such as evidence of a choice or merely factual understanding of the situation. The less specific the standard, the less protection is afforded vulnerable subjects with diminishing or depleted autonomy and failing cognitive functioning.

The decision to participate in research should be sound. It should be based on reasons that the individual can explain, and on an accurate understanding of the information provided in the research and his particular circumstances. A refusal is not sufficient grounds for considering an answer irrational. At the same time, the reasons for a refusal might well indicate the need to query the individual's competency to consent to research.

The two-pronged approach, of tightening the consent process and modifying the requirements for an ethical design is the foundation for a number of proposed recommendations to supplement existing research codes of ethics for SDAT research.

These recommendations propose that clinical research (both therapeutic and non-therapeutic research) and the employment of SDAT patients regardless of their mental status, be permitted if the following recommended guidelines are followed.

- (i) The research design does not present any known serious risk for the research subject (i.e. not above minimum risk).
- (ii) Alzheimer's patients involvement in research should be restricted in respect to:
 - (a) the type of research (not above minimum risk) and
 - (b) frequency of participation.
- (iii) A valid consent is obtained from:
 - (a) a subject who is competent to consent to research, that is understands the consequences of consenting, or,
 - (b) from a surrogate decision-maker (e.g. next of kin). When surrogate consent is necessary, consent must also be given by an independent third party.
 - (c) Competent patients should be encouraged to appoint a person with durable power of attorney (DPA) to make decisions regarding research participation (in addition to other personal matters and financial affairs). The patient should communicate his preferences and values to the DPA.
- (v) Health care professionals providing care to the affected patient and/or his caregivers should not ask these individuals to be research subjects or to give surrogate consent for research participation.
- (vi) A subject's refusal to participate (e.g. any indication of lack of co-operation) should overrule a previous consent by the subject, surrogate or independent third party.

- (vii) When a substitute decision-maker is unavailable, a Public Trustee or Guardian for personal affairs should be appointed. This specially trained, independent individual has the responsibility of being an advocate for the patient's best interests.
- (viii) All research involving Alzheimer patients should be reviewed by a Research Ethics Board.

The philosophical underpinnings of research are respect for persons, non-maleficence, beneficence, autonomy and justice. These underpinnings are in combination with a developmental theory of autonomy and the assumption that mentally incompetent subjects, by virtue of being moral subjects, have moral worth.

Depending on the status of the subject the ranking of the principles varies. For instance, when the subject is unable to consent to research, the ethical priority of society, the caregiver and the researcher is to respect the individual and protect him from harm (principle of non-maleficence). Concurrently, the researcher's priority in relation to society is beneficence. However, when the subject is competent, the researcher, caregiver and society have a moral obligation to respect the subject's autonomy. Regarding society, again the ethical priority is to advance well-being at both the micro and macro levels (principle of beneficence). In this instance, "well-being" is a general term including social and health benefits consistent with recognising the social dimension of health problems and with health as an instrumental good.

The goals of these recommendations in tandem with the conjunctive definition of competency to consent are:

- (i) to serve the specific needs of a vulnerable population
- (ii) to assist researchers striving to respect research subjects
- (iii) to assist society in its efforts to support SDAT research designed to reduce the social and economic costs of Alzheimer's Disease, and, at the same time, respect vulnerable members of the community.

The recommendations regarding the ethics of design are not intended to replace the consent process: both pillars of health sciences research are essential. The proposed conjunctive definition of competency to consent to research will reduce the number of Alzheimer patients able to consent directly and increase the reliance on surrogates. Thus, when the type of research permitted is expanded, and the competency standard made more precise and stricter, a balance is reached which can lead to (i) the promise of increased social good, and (ii) increased protection for mentally incompetent subjects.

6.2 Response to Medical Research Council of Canada:

In its latest Guidelines, the MRC states that research into the diseases of the elderly, including Alzheimer's Disease, poses special problems regarding subject selection, research design, the consent mechanism and the involvement of mentally impaired individuals in non-

therapeutic and/or invasive research. One of the objectives of this thesis was to respond to the issues raised by the MRC and therefore, at this stage, the six ethical issues identified by the MRC and listed in the introductory chapter will be responded to.

The MRC's first worry was in respect to involving affected patients in uncomfortable and above minimum risk research. This important concern was addressed by the thesis advanced in chapter four, that mentally impaired individuals should not be associated with research above minimum risk. Although the MRC does not explicitly make this inference, it expresses the concern in a way that is consistent with the position advanced. While there is no justification for exposing vulnerable subjects to more than minimum risk, there is no grounds for not exposing them to minimum risk when (i) the notion of minimum risk is fleshed out, (ii) the research design is sound, and (iii) the consent mechanism has been appropriately reinforced to afford greater protection to the weak and vulnerable.

Hence, it is recommended that Alzheimer patients only be associated with research ranked by the objective assessment (done by the researcher and REB) at minimum risk or lower. Also, it was recommended that the traditional classification be replaced by the generic category of clinical research embracing the two traditional categories of "therapeutic" and "non-therapeutic". Yet this move is not a go-ahead for researchers to

recruit Alzheimer subjects for any study, including one that does not offer benefits to the subject. The recommendation regarding research design should prevent vulnerable subjects from being exposed to research that poses a serious threat to their well-being.

Under present rules, the first test, for accepting or rejecting a SDAT research proposal when mentally impaired patients are needed to be subjects, is whether the research is "therapeutic" or not. If the protocol is therapeutic then the research may proceed through the "normal" review process and, if approved, subjects can be sought. Under this system "therapeutic" research rated higher than minimum risk could be approved by an REB but "non-therapeutic" research classified as minimum risk could be rejected by an REB.

In place of categorizing research as therapeutic or non-therapeutic it was recommended that there be one general category of clinical or health sciences research and that the SDAT research be assessed in terms of the level of risk.

Secondly, a modification of the criterion of an ethical design when the research subjects are SDAT patients, was proposed. Specifically, it was recommended that SDAT patients should not be associated with clinical research classified higher than minimum risk by the researcher. Also, the

protocol should always be reviewed by an REB. The rationale for the adoption of a minimum risk criterion for SDAT patients is as follows.

- (i) The notion of benefit is ambiguous for SDAT patients who are terminally and chronically ill.
- (ii) The patients are terminally and chronically ill and therefore, they should not be exposed to excessive inconvenience or harm.
- (iii) The majority of SDAT research holds no promise of benefiting SDAT patients directly (the disease would not be cured nor would they be put into remission). It is acknowledged that a subject can have "subjective" benefits even though the research does not influence the progress of the disease.
- (iv) Given that there can be no benefits, few benefits and/or the benefits can be hard to measure, it is not justifiable to expose the subject to more than minimum risk.

On the occasions when the research offers some direct benefits to the subjects (e.g. research aimed at improving the subjects' quality of life), or the subject is pleased to participate in research which will not benefit him directly, the minimum risk criterion should continue to apply. In the case of quality of life research, the probability of benefits has to be compared to the level of risk. In order to meet the requirements of a sound ethical design, the risk-benefit ratio must be favourable, that is to say, the probability of benefit has to justify the subject being exposed to minimum risk.

Therefore, in response to the important concerns raised by the MRC, it was recommended that SDAT patients can be subjects in clinical research on condition:

- (i) the research meets the criterion of an ethical design which included requiring that the level of risk be rated as minimum.
- (ii) subjects who consent should be competent to consent to research participation and their direct consent must meet the criterion of a valid, direct consent.
- (iii) when subjects do not meet the standard of competency to consent to research, third party consent is sought and third party consent meets the criterion of valid indirect consent. It was also recommended that an independent third party give consent when the subject is mentally impaired.

In chapter two, the catch 22 situation facing researchers and clinicians was discussed. The fact that SDAT patients are vulnerable is a block to conducting some types of research that hold the promise of learning more about SDAT and consequently would contribute to reducing the incidence of SDAT and improving treatment interventions. The proposed modifications to research design, subject recruitment, and the consent process constitute a resolution to some of the ethical problems facing SDAT research. Therefore, the recommendations should help clinicians, researchers and patients break out of the current "vicious circle" in which they find themselves.

Thus, there is a restricted class of non-therapeutic research to which a surrogate can indirectly consent: to be precise, research that is not expected to harm the subject, that is to say does not expose the subject to more than minimum risk. In response to the question "Can a surrogate consent for the participation of a mentally incompetent patient in a non-therapeutic research?", the answer is a qualified yes. First, the surrogate must be guided by the patient's wishes, stated when he was competent. These wishes might require the surrogate to consent or to refrain from consenting. If the patient's wishes are unknown, the third party can consent if the research offers no promise of direct benefits but at the same time, presents a risk no higher than the risk associated with daily living.

The third and fourth points were about securing a valid consent from affected patients and the responsibilities of surrogates. The protectionist stance developed in the thesis defends the position that surrogates can refuse consent for research involving above minimum risk on the grounds that the research has not met the ethical requirements of research design. Also the surrogate has the responsibility to act in the subject's best interests which precludes consenting to the patient being a subject in research classified as above minimum risk. Recalling that the goal is protection of the weak and vulnerable (e.g. mentally impaired SDAT patients), the affected patient should not be involved in above minimum risk

clinical research because he would be exposed to the risk of serious physical and psychological harm. To resort to an over-used graphic expression, to permit mentally impaired individuals to be subjects in research placing them at risk and offering them no benefits, reduces the subjects to being experimental data or "guinea pigs". Furthermore, the surrogate who grants permission for a vulnerable subject to be a subject in above minimum risk research has not fulfilled his responsibility to act in the patient's best interests.

Comparing a higher and a lower standard of competency, the higher standard is preferable because it provides more protection to the vulnerable subject. Accepting a higher standard of competency would reduce the number of mentally impaired, prospective subjects able to consent directly, and it will increase the incidence of surrogate consent. The combination of strengthening the consent mechanism and requiring that the research not pose more than minimum risk, provides the vulnerable subject with protection from harm. In contrast, a lower standard would allow more SDAT mentally impaired patients to consent directly to research participation, with the research holding more than minimum risk.

Let us look at the worst case scenario if the higher standard of competency approach is taken. The combination of research that is poorly designed (e.g. high risk) and a coerced, passive, and/or an uncritical

surrogate who might consent to the patients involved in the research presents a threat to the patient's best interests. The recommendations are designed to prevent this situation from arising. First, the researcher has an obligation to design research that is ethically acceptable. This would exclude high risk research for the SDAT population who are mentally incompetent. Second, the Research Ethics Board should identify research which is poorly designed and recommend revisions of the experiment's design before approving the research. Also, the subject's treatment team has an obligation to act on the patient's behalf and prevent him from being associated with any activities which threaten his well-being. If the subject is in an institution, the administrators also share the responsibility to act the patient's best interests and halt his participation in the research.

In concert, the requirement for both an ethical research design and a proper consent mechanism contributes to protecting the vulnerable subject. It is recommended that, before the patient becomes incompetent, the patient state his wishes. This would minimize the chances of his involvement in activities jeopardizing his well-being. Second, it was recommended that he appoint a Durable Power of Attorney, if he thinks that his next of kin would be ineffective as a surrogate decision-maker. The establishment of the role of a Public Trustee or Guardian would provide a greatly needed advocate for the mentally incompetent in the situation

described. Other family members, health care professionals, and administrators could appeal to the Public Trustee if they thought that the fundamental needs of a mentally incompetent patient were not being honoured.

The assessment of risk and benefit and the risk-benefit ratio occurs on two levels. The first "objective" assessment by the researchers is integral to designing an ethical research project. The second or "subjective" assessment is part of the consent process. When the subject or surrogate evaluates the risk-benefit ratio of a so-called "non-therapeutic research" the prospective subject can disagree with the researcher's assessment. If the subject is competent, he can be invited to participate in research classified as above minimal risk. However, if the subject is mentally impaired, his association with clinical research is restricted to research classified as minimal risk (at the objective level of assessment). The decision of the subject or surrogate must be respected.

Certainly, subjective and objective assessments can differ in all types of research. However, SDAT researchers are at a disadvantage when predicting risk and benefits because they lack sufficient empirical research about the risks associated with aging and also about how the elderly and SDAT patients perceive risks associated with daily living. Hence,

researchers should be conservative and cautious when assessing the level of risk for SDAT subjects.

The third issue raised is that subjects may lack competence to consent; this is not a problem peculiar to SDAT research. The usual route is to turn to surrogates but at this juncture problems do arise for SDAT research which are identified in the fourth issue raised by the MRC. Guardians are not permitted by law to volunteer mentally incompetent individuals to be subjects in non-therapeutic research.

The fifth and sixth issues identified by the MRC address whether and if so, under what circumstances a guardian can consent indirectly for the participation of mentally incompetent individuals in non-therapeutic research. "The rights to integrity of the mentally disabled" are protected by the Charter and can not be violated by a third party. The MRC does not define what is meant by the right to integrity but the text indicates that integrity includes the physical and psychological well-being of the individual. A right to integrity entitles the mentally incompetent to protection of their physical and psychological well-being. Research offering no benefits to the subjects does not enhance their well-being. Therefore, the surrogate can not volunteer the mentally impaired individual to participate in research that is expected to threaten the subject's integrity or well-being.

My compromise position, that the surrogate can volunteer the mentally impaired individual to participate in research that is ethically sound and is not expected to harm the subject, should overcome the obstacles raised by the MRC. Although no direct benefits (objective benefits related to disease process) are expected, neither is harm expected. In contrast, if the research is classified (at the level of objective assessment) as above minimum risk, then the proposed requirements for an ethical design have not been met and the involvement of a vulnerable subject in the study, should not be considered. In addition, the surrogate can not consent for the vulnerable individual to be in a study that exposes the subject to excessive risk. To give consent, would threaten the affected patient's integrity (their physical and/or psychological well-being). Thus, there is room to manoeuvre when it comes to the question of surrogate consent for mentally incompetent patients to be subjects in so-called "non-therapeutic" and "invasive" research. Some instances of invasive research, it will be recalled, are not harmful (that is not above minimum) and can be less harmful than some examples of non-invasive research.

In light of this conclusion, the mentally incompetent could be a subject in research not related to therapy when (1) the surrogate has given a valid consent, and (2) the research is not classified higher than minimum risk. Thus, the concern regarding violating the mentally incompetent's

right to integrity has been addressed because it is not expected that he will be harmed (nor benefit directly in objective terms). The proposed resolution does not minimize what the MRC calls the mentally disabled's right to dignity. In fact, the resolution serves to protect the fundamental needs or well-being (read right to dignity) of the mentally disabled.

The sixth issue raised addresses protecting the rights to integrity of the mentally disabled, stating that it can not be overridden by a REB. The MRC is correct: the rights of vulnerable individuals should not be disrespected or diluted by organizations and researchers, no matter what benefits the research promises to yield. The position advanced here supports the MRC's statement. At the same time, it has been argued that the rights (or fundamental needs) of the mentally impaired subjects associated with non-therapeutic research are not overridden by non-therapeutic research that does no harm. Thus, this specific kind of research may be permitted on condition that we use the established consent mechanism for obtaining an indirect consent from a guardian.

In summary, at present, surrogates are prohibited from consenting to all non-therapeutic research. The proposed position expands the range of research to which a guardian may provide indirect consent to include clinical research not exposing mentally impaired subjects to more than minimum risk research.

The seventh point raised by the MRC, concerns seeking consent from the court for the involvement of mentally impaired research subjects in non-therapeutic research. If surrogates are permitted to consent indirectly for clinical research (including non-therapeutic research classified as minimum risk research, researchers would only have to seek consent from the courts to involve mentally incompetent subjects in research classified above minimum risk. When the research goes beyond the threshold of minimum risk, what the MRC calls the right to integrity is threatened and in these cases, the MRC rightly recommends the involvement of the courts.

The courts have an important role, based on the authority of parens patriae, and also by the Charter, to act in the best interests of weak and vulnerable members of our community, (e.g. SDAT patients). On this point, the status quo should be maintained and consent sought for involvement of subjects in non-therapeutic research, which poses more than minimum risk to mentally incompetent subjects. Alzheimer patients should not be subjects in such studies when the risk is unacceptably high. Thus, such proposals should be rejected by an REB on the grounds that the design is unethical. If the court is asked to approve invasive, non-therapeutic research, it is reasonable to presume that the court will follow the line of reasoning used in the Eve case. In writing his summary, Judge La Forest stated that the court should exercise its parens patriae authority and act on

behalf of the mentally incompetent individuals. Thus, this argument would support a protectionist position, in the event that the courts were asked to consent to the involvement of a mentally impaired individual in non-therapeutic research.

The proposed recommendations depend greatly on the evaluation of the research protocol's design, specifically, the degree of risk associated with the intervention. To achieve more effective objective evaluation of the level of risk, further research is required. This problem will be addressed as more SDAT research is conducted and the body of knowledge to be drawn from, when predicting the level of risk, increases. Also, further research devoted to developing standardized evaluations of the course of SDAT, and tracking the deterioration of specific capacities in more detail will greatly assist in the assessment of competency to consent to research and of mental impairment.

To assist the surrogate and other third parties to decide what the subject would have considered minimum or high risk, it is recommended that Alzheimer patients when competent, make a statement of their desires, values and goals. Furthermore, the Alzheimer patient is advised in the recommendations to appoint a Durable Power of Attorney to act on his behalf if he prefers this individual to a next of kin. This manoeuvre

enhances the possibility of the mentally incompetent's wishes being respected if the next of kin, in the patient's view, is unsuitable for the role.

Moreover, the recommendations cover mentally incompetent individuals who have no next of kin able and/or willing to be a substitute decision-maker. The transfer of this role to an administrator or another interested party could exacerbate the prospective subject's vulnerability. Hence, the appointment of a third party to act on behalf of the mentally incompetent patients is a move that would enhance protection of the patient's fundamental needs.

The importance of defining the degree of risk emphasizes the necessity for all SDAT research to be reviewed by an objective and independent REB recommended in the MRC's Guidelines.

However, it is possible to circumvent the proposed recommendations and also the current ones regarding the association of mentally impaired patients in "non-therapeutic" research. Two possibilities are:

- (i) state that a non-therapeutic research study is therapeutic, and/or
- (ii) minimize the degree of risk.

Either of these manoeuvres would place a non-therapeutic research proposal which presents more than minimum risk to the subject in the category of

research that can be consented to by a guardian. When the subject is incompetent, the consequences are more serious. Hence the Law Reform Commission is wise to recommend that there be legal statutes protecting mentally impaired subjects in all biomedical research (only research classified by researchers as above minimum risk). This recommendation closes the loophole of classifying research as therapeutic and thus exempted from seeking permission from the courts to recruit mentally impaired subjects. Secondly, an REB could approve research that is wrongly classified and thus, the second check on design breaks down. These mistakes can be made "in good faith" because SDAT is a new field and there is a scarcity of evidence about how the planned intervention will affect the SDAT population. In addition, the current classification system of therapeutic and non-therapeutic has legitimate problems and it is difficult for the researcher to predict what will and will not benefit the subject. Also, recommendations made by the Law Reform Commission, to extend legal protection of all SDAT subjects, would include those associated with below minimum risk research.

Turning to the MRC's final point about coercion, it was suggested in chapter five that total elimination of coercion is impossible and that instead, reduction and management of coercion is a more realistic goal. The high risk of institutionalized prospective subjects volunteering because of

the promise of advantages or the threat of reprisals identified by the MRC must not be ignored. Caregivers themselves may be caught in the same web of covert or overt coercion and therefore, in some cases, can not be effective guardians for their wards. Institutionalized patients as well as those heavily dependent on the health care system are restricted in the ways that they can choose to resist pressure. It would be myopic and unrealistic for moral philosophers or others to not acknowledge the difficult position of patients and caregivers when asked to consent, especially when a member of the patient's Treatment Team is recruiting subjects. A patient and/or caregiver must be strong, physically and mentally, and have other resources in order to question "to bite the hand that feeds them". The recommendations regarding an independent third party working with a surrogate should reduce coercion. Also, the recommendation that the health care providers associated with the patient and caregivers not recruit subjects will reduce a major source of coercion. Reduction of the influence of rewards and punishments for either consenting or refusing is largely in the hands of the researchers, the REB's and society. In addition, administrators of institutions have a responsibility discriminately to intervene to reduce coercion of the residents. Patient advocate groups can play an important role in reducing coercion. A patient representative on an REB should address the same problem.

Thus, all the points raised by the MRC regarding research employing elderly subjects, including those with Alzheimer's Disease have been addressed. According to the view developed in this thesis, some "non-therapeutic" research involving mentally impaired subjects may be permitted without violating the subject's dignity and integrity and without recourse to the courts for approval.

6.3 Response to Questions Posed by International Summit Conference on Bioethics, 1987:

The International Summit Conference entitled "Towards an International Ethic for Research with Human Beings", hosted by the MRC in Ottawa during 1987, raised several important questions regarding research involving subjects with restricted ability to give consent which would include Alzheimer patients. The proceedings of the conference summarize the dilemma facing researchers who need to use subjects with limited ability to consent, stating "Research with vulnerable subjects with restricted ability to give consent poses special ethics problems.... However, in some instances results of research undertaken in competent adults can not be extrapolated to the vulnerable population. If research is to be done on such topics as sudden infant death, appropriate paediatric drug dosages, and Alzheimer's disease, then members of vulnerable populations must

apparently serve as subjects". Yet in the next paragraph they address this concern by stating, "Despite the ethical difficulties intrinsic in the participation in research of such subjects, it can be seen as equally objectionable that research in such conditions should cease".⁹

Having decided that research using vulnerable individuals as subjects is necessary, the conference raised six questions for discussion which were raised in the first chapter and now will be responded to.

Regarding the first question about when those with restricted capacity to consent can be subjects, the conditions under which individuals with restricted ability to give consent can be permitted to be subjects has been dealt with in depth. When those with restricted ability include those lacking the capacity to consent to research participation, then these individuals can only be research subjects if the following conditions are all met:

- (i) a valid consent was obtained from a guardian who may be a next of kin or a Public Guardian.
- (ii) The experiment's design is ethically sound which is to say that the degree of risk must not exceed the level of minimum risk.
- (iii) A mentally impaired individual should be withdrawn immediately from a research study which a SDM has consented to, in one or more of the following situations:
 - a) lack of co-operation or any indication of refusal

- b) any indication of adverse side effects before, during or after the research intervention
- c) if chemical or physical restraints are needed to gain the subject's co-operation.

Thus, the individual with impaired ability would not be part of a research study which exposed the subjects to more than minimum risk whether therapeutic or non-therapeutic in design. A more demanding standard of competency is required to refuse than to consent. Also, any signs of psychological and/or physical distress caused by participating is sufficient grounds for terminating participation. Hence, health care professionals, family and researchers must be vigilant and look for indications of adverse side effects and the possibility of their occurrence. For instance, returning to the example of the SDAT subject having a CT scan, if the subject has increased irritability, anxiety and/or is aggression or unco-operative when waiting to have the scan and during the procedure, he should be withdrawn from the project immediately. After the scan is completed, increased confusion or depression would be grounds for removing the subject from the research immediately. In some cases, explaining the procedure can remedy the subjects' concerns but if not, their participation must be cancelled.

The second question queries whether minimum risk has relevance for chronically and terminally ill patients. The criterion of minimum risk

(meaning risk associated with daily living) is problematic and hardly sophisticated enough, at this stage in the history of SDAT research. Nevertheless, it provides a workable starting point. Minimum risk is defined as the level of risk that is not expected to jeopardize seriously or permanently, the physical and psychological well being of the subject. In this case, even though the subject has SDAT and can be in the final stages, a threat to their well-being has relevance. The mentally impaired are as susceptible to harm as mentally competent subjects: being mentally impaired confers no immunity against being harmed. For example, mentally incompetent SDAT patients can be emotionally labile and easily distressed by a change in their routine or an embarrassing situation.

It is necessary, as has been mentioned several times, to investigate the impact of aging and dementia on the subject's appreciation of risk. Also, the two levels of risk assessment must be respected. The researcher and the REB may decide that the research poses minimal risk. However, the subject may have a different perception and be unco-operative. In this situation, the mentally incompetent subject's refusal (for whatever reason) must override the surrogate's consent.

It is interesting that the question of whether therapeutic research is a workable concept was not raised, because this question focuses on the more important question of whether any SDAT research may benefit

permanently (as opposed to transitorily) mentally impaired patients and therefore, should they be subjects in research that can only benefit others? The MRC's prohibition of non-therapeutic research is based on the faulty assumption that non-therapeutic is equivalent to harmful. This is not the case as I have tried to show earlier. However, it must be emphasized that clinical work is required, to clarify and then improve the implementation of the concept of minimum risk for Alzheimer's Disease patients.

The third question asks who acts on behalf of these subjects? A number of individuals and organizations are delegated to protect the fundamental needs (the right to integrity) of individuals with restricted ability to consent. The first line of defence, so to speak, is the next of kin who assumes the role of surrogate and guardian. In the absence of a family member or friend prepared to take on this onerous role, and in the event that a durable power of attorney was not appointed, it was recommended that a Public Trustee or Guardian act on behalf of the mentally incompetent individual. These guardians are accountable to the courts and do not act in a vacuum, without direction. First, they should endeavour to honour the patient's previously stated wishes or, if not known, to respect their fundamental needs to be protected from harm and have their welfare needs met, or in other words, to act in their best interests. Also, their actions must comply with the laws and research codes of the given jurisdiction, for

instance, in Canada, their decisions must comply with the Canadian Charter of Rights and Freedoms, and the MRC's Guidelines.

In addition, the researcher and the health care team act on behalf of the research subject. If they suspect that the prospective subject is unable to consent to research, the prospective subject must be assessed and if found incompetent to consent to research, then they must seek permission from a guardian. To seek consent from an individual whose competence is in doubt, is not to act in the individual's best interests. The jurisdiction's legal statutes and research codes of ethics must be used to protect vulnerable subjects from harm by health care professionals, researchers, society and lawyers.

The fourth question asks if a prospective subject with restricted ability to give consent can assent to participating in research. In other words, can evidence of a choice be a standard of competency for consent to research, and can there be a sliding scale of competency for consenting to research? The answer to both questions is "No". In chapter five the problems with the standard of evidence of a choice and a sliding scale of competency were discussed. Assent or co-operation does not, on its own indicate that the prospective subject appreciates the consequences of consenting which is necessary for a consent to be valid. Consenting to research involves a sophisticated decision-making process regardless of the

level of risk associated with the intervention. Thus the evidence of choice and the sliding scale standard conception of competency are inadequate. The question of what role, if any, there is for dissent is worth raising because dissent is important when the subject has restricted ability to consent. Lack of co-operation or dissent trumps an indirect consent or a direct consent given by the subject when competent. Under no circumstances can dissent be ignored. Thus, for refusal to consent, a less demanding standard of competency is acceptable.

The next question of how to weigh the expected benefits for society with the promised benefits for the individual falls outside the scope of the thesis. The major ethical dilemma is not how to weigh benefits of the majority (society) versus benefits to the individual. Rather, the question is how one weighs protecting the subject from harm and benefiting society. In short, at what cost is social good acquired? If both the subject and society stand to benefit, then there should not be an ethical dilemma. The dilemma arises when advances in controlling a disease are to be gained at the cost of possibly harming subjects. It has been proposed that mentally incompetent subjects can be associated with both "therapeutic" and "non-therapeutic" research (which has been labelled clinical research) if certain strict regulations designed to protect their fundamental needs are met. These proposed regulations "apply the brakes" to clinical research, but this is the

price to be paid when respect for vulnerable members of the community is accepted as morally obligatory.

It is estimated that Alzheimer's Disease is the fourth leading cause of death in Canada, and it is a terminal illness. Hence, the sixth question regarding what criteria should guide the ethics of experimentation with the terminally ill is relevant. The recommendations proposed in the previous chapter address this very question and are designed to protect terminally and chronically ill patients from involvement with research that will jeopardize their fragile health while offering them no direct (objective) benefits. A competent, terminally ill patient can, of course, consent to be a subject in non-therapeutic research because he gains "subjective" benefits from being a subject (for instance, the opportunity to get away from the hospital ward, or to feel proud about contributing to assisting others).

The great fear is that terminally and/or chronically ill patients will be involved in highly risky experiments because it is perceived that they have little to lose. The recommendations proposed should prevent this "worst-case" scenario from occurring because SDAT subjects who are unable to consent to research should not be considered eligible for any research posing more than minimum risk or in other words, having any expectation of harming them seriously.¹⁰

Thus, in the process of proposing a way for society and researchers to fulfil their respective obligations and concurrently protect vulnerable subjects, the questions raised by the International Summit have been responded to in the thesis.

6.4 Conclusion:

The thesis began by identifying some of the ethical problems associated with conducting Alzheimer's Disease research. In many respects, the ethical problem of whether and if so, under what conditions can these vulnerable individuals be research subjects, is the same one troubling paediatric research. The common perception is that there is a tension between promoting the good of society and protecting the inviolable rights of Alzheimer patients. As the investigation unfolded, it became evident that the tension is between acting in a non-maleficent manner to the SDAT subjects and acting beneficently to others.

The current situation of strict regulations regarding design and lax rules regarding competency is unacceptable and unhelpful for subjects, researchers, caregivers and society. Society is deprived of the benefits of possible research advances. The subjects are at risk of being asked to make a decision they are incapable of making competently. Thus, the subjects could unwittingly expose themselves to physical and psychological harm

when they are erroneously assumed to be autonomous moral agents and sufficiently competent to consent. Researchers are prohibited from conducting research that offers the promise of reducing future SDAT morbidity and mortality rates. Thus, the current situation restricts the possibilities to promote social good through SDAT research and increases the possibility of subjects being exposed to risk.

Surrogate consent for SDAT research presents serious moral and clinical problems. The most pressing, is one raised by the MRC, that guardians may not nominate mentally impaired individuals to participate in non-therapeutic research. The resolution of this "hard case" consists of combining a generic definition of research, a modification and the research design based on the ethical priority of protecting weak and vulnerable subjects. In addition, surrogates may consent for a vulnerable SDAT patient to be a subject if the research does not expose the subject to more risk than is associated with daily living. Thus, the subject is not expected to benefit directly but neither is he expected to be harmed.¹¹

When all the recommendations regarding research design, consent process and standards of competency to consent are integrated the results are beneficial for the Alzheimer patient, the SDAT subject, researchers and society. A systemic relationship is established between all parties benefitting society at the micro and macro level. Figure 2 (Appendix B)

illustrates the systemic, interactive relationship between all parties and how protecting the fundamental needs of SDAT patients and will lead to benefits for society which in turn will feedback to the SDAT patient.

If we begin with Alzheimer subjects, they have fundamental needs to be protected from harm and have their welfare needs met. If you prefer, they have inviolable rights to dignity and integrity. However, being dependent and vulnerable (dependent moral subjects) they rely on autonomous, independent members of the community to protect their fundamental needs. In addition, society has an obligation to lower the cost of caring for an increasing Alzheimer population. How do we balance respecting Alzheimer patients and reducing the cost of attending to this population? Society responds by having a comprehensive health care programme, but clinical research is needed to halt the rise in incidence, and to ameliorate the condition of present and future sufferers. Clinical SDAT research must be conducted in a manner that respects the basic needs of Alzheimer patients. To assist researchers, guidelines were developed which incorporate responsibility for the subject's fundamental needs and establish the dominance of non-maleficence in respect to the research subjects.

Conducting research to improve the health and social conditions of society's members is a noble aim. However, this goal can not be achieved at the cost of reducing mentally incompetent subjects to mere means. The cost

to society, of ranking the promotion of the social good above respect for the needs of mentally incompetent individuals, is high and does not justify exploiting defenceless members of the community. For researchers, the proposed resolution will approve the majority of Alzheimer's research not rated higher than minimum risk and thus, the researcher will have freedom to conduct more research than current guidelines permit. As a consequence, the pressure to use mentally incompetent subjects in high risk research should be reduced. Also, so-called non-therapeutic research previously prohibited can be permitted under certain circumstances.

The subject, researcher and the community benefit when social and research policy is based on the proposed recommendations regarding research and the treatment of the mentally incompetent. The subjects benefit because they have moral standing and social worth in the community, and in turn have their fundamental needs met. Society benefits because SDAT research is conducted in a manner that respects subjects, their caregivers and society in general. The research policy should provide researchers with more direction in an area of research troubled by ethical questions. Advances made by researchers will feed back into society and eventually benefit individuals and society as a whole. With more knowledge about the management of Alzheimer's Disease, the ability to respond to the patient's basic needs is enhanced and the patient's and the caregiver's

quality of life can improve. Thus, this feed-back loop demonstrates that respect for the mentally incompetent will lead to benefits for the researcher, patients (some of whom were subjects) and society if the fundamental needs of vulnerable, dependent Alzheimer patients are respected.

In closing, a few words about the title is necessary. The starting point was to question how to balance the needs of the research subject and those of society and to query if respect for individual autonomy can be maintained in the face of pressure to learn more about SDAT and consequently promote the social good. Quickly, it was evident that the autonomy model was not appropriate for the field of SDAT research and another fundamental question arose revealing that the ethical tension was between non-maleficence and beneficence. The Nuremberg Code is based on the assumption that subjects are autonomous, competent to consent to research and mentally competent. Thus, some of the Nuremberg Code's recommendations miss the mark because SDAT subjects are characterized by a loss of self-determination. Other research regulations have sanctioned mentally impaired subjects to be subjects but have not addressed the ethical issues related to SDAT research. Thus further work was needed to supplement these guidelines in order that they would serve to respect and protect the needs and interests of SDAT subjects, researchers and society in general. The proposed additional recommendations for the SDAT

population are based on an examination of the moral underpinnings of the purpose of research and society's obligations to its vulnerable members.

In the course of investigating the ethical problems associated with SDAT research, two different points in respect to the title have been established.

- (i) The tension between autonomy and beneficence is the standard dilemma in medical research. However, in the realm of SDAT research when the majority of subjects are vulnerable and mentally incompetent, the tension is replaced by that of treating research subjects in a non-maleficent fashion and conducting research that will promote the good of society as a whole. The position advanced is that non-maleficence should take precedence over beneficence or in other words, social good should not be gained at the cost of harming Alzheimer patients. In addition, it has been argued that ranking non-maleficence over beneficence, will benefit society in the long run because of the high social costs of disrespecting vulnerable members of the community and the social benefits associated with respecting this population.

- (ii) It has also been argued that a balance between beneficence and non-maleficence can be obtained if the recommendations regarding conducting Alzheimer's research are added to current research regulations. The proposed additional recommendations assume that, the task-specific criteria of competency to consent to research based on a more demanding standard of competency, are adopted. Also, the recommendations require that the level of risk ratio be analyzed carefully and that mentally impaired SDAT patients not be subjects in research exposing them to more than minimum risk. Thus, the research may not offer benefits to the SDAT subject but at the same time, it must not offer a significant risk of harm.

Alzheimer's Disease is a tragic phenomenon that challenges caregivers, health care professionals, researchers and society to behave in a respectful manner towards affected individuals who are shadows of their former selves. A society can be judged by how well it treats its dependent, less fortunate members. The pressure to "bend" rules or change research policies because the patients are seriously ill, with failing mental capacities or mentally incompetent, and perhaps, unaware of their surroundings should be challenged. The promise of social good should not legitimize involving these individuals in research that may assist others but at the

same time could exacerbate the subject's distressing condition and capitalize on his vulnerability. To condone the exploitation of a vulnerable sector of society is too high a price to pay for the expected advancement of the social good. The proposed resolution to some of the ethical problems associated with Alzheimer's Disease research presents a way to overcome the ethical dilemma of how to respect the needs of Alzheimer's Disease patients and at the same time, to promote the social good.

Notes

1. Simpson, E. "The Priority of Needs over Wants", Social Theory and Practice, Volume 8, no. 1, p. 107.
2. Beecher, H. "Ethics and Clinical Research". The New England Journal of Medicine. Vol. 274, no. 24, pp. 1354-1360.
3. I am indebted to Dr. W. Sumner for this insight. Conversation with Dr. Sumner, December, 1989.
4. Sumner, R.W. The Moral Foundation of Rights. p.205.
5. This statement was made by Chief Justice John Marshall at the conference, Legal and Ethical Issues in Alzheimer's Disease Research, held in Toronto, Jan. 20, 1989.
6. L.R.C. Working Paper 61.
7. The therapeutic and non-therapeutic distinction is concerned with the classification of research rather than the design of the research project.
8. This important work combining health care, law and philosophy is being undertaken by the Competency Clinic, Baycrest Hospital, Toronto associated with the University of Toronto. The Director of the Clinic is Dr. M. Silberfeld.
9. Proceedings of the International Summit Conference on Bioethics, April 5-10, 1987, Ottawa. Medical Research Council of Canada, Ottawa, Canada. p. 27.
10. The terminally ill can be moved by altruism to volunteer for risky research studies. Their generosity is admirable but should not be capitalized on. To accept their offer to participate in high risk research because they are going to die anyway, is to say that research with an unethically sound risk-benefit ratio is acceptable when the subject is terminally ill. The research's design is unethical regardless of the status of the subject. In addition, the mental competence of an individual volunteering for an activity that poses a high risk to his health should be

questioned. In short, the willingness of subjects to enter high-risk research does not correct an unethical experimental design.

11. However, the subject could benefit if the research was quality-of-life type research or if he gained a benefit that was specific to the subject, for instance, he benefited from making a contribution to learning more about SDAT.

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