BODIES OF SCIENCE

BODIES OF SCIENCE:
THE EXPERIENCES OF HUMAN RESEARCH
PARTICIPANTS OF HEALTH STUDIES

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ABSTRACT

This dissertation examines my investigation of the experiences of participants of university-based health research. My primary research questions were: (1) Why do people participate in health research, despite its risks? (2) Why are people asked to participate in health research? (3) What factors influence local research environments? I employed a critical-interpretive medical anthropology framework to investigate and describe three studies: a Phase 2a asthma drug study, a Phase 1 oncology drug study, and a muscle regeneration study. I followed each of these studies, conducting hundreds of hours of participant observation and interviewing 31 participants multiple times during the course of their enrolment. To learn about the organization and governance of university-based health research I also interviewed researchers, research coordinators, and ethics experts. In addition, I conducted participant observation at three different research ethics boards (REBs) and two industry conferences. Participant enrolment was significantly influenced by: belief in the "good" of medical research, the enjoyment they experienced as former participants, and desire to receive benefit, including remuneration and possible health benefits. Participation often entails long hours, and much of this time is spent socializing with the research team. Participants often develop trusting relationships with the research team, and learn to adopt its scientific language, in addition to its interests and perspectives. Thus, participants rarely question how research is funded and who ultimately benefits from research. They also do not identify as participants, but rather as volunteers or guests. This is a significant obstacle for participant organization. Since they are not organized to voice their interests collectively, REBs are responsible for protecting their interests. Research ethics board focus almost exclusively on reducing risk and rarely address increasing the potential benefit of researcher to the participants. I conclude my analysis with recommendations for REBs, policy makers, and researchers.

ACKNOWLEDGEMENTS

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CHAPTER 1: INTRODUCTION

A) Purpose of Research

In this study, my main objective is to understand, primarily from the perspectives of research participants, the world of university-based health research. My research questions are:

1. Why do people participate in health research, despite its risks?

2. Why are people asked to participate in health research?

3. What is the research environment like? What factors influence this environment?

I am interested in health research because I find it fascinating that people put their health at risk and undergo sometimes inconvenient, painful, or difficult procedures for strangers. Moreover, these participants are often paid by multi-national pharmaceutical companies, which have been known to value shareholder interests over human life and safety (Angell 2004). I am also genuinely interested in research activities. As a Master's student, one of my part-time jobs was to interview National Science and Engineering Research Council (NSERC) recipients about their research and write articles about them for the faculty newspaper. I enjoyed this work immensely because it enabled me to speak with researchers about their dreams and passions. Participants of health research, in many ways, also have opportunities to inhabit the worlds of medical researchers, and to help them actualize these dreams. At the very least, they

become exposed to the worlds of researchers; their strange language, obsession with measurement, and plodding logic.

B) Health Research in Canada

Health research in Canada is conducted in a variety of contexts. Much of it is conducted in universities and colleges. Such research is funded by both private and public sources. Other "public" research is conducted in government-based laboratories. Finally, private industry, such as biotechnology firms and pharmaceutical companies, often fund their own research. This research is either conducted "in house" or is contracted to contract research organizations (CROs) who are responsible for conducting the research on their behalf. CROs are important and under-researched actors in the current health research milieu and will have significant impact on how the industry evolves (Mirowski and Van Horn 2005). However, my research concerns university-based health research only.

Private industry is growing and challenges both the academy's domain over research and modern research ethics. Academics now compete with CROs for research funding from private industry. Industry does not necessarily rely on the academy to develop and test drugs and medical devices; it can pursue its research and development goals through partnering with CROs instead of academics (Petryna 2009). In addition, industry-sponsored studies are often multi-sited, increasing the complexity of research governance (McDonald 2005). By focusing on "public", rather than "private" research, I am documenting the

experiences of research participants and researchers within the public context, no doubt a very different world than research conducted by CROs. CROs are a growing industry, the economy and practices of research are becoming more privatized. However, research participation in public institutions continues to be intellectually and technically important. Publicly-funded health research may be a shrinking field, so this is an important documentation of the practices and discourses of the sector.

There are numerous types of health research involving humans, ranging from health behavioural research to clinical trials. When people are invited to participate in health studies, they are typically invited to complete a survey, or participate in an epidemiological study, kinesiology study, a psychological study, or a clinical trial. Investigators survey people for a number of reasons, but primarily to explore participants' knowledge, attitudes and behaviours. Epidemiological studies typically follow populations over time and attempt to link health outcomes with exposures to substances or events. Kinesiology studies explore bodily movement and function. Psychological studies investigate numerous cognitive, emotional, and behavioural responses in humans.

Clinical trials are studies which determine the effectiveness and safety of drugs and medical devices (Cancer Research UK 2006). After bench testing and safety testing on animals, drugs are typically tested on humans in four phases. Testing can stop at any phase if evidence suggests the drug is unsafe or ineffective. Phase 1 tests the safety, toxicity, and side effects of a new

intervention. Most Phase 1 studies use a dosing cohort design to determine the

maximum tolerable dose. Participants are put into dosing cohorts, where each

cohort receives a different dose to learn the maximum safe dosage. Phase 2

tests preliminary effectiveness and further evaluates safety. Phase 3 tests the

effectiveness and side effects of the intervention compared to placebo and/or

commonly used treatments. Phase 4 trials are post-marketing studies designed

to further investigate long term risks. Generally, the number of participants

required increases per phase, ranging from a few dozen (depending upon the

study) for a Phase 1 study, to up to several thousand for a multi-sited Phase 3

study (National Institutes of Health 2008).

C) Literature Review – experiences and perspectives of research participants

There is a growing literature on the experiences and perspectives of

research participants in medical studies. Much of the research is survey-based

and focuses on the motivations of participants and informed consent. The

implicit question behind many of these studies is "Are we conducting these

studies ethically?" From a participant-focused perspective, an ethical study is

typically one where research participants: (a) are not coerced, (b) understand

what will be expected of them, and (c) appreciate the risks and benefits.

Investigators have most often employed quantitative surveys and other

numerical measures to determine the perspectives of research participants.

There have been a number of noteworthy qualitative studies, which I will

highlight in this review. In addition, although most research in this area focuses

on research participants, a few studies have investigated the perspectives of

those who have been approached to participate in a study, but declined. The

literature on medical research participation focuses on the following: why people

agree or refuse to participate; issues around informed consent, including

understanding of difficult concepts such as equipoise (that physicians do not

know what treatment is best) and randomization; and finally, the social and

physical experiences of participants. These areas will be addressed in turn.

i)   Motivations of participants

The motivations of trial participants and non-participants vary and

depend significantly on the purpose of the study (therapeutic or non-

therapeutic) and the participant population (most significantly whether they

have a terminal illness). In studies involving people who do not have life

threatening illnesses, motivations vary, although the desire to help others is

common. One research team analyzed questionnaires completed by 79 non-

oncology patients who were enrolled in research studies at study entry, during

the study, and after participation (Madsen et al. 2000). They found that

participants were motivated by the idea that they could help future patients and

the expectation that they would be a "special patient" and receive better care by

enrolling in the trial. Another research team surveyed almost 2000 participants

in a wide variety of medical studies across the United States and found that

participants were primarily motivated by their interest in helping others and in

helping science (Sugarman et al. 1998). An interview-based study of British women who participated in a diagnostic testing study, found that participants were motivated by their desire to help further scientific knowledge and "give back" to the health care system (Morris and Balmer 2006). Another survey-based study of 66 participants enrolled in a variety of out-patient clinical trials found that the most common motivations were: to help others, to improve their own treatment, and to comply with the doctor's request (Bevan et al. 1993). Some participants are motivated by monetary remuneration and access to free health care, such as some women in a birth control trial who attempted to enroll in the same trial multiple times under different aliases (Steiner et al. 2001).

Some researchers have further investigated participants' motivation to help others, asking what types of people enroll in studies to help others, and what motivates them to do this. Lowton (2005) interviewed 31 adults with cystic fibrosis who were participating in studies at a cystic fibrosis clinic. When describing why they were motivated to help others, they often invoked their own health history. They felt lucky for the good care they had already received and wanted to contribute to improving health care. They also felt that since they had self-described "mild" forms of the disease; they were lucky and relatively healthy and were in a better position to give of themselves. These motivations indicate their identification with others with the same chronic disease. According to another study about altruistic motivations, participants who reported altruistic reasons for participating in clinical trials were more likely to

be college graduates and to report higher social support and functioning

(Rosenbaum et al. 2005).

Participants with a life threatening disease tend to be motivated to a

lesser degree by a desire to help others, and more by a desire to improve their

prognosis or quality of life. Their motivations are often influenced by hope for

survival and desire to find meaning from their suffering. Participants of a Phase

1 colon cancer chemoprevention trial completed a questionnaire designed to

assess their perceptions of participation. According to the survey, most entered

the trial because they thought it would be of personal benefit and found they

received satisfactory care (Suchanek Hudmon et al. 1996). Cox and McGarry

(2003) reviewed the literature on why oncology patients accept or refuse to take

part in cancer clinical trials. Patients who volunteered tended to report

motivation to help others, to please their family members, hope for tumour

response, to help their trusted physician, and to take advantage of the support

offered to trial participants. Participants also conceive that they will receive

better care while enrolled in a Phase 1 study than they would otherwise

(Hutchison 1998).

A review of the literature on the motivations of cancer study participants

concluded that hope for personal gain is the most significant motivator (Wray et

al. 2007). Wright and associates (2004) explored why cancer patients enter

randomized clinical trials and found that most often they were motivated by

perception of personal benefit, and were influenced by whether the research coordinator helped them make their decision. Similarly, others found that "cancer patients who participate in phase I trials are strongly motivated by the hope of therapeutic benefit" (Daugherty et al. 1995:1062). An interview-based study of Phase 1 oncology study participants concluded that cancer research participants enroll in studies because they offer hope and allow patients to "try everything" to fight their disease (Moore 2001). A survey of 163 Phase 1 cancer study participants and found that their primary motivation was to treat their tumour (Agrawal et al. 2006). In summary, motivation to help others seems to be dependent upon an individual's ability to help others, in terms of income and health status.

ii)   Motivations of non-participants

Of the patients who are invited to participate in clinical trials, many decline.[1] It is difficult to access these individuals and learn why they decline to participate. Cox and McGarry (2003) reviewed the available literature on why patients do not participate in clinical trials and found that there was very little understanding of the perspectives of these patients and whether any instrumental factors could influence their decisions. However, some research provides insight into the perspectives of those who do not participate. Phase 1 study participant accrual rates of cancer centres vary from between about 14% to 30% (Ho et al. 2006). Patients refuse because they do not have the time, feel unwell, are adverse to the medical procedure, or desire to pursue other forms of

treatment or no treatment. Researchers surveyed cancer patients who agreed

to enroll in a Phase 1 study and those who declined (Meropol et al. 2003). They

found that those who declined reported being less optimistic about participation

than those who enrolled. Lowton (2005) found that her informants (with "mild"

cystic fibrosis) were regularly approached to participate in studies and they were

more favourable to low-intensity, later-phased studies and were more apt to

decline participation in high-intensity, earlier-phased studies.

Another study surveyed adults with advanced cancer who had accepted

or declined participation in a Phase 1 study to measure their uncertainty in

making health decisions (Flynn et al. 2008). Investigators found that the

decliners were more uncertain about the study and indicated that they felt less

informed about the study, perceived less benefit, and felt more pressure to

enroll. In their study of patients' reasons for accepting or declining to participate

in randomized clinical trials, Jenkins and Fallowfield (2000) found that those who

declined were most often worried about being randomized into a non-treatment

arm. Those studies that offered treatment for all study arms had higher

acceptance rates. In summary, decliners felt less optimistic about the benefits or

risks of the study and were often less healthy than those who enrolled.

iii)   Informed consent

Informed consent in clinical trials is complex and difficult to ensure because

patients can under-recognize the experimental nature of the trial, due to a

number of social and contextual factors. Thus, researchers and ethicists alike

question how well participants of medical research are informed. Patients are likely to think of researchers as physicians, and although in many cases they are, as researchers their relationship with the patient is contractual rather than therapeutic (Thomas 2000). The physician's goal is to cure, while the researcher's goal is to learn (without exposing the patient to undo risk). In addition, when a patient's physician invites them to participate in a clinical trial they are involved in, there is a level of coercion because patients may not perceive that they have a choice or may worry that they will not receive proper care if they refuse to participate (Featherstone and Donovan 2002;Thomas 2000). In a large qualitative study, investigators interviewed 200 cancer patients and found that physician emphasis on numbers and probabilities shaped both patients' attitudes to their treatment and their experience (Thorne et al. 2006). Numerical data was not neutral, and physicians used statistics subtly to instill hope.

Research participants often sign consent forms without fully appreciating what will happen during the trial and why. Participants often express understanding and satisfaction with the information provided during clinical trials (Ferguson 2002) but their perception of their knowledge and understanding may significantly exceed their actual levels (Joffe et al. 2001). Edwards and colleagues (1998) reviewed the literature on comparative methods of informed consent and found that in general, providing people with more time and more information was associated with lower consent rates. However, they

found that the more patients knew about medical trials *before* being asked to participate in a trial, the lower their anxiety levels. They conclude that there may be an "optimal amount of information which enhances patient understanding and which might, in turn, reduce anxiety" (Edwards et al. 1998:1825).

In an innovative study, Sankar (2004) observed 16 informed consent sessions for a Phase 1 oncology study. She found that, even though the investigators could not know whether participants would react favourably to the drug, and even though the purpose of the study was to learn about toxicity, and not effectiveness, the investigators gave subtle cues to indicate that they thought the participant would benefit from the drug. Ensuring that participants are adequately informed about a study is challenging when investigators give subtle messages which contradict formal messages on the consent form. Other researchers conducted a similar study, with similar results (Kass et al. 2008). They found that investigators gave potential participants mixed messages, such as referring to the Phase 1 study drug as a "treatment". They recommend that investigators use precise language and clearly distinguish Phase 1 studies from treatment.

Corrigan (2003), in her qualitative study of participants in clinical trials, found that participants did not take the informed consent process seriously. She believes that this phenomenon is partly explained by wider trust in medicine,

research, and expert systems. Corrigan also argues that informed consent for

participants is complicated by their own life stories and their own circumstances.

> There needs to be a realization that the type of illness a patient is
> suffering from, her anxiety about the likely trajectory of her illness,
> her expectations about treatment and, in general, her implicit trust
> in the doctor and medical science mean that 'informed choices'
> based on the adequate understanding of the information and on
> careful consideration of the potential benefits and risks, are difficult
> to achieve in practice. (Corrigan 2003:789)

One study found that participants of CRO-based clinical trials are not very well

informed about the methods, purpose, or risks of the studies they are enrolled in

(Fisher 2006). The investigator attributed this to (a) a lack of interest in the

details of the research and (b) general lack of knowledge about specialized

research.

Others suggest that the current atomistic and individualistic model of

informed consent ignores consent as a social process. Socioeconomic

background and literacy (Kuczewski and Marshall 2002), ethnicity (Barata et al.

2006), and trust of the medical profession influence the informed consent

process and an individual's ability to make an autonomous and informed

decision (Sherwin 2000). Patient decision-making is influenced by relationships

with family, friends, and health care providers, and increasingly by information

received from support groups and the internet (Kuczewski and Marshall 2002).

iv)   Clinical equipoise and randomization

Assessing knowledge and understanding of complex concepts such as clinical equipoise and randomization is challenging. In clinical research, equipoise refers to the fact that the researchers do not know what the results of the research will be. Featherstone and Donovan (1998) interviewed 20 participants in a trial which tested three different treatments for lower urinary tract symptoms related to benign prostate disease. They found that clinical equipoise was the most difficult concept for participants to understand. In ordinary medical treatment, the best treatment is often known and is based on a variety of factors such as an individual's symptoms, condition, and age. Perceptions that caregivers tailor treatment to individuals according to their particular circumstances were confirmed by the volume of tests and questionnaires completed during the trial. Thus, the concept of equipoise – that clinicians do not know the best treatment – was confusing as it contradicted their experiences both as patients and as clinical trial participants.

In a study of the knowledge and attitudes of parents of critically ill babies who consented to enroll their babies into a randomized controlled trial, investigators found that few parents understood that the treatment their baby received was allocated at random (Snowdon et al. 1997). Many parents thought that they would choose which treatment their baby would receive. The authors suggest that all efforts should be made to ensure that people understand trial methods (such as asking potential participants to communicate their

understanding of the trial to the trial coordinator) to promote informed decision-

making. In a similar qualitative study, investigators found that most of the trial

participants they interviewed did not understand that their treatment would be

chosen at random (Featherstone and Donovan 2002). In fact, better informing

patients about the process of randomisation may increase trial enrollment.

Researchers compiled the results of surveys completed by 315 cancer patients

and found that about 45% of respondents were comfortable with the process of

randomisation, and an additional 23% became comfortable with it given a fuller

explanation of randomization (Fallowfield et al. 1998).

v)   Social factors

Despite questions surrounding the degree to which clinical trial

participants are fully informed about the methods and possible risks and

potential benefits of participation, and that clinical trials primarily benefit future

patients, most participants report a high degree of satisfaction with their clinical

trials. In general, clinical trial participants report high satisfaction with their care

(Terenius 2000). Cox (1999) found that cancer patients enrolled in Phase 1 and 2

clinical drug trials had similar experiences. First, many participants discussed

issues that reflected a therapeutic alliance with their care givers (they felt their

care providers were hopeful that the trial would help them, they felt honoured

to be invited into the study, and they were influenced by how their providers

framed the study). Secondly, they discussed the trial burden, which took

physical and emotional toll. However, despite and perhaps even because of this

burden, they maintained that the trial was worthwhile as it provided them with self-worth. Finally, participants spoke of their search for meaning: their continued desire to live despite poor trial outcomes, their desire to help others, and their interest in being kept informed of the trial results. In a survey of clinical trial participants in the Netherlands, investigators found that on average participants were very satisfied with their experience, and this had no relationship with whether they benefitted medically from the study (Verheggen et al. 1998). In addition, the research team found that satisfaction was associated with trust in the medical system, interest in science and medicine, and perceptions of the investigators.

The topic of trust - trust in researchers and trust of research activities - emerges regularly in the literature. McDonald and colleagues (2008) interviewed 41 Canadians who had participated in a variety of medical studies and found that trust was an integral part of their experiences. Trust between researchers and participants is developed through a dynamic, reciprocal and negotiated process. Participants trusted researchers based on their perceived competency, their association with universities and hospitals, and professional status. However, participants were generally distrustful of pharmaceutical companies. The authors warned that "trust is not always desirable in research... subjects may have misplaced trust in health professionals" (McDonald et al. 2008:43).

Other researchers have also noted trust in the research setting. As mentioned, Corrigan (2003) found that participants trusted expert systems, of which they had little knowledge. Research participants in a cystic fibrosis clinic also displayed trust, and this trust was habituated and developed through their experiences as patients in the clinic (Lowton 2005). Medical research participants are often very clear and articulate about their trust in medicine and medical science (Sugarman et al. 1998). In another study about trust in medical research, investigators found that participants trusted the safety of medical studies because they believed that study doctors would never ask them to do anything unsafe (Kass et al. 1996).

The other theme that emerges in the literature regarding the experiences of research participants (primarily oncology study participants) is hope. Cox (1999;2000) noted that a desire to maintain hope was a significant motivator for the Phase 1 cancer study participants she interviewed. Moore (2001) found that participants in Phase 1 oncology studies maintained a complex balance between hope and the reality of living with an incurable disease. Hope for a cure encouraged participants to try anything. This need is a "reflection of Anglo-American culture where people with cancer are expected to be brave and not allow themselves to give in to disease" (Moore 2001:743). It's important to note that Phase 1 oncology study participants hope for a cure, rather than expect one (Kass et al. 2008).

D) Critical-interpretive medical anthropology: its development

The literature on clinical trial participation and the experiences of clinical trial participants focuses on motivations, informed consent, and the influences of social and affective factors such as trust and hope. What we do not understand from this research is what it is like for these participants to be in a study, what makes them stay, and their perspectives on research. In addition, the current literature (with some notable exceptions) in general, does not consider the wider cultural and economic factors that make medical research on human participants both reasonable and possible. How the experiences of human research participants are influenced by their relationships with their health providers and their social support network, both within the context of cultural understanding of autonomy and the body as a commodity, as well as the economic and social power and prestige of the medical research industry, requires examination.

Critical interpretive medical anthropology emerged in the 1980's. Scheper-Hughes and Lock developed the framework to help medical anthropologists connect individual suffering, social meaning, and broader political and economic forces. During this era, there was a concerted effort amongst many medical anthropologists to forge a new approach to medical anthropology, one less fascinated with exotica (Scheper-Hughes and Lock 1986) and more attenuated to the economic and political realities of people's lives. Critical interpretive medical anthropology is a permutation of critical medical anthropology, but with an increased focus on individual suffering and symbolic

meaning (Scheper-Hughes 1990) and less emphasis on political economy

(Morgan 1987).

Critical medical anthropology (CMA) is a theoretical school, developed in

the 1980's (Singer and Baer 1995), and continues to be one of the most

influential approaches in the field today. Critical medical anthropology is the

study of health and healing "with the recognition that disease, illness, and

treatment occur within the context of the capitalist world system" (Baer et al.

1986:95). By employing Marxist approaches to medical anthropology, scholars

can account for the impacts of capitalism on health, illness, and healing. The

purpose of this approach is to understand, critique, and ultimately change the

medical system. The goals of CMA are to increase access to medical care, and

change the relations of production to improve global health and well-being (Baer

et al. 1986). Critical medical anthropology seeks to correct some of the

weaknesses of "mainstream" anthropology. "Mainstream" anthropological

studies examine the local dynamics of communities, while ignoring the impacts

of "the unifying effects of phenomena like proletarianization, commodification,

and mass advertising" (Singer 1989:1198). The approach is similarly "critical" of

orientations which ignore or obscure the impacts of economic policies like

structural adjustment programs and free trade agreements, and those that

consider "culture" as a causal factor for high rates of diseases such as AIDS

(Farmer 1999) and type 2 diabetes (Garro and Lang 1994).

Baer and Singer were influenced by scholars of the political economy of health (Singer 1989), especially by Morsy's argument that the political economy of health was the "missing link" in medical anthropology (Morsy 1979). The political economy of health links medical anthropological studies of small-scale communities to poverty, disenfranchisement, and control over resources (Baer 1982:1). By incorporating perspectives from the political economy of health, anthropologists can study "health-related uses within the context of the class and imperialist relations inherent in the capitalist world-system" (Baer 1982:1). The political economy of health approach is a reaction to studies of disease which ignore the social factors of ill health and the unequal patterns of disease burden. Implicit in this critique is that by ignoring the political and economic aspects of disease, anthropologists support their continuation. With the injection of a more critical, global, class-based, and ecological perspective, medical anthropology can realign itself and become more historical and relevant (Singer 1990).

Critical medical anthropology is also influenced by classic Marxism and critical theory. A classical Marxist approach to illness and healing frames both the experiences of and responses to illness within relationships and modes of production. The exploitation of labour creates physical and social stresses which lead to and exacerbate illness; health-related issues often have a class element (Baer 1982). In addition, most western modes of healing are controlled by the capitalist class, transforming health into a commodity and underscoring class

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divides (Navarro 1976). As Baer and colleagues assert, "a critical medical anthropology must address questions of who ultimately controls biomedical institutions and the implications of such control" (Baer et al. 1986:95). However, I agree with Morgan that critical medical anthropology studies are often guided by dependency theory and rarely rely on analyses of more fundamental Marxist concepts such as relations of production and struggle over the means and modes of production (Waitzkin (1986) is a notable exception).[2] This may be because a class-based analysis is not the most appropriate approach to a cross-cultural and holistic medical anthropology. Thus, critical medical anthropology has tended to focus on how poverty, racism, and sexism - rather than class - shape health and healing.

Marxist influences have also reached critical medical anthropology through Critical Theory. Critical medical anthropology has been influenced by Critical Theory and the Frankfurt School.[3] We can see the influence of the Frankfurt School in CMA. For example,

> [C]ritical medical anthropology understands health issues in light
> of the larger political and economic forces that pattern
> interpersonal relationships, shape social behaviour, generate
> social meanings, and condition collective experience. (Singer
> 1990:181)

Issues of meaning, collective knowledge, and collective responses (however illogical they may seem) are all elements of a critical medical anthropology.

However, these must always be understood according to their relationship with

broader political and economic forces and trends.

Critical medical anthropology is a framework that incorporates both the

micro- and the macrolevels.

> It is the view of critical anthropology that the microlevel is
> embedded in the macrolevel, while the macrolevel is the
> embodiment of the microlevel but is not reducible to it. However,
> there is no empirical separation, rather, a heuristic division is
> made to facilitate examining the connection between unique
> configurations and general processes. Herein lies the special
> contribution of anthropology, a discipline committed to close
> encounters with local populations and their lifeways, systems of
> meaning, motivations for action, and daily experiences, to the
> encompassing holism of the political-economic approach. (Singer
> 1990:181)

According to this description, anthropological fieldwork into the lives, activities,

and meanings of local people acquires depth and relevancy through linking it to

larger political and economic processes. The apolitical becomes political through

this step and policies and economic relationships which cause suffering and ill

health are questioned rather than ignored.

CMA has become a popular and influential movement in anthropology

(Baer et al. 2003;Singer 1989). Nevertheless, some critics feel that CMA has a

tendency to overemphasize the impact of the global economic system, thus

ignoring local meaning and experience (Gaines 1991;Pelto 1988;Scheper-Hughes

and Lock 1986). As a response, medical anthropologists Nancy Scheper-Hughes

and Margaret Lock developed an alternative framework: critical-interpretive medical anthropology. Lock and Scheper-Hughes (Scheper-Hughes and Lock 1986:137) contend that many CMA-oriented studies have:

> tended to depersonalize the subject matter and the content of medical anthropology by focusing on the analysis of social systems and *things*, and by neglecting the particular, the existential, the subjective content of illness, suffering, and healing as lived events and experiences.

Critical-interpretive medical anthropology attempts to reinsert individual experience into the analysis while still attending to economic and political factors.

According to Lock and Scheper-Hughes (1990) the critical-interpretive approach in medical anthropology has three broad purposes: (1) to describe the metaphors used to understand the body (2) to explore how practice and social context influence knowledge production and (3) find the relationship between cultural beliefs and practice. To relate metaphors, individual experience, knowledge, local practices, socio-economic conditions, and cultural beliefs requires investigation into a range of different domains. For analytical purposes, Lock and Scheper-Hughes (1987;1990) propose that research questions about health and health care examine what they call "the three bodies": the individual body, the social body, and the body politic.[4] They examine each body using a different theoretical orientation.

i)   The individual body

The *individual body* is an apparent universal, although conceptions of

individualism and individual rights are not (Scheper-Hughes and Lock 1987).

Most people have a sense of themselves as bodies physically separate from

other bodies. The connections between mind and body are experienced variably

across and within cultures. Studying embodiment (how the mind and body

connect) attends to a range of experiences, including how bodies suffer, develop

tacit expertise, and practice their art. Thus, embodiment is important in

understanding not only the patient perspective, but also how health researchers

develop expertise and practice in complex and stressful environments.

Phenomenological studies have influenced Lock and Scheper-Hughes'

(1987) approach to the individual body. Phenomenology[5], the "scientific study

of experience" (Jackson 1996:2) is based primarily on Merleau-Ponty's

(1962;1963) work on phenomenology[6], Dewey's (1960) pragmatism[7], William

James' (1912) radical empiricism[8] and Bourdieu's (1977) theory of habitus[9].

Phenomenological anthropology attempts to capture the experience of

individual lived bodies, because "things are lived and experienced more than

they are known" (Jackson 1996:3). Phenomenology struggles to understand the

pre-cognitive (although not pre-cultural) experience (Csordas 1990;Desjarlais

1993). For phenomenologists such as Merleau-Ponty (1962: vii)

> The world is always 'already there' before reflection begins – as
> an inalienable presence; and all its efforts are concentrated upon
> re-achieving a direct and primitive contact with the world.

Phenomenology is an attempt to ground the study of human behaviour and action in lived experience, rather than high theory (Jackson 1996). Phenomenological study represents a potential escape from interpretations and analysis which can isolate us from lived experience.

ii)   The social body

The *social body* is related to how society constructs and utilizes metaphors and symbols in order to understand itself. Modern medical systems are both symbols of our hope in scientific breakthrough, our hope that through scientific understanding we can overcome suffering, and symbols of the failure of bureaucratic medicine, where bodies are processed rather than cured (Lazarus 1988). The health care system is also a microcosm of our wider society, reflecting gendered roles and ethnic and class disparity (Singer and Baer 1995). In health care, the social body is comprised of policy makers, practitioners, consumers, and tax-payers. These stakeholders help shape health research environments.

Scheper-Hughes and Lock (1986) argue that the body is "good to think with" because it is a collective product (and producer) of nature, culture, and society. They draw on the work of social and symbolic anthropology (see, for example (Devish 1991;Douglas 1966;Geertz 2000b;Singer 1980;Turner 1975)) to elaborate on how the body in illness and health can be a symbolic metaphor for the group.[10] Sickness can also communicate social distress. Entire disease

categories, such as anorexia nervosa (Bordo 1985) and type 2 diabetes (Rock 2005) themselves be considered embodiment of social illness.

Medical anthropologists have likewise studied the symbolic aspects of healing practices including those employed in Western medicine. Shyrock (1966) has noted the symbolic effectiveness of "laying on of steel". Similarly, some evidence suggests that the *act* of surgery (beyond the effects of the surgery itself) (Moerman 1979) and the colour and branding of pharmaceuticals have some therapeutic effect (Moerman and Jonas 2002). However, as Margaret Lock (2001) reminds us, symbolic meaning has biological consequences and varies cross-culturally, helping form what she calls "local biologies".[11] Medical competence is an important symbol of healing. As Good (1995a:9) argues, "competence is not only an "empirical reality," an attribute of physicians, but a core symbol that mediates a variety of experiences and caries diverse meanings." Good (1995a) found that medical competence differs across cultures and locales and is significantly influenced by cosmopolitan medicine and local political economies of care.

Baer, Singer, and Susser (2003) argue that particular metaphors and beliefs – such as autonomy and militarism - are common to biomedicine and impact patient care, presumably negatively. Hahn (1985) shadowed an experienced internist for several months to gain an intimate understanding of medical practice and found that the internist used these same metaphors to

describe how he thought his workplace should operate, how patients should be treated, and his relationship with patients. Emily Martin (1992;1994) has traced how metaphors immunologists use to describe the immune system have changed from war metaphors to those emphasizing the immune system's adaptability, flexibility, and information processing capabilities. Interestingly, these same metaphors are used by business to describe the behaviour of high-performing businesses.[12] These examples highlight the connectedness between the individual and social body.

iii)   The body politic

Finally, expanding our view to the *body politic* brings our attention to how bodies are surveyed and controlled. We do not live in a world purely of metaphors, symbols, and culturally constructed meanings (Lock and Scheper-Hughes 1990). Power relations and structural inequalities impact access to health care, provision of health care, and health status. Bodies are controlled in acts of reproduction, sexuality, sickness, work, and leisure (Foucault 1995;Foucault 2003). Policies aimed at controlling bodies range from discipline, enticement, and punishment. Focusing on the body politic brings our attention to how institutions and states shape, define, and utilize bodies, and how these brute realities shape health, illness, and healing.

Social science has approached the body politic from generally two theoretical angles – the Foucauldian, and the political economic perspectives. Foucault wrote extensively on the creation of the modern citizen and the

circulation of power, arguing that power is not wielded from institutions but circulated by and between individuals, the study of which he termed a "micro-politics" of power (Foucault 1978). Perhaps his most significant contribution to medical anthropology is his concept of biopower. Biopower is "the matrix of force relations that brought life and its mechanisms into the realm of explicit calculations and made knowledge-power an agent of transformation of human life" (Boyer 2003;Foucault 1978:143). Through particular mechanisms (such as the clinical gaze, taking medical histories, surveys, and research) the individual body can be known and through this process becomes an object of knowledge-power. Modern individuals as subjects are impelled to control their own bodies through surveillance and normalization.

The political economic perspective focuses on resources rather than power and knowledge. Political economists of health understand illness as a function of socio-economic conditions. In a classic political economic analysis of health, Farmer (2003) traced Russian prison tuberculosis (TB) epidemic, which developed after the fall of the Soviet Union. Farmer linked post-communism political upheaval and the Russian prison TB epidemic, where scarce economic resources created conditions that both encouraged the epidemic and prevented sound medical treatment. Factors such as financial concerns, relationships with colleagues, and the hospital priorities often influence medical decision making more than scientific proof or concerns about the patient's best interests (Katz 1985).

iv)   The development of critical-interpretive medical anthropology

How then does critical-interpretive medical anthropology differ from critical medical anthropology? Firstly, the interpretive school, with the 3-bodies framework, focuses on three distinct levels (individual, social, and political), and borrows from different theoretical schools to help understand each body. Conversely, CMA made early claims to incorporate micro and macro analyses (Singer 1990), but later proposed a more specific structure, encouraging analysis on four distinct levels: the individual, micro social (immediate social relationships), intermediate social (local social and economic networks), and macro-social (global networks).

Beyond analytic framework hair-splitting, the two schools have different political goals. The authors of the critical-interpretive anthropology emphasize giving voice to the "submerged, fragmented, and muted subcultures of the sick and disabled" and paying specific attention to the metaphors of illness (Scheper-Hughes and Lock 1986:137). Patients often use metaphors to communicate their suffering. These metaphors are subtle protestations about their depth of suffering, social stigma of illness, and counter-narratives to a dominant and reductionist biomedical narrative of disease (Scheper-Hughes and Lock 1986;Scheper-Hughes and Lock 1987;Lock and Scheper-Hughes 1990). These metaphors are catalysts of political activity:

> A critically applied medical anthropology could develop around
> the potential of transforming symbolic and largely unconscious

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protest into more instrumental, collective, and conscious action.
(Scheper-Hughes and Lock 1986:139)

These metaphors question the universality of disease and the biomedical

hegemony over disease definition. The authors assert that much medical

anthropology, including critical medical anthropology, has not adequately

questioned biomedical definitions of disease, which is a barrier to understanding

the perspectives of the sick and suffering. Even when critical medical

anthropologists question processes such as medicalization, they do not explore

their meaning (Scheper-Hughes and Lock 1987).

Critical medical anthropology, in contrast, is concerned less with the

meaning of disease, and more with the causes of disease. Both schools admit

the importance of both domains, yet they emphasize one or the other. Critical

medical anthropology is also more explicitly critical of the organization of

medicine, the control of medicine, and the development of *bourgeois medicine*.[13]

The purpose of this critique is to change how medicine is funded, organized, and

delivered. Critical medical anthropology is also explicitly critical of the role of

neoliberal economic policies and trade agreements, post-colonial relationships,

and development projects, in the health of impoverished communities. Those in

the critical interpretive school, in contrast, place greater emphasis on lived

experience and the indecency of suffering (Scheper-Hughes 1992). The critical

interpretive school posits that it is interested in the medical anthropological

study of people, not just the study of things, as Scheper-Hughes (1990) claims

critical medical anthropology does.

Critical-interpretive medical anthropology is, to the developers of critical

medical anthropology, simply critical medical anthropology and does not need a

special designation (Singer and Baer 1995). I believe I have highlighted the

subtle differences between the two schools. However, they are remarkably

similar. I have a slight affinity for the critical-interpretive school because it has a

tighter framework and a broader theoretical foundation (although not superior –

simply broader, which allows for more flexibility and creativity). In addition, I

believe that since I tend to see things in terms of class first and foremost, the

critical-interpretive approach may broaden my perspective and help me explore

areas of clinical research I may not otherwise attune myself to.

However, I am uncomfortable with the subtext of smugness I read in the

critical-interpretive approach.[14] I think it is wrong to assume that exploring

meaning aligns the researcher with her informants (and them with her) or allows

her to speak for them and their experience. Alignment, advocacy, and voice are

offspring of field work methods, and have very little to do with the theoretical

framework employed. Both the critical interpretive and critical schools contain

seeds which may encourage anthropologists to develop strong and mutually-

beneficial relationships with their informants. However, the field work social

milieu and the existence of supportive structures for the field work have a much

greater influence on how well the anthropologists can speak for (or with? or

against?) his informants, advocate for change, and challenge political economic

or social forces.

E) Organization of Dissertation

The dissertation is organized thematically. Before exploring these

themes, I first describe the research settings and the methods I used in the

methodology chapter, Chapter 2. In this chapter I describe why I chose the

methods I did and where I hoped and assumed they would lead me. I also

describe the limitations and advantages of those methods. This chapter will give

the reader a solid understanding of the research setting, process, and my

approach as a researcher.

In Chapter 3, I discuss the political economy of university-based health

research in Canada. This chapter incorporates a review of the appropriate

literature. Since the dissertation is organized thematically, each theme has its

own literature from which I draw. This chapter provides the reader with

information about the economic context in which health research is conducted

in Canadian universities. In it, I also examine the economic perspectives and

realities using a critical-interpretive framework. Through this examination, I

show how the government's policies and approaches influence the social body

and individual researchers and research participants.

In Chapter 4 I use a critical-interpretive framework to explore how time is understood and organized in health research. Since there exists an extensive literature on time, I highlight what I see are the most common perspectives and demonstrate how each of these perspectives highlight important and unique features of health research participation. I found using multiple theoretical approaches to time helpful, each providing a unique lens through which to view time. I use Lefebvre's theory of rhythmanalysis as a recurring theme to weave the different approaches together. Chapter 4 refocuses the analysis to the research lab, exploring how participants and researchers use, manipulate, and interpret time.

In Chapter 5 I examine humour and laughter in research. Like Chapter 4, this is a close examination of the research setting. Like time, humour and laughter are vectors with which to delve into the worlds of research. In this chapter, I review the social scientific literature on humour and laughter. I think it is important to examine how these are used differently and have different meanings across studies. Since humour and laughter are inherently social phenomena, I focus my analysis on the social body.

Chapter 6 is a discussion of research ethics. The majority of the literature about research participants addresses the ethics of research from their perspectives. In this chapter, I summarize what my research contributes to the research ethics debates. I also make suggestions for research ethics boards

(REBs) and clinical researchers from the perspective of an anthropologist, a person on the periphery, and someone who has had an opportunity to witness and interrogate health research as it is carried out.

Chapter 7 is an autoethnographic account of my own experience as a research participant. While I was doing my M.A., I took part in a Phase 2 clinical trial for a birth control pill. I enrolled in this study because it gave me access to a new type of birth control pill, one that I thought would be better for me. Through my participation I also received free birth control medication and modest remuneration ($60 per year). The experience was interesting and I thought that being in a study provided a particular insight into the embodied experiences of human research participants otherwise not accessible through other qualitative methods, such as participant observation and in-depth interviews. This chapter is primarily from the perspective of the individual body – my body specifically. At the end of the chapter, I take the opportunity to explore the relationships between the three bodies and demonstrate how the social body and the body politic influenced my own experience and how my own body reflects on those bodies.

Chapter 8 is the summary chapter. In this chapter, I describe how the various themes form a larger picture. I also comment on the strengths and weaknesses of the critical-interpretive framework, as I employed it. I also reflect on the methodology I used and what this project taught me about research

methods and techniques. Finally, I describe other areas of research and research

questions ripe for anthropological investigation.

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[1] The agreement rates of studies varies; phase 1 oncology studies tend to have relatively high agreement rates (Ho et al. 2006) and oncology randomized controlled trials, for example, tend to have very low recruitment rates (Wright et al. 2002).

[2] Morgan (1987) argues that the political economy of health, and critical medical anthropology in particular, are heavily influenced by dependency theory. According to dependency theory, through colonial relationships and neoliberal economic policies, richer countries (the core) drain resources from poorer countries (the periphery), thereby maintaining dependent relationships and contributing to the underdevelopment of those countries (Wallerstein 1976). The world capitalist system draws all countries into it, and exploits those who do not control its terms. Morgan believes that the world systems theory treats capitalism "as though it were everywhere the same" and ignores non-capitalist modes of production (Morgan 1987:140). However, the world systems theory does highlight international economic relations and helps us question the sources and causes of poverty and illness.

[3] The Frankfurt School (the common name used for the "Institute of Social Research" at the University of Frankfurt, established in 1923) was a group of social philosophers who applied Marxist concepts to social and political developments during the first part of the twentieth century (of particular interest were the Russian Revolution and the rise of Fascism). In 1933 the institute relocated to Geneva (due to pressure from the recently elected National Socialist German Workers' Party), and in 1935 to New York. Its major contributors included Herbert Marcuse, Theodore Adorno, Walter Benjamin and Max Horkeimer. Marcuse greatly influenced political activist movements in Europe and North America, with his insights into how people come to support and believe in political parties and structures which are both tyrannous and socially crippling, and ultimately not in their own interests, but in the interests of the ruling class (Marcuse 1964). Benjamin, a literary critic, applied Marxism to understand imperialistic war, our changing relationships with art, and modern notions of progress (Benjamin 1968).

[4] Kirmayer (1992:342) has added a fourth body – the biological body that is not strictly bodily felt, social, or political, but indexical – measurably linked to the body's physical condition.

[5] According to Embree (1997) there have been four major "tendencies" or stages in phenomenology: realistic phenomenology (the search for universal essences of experience and knowing), constitutive phenomenology (which believes in a pre-conscious inter-subjective space for all things human and non), existential phenomenology (which is concerned with actions and movement) and hermeneutical phenomenology (with emphasis on how to interpret phenomena). Phenomenological anthropology has been influenced primarily by the existential and hermeneutical movements.

[6] The philosopher Merleau-Ponty (1962:vii) defines phenomenology more broadly, describing it as "the study of essences... the essence of perception, or the essence of consciousness, for example".

[7] According to the theory of pragmatism, truth cannot be found in an object or study's essence, but in its outcomes. Truth is as such linked with human activity and experience (Kemerling 2002).

[8] Radical empiricism holds that truth is that which can be directly verified, and as such, truth realms vary widely from person to person.

[9] For Bourdieu, habitus is a system of durable, transposable dispositions. Such dispositions shape actions and resultant experiences shape the habitus. One's habitus is shaped by one's social environment but is still wholly idiosyncratic. Habitus thus provides the foundation for a flexible, non-deterministic and non-deliberate theory of action. A habitus is "objectively 'regulated' and 'regular' without being in any way the product of obedience to rules, they can be collectively orchestrated without being the product of the organizing action of a conductor" (Bourdieu 1994:53).

[10] However, medical practitioners often make decisions based on medicine's own metaphors, either ignoring or disqualifying the patient's own interpretation (Kirmayer 1992:340).

[11] Lock's (2001:483) local biologies concept "refers to the way in which the embodied experience of physical sensations, including those of well-being, health, illness, and so on, is in part informed by the material body, itself contingent on evolutionary, environmental, and individual variables." Local practices and histories, and biological variables impact both phenomenology and symbolic healing.

[12] Interestingly, Boyer (2003) has noted a parallel between Rabinow's (1999) urge for social scientists to develop new knowledge of phenomena (rather than explaining phenomena in terms of historical models) to urges within the business community during the same time period to be innovative and "think outside the box".

[13] Singer cryptically defines bourgeois medicine as "not a 'thing' or a set of procedures and treatments as much as it is a particular set of social relationships and an ideology that legitimizes them" (Singer 1986:129). For him, bourgeois medicine is a project in which the knowledge and treatment of the body is developed, circulated, and hoarded by a particular class. Moreover, the ideology of medical treatment (primarily that it is a social good, an altruistic pursuit and a technical and scientific specialty) legitimizes and, in fact, encourages the class division of medicine. Bourgeois medicine gives the ruling class knowledge of and control over the working class.

[14] I read the emphasis on meaning as a moral, not analytical or scholarly exercise. This morality, I believe, sups on suffering and poverty. Evoking this suffering is possibly meant to reach readers and help them understand the lived experience of structural violence. However, I worry that it is a form of academic exploitation. I worry that the more gruesome the tale, the more prestigious the work.

CHAPTER 2: METHODOLOGY

A) Introduction

To explore the experiences of human research participants, I examined three different medical research studies. All of these were conducted by university-affiliated researchers and at university-affiliated sites. In addition to shadowing these three studies, I did other work to understand the social and bureaucratic environments which supported these studies: investigating research ethics boards (REBs) and research ethics conferences, and participating in a study myself. I will first describe my methods, why I chose them, and how they relate to my research question. I will then describe the different research sites, my reasoning in choosing them, the informants I met in each one, and my data collection methods. I will describe my "entry into the field", how I navigated the social environment, particular details about each social environment, and my reflections on how my presence and methods influenced the studies and consequently, influenced the data I collected. I will also discuss the ethical considerations of my work, and the ethical debates surrounding anthropological field work.

B) Research Questions and Assumptions

My fundamental research question is: "Why do people participate in health research?". I want to understand the motivations and experiences of research participants and the microcosm of medical data creation – the worlds and lives of those who literally produce data. I became interested about the world of research

participation through my readings about Evidence-Based Medicine (EBM) and the

literature arguing that clinical trial evidence is not generalizable because the participants

of clinical trials are different than those found in clinical practice. I began to wonder

what they *were* like and what it was like for them to be involved in this business of

creating evidence.

I was also interested in the topic because during my M.A. I enrolled in a clinical

trial for an experimental birth control pill. I did it because I wanted access to that

particular drug. It felt good to do something 'risky' like take an experimental drug which

would alter my hormonal cycle. However, it had a number of side effects and I think

because of those side effects I am critical about my participation. I found the

organization sloppy, the researcher friendly but more interested in collecting data than

addressing my needs, and the free drug company merchandise they gave me insulting. I

also vividly remember a missing blood draw (they took several vials of my blood and

promptly lost them) and an internal exam, to which I consented having a large audience

for 'educational purposes'. At the time I simply participated and thought little of it.

Only in retrospect have I become more critical and frankly curious.

Going into this study, I anticipated gaining insights from research participants

regarding research methods and research questions. I assumed participants would be

critical about research, although not worried about their safety. I assumed that

participants would not understand much about the research, but would know detailed

information about the methods. I assumed that the research environment would be congenial but cold, the participation uncomfortable but tolerable. Finally, I assumed the participants would be unusual people – quirky, diverse, unafraid, curious, and possibly adventurous.

C) Research Sites

i) Clinical Study Sites

In my research I followed three studies: an asthma drug study, a muscle regeneration study, and a cancer drug study. I chose these different studies for the following reasons: (1) to follow studies with different participant demographics, (2) to follow studies with very different study requirements, (3) to follow both therapeutic and non-therapeutic studies. I looked for university-based studies that were to commence within the first few months of my field work and whose principal investigator (PI) was willing to let me shadow the study. I learned about who was doing research involving human participants from my contacts at the university, scouting for study posters, and checking the university website. In total, I approached 7 researchers to get 3 suitable studies. Many studies were not suitable due to timing and logistical concerns. Two of the studies were delayed, the recruitment was already underway for one study, and the PI of another study felt the participants would not agree to speak with me (this was a clinical trial for anti-anxiety medication).

I chose to follow university-based research studies because I anticipated that access would be easier and because I assumed that following only contract research organization (CRO) based studies would give me a limited view of the world of research participation. My assumption was that, because CRO-based studies generally pay more, participants would be similar and similarly motivated by remuneration. I followed only adult research studies for several reasons: the vast majority of research participants are adults, following child studies would have been difficult and time consuming to navigate in terms of obtaining informed consent; and finally, because I have no experience working with or interviewing children.

When I spoke with PIs about working with them, I found they were very receptive to the idea. They were interested in learning more about the experiences of their participants and were open to having an outsider come in and learn about their work. Generally, the only concerns they had were (1) that I might interfere with their study by being a hindrance to the timing of the tests or interfere with the procedures, or (2) that participants might find participation in my study an additional hindrance, which would dissuade them from participating in the original study. To address these concerns I always checked with the research coordinators about appropriate times to speak with and observe participants, and delayed or paused any interviews to give priority to their study. I also worked with the research coordinators to recruit for my study. All research coordinators agreed that the best way to recruit was for them to tell participants who

had already agreed to be in their study about my project and ask them if they would like me to come in and speak with them about my research study.

Ultimately I did not like this recruiting technique because it forced me to rely on the research coordinators for recruitment into my study. They would often forget and I would need to phone, email, and visit them to urge them to help me with my recruitment. It is my experience that recruitment can be one of the most challenging and overlooked aspects of qualitative research. Asking for others to be responsible for this crucial step is frustrating and can significantly limit or endanger the research. In my case, because I wanted to follow specific studies, it was necessary for me to use the recruitment technique most amenable to the study coordinators and PIs. This method limited my recruitment for the cancer and muscle regeneration studies. In the future, I would be reluctant to be involved in a study where people outside the research team were responsible for recruitment.

When I met with participants, I told them about the purpose of my study, the risks and benefits, and the interview process. I explained that I was not affiliated with the study they were in, that I was doing independent research about the experiences of research study participants. I told them that the information they gave me would be anonymous, although I would share my general findings with the study researchers. I stressed that participation was voluntary; they could skip any questions or drop out at any time. Moreover, afterwards they could change their mind and take back their data. I

asked if they had any questions. I then asked them to read over the consent form and inquire if they had any additional questions before signing and dating the consent form.

I intended to interview participants at the beginning, middle, and near the completion of their study. I wanted to learn about how participants adapted to the research environment and how their understanding, appreciation, and attitudes might have changed over time. I assumed that their response to the study and their attitudes and experience might be temporally related. I also assumed it might be spatial, another reason for investigating multiple research sites. I wanted to focus on how the physical and social environments shaped experiences and participants' relationships to the research, approaching each study site as a microcosm.

In addition to interviewing the research participants, I interviewed the study researchers and research coordinators. I also interviewed researchers and research coordinators who worked in other, unrelated studies, at other sites. During my fieldwork I met and heard of others in the research community who were willing to give me their perspectives on the work they did, their understandings of the participants, and the challenges of the work. I did this to learn about their perspectives, their approach to their work, and their assumptions and questions about the experiences of research participants. I also chose this because, taking a critical-interpretive perspective, and learning more from the investigators, would illuminate more aspects of the social body and body politic.

a) Study #1: Asthma study

Participants of this study were required to have their asthma induced. This is typical of many asthma drug studies. Going into the asthma study, I thought it odd that people would voluntarily have their breathing restricted. I assumed that it would be a frightening experience for many. I also assumed that since it was a drug study, I would hear some critical discussion of the influence of industry on academic research. Finally, since it was a drug sponsored study, I assumed that the atmosphere would be business-like, efficient, and, frankly, cold. I did, correctly, think the participants would be primarily students.

What wasn't surprising was the environment. It looked like many other university labs I have been in. It certainly had an academic/scientific feel, more so than a medical or clinical feel. In addition, for me, it was not an emotionally challenging environment. The participants all had mild asthma and the disease did not significantly influence their lives, nor did it threaten to shorten their lifespan. Asthma is a common and treatable chronic disease, and an asthma diagnosis, although disappointing, is generally not a significantly traumatic moment in a person's life.

The asthma study was a Phase 2a[15], blinded placebo-controlled study designed to learn about the effectiveness of a new drug in treating asthmatic symptoms. Asthma is a chronic disease, affecting about three million Canadians (Asthma Society of Canada 2008). When people with asthma are exposed to a "trigger" (usually an allergen such as ragweed or pollen), their airways become inflamed and tighten, making breathing

difficult (Asthma Society of Canada 2008). This asthmatic response has a number of

symptoms, including: wheezing, shortness of breath, coughing, and chest tightness.

A university-based researcher specializing in pulmonary diseases was the

principal investigator for the study. She agreed to let me conduct participant

observation and interview any of her participants who agreed to meet with me. She was

supportive of my research and the only concern she voiced was that my study might

"get in the way" of her study. Several of the measurements used were time sensitive

and she did not want my work with the participants to influence the timing of her work.

She indicated that the sponsor, a large pharmaceutical company, supplied the funding

and the drug for the study. Her research team partnered with the drug company

because they were working on a drug that would target a new intermediate enzyme in

the asthmatic response. Her lab tested the drug and collected the sponsor's required

endpoints, plus additional endpoints to help them learn more about the mechanics of

asthma. The sponsor developed the study protocol and the consent forms (in

consultation with the principal investigator), while the principal investigator obtained

ethics approval from the institution.

The study was conducted by two research coordinators, both trained pulmonary

technicians with years of experience. They were the main contacts for research

participants. They were responsible for recruiting participants, completing the informed

consent process, scheduling the participants, recording all study data, and conducting a

number of pulmonary tests. Non-pulmonary tests (such as measuring vital signs, taking

blood, etc.) were conducted by two other workers in the lab, a technician and a study

nurse. In addition, a physician who specialized in asthma and other pulmonary

conditions was always available in case of an emergency.

The lab consisted of a number of rooms, each with a variety of pulmonary testing

equipment. Several graduate students and other research coordinators shared the lab

space and equipment. The research coordinators' office, where most of the testing took

place, was a long thin room flanked by two desks and several filing cabinets, and

contained pulmonary testing machines and several chairs. The space was tight and

sometimes there was standing room only. The office lead to a large central area littered

with gurneys, desks, pulmonary testing equipment, test tube racks, with an exercise bike

and an isolation chamber stored in the corner. Off of this larger room was another room

with additional testing equipment. It was a maze of counters, desks, computers, various

exercise and breathing equipment, pulmonary testing equipment, gurneys, chairs, and

stools. Beyond that room was a small private room for vitals testing that looked like a

clinical office and a number of other offices for graduate students, principal

investigators, and other research coordinators.

Research coordinators recruited participants using a number of methods: posting

study flyers in the institution, contacting former asthma participants, and through word

of mouth (participants' friends, classmates, etc.). Requirements were that participants

had both asthma and allergies, but otherwise be in good health. If someone was interested in the study, they contacted the research coordinators and arranged to come in, learn about the study, and take home a consent form to read more about the study and think about whether they were interested in participating. If interested, they brought in the signed consent form and began the screening process. During the screening process, the research coordinators determined whether the participant was a "dual responder", meaning that upon exposure to an irritant, their airways reacted, then recovered, and within the next 8 hours reacted again. In addition, they must have had relatively "mild" asthma, meaning their airway does not react significantly to irritants, and can withstand weeks of exposure to irritants and allergens.

After screening, participants made four visits to the lab for baseline testing. Testing included: vital signs, urine testing, blood testing, an NO test[16], a nasal lavage test[17], a sputum test[18], a methacholine challenge[19], and a manitol challenge[20]. Then, over the next 13 weeks, participants each visited the lab 17 times. The first day they received either the drug or placebo intravenously, had their vitals taken, completed a number of breathing tests, and provided a bone marrow sample[21]. A week later (Day 2 of the study), they completed a number of pulmonary tests, such as the methacholine challenge. The next day (Day 3 of the study) they underwent an allergen challenge, where they inhaled a controlled amount of a substance they were allergic to and performed a number of pulmonary tests to measure their asthmatic response. The research coordinators measured the degree the drug (or placebo) reduced this

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asthmatic response. These allergen challenges were "mini" asthmatic attacks, induced

and monitored in a controlled environment. Over the following two days (Days 4 and 5

of the study) participants completed a number of tests to monitor their airway response.

Over the next 12 weeks participants repeated this cycle (minus the drug, as the drug or

placebo is only administered once, on Day 1 of the study) 3 more times. Forty days after

the final test day, participants came in for follow-up testing and received their

remuneration ($2000).

There were 16[22] participants in the study; eight women and eight men. They

were between the ages of 18 and 60, non-smokers, and were not receiving any anti-

inflammatory drugs. The participants were either students (n=11) or employees of the

hospital or university (n=5). Three participants were either employees or graduate

students in the asthma lab. All but one participant (a student at a different institution)

were within a 10-15 minute walk of the lab. Participant proximity to the lab was crucial

due to the time requirement of the study. Thirteen of the 16 participants had previously

participated in an asthma study at the lab and were familiar with all of the tests. All but

two of the participants described themselves as having an interest in science or health.

All but one of the students I met majored in science or nursing; many had plans to

pursue a career in medicine or health sciences.

I found the study environment welcoming, social, and informal. This was echoed

by many of the research participants. It was clear that the research coordinators

worked to maintain this environment. They joked with participants, inquired about work or school, and even shared food. Surprisingly, they took a photo of each of the participants and posted it on their office wall. They even took a photo of me (audio recorder in hand) and posted it on the wall with the others. The wall had hundreds of photos of participants, researchers, office parties, conference trips, and even newspaper articles with stories about current and former participants. The wall was a topic of conversation and a symbol of the "research community". The room, crowded and narrow, physically brought research coordinators, technicians, participants, and the study physician together. The wall helped bring all of us together socially, transforming a tight space into an intimate space.

The research environment was obviously enjoyable for research coordinators, lab technicians, and participants alike. This, I think, was for four main reasons. First, the research coordinators created a joking and relaxed environment. They visibly enjoyed their work (they also later professed this) and thus, creating an enjoyable atmosphere seemed a natural extension of this. Second, I would describe the social dynamic as high energy, a consequence of the relatively healthy and young demographic of participants (most were in their early 20's). Third, the time doing research was "down time" for most participants. It was both a mental and a social break. Fourth, because participants would spend over a hundred hours in the lab during the course of the study and many were repeat participants; they developed relationships with the coordinators, other

people in the lab, and other participants. They learned about each other's families, hobbies and future plans. It literally felt like an extended family.

The research coordinators asked participants (usually during baseline testing) whether they would be willing to speak with me. They all agreed. My intention was to speak with each participant at three occasions during their participation – beginning, middle, and end. However, I was not always able to conduct three interviews with all participants, usually due to last-minute scheduling changes. Detailed information of all participants, including their age, gender, and number of interviews conducted, is detailed in Appendix A.

After meeting each participant, I explained the goals and methods of my study, what I would ask of them, their rights, the risks and benefits, and asked them if they were interested. If they said yes, I went through the consent form with them and obtained informed consent. Participants seemed amused by my study. I think because so many of them had participated in asthma studies like this one countless times, they did not feel their participation or experience was particularly interesting, unusual, or noteworthy. I was worried that participants would misinterpret my study as a branch of the asthma study, and thus feel compelled to participate. However, because I did not know or use the language of the asthma study ("allergen challenge", "FEV-1", "airway response") – a language participants quickly adopted themselves – I was clearly an

outsider. In addition, compared to most of the participants, I was a newcomer and not as socialized to the lab environment as they were.

I interviewed participants in either the study coordinators' office (if space was available) or the larger room adjacent to the office. Neither of these locations was private. I was reluctant to ask participants to conduct the interview in a more private location for two reasons. First, study participation meant having blocks of free time between tests. Participants had time to be interviewed during their research time and often did not have time to speak with me privately outside of the study because of the time commitment the study required. Thus, for the convenience of participants and for ease of scheduling, I chose to conduct the interviews during the study. Second, I personally felt that asking participants for an interview in a more private location would have given the impression that I was auditing or spying[23] on the researchers. To maintain good relationships with the researchers and research coordinators and to create an open atmosphere (rather than one of suspicion) with participants, I chose to interview participants in the study location. I also made it clear to the principal investigator, research coordinators, and in the consent form, that if, during the interview, a participant disclosed dissatisfaction or concern with the study, I would encourage them to communicate that to the research coordinators or REB. I saw any such reporting as their responsibility, not mine. Interestingly, on the few occasions I asked a participant to conduct the interview in an adjacent (and not private) room

because there was not sufficient space in the primary lab room, one of the researcher coordinators would make a comment (often something like "getting the real dirt").

This approach influenced the data I obtained. In the asthma study, the only occasion when a participant expressed dissatisfaction with the study was during our final interview which I conducted over the phone. It was the only phone interview I conducted and the only interview done outside of the study environment. The participant indicated that they were bothered by the airway testing, allergen challenges, and bone marrow testing. They found the side effects of the asthma challenge (coughing, shortness of breath) and the pain of the bone marrow testing more difficult than they anticipated. They said they would not participate again in another study, and only continued in the study for the remuneration. It is possible that other participants would have disclosed any concerns/struggles in a more private setting. As I have indicated, the lab had a very congenial and friendly atmosphere and, although the research coordinators were very concerned about participant safety and comfort, participants may have felt social pressure not to "complain" about the study out of loyalty or camaraderie. Therefore, my ethnography contains very little about the negative experiences or reactions of medical research participants. However, I was able to learn about the relationships fostered, the inside jokes, and a more intimate view of the subculture of the asthma study participants and coordinators.

During my trips to the asthma study lab, I spent time waiting for participants to complete tests, and conducted interviews between tests. During this time I observed a number of tests (exceptions include the urine test and bone marrow extraction), chatted with other participants, gossiped with the research coordinators, clarified aspects of the study, and took notes about the research environment and social interaction. In total, I made approximately 40 trips to the study lab and conducted over one hundred hours of participant observation.

Near the termination of the study, in order to understand more about the study background and organization, I conducted interviews with one of the research coordinators and the principal investigator. After the interview, the principal investigator expressed interest in my study and invited me to present my findings to the research group. After my initial analysis, I presented the data pertaining mostly to research ethics (summarized in Chapter 6) to the research group. I recorded this presentation and their feedback and incorporated their response into my final analysis.

b) Study #2: Muscle Regeneration Study

The primary feature of the muscle regeneration study was the muscle biopsy. I was first exposed to the world of muscle biopsy during a meeting with a researcher who performed a number of muscle biopsies for his research. He was primarily interested in helping athletes improve their performance. Because of this introduction, I assumed that the muscle biopsy participants would be athletes. He also said that some participants competed with each other to see who could do the most muscle biopsies.

Thus, I also assumed there would be a somewhat 'macho' element to the social environment.

Before meeting any of the participants, I met with the research coordinator. She discussed the difficulty she was having recruiting for the study. She had met with many interested people, but not many actually agreed to enroll. Her hypothesis was that the muscle biopsy scared them. She thought that was not fair because, according to her advisor, the muscle biopsy was pain-free. She had never undergone the procedure herself, but knew it to be safe and not painful. Because of our conversation I too assumed the biopsy was not painful, but I also assumed that those who agreed to enroll in the study were not paranoid or fearful.

The muscle regeneration study was the only non-drug study I followed. Its purpose was to learn more about muscle protein repair, with the ultimate goal of helping athletes improve their performance and recovery. The study tested the hypothesis that "super hydration" would improve muscle recovery by testing protein repair after muscle exertion with and without hydration. The PI was interested in my study (being a researcher and a frequent participant) and asked me to get in contact with his research coordinator. The research coordinator was a kinesiology graduate student, who obtained ethics approval, organized, conducted, and analyzed the results of the study as part of her graduate training. The PI mentioned that the work was publicly funded from his NSERC grant and was part of his larger program of study.

The research coordinator told me more about the study, in particular, the muscle biopsy portion. I was a bit surprised that they were looking for volunteers to have muscle biopsies. She explained that they took a very small sample of the muscle, it was a very low risk procedure, and many people did not even feel the biopsy because the area was frozen. She said that the doctor who performs the biopsies was very skilled and had done thousands of them and had had only a few minor adverse events (temporary numbness in the area). She explained that the procedure was generally not painful, as she understood it.

The study was conducted over the summer and participants were recruited through postings throughout the university and on the university website. The study lab was located in a quiet, remote area of a university-affiliated hospital. It was a large room with two patient areas and exercise equipment. Each patient area had a gurney, a table, a chair and could be curtained off for privacy. In one corner there was a TV, VCR, and a number of movies. In an adjacent room, graduate students worked in a large area with tables and computers. Numerous conference posters were hung on the walls in both the study area and the graduate student area.

Participants were men, ages 18-30, non-smokers, and recreationally active. These participants (n=8) were required to visit the lab on two separate days (about 30 days apart) to undergo testing with and without super hydration. Half of the participants had hydration on the first day, and half on the second. Participants arrived

at the lab in the morning after a 12 hour fast, first had a nutritional drink[24], then gave a

blood sample and had a leg muscle biopsy done. A physician performed the biopsies,

which involved freezing the area, making a small incision on the upper thigh, and then

inserting a biopsy needle (which was about the size of a pencil and contained three parts

to capture, cut, and remove muscle) through the incision, taking a small (about the size

of a dog food kibble) muscle sample. The muscle sample was immediately frozen in

liquid nitrogen for later analysis.

After the biopsy, the participant exhausted their leg muscle (the opposite leg

that the biopsy was performed on) using the "biodex" machine. For this test, the

participant sat in a chair with one leg strapped to the machine and extended

horizontally. A force was applied downwards, against which they resisted. The biodex

machine recorded their resistance force. They did 10 sets of 10 repetitions, which took

approximately 30 minutes. Immediately after the resistance exercise, the participant

underwent another muscle biopsy on the leg that was worked. If they were hydrated

that day, they received 1 litre of saline intravenously. If they were not hydrated that

day, they waited about 2 hours, the same length of time the hydration required. During

this time they had a second nutritional drink. After two hours, the participant gave a

final biopsy on the same leg. In total, each participant had six biopsies – three on each

day. They had another blood draw the next day. Within weeks of the end of the study,

they received a cheque for $250 in the mail.

The study took longer than anticipated because of difficulty recruiting participants. As a favour to the research coordinator I approached some of my friends to see if they would be interested in doing the study. Most of my friends did not fit the study criteria (being female, smokers, or over 30), but the few who did seemed puzzled that I thought they would even consider taking part in the study. Undergoing a "voluntary medical procedure" seemed completely ludicrous to them. They all agreed that the remuneration was inadequate for a possibly painful and risky procedure. I was shocked by their reaction, and subsequently shocked by my own shock. Everyone I had spoken to about the procedures up until that point described the risks as minor and the sensation as relatively painless. I was initially surprised that my own friends were so risk averse, possibly as surprised as they were that I would suggest that they participate.

The research coordinator asked seven of the eight participants if they wanted to speak with me about their participation (she forgot to ask her last participant). She later told me that she was initially worried that asking them to do additional work would make them less interested in participating in her study, but found that they were all agreeable to speak with me because it would take no additional time or testing. All of the participants the research coordinator informed about my study agreed to speak with me. I interviewed each participant twice – once during each visit. The research coordinator asked me to interview them during the waiting period between the second and third biopsy. When I arrived they were either receiving their saline infusion, doing homework, or watching movies.

All of the participants were university students; several were friends of the research coordinator. All but one were science or health science students. I conducted the interviews in the lab. The participant and I were usually the only ones in the lab, but occasionally, the research coordinator or other lab technicians or graduate students came into or passed through. I was surprised that none of the participants were self-described athletes, nor did they – save one participant – conceived of the study as a physical or emotional challenge.

Despite their similar demographics (age, sex, vocation), they all had very different personalities. Some viewed the study with an academic curiosity; others approached it as an adventure. Still, others considered it a favour to the research coordinator and seemed otherwise indifferent to the study and its procedures. One participant was very insightful about how the remuneration influenced his subjectivity. This, incidentally, challenged my own stereotypes of young college men majoring in science. I had not expected to encounter such insight and candour from a person from this demographic. This experience taught me about my assumptions and presumptions about the participants. Another participant mentioned that he had participated in several other studies at the university, as a way of learning more about the body while making some money. Yet another participant was himself involved in similar research and was excited about the research, especially its profit potential. Participants approached the research in very different ways, despite their shared demographic. I wonder if this diversity in attitudes and approaches inhibits collectivism.

The PI and research coordinators worked in a kinesiology department. They were my first introduction to the world of kinesiology. Kinesiology is the study of the mechanics and anatomy of the body in relation to human movement. It is the confluence of science and sport. Most of the kinesiology researchers and research coordinators I met were athletes or former athletes. Much of the lab equipment was what looked like exercise equipment hooked up to computers. The study had a distinct "jock" flavour. While exhausting their leg muscles on the biodex machine, participants were instructed by the technician and the research coordinator, who yelled encouragements like "push" "go" and "harder". It felt like a coach/athlete relationship. The "coaches" used familiar monikers such as "buddy", "dude", and "man". The participants responded to these encouragements; many later told me that it was both physically and emotionally encouraging and helpful.

The atmosphere was relaxed and friendly. The PI told me that they intentionally tried to create this environment to improve the experience of the participants. The research coordinator came across as very professional, competent and organized[25], which some participants said made them feel confident that the study was being done well, making them feel safer. Since participation was not terribly time intensive and participants were not previous patients (as in the cancer study) or "regulars" (as in the asthma study) the social atmosphere felt less intimate. The PI and research coordinator were friendly, respectful and grateful towards the participants as well as open and accommodating to my request to follow their study. However, due to the nature of the

study there was less intimacy (fewer jokes, fewer queries about personal life, fewer

stories shared) in this study. This was interesting because on some level, this was a very

intimate study as it was the most physically invasive of the studies and participants were

in a more vulnerable position. By vulnerable, I mean socially and physically vulnerable.

Since the biopsy can be painful, experiencing and reacting to this pain in front of people

who were essentially strangers, can be a very unusual and socially uncomfortable

situation. Thus, despite the minimal social intimacy, participants adapted to this

invasive procedure.

c) Study #3: Cancer Study

I was often apprehensive before my visits to the cancer centre. I was worried

about being an additional burden to the study participants. I also anticipated that the

participants would be in a sombre mood. Although my dad is a cancer survivor, I have

very little familiarity with cancer treatment and the emotional impact of a cancer

diagnosis. I found out that he had thyroid cancer after his surgery, and have

subsequently learned very little about my father's diagnosis and treatment. Written

down in this way, this seems odd and unhealthy. I feel that I do have a very close

relationship with my dad, but for whatever reason, I have very little knowledge or

understanding of his cancer diagnosis and treatment. I think that this experience with

my father taught me that cancer is private and should be kept from others to protect

them.

These attitudes influenced my initial orientation towards working in the cancer centre. I did not know how to talk about cancer; I only knew how to avoid talking about it. I was apprehensive speaking with not just cancer patients, but people with end-stage cancer. What added to my feelings of dread was that at the time, a friend of the family had been diagnosed with end-stage cancer. Sometimes, while in the waiting room, I would think of him and his treatment and cry. Surprisingly, I never witnessed another person in the cancer centre cry. In fact, I found the participants in general very open, insightful, and in short, very warm and wonderful people.

Since most people I spoke with had had cancer for many years, and their diagnoses and treatments were a part of their daily routine, the cancer study participants I met were not in emotional distress. They all expressed hope for the future. Due to their extended experience in the health care system, these participants often had insightful remarks and critiques of the political economy of cancer treatment and the Canadian health care system. I did not ask participants about their cancer or their cancer diagnosis. My questions were gauged towards their experiences in the study. Nevertheless, some participants spoke about their diagnosis and previous cancer treatment. They felt the information was necessary to help me understand their decision to participate in a Phase 1 trial. However, other participants chose not to speak at length about their cancer and instead focused on the challenges of the study schedule, their relationships with the study nurses, and other aspects of the study. A few indicated to me that they felt relieved not having to talk about "it".

In many ways the cancer study participants were my "favourite" informants. They were all courageous people, willing to take a new drug for the possibility of personal benefit and benefit to other cancer patients. They were the oldest age group of all of the studies and I felt were insightful about both the medical system and their own motivations and values. They were well informed and engaged in the study. Moreover, they were all very different people, in terms of their background, education, and spirituality (informants' spirituality did not emerge in other studies). I found it exciting and engaging to meet such a wide range of people. I also felt I came to know these informants more than any others. This is probably because I spent more time with them than other participants (in the waiting room and chemotherapy area), they shared more personal information with me, and also because, I think, some could sense my apprehension and consciously tried to make me feel at ease and welcome.

Despite my admiration and connection with many of the participants, I doubt I would make the same decisions if faced with end-stage cancer. I would either seek alternative medical treatments (hopefully not getting fleeced in the process) or retreat from medical treatment altogether, hoping for the best quality of life in my final months. However, I am saying this as someone without dependents, who has not had the experience of a medical team working hard for them, and who is not currently facing death. Also, after learning about the medical research industry, I am skeptical about the benefit of individual studies, and would be hesitant to enroll in a study simply for the benefit of medical science.

Since I did not see most of these informants again on subsequent visits to the cancer centre, and since they were all battling end-stage cancer, I assume that many of them have passed away. Meeting these people, and seeing their strength, courage, and humour has been comforting and helpful to me on a personal level. Because I know that the prevalence of cancer is very high and the incidence is increasing, I fear that this will not be the last time cancer touches my life. Meeting these people helped me think about my own mortality and taught me about the power of courage and mirth.

Cancer is the abnormal growth of cells which can proliferate uncontrolled and damage nearby organs and tissues (American Cancer Society 2004). In 2009 over 171,000 Canadians will be diagnosed with cancer, and over 75,000 Canadians will die from cancer (Canadian Cancer Society 2009). About 40% of Canadian women and 45% of men will develop cancer in their lifetimes. In total, about one quarter of the Canadian population will die from cancer. The most common types of cancer are lung, colon, breast (in women) and prostate (in men)(Canadian Cancer Society 2009). The incidence rates of cancer are growing, primarily an artefact of an aging population, while the mortality rates are slowly decreasing (save mortality rates from lung cancer in women) (Canadian Cancer Society 2009). From these statistics, we can see that cancer has a major influence on Canada's health burden.

At the cancer clinic I met people enrolled in Phase 1 drug trials. Since the recruitment rates of Phase 1 studies are so low, I actually spoke to people enrolled in

three different Phase 1 drug trials. These studies were very similar in terms of the study schedule, the testing, and the time required by patients. The only major difference was the drug itself. The drugs all showed "activity against cancer" in the laboratory and in animal studies. Since the purpose of a Phase 1 drug study is to determine the drug's toxicity, not its effectiveness, it is never compared to another drug or placebo. All participants receive the drug.

These drug studies, like most Phase 1 studies conducted at the cancer centre, were funded by pharmaceutical companies. The companies both supplied the drug and covered the other costs of the study. In addition, principal investigators received monetary incentives for each participant they recruited. The Phase 1 studies are generally multi-sited, with sites across the nation or the globe. The principal investigators at each site obtained ethics approval and organized the study, ensuring adequate monitoring of participants and timely transmission of data to the sponsor.

When a patient's tumour does not respond, or stops responding to standard treatment, their oncologist might inform them about one or more investigational drugs. Usually the oncologist tells the patient what their options are and may recommend a particular study drug. If the participant is interested in learning more about a study, a research coordinator (who usually has a nursing background) contacts them and tells them more about the study, what is required, and the risks and benefits. The research coordinator reviews the consent form, answers any questions, and asks the patient to

take the consent form home with them to think about whether they are interested. If

the patient is interested, they contact the research coordinator and that person

arranges their enrollment, including: ordering the drugs, scheduling time in the

chemotherapy clinic, and arranging for other testing in the cancer centre.

Two research coordinators were the main contacts for the participants. The

studies required participants to travel to the cancer centre to receive the drug five days

a week for four weeks. Some of those days were "long days", where blood was drawn

several times over 8 hours after drug administration to determine the concentration of

the drug in the bloodstream over time. However, most of the days were "short days"

where participants received the drug through IV, followed by a saline flush to remove

any residual drug in the vein, which could cause irritation. These visits usually lasted

about 2 hours. A week after the final dosage, the participant had a CT scan so the

principal investigator could determine what impact, if any, the drug had had on their

tumour. If the investigator and the patient believed that continued treatment might be

beneficial (or at least not harmful) to the participant, the participant waited an

additional week and started another 28 day cycle. Usually, the maximum number of

cycles was four, but if a participant was continuing to benefit from the drug, the study

might be extended. If either the participant or the principal investigator felt that the

study should be terminated before the 4 weeks (based on how the participant was

feeling, or any medical indication), it was.

Study participation was very similar to standard therapy cancer treatment, except drug administration was much more frequent (5 days a week, instead of once every 1-3 weeks), and the monitoring was more extensive. Participants arrived at the chemotherapy clinic, usually first thing in the morning. They checked in at reception and received a number. They sat in the waiting room and waited for their number to be called (no names were used for confidentiality reasons). Eventually (15-90 minutes later) a nurse came out, called their number, and lead them into the large treatment area, with gurneys on one end and chairs on the other. The sicker patients received gurneys, and others chairs. After the participant took a seat, the nurse would measure several vitals (temperature, blood pressure), take a blood sample, and then hook them up to the drug IV. Some days the nurse also did an ECG test to monitor the participants' heart rhythms. During drug administration, the nurse would come around to check vitals at certain intervals (and sometimes draw blood), and ensure that drug administration was working properly. After the drug administration and saline flush were complete, participants were required to wait an additional 20 minutes before they were allowed to leave. This was in case they had any immediate adverse reactions. If it was a "long day", the participant went to another clinic in the cancer centre for additional blood draws and further monitoring.

When participants began the study, the study coordinator told them about my study and asked them whether they would be willing to meet with me. The research coordinators sometimes forgot to ask each participant (they juggled multiple studies at

once and kept a hectic schedule). I was told that "most" participants were agreeable to meet with me, although the research coordinators could not give me an exact number. Over the course of 16 months I was able to meet and interview eight cancer study participants. I met an additional 2 participants who initially agreed to meet with me, but when I visited them at the cancer centre they were feeling too poorly to be interviewed (one was very nauseous and the other was in emotional distress). I asked both of them if I should come back another time. In both cases they agreed that I should come back later and see how they felt about participating then. When I came back a few days later, I learned that each had withdrawn from the study. This reinforced that the cancer study participants I spoke with were unique; not all participants were able to withstand the study demands.

Upon meeting each participant (they were usually pointed out to me by the receptionist and I introduced myself) I explained my study to them and asked them if they were interested in participating. I stressed that it was voluntary; they could skip any of the questions or end the interview at any time. I felt it was important to clearly communicate that I did not want my study to be an additional burden for them. All of the participants were very sick. Some were clearly suffering, while others seemed to have high energy and spirits.

My intension was to interview[26] all participants three times – at the beginning, middle, and end of their 28 day cycle. Due to scheduling difficulties (I often arrived at

the time I was told, but learned that they had already left) and occasional participant early withdraw from the study, I was able to interview only two of the participants on three occasions. I interviewed four participants twice and two participants once. Of the eight participants I spoke with, two withdrew from the study early. One was told by the principal investigator to withdrawal from the study because they felt the side effects of the drug (mainly fatigue) were too severe for him to continue with the study. The other participant was withdrawn from the study because she became very sick and died shortly after withdrawal from the study. Only one participant (to my knowledge) remained in the study for more than one cycle. This information was confidential and the only reason I learned of this was because I later saw the patient in the cancer centre and the patient told me.

The study participants had various types and locations of cancer – primarily colon, breast, and intestinal. The participants ranged in age – between mid 30's to early 80's. About half of the participants were "otherwise healthy" (in their own words); they worked part-time and were reasonably active (went fishing, shopping, worked on carpentry). The others did not work and did not refer to themselves as healthy. The side effects of the drugs did not include loss of hair so the participants were not obviously physically marked as cancer patients. Several participants had a port, an implanted device whereby medicine is injected, avoiding repeated needle pricks. Some participants seemed fatigued – especially later on in the study – but only once was I shocked by anyone's condition. This was the participant who died shortly after our

interview. She was very thin, with dark circles under her eyes, papery, almost

translucent skin, and rail-thin arms scarred from numerous IV's. She was a young bright

charismatic woman with lots of hope and determination. During our interview the

research coordinator and several doctors dropped by to see her. They were all very

enamoured with and concerned about her. During our interview she received 4 or 5

visitors – an unusual number, and in hindsight an indicator of the severity of her

condition and her popularity as a person and a patient.

The cancer centre was typical of many cancer centres across the country – it was

a large modern building which houses both cancer treatment and cancer research.

Large banners communicating "hope" and "excellence" flanked the main doors.

Entering through the glass doors, you are greeted by a volunteer, and then you pass by

the information desk and a person selling hospital lottery tickets. Closer to the elevators

you approach two hand sanitizing stations and a beverage cart. The main lobby was

spacious and full of light. The colours were calming neutrals; the materials wood, steel

and glass. Due to the army of smiling volunteers, the subdued wood tones and natural

light, and the adult contemporary music playing softly in the background, the centre had

a warmer and calmer atmosphere than most hospitals. This was accentuated by the

older clientele and the absence of Urgent Care.

My normal route was to take the elevators up to the chemotherapy area, get a

"Visitor" badge from one of the volunteers, and sit in the waiting room. The capacity of

the waiting room was about 50. It was usually between 50 and 100 percent capacity.

Some people came for treatment alone, others with a family or friend. The population

was older, and primarily Caucasian. Juice, coffee, tea, and cookies were available at one

end of the waiting area. Baskets of knitting needles and yarn sat here and there.

Occasionally someone would pick up a basket and continue the work that another had

started. A variety of newspapers and magazines were scattered throughout the waiting

area (an odd collection, I became a regular reader of "Ontario Dairy Farmer"). One side

of the room was windowed, looking out on a small garden and the back side of the

cancer centre. The waiting room, like the rest of the centre, was tastefully decorated in

neutrals and clean and well kept. It was more comfortable and better serviced than any

hospital waiting room I have been in, save other cancer centre waiting rooms. These

facilities had a remarkable influence on my impression of cancer. Cancer is clean, almost

genteel; other diseases, such as asthma and diabetes are run-down afterthoughts. Of

course these impressions have no bearing on the diseases themselves, but are

reflections of the funding (both public and private) of healthcare.

The cancer centre was unique primarily because it was dedicated to treating

cancer, a life changing and often terminal disease. A cancer diagnosis, for many people,

is life altering; cancer often influences how people think of themselves and it can

become their primary identity marker. Although not synonymous with death, when

people learn they have cancer, they often interpret it as a death sentence. They can,

however, almost always look forward to intensive and difficult radiation, chemotherapy,

and/or surgery. Phase 1 study participants have end stage cancer and as a result, participation takes place in the shadow of one's mortality. This is a unique condition for them and colours their experience. These participants also have extensive experience in the health care system and are more familiar with medical procedures and medical testing than participants in most other studies. Terms like "risk" and "benefit" have, therefore, very different meanings to these participants.

ii)   Research Ethics Community

Because the research ethics community – specifically REBs – are responsible for the protection of research participants, how they construct research participation is important. I chose to learn about how the research ethics community thinks and functions through observing REB meetings and conducting in-depth one-on-one interviews with research ethics board members, chairs, and ethics scholars. To learn more about the research ethics process, the approach to research ethics, and the social organization of research, I attended meetings of three different research ethics boards. Research ethics boards commonly have observers (I was actually one of three observers at one of the meetings) and my presence was not considered unusual or unwelcome.

During my Master's, I was the graduate student representative on our local humanities REB. I was one of about 12 university-based and community-based volunteers who conducted ethics reviews for humanities and social science research projects involving humans. Because of this prior experience, I was familiar with many of the assumptions of REBs. Thus, it was difficult for me to approach the research

community as an "outsider". Many of the unusual or quizzical aspects of the research

ethics community that an outsider might notice were imbedded in my own view of what

was normal or natural about research ethics. My prior experience helped me

understand the terminology of research ethics, but also limited my analyses and

perspectives.

All Canadian public institutions where research is conducted have at least one

research ethics board (or share a board with other institutions). All research involving

humans or animals conducted at the institution must be reviewed by the research ethics

board (REB) before it is approved. The purpose of the REB is to protect research

participants. All human research related REBs are required to follow the TCPS, the Tri-

Council Policy Statement on the Ethical Treatment of Human Research Subjects

(Interagency Secretariat on Research Ethics 2005). These guidelines are based on the

principles of: free and informed consent, respect for persons and privacy, justice,

inclusiveness, and balancing harms and benefits. These principles reflect the Declaration

of Helsinki (World Medical Association 2004), a code developed (the first draft was in

1964, the most recent in 2004) by the World Medical Association which outlines ethical

principals which should guide medical research. The Declaration of Helsinki was

developed in response to the Nuremberg Trials, which brought to light medical research

atrocities committed by Nazi party doctors on prisoners of war during the Second World

War.

Before commencing a project involving human participants, the lead investigator

must receive approval from the appropriate REB (many universities have multiple REBs,

separating human from animal studies and medical research from non-medical

research). He or she sends a study protocol to the REB, which outlines the purpose and

methods of the study and details the risks and benefits to the participants, the process

of informed consent, recruitment techniques, and details how participants'

confidentiality and privacy will be protected. The REB administrator checks to ensure

that application is complete and distributes copies to REB members. REBs are composed

of employees of the institution and "community representatives".[27] The REBs I have

seen had between 6 and 15 members. Employee representatives on the REB must

include researchers, ethicists, and lawyers (consulting lawyers, if necessary).

Community representatives are lay persons who are to advocate for the community's

interest. The community representatives I have met were well-educated and generally

either retired or working part time. Their guidance is often solicited to determine

whether consent forms and other materials that participants receive are understandable

and jargon-free. They are otherwise full members of the REB.

Most REBs meet monthly or biweekly to review protocols. Prior to the meeting,

all REB members are to have read all protocols being reviewed that day. These meetings

are led by the board's chair, often a senior researcher or ethicist. Protocols (either all

high risk[28] protocols or all protocols, regardless of risk) are reviewed by the group, with a

few members leading the discussion. In my experience, each protocol review takes 10-

30 minutes. Some REBs decide to have a few individual members review minimal risk[29] protocols and submit their responses to the administrator.

One of the boards I observed invited the PIs of all studies under review to the REB meeting to summarize the study and answer any questions. The benefit of this was that any questions or concerns could be dealt with at the meeting and approval or non-approval could be determined at the meeting. Generally all protocols were approved at the meeting (usually pending minor changes to the consent form or other aspects of the protocol). At times, protocols were not approved and comments and suggestions sent back to the lead investigator, who made the appropriate changes and resubmitted the protocol. It is extremely rare (according to my REB informants) for a protocol to be ultimately rejected.

In total I interviewed five REB members, including three chairs. I also had casual conversations with several REB members before and after meetings. Members expressed interest in my research and inquired if I had any questions or needed any clarification. At one point one member commented that I seemed "eager and interested" during the meeting. I took notes during the meetings about the process, the nature of the conversations and debates and the key areas on which the REB members focused. I was asked to sign a confidentiality agreement by each REB. By signing the form, I agreed not to disclose details of the protocols.

iii)   Conferences

I conducted participant observation at two conferences. The first was the First

Annual Clinical Trials Conference in the spring of 2006. It was a small (about 50

attendees) 2-day conference in Toronto. The conference was generally geared towards

clinical trial PIs and research coordinators. The majority of the research coordinators

were from private companies and the majority of the PIs were physician-investigators

employed in public institutions. Research ethics was essentially the primary focus of the

conference, although, other dimensions of clinical research were also covered. The

presentations covered topics such as: research ethics, securing ethics approval, Health

Canada guidelines and other regulations, participant recruitment, and obtaining funding

for research. The presenters included experts on conducting and overseeing clinical

trials, research ethics experts (from both Canada and the United States), representatives

from the Canadian Institutes of Health Research (CIHR) who outlined the CIHR's mission

and program, representatives from a private ethics consultation company who spoke on

regulation compliance, and a biotech entrepreneur who spoke of her success in the

biotech industry.

The conference fee was approximately $1500. I emailed the conference

organizer and explained that I was interested in attending the conference as a context

for my research and asked if I could volunteer for the conference for a reduced

registration fee. He contacted the conference company and was able to waive the

conference fee for me. Since the conference was organized by a private company, they

did not require any volunteer services. The conference was in a modern office building suite, and was more upscale than most hotel conference facilities. The conference was organized to encourage networking and develop business contacts. During the conference I took field notes, recording content, the nature of the questions raised, the social environment, my interaction with other attendees, the gender dynamics, and any interesting side bars. I also recorded what I thought were my limitations as an observer due to my recent introduction into the field. In hindsight, I attended this conference too close to the start of my research and did not know enough about the industry to adequately understand the content or make insightful observations. My lasting impressions from the experience were (1) that industry is concerned with ethics and recruitment from compliance and time management perspectives and (2) industry representatives are primarily young, attractive women, and academic representatives primarily (although not exclusively) older men.

The second conference I attended was the NCHER/PRE (National Council on Ethics in Human Research/Interagency Advisory Panel on Research Ethics) Conference in Ottawa in the winter of 2007. This was a much larger conference, with around 300 attendees. Attendees included: REB members, REB chairs, ethicists, regulators, administrators, participants, researchers, and educators. The breakout sessions ranged from ethics in education, qualitative research, challenges facing REBs, the experiences of human research participants, to the experiences of community REB members.

I took field notes during the keynote speaker presentations and the breakout

sessions. I also met a number of other people interested in research ethics (including

former research participants) and spoke at length with them about their concerns and

interests. This conference was much more interesting and productive for me as an

observer. I felt it was a more student-friendly environment and it was more

academically focused, which coincided with my own worldview and my area of research.

iv)   Participation in a study
My initial intention was to enroll in one of the studies I observed. In this way I

could develop firsthand experience and compare my perceptions and experiences with

the other participants to gain some understanding of my own experience in relation to

the others. This was also a method of situating myself as a researcher and making

explicit some of my own biases and assumptions. However, it was very difficult for me

to find a PI who was currently recruiting, would allow me to work with them, and had a

study where I fit the inclusion criteria. As a woman over 30 and disease-free, there were

few studies being conducted at the university or university-related institutions that

needed someone with my profile. Near the end of my fieldwork, I found a study where I

met the inclusion criteria. Further details about finding a study and the complications of

autoethnographic fieldwork are located in the *Autoethnography* chapter.

D) Research Ethics

i)   The ethics of anthropological fieldwork

Anthropology, as a discipline, has its own ethical framework and approach. The ethics of anthropology are heavily influenced by the history of anthropological fieldwork and the ethical mires and missteps of the past. The discipline admits that early studies of colonized peoples were fuelled by Western assumptions that they were uncultured, uncivilized, uneducated, unhealthy both spiritually and physically, and fundamentally unable to take care of themselves. This research hinted at the necessity of colonial governance. In addition, some anthropologists, such as those with an insight on native customs and knowledge of the language, aided colonial governments in assimilation and governance programs. These anthropologists gained the trust of indigenous communities and then betrayed them, smearing the public image of anthropology and permanently influencing the self-image and identity of the field.

Thus, the question of who's 'side' the anthropologist is on plagues the discipline even today. This was a central concern in my research, because I, like many other researchers, inherently conceive research involving humans as a researcher-based enterprise that requires the consent and involvement of research participants.[30] This creates an opposition between the interests of researchers and those of the researched. In my situation, this was even more complex because the labels 'researcher' and 'participant' were context specific. The medical researchers I interviewed were also participants in my study. In the autoethnographic portion of my work I, the researcher,

was a participant and a subject of my own analysis. In addition, I, as the qualitative

researcher, observed the relationships between the medical researchers (participants in

my study) and the medical research participants (also participants in my study). My

allegiances and sympathies were multiple. I could relate to the researchers more than

the participants, although I was most interested in the perceptions of participants. I am

ultimately interested in providing insight which might improve the experiences of

research participants. It is very likely that this could help researchers by improving the

retention and satisfaction of participants.

The broader ethics of my study, such as questions about who owns the data,

what the data will be used for, and for whom, if anyone, might I advocate, are unclear to

me. I have shared my data with researchers, REB members, and ethics scholars. In

doing so, I have received helpful feedback and alternative interpretations. I have not,

however, shared the results with research participants. I did not engage explicitly in a

member checking process, although sometimes I had opportunities to clarify points with

participants during subsequent interviews. My lack of member checking for this group

was partly because the research participants I met and worked with were not organized;

I could not meet with them as a group, as I did with the others. Individual member

checking, in the form of getting feedback on data interpretation and analysis, is

extremely time consuming and resource heavy. I chose not to engage in this process for

selfish reasons, primarily that I did not want to delay my research and my program any

further. In addition, it seemed to me that this step was dependent on the graduate

student's inclinations and not encouraged by REBs or departments. I provided all participants my email address so they could contact me if they wanted to receive a summary of my finding. No participants ever contacted me.

Informed consent in anthropology is often difficult to navigate. Like all other researchers who conduct research involving humans, we must obtain informed consent from our participants. Often we obtain informed written consent. In fact, this is the default position of the TCPS. The TCPS does recognize, however, that written consent is not always appropriate. Examples may be where informants are illiterate or in groups where signed contracts are symbols of colonial deception (Shannon 2007). In anthropological fieldwork, informed consent is often negotiated. For example, during my master's fieldwork, I negotiated with the community, the health authority, the health station, and individual informants about the goals and methods of the research, and the circumstances, timing, and content of the interviews.

In my research I obtained written informed consent from my participants. I first obtained written informed consent from the principal investigators of the studies I followed. As I mentioned, they were very open to my research questions and were interested in learning about my results. I asked them if there were any particular aspects of research participation about which they were curious. I also conducted one-on-one interviews with these principal investigators. Before the first interview with each informant I explained the purpose of my study, why I wanted to interview them, the

types of questions I would ask them, my data storage process, and their right to

terminate the interview at any point or withdraw their data. For the key informants,

such as the PIs, the informed consent process was generally rushed because they were

busy academics, but also because they did not take the risks or the informed consent

process very seriously. They joked about the risks, did not ask any questions, and

skimmed over the consent form. Shannon (2007) hypothesized that this kind of reaction

from academics is a reaction to the meaning attached to the documents (bureaucratic

necessities) and the implicit trust between researchers.

Research participants, likewise, did not take my informed consent process very

seriously. Typical replies were, "you just want to talk to me?", or "sure, as long as it

won't take too long". This was an indication that they understood the risks of research

participation primarily as physical risks, and not cultural, social or psychological. It was

also an indication of their familiarity with the informed consent process and consent

forms, and possibly an indication that I did not communicate the risks clearly. My failure

to explain the risks clearly may have been my lack of experience at the time with bad

outcomes resulting from lack of informed consent. Although I had theoretical

knowledge of the importance of informed consent, and I was ideologically committed to

it, I wonder now if I myself took the risks of my study lightly. I think that, like my

participants, I considered my research relatively risk free compared to the studies I was

following, as if different categories of risk (physical, psychological, cultural) could be

ranked. I had subconsciously assumed a biological focus regarding risk, no doubt

resulting from my recent introduction and familiarization with the vast literature on risk in medical research.

In her study of medical research participation, Fisher (2006) likewise found her key informants dismissive of the risks of participating in her study. She attributed this to a procedural misconception – that participants made false assumptions about research by responding to what was similar to non-research environments, while overlooking what was different (Fisher 2006:253). Qualitative interviews are like conversations, but focused conversations. The differences between the conversations in qualitative interviewing and natural conversations are, that in qualitative interviewing the conversation is generally unidirectional, one speaker (the interviewer) rarely interrupts the other, the conversational flow is often pre-determined (depending upon how structured, semi-structured, or open the interview style is), and finally, one speaker reveals little. As an interviewer, when I do reveal information about myself, it is strategic and intended to gain rapport, encourage the informant to elaborate, or to act as devil's advocate. In addition, unlike most natural conversation, the informant's words and remarks become fetishized. Instead of temporal ramblings with friends, what is said to a qualitative interviewer gets written down, stored, analyzed, and inspected.

E) Data analysis

During the data collection phase, I transcribed my interviews and reviewed my notes to evaluate the usefulness of my interview guide. I adjusted the interview guide,

adding a few questions (these are marked with an asterisk in the interview guide in Appendix B). I found that the questions about risk and general experience were difficult for some populations to answer. My initial question, "What are the risks of the study?" was often misinterpreted. It was sometimes interpreted either as an invitation to disclose the "dangers" of the study, or it was interpreted as a test to determine whether participants could accurately recall the risks as listed on the consent form. My question "How is it going so far?", not surprisingly, elicited few insights. Typical answers were "not bad", "okay", and "fine". I added probes, such as: "What is it like to come here?", "How do you feel when you are here?", and "Is your experience changing as you continue in the study?" to encourage more disclosure.

Despite revamping some of my interview questions, I found many of the exploratory questions designed to understand the embodied experiences and perspectives of participants unfruitful. During my data collection I had assumed that I was simply not asking the right questions or approaching the issue in the right way. That is entirely possible. However, I have recently formed an alternative hypothesis. The television at the gym I go to is always tuned to one of the sports channels. On one of my visits I took notice of a newsman interviewing several hockey players. He asked a number of questions, both complex and simple, almost all of which evoked responses such as "I dunno", "sure", and "fine". It felt very familiar. In fact, I felt like I was back in the asthma lab (some of the asthma study participants were the least forthcoming). I believe these hockey players responded in a similar manner for two reasons. First, I do

not think they really wanted to speak to the interviewer, even though they agreed to the interview. Second, I think that they just played hockey, they did not talk about playing hockey or analyse playing hockey. I was unsuccessful in obtaining more experiential responses partly because the participants agreed to speak with me out of politeness and did not really care about the interview and because they were more inclined to do the research than discuss it.

During most of the data collection phase I worked as a teaching assistant and volunteered a significant amount of my time (20-30 hours a week) for my union attending meetings and demonstrations. In all honesty, although I did my best to conduct analysis while collecting data, I was not able to commit a significant amount of time and mental energy to data analysis. This is a weakness in my methodology. I am confident that I would have been able to collect more and better data during my interviews and participant observation if I had been able to commit more time to data analysis during the collection phase. This I believe is an interesting complication of doing field work "at home". Other commitments and projects can distract the researcher from research. In addition, I was not totally immersed in my research and often travelled "to" and "from" the field multiple times a day or week. Total immersion has its advantages because the researcher is more likely to spend more time thinking about their research and adapting their methods during the field work. If I were to ever conduct field work "at home" again, I would dedicate a set amount of time each week to think about my field work, my emerging data, and my methodology. It was my

experience that while doing research at home, dedicated and consistent query could easily get lost in the demands of everyday life.

I analyzed all of my interviews and field notes. Not all of the data has made it past the analysis phase. A few key informant interviews did not help me understand my larger project and thus, are not included in this dissertation. These key informants were either ethicists or clinical researchers not directly involved in any of the studies I was following. I thought that by interviewing them I could expand my appreciation and perspective. In this aspect, the process was successful. I also thought that I would learn more about how the industry thought and understood itself. Unfortunately, I do not have the insight or the data for this larger project and primarily focused on the three studies, their participants, research coordinators, and principal investigators. However, I did learn that the micro environments of the clinical studies were more interesting for me and I was more comfortable with this data collection and analysis, because this required a classic anthropological approach. I think that a broader analysis and cultural critique could be either a larger future project or left to someone with more appropriate training and skills.

I used QSR's NVivo7 to help me organize and analyze the data. I used thematic analysis techniques (Richards 2005) to organize and code the data. My purpose was to understand how participants approached, understood, and gained from their experiences. I was also more broadly interested in how people understood risk, ethical

behaviour, and the importance and challenges of research. I initially began to code data in "free node" categories, linking codes into trees as I proceeded. When coding, I tended to code data very generally. For example, if someone talked about how they did not have enough time in their day and had less time than they used to, I would code that as "time – not enough time", instead of something more specific like "has less time than used to". I did this in order to see the differences in how people spoke about and understood similar topics. This I think comes across in the ethnographic analysis. For my thematic analysis I wanted to show broad, but non-homogenous themes because I was often struck by the subtle differences in how people articulated very similar ideas. At the same time I was intrigued by the outliers – the people who did not care about research, or the people who expressed pain or suffering.

F) Data collection, security, and retention

I recorded all interviews on a digital recorder and took field notes in a field note book. I conducted multiple semi-structured interviews with research participants; the questions I posed to participants were different at each phase of the study. I also asked different questions of participants, researchers, and ethics experts (see Appendix B for the interview schedules). If I was unable to speak with a participant at an earlier phase of the study, I modified the interview guide to incorporate any missed questions, as appropriate. I transcribed all of the interviews, omitting identifying data (names, jobs, etc.). I gave each participant a code number and recorded their name and code number in a separate file. I stored the transcriptions and participant lists on my personal

computer (which is password protected and equipped with a strong firewall). I will

destroy all of the data in five years. A list of all informants, their roles, approximate age,

and the number of times I interviewed each is detailed in Appendix A.

G) Overall methods

I used a number of methods and included multiple study locations in my

research. My research questions encouraged me to look at several studies. I wanted to

explore a range of studies, to see the uniqueness of each lab and whether there were

any themes or similarities. The contingencies and needs of the studies influenced my

own methods and my role as an outsider influenced my behaviour and reactions. My

theoretical orientation provoked me to also explore the governance of research, which

entailed investigating REBs, interviewing experts in the research and ethics fields, and

attending industry conferences. These situations provided some background, although,

as mentioned above, I was limited in the information and understanding I could garner

from these settings. The range of methods and settings produced a vast quantity of

data, much of which was unique to each setting. This has posed an analytic challenge; it

is difficult to bring together data from multi-sited research, while still exploring the

uniqueness of each site and perspective. Thus, the thesis is organized thematically,

reflecting the methodological approach and theoretical orientation.

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[15] Phase 2a studies are "proof of concept" studies, where a drug is tested to determine its effectiveness and to learn more about side effects. A Phase 2 study is not a definitive study regarding the effectiveness of a drug, but gives an initial indication regarding the effectiveness of a drug on humans.

[16] An NO test measures the concentration of nitrous oxide in exhaled breath. When the lungs are inflamed the concentration of nitrous oxide increases. For the NO test, participants breathe at a constant rate through a tube, which runs into a machine that measures the NO concentration.

[17] For the nasal lavage test, participants tip their heads back and pour a buffer solution into their nose. They keep it there for several seconds and then expel it into a jar. The material is sent to a lab, where they measure the concentration of antibodies in the nasal mucous. This is one of the methods used to quantify allergic response.

[18] For the sputum test, participants inhale vaporized saline solution for seven minutes. This solution promotes mucous production. Participants then spit this mucous into a jar. The material is sent to a lab, where they measure the concentration of antibodies in the nasal mucous. This is another method of quantifying a participant's allergic response.

[19] A methacholine challenge measures the airway response after introduction of an airway irritant, methacholine. Participants inhale increasing amounts of liquid vapour methacholine and after inhaling each dose for a set period of time, perform an FEV-1 test, where the volume of forced air they can expel in one minute is measured.

[20] A manitol challenge is similar in function and form to the methacholine challenge. The only difference is that the manitol is inhaled, not as a liquid vapour, but in a powder form.

[21] The bone marrow sample is taken from the iliac crest (the area is first frozen). The purpose of the test is to measure the concentration of particular antibodies in the bone marrow. It is performed by a trained health professional and takes approximately 10 minutes.

[22] One participant was asked to withdraw from the study because the study coordinators and study physician determined that that individual's asthma response was too strong and it was not appropriate or safe for them to continue with the study. This occurred about two weeks into the study.

[23] At one point during the asthma study, one of the lab workers referred to me as a "spider".

[24] This dietary control was necessary to eliminate diet as a factor that would influence muscular water content.

[25] When I asked the research coordinator what it was like to be the only woman working with men, she simply replied that she tried hard to be organized and competent on the study days, hiding any frazzled feelings from participants. For her, to work with men successfully, she had to suppress any lack of confidence.

[26] My interviewing methods were the same as those for the asthma study described above.

[27] Cranley Glass and Kaufert (2007) urge REBs to define what a community is and consider what community consent might mean. Their area of interest is primarily in aboriginal health research, although

they argue that these considerations can and should be expanded to non-aboriginal communities. This approach takes into account a collective notion of autonomy and consent.

[28] According to the Tri-Council Policy Statement, a study is high risk when it entails more than minimal risk to participants. See below for definition of "minimal risk" (Canadian Institutes of Health Research et al. 2005).

[29] According to the Tri-Council Policy Statement, a study is minimal risk when "participants can reasonably be expected to regard the probability and magnitude of possible harms implied by participation in the research to be no greater than those encountered by the subject in those aspects of his or her everyday life that relate to the research" (Canadian Institutes of Health Research et al. 2005).

[30] Not all researchers approach research in this fashion. Participant-Action Research, for example, is a theoretical and methodological approach to research which enables community members (traditionally 'participants') to develop research questions and participate in data collection and analysis. This is but one approach that tries to bridge the researcher/participant divide.

CHAPTER 3: THE POLITICAL ECONOMY OF UNIVERSITY-BASED HEALTH
RESEARCH

A) Introduction

Public universities[31] are a vital element of Canadian society because they are

necessary to develop "Canada's competitiveness in a global knowledge

economy" (Association of Universities and Colleges of Canada 2007a). As

Canadians, we must compete in this "global race" for talent and ideas through

building skills and knowledge and through research and innovation (Association

of Universities and Colleges of Canada 2007a). As part of the federal

government's "Advantage Canada" economic plan, the federal government is

dedicated to "creating the best-educated, most skilled, and most flexible

workforce in the world" (Richer and Gamble 2007). To achieve this vision, the

federal government has increased funding for university-based research, through

attracting and retaining high profile academics through funding Canada Research

Chair[32] positions, and funding "excellence" in faculty and graduate research

(Canadian Institutes of Health Research 2007;Lewkowicz and Schellenberg 2006).

While operating budgets for Canadian universities have effectively shrunk since

the early 1990's[33] (Canadian Association of University Teachers 2005), funding

for university-based research has grown. Over the last decade, funding for

university research has increased by 150% (Association of Universities and

Colleges of Canada 2007b), largely through federal and provincial educational

grants and transfers.

This chapter explores how these trends in university-based research funding (concentrating on health-related research) are shaped by the federal economic vision. These policies, in turn, impact university-based researchers, institutional research ethics boards, and human research participants. Linking these various actors will highlight the role of the federal policy and vision in university-based research and show how it influences the social and economic settings within which research is conducted. The federal government's commitment to university-based research is altering how research is being conducted and is intensifying research activities. The government's increasing emphasis on the productivity of knowledge work impacts the work of faculty and graduate researchers, influencing what research questions they ask. The intensification of research is changing the activities of institutional research ethics boards and providing greater opportunities for those in the university community to participate in research. Research intensification also increases the wider community's exposure to research (often as human research participants), socializing its members to the logic and goals of the research industry.

B) Critical-Interpretive Medical Anthropology

Here I explore the economic environment in which medical research is currently conducted in Canada. This environment frames how researchers conduct research and what types of questions they ask and significantly impacts universities that often perceive research as an important source of funding and an activity which can bring the university prestige and income. This chapter

frames the world in which research is conducted at public institutions in Canada.

It describes the "body politic", the larger economic and political conditions and

actors. This forms one level of analysis. Two other levels of analysis are at the

social body – the community of researchers, coordinators, and participants – and

at the individual body, the experiences and meanings of research participants.

Together these three levels of analysis form what medical anthropologists

Scheper-Hughes and Lock have coined "the three bodies" (Lock and Scheper-

Hughes 1990;Scheper-Hughes and Lock 1987). By exploring all three bodies, I

will take a critical perspective, highlighting the economic and political forces that

frame the world of these actors. I will also explore relational and personal

experiences and meaning. This approach uses the strength of anthropological

methods and analysis to elicit personal experience and meaning, while still

understanding that this experience exists within a larger framework, often

consisting of power imbalances and inequalities.

C) The Federal Vision

The Federal government invests in research and development[34] in three

areas: university-based research; research conducted within its own

laboratories; and private research.[35] In 2005/6, the federal government invested

$2.5 billion in research and development in higher education (Statistics Canada

2007a), $2.2 billion in intramural research, and $1.6 billion in private research

(Statistics Canada 2007b). The total federal government expenditure on

research and development during this year was 0.5% of the nation's GDP. To

give these figures some context, the total investment in research and

development from all sources was $9.5 billion in the higher education sector

(Statistics Canada 2007a) and $15.36 billion in the industrial sector (Statistics

Canada 2007c). The federal government's commitment to university-based

research and development has grown significantly since 2001/2002, when it

invested $1.29 billion (as compared to $2.54 billion in 2005/2006) for research

and development in the higher education sector.

Canada's "New Government"[36] is continuing federal commitment to

university and college based research and development.   In February 2006 the

Conservative Party of Canada formed a minority government. In October 2006

the Minister of Finance published a document entitled "Advantage Canada"

(Department of Finance Canada 2006). The document:

> is an economic plan designed to make Canada a world leader for
> today and future generations. It will build a strong Canadian
> economy and make our quality of life second to none through
> competitive economic advantages. (Department of Finance Canada
> 2006:6)

Canada's economic advantages fall into five categories: tax advantage, fiscal

advantage, entrepreneurial advantage, knowledge advantage, and infrastructure

advantage. The policies and vision salient to university-based research and

development are contained in the "entrepreneurial advantage" and "knowledge

advantage" sections.

The government's vision is to socialize and prepare young Canadians to work in and contribute to industry by: (1) investing in research equipment and facilities in the higher education sector, (2) increasing graduate scholarship support, specifically in science and engineering, and (3) exposing more students to private sector research through internships and collaborative research (Department of Finance Canada 2006:52).

The federal government is also committed to generating more value from publicly funded research and development activities. It proposes to do this by altering the operations of its granting councils (SSHRC, NSERC, and CIHR[37]), through which it provides most of its university-based research and development funding. This will require increased emphasis on the outcomes of research and direct more funds to "high priority" areas, such as energy and defence (Department of Finance Canada 2006:59).

As part of generating more value from publicly funded research and development, the federal government has created policies and programs to align post-secondary research with business needs. It intends to strengthen:

> ...the links between universities, colleges and the private sector through mechanisms such as business-led Networks of Centres of Excellence to enhance the commercialization of Canadian ideas and knowledge. (Department of Finance Canada 2006:62)

This policy is presented as being driven by an interest in the public good and premised on the efficacy of trickle-down economics. The government subscribes

to what Atkinson-Grosjean (2006) describes as the 'open science' model, where research activities ought to be oriented towards industry to increase its relevancy and economic impact.

> Partnerships of researchers and entrepreneurs are important because they bring research strengths to bear on market-driven challenges and opportunities. There is a role for public support for such partnerships because the benefits they provide spread across the economy. (Government of Canada 2007)

The federal government proposes several methods of strengthening these links and obtaining the greatest "economic advantage" from university-based research capacity. These include: aligning the activities of research organizations (such as NSERC) to promote commercialization of research, increasing funding for and allowing greater private industry influence over the Networks of Centres of Excellence[38] (which link university researchers with industry), establishing a new Centres of Excellence in Commercialization and Research program, and creating a new tri-council private-sector advisory board (Government of Canada 2007). Finally, to speed the transfer of technology from the university to the private sector,

> [a] review will be launched to uncover factors that might be inhibiting S&T (science and technology) collaboration between industry and the higher-education sector (universities and colleges). This review will include an assessment of whether a new approach to intellectual property management of university research is warranted. (Government of Canada 2007:57).

The federal government argues that Canada must become more competitive in the global marketplace by taking advantage of the knowledge and economic capacity of its universities. It can do this through strengthening the university's ties to industry to capitalize on research activities, and by transforming scientific discoveries and knowledge (which are traditionally held in the public domain because they are produced in the public education sector[39]) into patentable and marketable commodities.

Atkinson-Grosjean (2006) argues that personal relationships among powerful scientists and policy makers, global pressure, and the soft boundaries between public and private industry have fuelled the growth of this policy trend. Up until the 1960's federal science funding was often based on social capital and social networks and less on scientific merit. Today, these personal influences are more subtle, but still exist because it is a relatively small social world. Atkinson-Grosjean (2006) also observes that Canadian policy makers are heavily influenced by policy fashions developed by the G8 and the Organization for Economic Co-operation and Development (OECD). We tend especially to adopt American and British approaches to science policy. For example, the American push for more public/private partnerships in research during the Reagan era[40] had an enormous influence on Canadian policy makers. Finally, Atkinson-Grosjean argues that the differentiation between private and public institutions in Canada has been historically unclear. She shares Phillipson's example of the Canadian Standards Association, which was established in the 1920's as an

advisory group composed of industry and researchers. In the 1940's it incorporated, and today it is a non-for profit organization, but still has the authority to develop and enforce standards (Atkinson-Grosjean 2006:41).

Public-private partnerships are not new to Canadian universities and are not universally regarded as a positive trend. In 1951 the Massey Royal Commission warned that the intellectual vision of Canadian universities was at risk from low funding and commercial influences (Tudiver 1999:xxi). In the 1970's and 1980's the government reduced its investment in the post-secondary education sector and private investment took root (Tudiver 1999) and formal public-private partnerships, such as The Networks of Centres of Excellence were formed. The Networks of Centres of Excellence was founded in 1989 and its function is to organize research in a number of different areas, for example gerontology, robotics, public school safety, and genetic diseases. The policies outlined in "Advantage Canada" and "Mobilizing Science and Technology to Canada's Advantage" purport to further strengthen and entrench these relationships. The current federal efforts to support, intensify, direct, and commercialize public research represent a new phase in private sector participation, direction, and benefit from public sector research.

I categorize opinions about the commercial orientation and industry involvement and sponsorship of university-based research into three major perspectives. The first is that universities are places of higher learning and

should be concerned only with furthering knowledge through education and research endeavours. Applicability and commercialization should not drive research, but rather scientific curiosity and the quest for truth. The second perspective is that as public institutions, universities have an obligation to be relevant. Thus, their knowledge generation and translation activities should support products and programs that benefit the people. Research has the capacity and responsibility to improve public policy and government-owned technology (for example, green energy or health promotion technologies). The third orientation is that university-based research should be relevant to the public, and the best way of doing this is through supporting industry initiatives and letting the market determine which products and services are valuable to the public. A popular argument against this last perspective is that it is unsound because it supports the corrupting influences of commercial interests and jeopardizes the purity of science.

I personally support the second perspective. Relevancy in research is important because it connects universities with the public and addresses important and serious issues – often times ones never addressed by industry (such as health promotion). I believe that university-based research should be driven by public interests (a goal not always possible in the current environment), although industry should be able to use this knowledge and innovation to support its own endeavours. However, industry-focused and oriented research should remain private. I do not support the idea that the

public should have to pay twice, once as taxpayers supporting the development

of goods and services, and once as consumers. Petryna (2009:30) argues that

the clinical trial industry siphons public monies, and is able to do this by

portraying itself as a social good. This is insightful because clinical drug research

is based on the assumption that drug research is one of the only methods of

improving health. It also assumes that the pursuit of health is a worthy (perhaps

the most worthy) endeavour. If the result of a study is possible health

improvement, we are willing to allow siphoning of public money and testing of

drugs on humans.

D) Industry funding of university-based research

A significant proportion of the research activities in Canadian universities

is in the area of "health sciences".[41] Health sciences research is varied, ranging

from research involving nursing care, to medical imagining development, to drug

trials. In 2005/6 health sciences research and development expenditures in the

higher education sector totalled $3.8 billion (almost 40% of the total research

and development expenditures across all disciplines). Approximately 21% of this

funding ($0.8 billion) came from business and private non-profit organizations.

Health sciences research receives the most private funding of the three major

fields of science (the two other major fields are social sciences and humanities

and natural sciences and engineering).

The federal government committed almost $1 billion to university-based health research in 2005/2006. The majority of federal investment is managed by the Canadian Institutes for Health Research (formerly the Medical Research Council of Canada, which transitioned to the CIHR in 1999), which funds nearly 9,000 grants and awards every year (Canadian Institutes of Health Research 2007). In 2005/2006 CIHR's operating budget was $816 million. These funds support open research, research in targeted areas, Networks of Centres of Excellence, and Canada Research Chairs (Canadian Institutes of Health Research 2007).

On the industry side, the biggest supporter of health care research funding is the pharmaceutical industry. Manufacturers of patented (separate from generic) medicines reported[42] spending a total of $1.2 billion on research and development in 2006. Approximately 16%, or $200 million was invested in research and development conducted at universities and hospitals (Patented Medicine Prices Review Board 2007). Thus, approximately one quarter of private funding that goes to university-based health sciences research and development is provided by the manufacturers of patented pharmaceuticals.[43] This is not surprising, as the pharmaceutical industry often directly benefits from health sciences research. Developing these links with academia helps firms increase the likelihood of financially benefiting from university-based research. A classic example[44] of this is the case of the first successful HIV drugs, where industry partnered with governments and academia, invested the least, yet in the end

obtained patent rights and substantial profits (Goozner 2004). Most

breakthrough[45] drugs have been discovered by academia, not industry, yet

industry has ultimately gained control over their ownership, production, and

distribution (Angell 2004).

E) University-based health sciences researchers
Health sciences academics have responded to the encroachment of

industry – industry money, industry presence, industry interests – in mixed ways.

Numerous academics warn of the dangers of these partnerships with industry

(Angell 2004;Lewis et al. 2001), document ethical transgressions (Healy 2003),

and tally the impact of industry funding on research outcomes (Bekelman et al.

2003;Bhandari et al. 2004). There is little in the academic literature espousing

the benefits of partnerships with industry, yet these partnerships continue to

proliferate. It seems likely that most academics see these partnerships as sub-

optimal, but necessary for them to do their academic work. In his interviews

with medical researchers at a western Canadian university, Mather (2005) found

that they believed that industry presence in the university was beyond the

control of individual scientists. They felt that the universities encouraged these

relationships. As such, some felt the university could not be relied on for ethical

guidance concerning relationships with industry.

In my discussions with medical researchers, similar ideas surfaced. I

asked researchers what challenges they faced conducting research, how

research was changing, and their perspectives on relationship between

university-based research labs and private industry. One academic researcher,

who conducts primarily industry-sponsored research, spoke of its benefits to the

institution.

> KI7: The funding for these projects are largely pharmaceutical
> based. The government is not funding these trials – that is up front.
> When we apply for ethics approval the ethics board they charge us
> $2000 to review the protocol. The university charges us 30% - 30%
> of all of our funding goes directly to the university. In many ways
> these studies are identified – it is very obvious that a lot of money is
> going to change hands when these trials take place and the
> university wants to take their share.
>
> Leigh Hayden: So it's good for the university that you are doing
> pharma sponsored research?
>
> KI7: It is. It's supposed to pay for the lights and things like that, but
> 30% is a lot. For our part of one of these studies you've been
> looking at is $600,000 to $800,000, so the university does get a fair
> bit of money from us each year. That's just from one study. So it's
> all acknowledged that it's pharma sponsored.

Another informant discussed how the university benefits from industry-

sponsored research. Even the university's Research Ethics Board (REB) benefits

from industry sponsorship.

> The university and the hospital also benefit. The hospital gets 17%,
> the faculty of health sciences 10%, and the individual researcher 3%.
> Plus, the REB gets $2000 for each industry protocol they review so
> they are happy too if we are doing industry sponsored work. (KI11)

The same informant also explained how institutions maximize their income from

industry-sponsored studies:

> *Industry pays us per subject we recruit in addition to any*
> *treatment/drugs/ monitoring required by the study above and*
> *beyond standard treatment. There is more of a nickel and diming*
> *mentality these days. Every single test that industry could pay for*
> *possibly they should pay for. This was not the case 8-10 years ago*
> *because there was much more funding. (KI11)*

Since the government has limited funds, some researchers seek industry funding

in order to carry out their research. This usually involves developing a project

that meets both the research needs of the investigator and the product

development needs of the sponsor. Developing these relationships can meet

investigators' need for funding. However, researchers also see drawbacks,

including: conducting research that is not of great interest to them, distracting

them from their own research questions, and reducing their ability to publish

(Gwynn 1999).

> *We had a company last year not want to register their trial because*
> *they didn't want their competitors to know where they were at with*
> *the drug. We said well we want to be able to publish the findings*
> *and if we're going to be limited to what journals we can publish in*
> *because it isn't registered that isn't good for us. So there was a bit*
> *of a tug of war and back and forth and in the end it didn't get*
> *registered and we are kicking ourselves because we found that they*
> *were fantastic findings. (KI7)*

I found it surprising that individual researchers were responsible for developing

and abiding by contracts with industry sponsors. I had always assumed that

these financial and legal details would be arranged by another department. In

fact, PIs in some labs must act as lab managers and negotiate with sponsors.

However, when researchers are organized, individual researchers have fewer

managerial responsibilities and can concentrate on their research. I spoke with

one researcher who worked at a university-affiliated cancer centre where they

collectively organized their research program and negotiated with sponsors. This

researcher did not have to negotiate with sponsors as a free agent. This was

conducted at the institutional level.

Industry funding, although commonplace, is not prestigious. Some

investigators detect a tension between the need to attract funding and the

stigma of relying heavily on industry funding.

> One thing I should mention is how the university perceives this. For
> a PI it's like icing on the cake to have CIHR funding. You've
> competed against your peers and won. It's a big feather in your cap
> and the university looks very highly at that. To bring in money from
> clinical trials, I don't think they see it as highly. Great they get 30%,
> but as a researcher, I don't think you're given quite the same degree
> of respect as if you had competed for that money. And rightly so.
> These clinical trials – the perception is that it's dirty money and it's
> not as highly regarded. (KI7)

This "dirty money" is used for pragmatic reasons: to enable the pursuit of

academic research questions and to "keep the lab running".

> As a PI it's far easier to work with pharma companies than to
> continually apply for grants. Each application takes so much work. I
> can spend the same time putting together a protocol and working

> *with a pharma company for money I know I am going to get and*
> *money that will help me run my lab for the next year. So, it's pretty*
> *tempting. You are responsible for keeping your lab running. It may*
> *not be perceived as the best way of obtaining money, but in some*
> *ways it is a responsible way to make sure staff aren't laid off. (KI7)*

In this environment, where public funds are limited[46] and industry funds "dirty",

academic researchers are required to act as both scientists and managers. On

the one hand, they are responsible for contributing to scientific knowledge,

working on novel contributions to the field, and publishing their work. On the

other hand, they are responsible for "keeping the lab running" by attracting

funds and generating business.

The manager role can necessitate developing a relationship with industry,

which may jeopardize the researcher's role as an independent scientist. One of

the researchers I spoke with was ambivalent about this tension between the

roles of responsible manager and independent scientist.

> *I'm still doing my research. If I didn't get any funding then I would*
> *be sitting in my office twiddling my thumbs. It's a way of keeping*
> *things moving and that's the way things are going. The government*
> *doesn't have enough money to fund all of the research that's*
> *happening and people have to look elsewhere. I think as long as*
> *your own personal research goals are being met that's okay because*
> *money is money. (KI7)*

Not all researchers were as forthcoming about the stigma of industry money.

One cancer researcher disagreed with my description of his field as an

"industry".

> *LH: How long have you been in the clinical trials industry, if you*
> *don't mind me calling it an industry?*
>
> *KI10: I don't mind you calling it an industry, but that's not what it is*
> *because the clinical trials – recognizing there may be a business*
> *component to it in terms of developing technologies that are*
> *patentable – clinical trials is a form of inquiry and using rigorous*
> *scientific methods to try to figure out what the best way of treating*
> *individuals is.*

I found his response somewhat defensive. I also found it curious that he felt

scientific methods protected his work from the impacts of industry. This reminds

me of Lefebvre's description of technology as an organizing and mystifying

ideology of capitalism. Here, scientific methods obscure the economic aspects of

the clinical trials industry.[47] There is a general opinion that if the scientific

method is followed, then the scientific truth will emerge, and this truth will help

future patients. The problem emerges when private ownership taints science,

not when it appropriates it. Scientists are concerned with scientific validity and

purity; we are generally less concerned with who generates knowledge and how

it is used. By focusing on the "nuts and bolts" of research, scientists can remove

themselves from much more difficult and political aspects of our work. I believe

that we assume that others are regulating the system, creating policy, and

policing private sector ownership and use of scientific information.

i)   Concerns with industry-university partnerships
One of the scientific community's most significant concerns with industry

partnership is increasing the potential for bias. In order to increase the

probability of a positive study outcome, a sponsor may influence the study

through things such as: altering the inclusion criteria, changing the endpoints, or

massaging the data analysis. These activities can bias the outcomes in favour of

the sponsor. Study bias can positively influence a sponsor's bottom-line. One of

the cancer study participants I met critiqued the money-making aspect of

medical research and treatment. He spoke about his cancer and mentioned:

> *They have already found a cure for it (cancer), but it won't make*
> *people enough money so they're working on these drugs. I read*
> *about it a while ago, but then heard nothing about it. Dropped.*
> *(KI9)*

It goes without saying that the medical literature does not reflect this viewpoint.

However, I have encountered exposés on the cancer industry, which detail

attempts by the medical industry to denounce and fabricate evidence against

inexpensive and successful cancer treatments (Lynes and Crane 1987;Moss

1989).[48]

The medical literature primarily investigates the impacts of industry

funding on bias in research methodology (Lexchin et al. 2003;Perlis et al. 2005)

and interpretation (Baird 2003). Interestingly, even though multiple studies have

found that industry-sponsored research has a much higher probability of positive

findings (Bhandari et al. 2004;Friedman and Richter 2004;Lexchin et al.

2003;Okike et al. 2007;Perlis et al. 2005), individual researchers do not believe

that industry funding biases them personally (Mather 2005). The following

quotes from a study coordinator and principal investigator illustrate this point:

*They're only paying me to do that study. I'm not getting paid
additional money if the study gives a positive finding. There
shouldn't be bias in the interpretation of the data. If we register
and let people know what measurements we will be taking and
what endpoints we deem to be important, then it really creates a
better feeling that nothing is being hidden. (KI7)*

*I don't work for the drug company. I couldn't care if the study works
or doesn't. I don't get any money from it. If it's a positive study, if
it's a negative study, it doesn't mean anything to me. (KI2)*

The philosophy that funding bias is a matter of individual ethics and

practice, and not an artefact of the relations and mode of production of the

research industry is commonplace (Mather 2005). Relationships with industry

are framed in a risk-reward model, not dissimilar to the ways in which

participation in medical studies is conceived. There are benefits and risks to

both, and individuals (researchers, study participants) must decide what their

tolerable risk is and act accordingly. The only declared benefit to industry

sponsorship is the funding of important research, research that presumably

would not be pursued otherwise (Okike et al. 2007). The risks of industry

funding include: jeopardizing the safety of human research participants,

restricting publication, evaluation bias[49], and public perception that scientific

integrity is being compromised (Okike et al. 2007).

Moreover, as these relationships deepen, the university culture is at

increasing risk of being compromised by industry interests (Lewis et al. 2001).[50]

The relationships themselves are rarely denounced. But rather, they must be

carefully negotiated (Lewis et al. 2001;Montaner et al. 2001) because they

"promote technological advance" (Okike et al. 2007) and are "valuable" and

should be "nurtured and perfected" (Montaner et al. 2001). Thus, it is a matter

of carefully "dancing with the porcupine" (Lewis et al. 2001) or of "wielding a

sword capable of cutting-edge advances with care" (Montaner et al. 2001).

For some, risk mitigation requires bureaucratic intervention. Most

universities have conflicts of interest guidelines. The University of Toronto, for

example, requires speakers at all teaching events in clinical settings to disclose

any conflicts of interest to allow the students to decide for themselves whether

the information is biased (Catton 2005). Many journals require researchers to

declare conflicts of interest[51] (DeAngelis et al. 2001). Some journals also refuse

to publish articles if any of the authors receives financial compensation (in the

form of stocks, honoraria, etc.) of $10,000 or more in the past year (Canadian

Medical Association Journal 2004). An informant, a principal investigator,

echoed the $10,000 watershed mark.

> *For industry studies, the individual researcher gets 3%.*
> *Three percent isn't all that much – for each trial it is less*
> *than $10,000 and we think that anything under $10,000*
> *isn't worth getting too excited about. This remuneration*
> *is an incentive for them to recruit more patients. (KI11)*

Declaring conflicts of interest and ensuring financial conflicts of interest are less

than $10,000 are considered practical ways of reducing the risks involved in

working with industry.

These approaches – requiring researchers to declare conflicts of interest, and limiting financial conflicts of interest to under $10,000 – are inconsistent with social science research, which suggests that individuals are unable to remain objective, even when they are aware that they are motivated to be impartial, and that even small gifts influence decision making (Dana and Loewenstein 2003). Babcock and colleagues (1997) found that informing people (in their case, lawyers) of bias made them expect it from others, but not themselves. When individuals did acknowledge their bias, they underestimated its strength. Dana and Loewenstein (2003) argue that financial bias is unconscious and unintentional, and as such difficult if not impossible to control, even if identified. Mather (2005), using Mauss' (1967) gift theory, argues that gift-giving by industry to academics creates a relationship and implies reciprocity.

Some suggest even more bureaucratic measures to control risk of bias in industry-sponsored research. Many authors recommend (Chalmers et al. 1992;DeAngelis et al. 2004), and some journals require (Bland et al. 2007), that all clinical trials be registered in a clinical trials database, to ensure that all findings are made available to mitigate publication bias. Lewis and colleagues (2001) suggest a number of rules for governing industry-university relationships, including: establishing Canada-wide standards for industry-university contracts, developing guidelines to evaluate industry-sponsored projects for quality and intellectual contribution, writing debriefings after each industry-lead project, and

instituting a certification and rating system that evaluates industry partners

based on scientific integrity and commitment to intellectual freedom.

Montaner and associates (2001:1895) suggest academia establish bodies

to "foster and monitor this relationship". Okike and colleagues (2007) suggest

establishing an independent body to conduct all industry-sponsored study

analyses. Barnes and Florencio (2002) suggest universities establish a conflict of

interest board to oversee and manage conflicts of interest. Brennan and

associates (2006) suggest that grant money be awarded to institutions, rather

than individual researchers to reduce the opportunity for a conflict of interest.

However, shifting the risk to the institution is unlikely to solve the problem due

to the underfunding of universities and the transition of these institutions to a

business model (Barnes and Florencio 2002;DuVal 2004). Few sources (Canadian

Association of University Teachers 2005;Sismondo 2006) advocate addressing

these risks associated with industry sponsorship, not through bureaucratic

measures, but by removing private funding of research and increasing public

funding.

F) The University Research Ethics Board (REB)
The influx of money to the university from industry, however, has created

benefits at the Research Ethics Board (REB) level that the literature generally fails

to address. The literature does address risks associated with industry funding at

the REB level. These include potential conflicts of interest of REB members who

may hold equity in biotech or drug companies, and pressure REBs may encounter

from the university to support potentially academically or financially important

studies (Barnes and Florencio 2002;Levinsky 2002).

As a result of the increasing investment in health research in Canada, the

number of protocols submitted to REBs has increased significantly in the last

decade. The exact figures are difficult to obtain, but one source cites a 20%

increase in the number of protocol reviews in the "last few years" (National

Council on Ethics in Human Research 2002). An article in the National Post in

2004 claimed that one in 20 Canadians are participants in a drug trial at any one

time (Munro 2004). Another estimate puts the total number of Canadians who

participate in any research study as 1 in 10 (Davey et al. 2004). With these

figures, it is no wonder that REBs feel strained (Bell et al. 1998). One of my key

informants discussed the workload of REBs:

> *Research ethics is a black hole. This has been well documented.*
> *Once people become involved in research ethics it tends to take up*
> *most of their time. This is because there is so much work to be*
> *done; the work needs to get done. It has to get done for research to*
> *get done. (KI13)*

During an NCEHR (National Council on Ethics in Human Research) conference in

Ottawa, I observed that several REB members and chairs complained of the time

and energy required to complete the work, the lack of institutional recognition

for the work, and the difficulty this creates for attracting new members. The

following are some comments I recorded while listening to a university-based

REB chair present the experiences of his board.

> They are "working flat out". Their volume has gone from 581
> protocols in 2004 to 700 protocols in 2006, with no additional
> resources. They feel like they're always on the edge, "small voices
> crying in the wilderness". The university "wrings every single minute
> of labour out of us". As such, succession planning is difficult. [from
> field notes]

A positive aspect of this is that growing demands on REBs has created a

cottage industry. In Canada alone, there are several conferences every year to

address the concerns of research ethics and the functioning of REBs. Articles

about research ethics and research ethics boards can be found in hundreds of

academic journals, including several dedicated to the topic (IRB, Journal of

Empirical Research on Human Research Ethics). Education seminars are available

for training and educating research ethics board members and chairs. Due to the

sheer volume of work, research ethics offices have been established, employing,

mostly female (Bell et al. 1998) peri-professionals to organize and oversee the

functioning of the REB.

Most university and hospital-based REB work is voluntary. Staff,

researchers, and community members volunteer their time to read through

dozens of protocols a month and attend regular meetings. In addition, REBs

require members to participate in training of some form. The time, dedication,

and education required of REB members is not recognized by most institutions.

As one key informant stated:

> *One of the issues for REBs themselves is the amount of time it takes to do this work and the recompense from institutions for doing this. This is not just another committee, but a huge load. It should be somehow acknowledged in terms of promotion and tenure. This impacts how people deal with things. That has been a sticking point for a number of years. The work hasn't been recognized. (KI 13)*

Although the work is not recognized by the university in evaluating promotion

and tenure, it is an aspect of many board members' professional development.

For many board reviewers the work is engaging, fascinating, and rewarding

(Slaven 2007). The following are excerpts from my field notes while observing

ethics conferences and REB meetings.

> *People loved talking about and debating the ethical issues.*
>
> *The education break-out session was intense. There was much disagreement and discord. People seemed really hungry to resolve the issues, discuss specific topics, and share their stories.*
>
> *She told me that even though her work on the REB isn't valued academic work, she did it because she finds the work important and intellectually rewarding.*

Almost all of the people I have met in the research ethics industry I consider

passionate about and dedicated to the work. The research ethics community

acts as a (generally peer) watchdog and moral compass. A growing community

of academics is responding to the risks associated with industry funding of

research. They join REBs, give seminars, and write papers, out of passion, hope,

and even disgust. They may be "small voices crying out in the wilderness", but

they are engaged and connected.

i)   Allegiances of the REB

I had the opportunity to observe Health Sciences REB meetings of three

separate institutions.[52] These REB's are funded primarily from fees generated by

reviewing industry protocols and rely heavily on the volunteer efforts of the REB

members.[53] Two of the boards operate independently and are not required to

report to a university or hospital administration. One REB member explained:

> So, although we report to those sources [the university office of
> research services], they recognize that boards have to be
> independent in their substantive decision making. For example, the
> board finds that there is a major problem with some element of
> research, and we make the decision that the research needs to be
> stopped or modified. Nobody can – the hospital or the university –
> nobody has the right to say it isn't correct. They may express
> concerns about the decision and use the appeals process, although I
> don't think the appeals mechanism has ever been used. But, there is
> independence, where REBs act independently, uninfluenced by
> either the faculty or the hospital. (KI14)

This describes how REBs are sheltered from direct influence from institutional

administration, but does not address potential conflicts of interest.[54]

Although independent, some REBs see themselves as responsible for both

protecting research participants and supporting important research. The same

REB member went on to say:

> There's a pride in research, a pride in Canadian research. I think
> people want to think that research is very well done. So while

> *protecting patients and making sure everything is done properly,*
> *we've got to make sure we support research because it's also for the*
> *benefit of the public. For me the biggest single challenge is to make*
> *sure we do our job well without being perceived as a barrier to*
> *research. (KI14)*

Another key informant mused about the responsibility of REBs to enable

research.

> *There will be more restrictions on research, but it's important to*
> *keep in mind that research must go forward. That's an interesting*
> *thing to me – what are our obligations to be part of research? We*
> *take advantage of the health care that research brings, but do we*
> *have an obligation to ensure the knowledge goes forward? From an*
> *ethical perspective this is an interesting question. (KI13)*

This is, of course, a balancing act. REB members are concerned about the

protection of research participants and the ethical conduct and implications of

research more broadly. During one REB meeting I attended, the board members

expressed concern regarding a large multi-sited industry funded proposal. Board

members did not feel that the study put the research participants at an

unacceptable level of risk, but they were concerned with the broader social

implications of the study. They came to a consensus that it was not their

purview to concern themselves with broader social implications of research and

they were strictly responsible for protecting the safety of research participants.

After the meeting, I bumped into one of the REB members and asked them

about why the study was of such concern. My field notes explain what that

person translated to me.

The individual thought people [board members] were uncomfortable with the study because the PI has become rich and famous for being involved in other research and isn't much of a team player, so they begrudge the PI for that. The individual said they think it is personal rather than ethical. Although, they also said that the REB won't be able to shut down a trial with as much fame and money as this one.

According to this informant, social factors influence how board members react to and assess research protocols. REB review is not anonymous or "objective" and is influenced by personal relationships – both good and bad. In addition, this individual felt the board was under pressure to approve high profile studies, demonstrating that the interests of the institution are a factor in ethics reviews. Other research ethics board members have expressed similar opinions (Lemonick et al. 2002). Robinson (1990), in his study of drug trials for multiple sclerosis, found that the ethics debate was informed by more than the scientific aspects, but also broader issues such as individual career interests and policy considerations.

Both of the above examples caused me to wonder whether REB members ever felt an obligation or comradeship towards their colleagues who also conduct research. I asked a member of an REB about this.

LH: Since most REB members are also researchers, is it difficult for them to not be influenced by the research community?

KI13: Yes and no. My experience is that a lot of the clinician/researcher/REB members have strong egos and they have no problem about saying they think this is the way it should be. You can argue with me but that's my position. I understand your point, but my experience has been generally that they don't care. They

> *work in a system where that's valued. Their colleagues might be*
> *unhappy, but that's fine with them. On the other hand I have seen*
> *that they lobby for more stringency, but the community members on*
> *the REB tell them that they are getting carried away. There is only*
> *so much you can do to protect people from themselves. The*
> *community members protect against REB paternalism. This is why*
> *strong community members are so important on an REB.*

So, according to this informant, board members who are also researchers tend

to be less "research friendly" than community board members. In contrast, the

general perception of researchers outside of the REB (based on a number of

conversations with medical and social science researchers) is that they are overly

stringent and inconsistent in their requirements and focus. Nevertheless, a

potential for professional bias on REBs has some worried and others sceptical

about the ability of REBs to critically assess research protocols (Levinsky

2002;Wolf and Zandecki 2007;Lemonick et al. 2002).

According to the Tri-Council Policy Statement (TCPS) for the ethical

conduct of research involving humans, the purpose of the REB is to protect

human research participants (Interagency Secretariat on Research Ethics 2005).

One REB member affirmed this to me.

> *Every REB has a primary responsibility for looking after the welfare*
> *of the participants, whether they are patients or volunteers. (KI11)*

The primary method of protecting these research participants is by determining

the "risk" of each study. Studies are usually categorized as "minimal" or "high"

risk. For high-volume REBs, minimal risk studies are usually evaluated by two or

three REB members, who provide feedback to the research team, indicating

whether changes are required to the study protocol. High risk studies are usually

reviewed by all REB members and they are discussed at the REB meetings. In my

experience, high risk protocol reviews took approximately 10-20 minutes.

According to the TCPS, a study has minimal risk if:

> Potential subjects can reasonably be expected to regard the
> probability and magnitude of possible harms implied by
> participation in the research to be no greater than those
> encountered by the subject in those aspects of his or her everyday
> life that relate to the research. (Interagency Secretariat on Research
> Ethics 2005)

Thus, risk is not inherent to the study protocol, but dependent upon the research

participants enrolled in that study. This definition's purpose is presumably to

accommodate for studies where participants have shown a willingness and

ability to tolerate certain risks. However, the above definition of risk implies that

it is acceptable to expose individuals with certain lifestyles, genders, ethnicities,

and locations of residence to greater risk. It is worrisome that those people,

whose lives are most fraught with difficulty and danger, are in some ways the

least protected, according to this perception of risk. However, this approach

avoids paternalism and acknowledges the situatedness of risk and benefit.

The REB's duty is to protect individual research participants. The TCPS,

the document that guides all Canadian REBs, is rooted in the principles laid out in

the Declaration of Helsinki (World Medical Association 2004). These principles

include respect for human dignity, integrity, privacy, confidentiality, and

autonomy. The declaration also states that medical researchers have a duty to

inform potential participants of the potential risks and benefits of the study, in

addition to the study's goals, methods, and funding. Moreover, it states:

> In medical research on human subjects, considerations related to
> the well-being of the human subject should take precedence over
> the interests of science and society. (World Medical Association
> 2004)

However, the authors of the document also assert,

> Medical research involving human subjects should only be
> conducted if the importance of the objective outweighs the
> inherent risks and burdens to the subject. This is especially
> important when the human subjects are healthy volunteers. (World
> Medical Association 2004)

These statements illustrate a tension between the rights of individual research

participants and the good of the larger group or society. In both the Declaration

of Helsinki and the TCPS, the social benefits of research are used to justify any

risks to research participants, presuming the research is methodologically sound,

is reasonably thought to have potential benefit, and these benefits outweigh the

risks to the participant. It is the REB's role to determine whether such risks are

reasonable, given the potential benefits.

In the example above, where the REB was concerned about the potential

social impacts of the study, the risk to society, not individuals, was of primary

concern. The REB members discussed their concerns, but in the end they

decided that the social good was not in their mandate. I asked an REB member

of another committee whose mandate it was to deal with these larger issues.

This REB member replied:

> *Individual REBs can't address them very well, which is why*
> *associations such as CAREB (Canadian Association of REBs), NCEHR*
> *(National Council on Ethics in Human Research), and PRE (Panel on*
> *Research Ethics) have grown up and there are list serves for people*
> *to discuss these issues. There are lots of different groups that are*
> *trying to reach consensus on how to deal with these issues. (KI14)*

For the time-being, however, REBs follow their mandate to protect individual

human research participants.

The REBs fill this role because human research participants are "free

agents". The REB is a buffer between research participants and researchers (and

sponsors), who, as we have seen, have multiple and competing interests and

may not be able to dispassionately weigh the risks and benefits of their own

research. Research participants must be "protected", to ensure that their rights

to dignity, integrity, and autonomy are maintained. In lieu of other bodies

(research participant organizations, associations, or unions) that may have that

authority, and mandate, REBs fulfill that role. Some (Latterman and Merz 2001)

argue that research participants should be unionized to protect the rights of

these workers. Others (Helms 2002) argue that other forms of organization

would be more successful because if unionized, human research participants

would, on the average, obtain less remuneration and have less autonomy.

I argue that the research community's emphasis on and preoccupation with individual rights promotes an approach to research which prioritizes and supports private interests. Federal policy emphasizes the economic and not social value of research and strives to create conditions where industry interests flourish. Encouraging public-private partnerships capitalizes on the value of industry-based research. At the university level, administrators react by embracing industry funding as a new and much needed source of income. Researchers are wary of such partnerships, but generally choose to strategically negotiate, rather than refuse them. The REB, too, benefits from industry funding. Due to the increase in research activities, research ethics in Canada has blossomed into a cottage industry and levies from industry-sponsored research partly fund this industry. The REB members I observed and spoke with were concerned about the adverse effects of industry relations on medical science. However, they did not feel that it was within their mandate to address these larger issues. Thus, there is an interesting parallel between the federal government's emphasis on private interests and the REB's focus on individual interests. Next, I explore the implications of emphases on private interests and individual rights for research participants.

G) Research Participants

Much of the literature on medical research participation focuses on the demographic differences between participants and non-participants to understand why people agree or refuse to participate. Clinical trial participants

are often healthier than so-called average patients. Patients excluded from trials

tend to have higher fatality rates than those included, which may skew the

results and representativeness of the data (Boissel 1989). This is often because

in order to qualify for entry into the study, most studies do not allow participants

with serious co-morbidities (Fletcher 2002).

The differences between participants and non-participants vary with the

type of study. A team of researchers examined 164 cancer studies conducted by

the Southwest Oncology Group between 1993 and 1996. They found that across

cancer types, the primary difference between those eligible to enroll in a cancer

clinical trial and those who did, was that participants tended to be younger

(Hutchins et al. 1999). Murthy, Krumholz and Gross (2004) found that (adjusting

for cancer type) cancer trial participants were more likely to be white, male, and

younger. As compared to all heart failure patients, those involved in clinical

trials tended to be male and younger, and those who declined to participate

perceived themselves as being too old, too unwell, or too busy (Lloyd-Williams et

al. 2003). In their systematic review of barriers to the enrollment of elderly

patients in oncology studies, Townsley, Selby, and Sui (2005) found that

physician perceptions, functional status, and the existence of co-morbidities

were significant factors which either excluded or discouraged older oncology

patients from enrolling in studies.

Participation in non-oncology randomized controlled trials (such as the asthma study I followed) tends to vary according to disease population. In a study of participant attrition in a long-term rheumatoid arthritis study, the authors (Reisine et al. 2000) found that women, participants with university degrees, those who were employed, and people who had more sites with rheumatoid arthritis, and those with greater social support were more likely to remain in the study. They found that social factors were more important than disease factors (self-described pain, disability, and duration of disease) in predicting participant retention. In a review of pulmonary arterial hypertension[55] clinical trials, participants were found to be primarily white, male, people in their fourth and fifth decade, and, in more recent studies, had relatively healthier disease profiles (Hill et al. 2008). In a review of clinical trials for heart failure clinical trials, reviewers found that clinical trial participants were not representative of the patient population (Heiat et al. 2002). They were disproportionately male, under 70 years of age, white, and did not have certain disease complications. The authors suggest that these discrepancies are partly due to inclusion criteria, and partly due to the demographics of the participant group. They suggest targeting older people, women, and minorities to determine if there are differences in how these groups respond to treatments (Heiat et al. 2002).

Barriers to participation in randomized controlled trials (RCTs) include: desire for treatment and not placebo, inadequate remuneration, and the

frequency of clinic visits required (Thomson et al. 2008). In a systematic review

of barriers to recruitment for maternal and perinatal trials, the authors found

that women who were motivated to help others and trusted research were more

likely to enroll (Tooher et al. 2008). Another study found that younger and

healthier people were more likely than older people with health complications to

enroll in an RCT (Fletcher et al. 2007). A review of the participants of two ocular

melanoma clinical trials found that lower education and closer residence to the

study site predicted participation (Diener-West et al. 2001). A systematic review

of the barriers to RCT participation found that additional study demands, worry

about uncertainty and concerns about the information and consent were the

most common barriers (Ross et al. 1999).

In my research, participant motivation varied. However, in the asthma

and muscle regeneration studies, remuneration and interest in science were the

most common ones reported. In the cancer study, primary motivators were

treatment and the opportunity to help others. These data are presented in more

detail in the next chapter. The asthma and muscle regeneration study

participants were primarily students, which is not surprising since they were

university-based studies and students would be most likely to hear about it

(these cannot be advertised outside of the university or hospital) and be

available to make multiple trips to the lab. Like many other university-based

studies, students - due to their availability, familiarity with research and its

importance, and limited income generation - contributed significantly to these studies.

The growth of industry-funded medical research has provided an opportunity for those who are interested in participating in medical research to become "professional research subjects". These people participate in multiple studies throughout the year and earn a good portion of their income through research participation. They are generally financially disadvantaged – students, temporary workers, unemployed and deskilled workers, underemployed professionals, and sex trade workers. Robert Helms, possibly the most famous and prolific human research participant explains his work.

> When I rent my healthy body to medical science, I am the temporary employee of a research team, paid as a contractor for each job. I do my bleeding, pissing work in a blurry area between patient and subject. (Helms 2002:VI)

For healthy research participants, often the best pay and most frequent work are at Clinical Research Organizations (CROs) like Biovail and Quest Clinical Trials. The most lucrative work involves living at a research facility (typically for between 1 and 28 days) so activities, food intake, and medications can be tightly controlled to help ensure high quality data. University-based research is generally less lucrative, but less restrictive.[56]

Among the research participants whom I met through their enrollment in the asthma and muscle regeneration studies,[57] several had been in multiple

studies, but none considered themselves "professional research subjects". Of the 16 asthma study participants with whom I spoke, 13 had been in various asthma studies in the same lab previously. They enjoyed the experience and found the money "worth their while", so they decided to enroll in additional studies.

> *Why did I decide to enroll? The money. And interest. I thought it would be interesting as well. (AP12)*

In the muscle regeneration study, only one participant had been in a study previously.

> *MP5: I took first year psychology and you have the option of taking part in 2 studies to get 5% of your mark. I did that and I found they [research studies] were pretty interesting and enjoyable. I saw this one and thought it looked interesting so I signed up.*
>
> *LH: Why did you think this was interesting?*
>
> *MP5: I'm in health sciences so I'm interested in the science. Also it's $10 an hour.[58] You learn something and you make a bit of money so it seems like a good venture.*

I asked him since he was interested in the science if he would have enrolled in the study had there been no remuneration.

> *I wouldn't be as willing to. Probably because of the time commitment because it's a pretty long study to participate in. (MP5)*

As he was the only person I had encountered who actively looked for various studies to enroll in, I was curious about whether he had ever turned down a study.

> *There was one they sent me an email about. It was kind of gross. They examined the effect of anxiety on touching objects. They pay you but you have to touch diapers. I don't think that's my kind of thing. I don't like dirty. I like clean. I like to keep my area clean. I'm one of those kinds of people. So, I wasn't really interested in their study. (MP5)*

This participant indicated that he was motivated by both remuneration and an interest in science and research, but he had limits to the kinds of research he would engage in.

Many people in the asthma and metabolic studies indicated an excitement about the scientific work and an interest in the research process.

> *It feels good to contribute. Like I said, it's not about the money, it's about contributing to science. I saw the results from a similar study and that made me excited. I will bet to see the results from my own study at some point, which is really satisfying. I will tell my friends about it. I am looking forward to seeing the scientific article. (MP4)*

> *It's really interesting – everything you learn here is really interesting. The things they teach you – they've taught me things my doctor has never told me. (AP16)*

> *I've had asthma since I was a young kid and I've been interested in learning more about it and more about the research that goes into studying it. I heard there was a trial going on examining the effects of new medication. I thought I'd give it a try. (AP14)*

> *I enjoyed the last one I did. I learned a lot from it. I am in kinesiology so I'm interested in that kind of thing to start with. It pays a lot, which is nice. I think it's important to have people do this kind of research in order to better the medication out there. (AP5)*

> *You asked about motivations too right? I love science. I've been involved in science since Grade 2. (MP1)*

> *I like anything medical. It's something new. It's in the same area that I'm in so I thought it sounded cool. (MP3)*

Participants indicated that participating in scientific experiments was both exciting and fulfilling. It gave them an opportunity to learn about their bodies, about research methodology, and new areas of scientific research. It is my assertion that enrolling participants in studies and creating positive experiences for them (by treating them with respect, educating them, creating a good working environment, and adequately remunerating them) makes these participants sympathetic to medical research. They believe that contributing to medical science is a positive activity that brings rewards to participants, researchers, and future patients or consumers. This is critical for repeat recruitment, referrals to friends and family (which occurred in both studies), and developing a population that believes in medical research. As the emphasis on medical research grows, so does the number of people who participate in medical studies and who are influenced by them and who are supportive of the movement. If one out of every 20 Canadians participates in medical research

this year, this socialization may have a significant impact on how Canadians

perceive the importance and logic of medical research.

Study participants are also a pool from which new researchers and

research staff come forth. In the asthma study, I spoke with three participants

who were either employees or graduate students in the lab. All of them came to

the lab first as research participants, and then became involved either as staff or

graduate students.

> *I loved these studies. Even though it was poking and prodding and I*
> *kind of hated that part. I liked being here so much that I got a job*
> *here. I liked that so much that I decided to become a graduate*
> *student here. (AP3)*

These workers and researchers approached the work first as participants. It is

possible that as participants or former participants, these workers and

researchers may be more sensitive to the concerns of the research participants.

> *I try to reassure them [other research participants] and make them*
> *comfortable. Knowing that I've been in their shoes and I've done a*
> *lot of things I think I could help them on a more personal level. I*
> *understand the ins and outs of what's going in the study because*
> *I've worked here so I know both sides. (AP2)*

This is likely comforting to other participants. It may also be subtly coercive. In

addition, since these workers and researchers were introduced to medical

research as participants, they may replicate the focus and perspectives of the

environment they came from, thus influencing the direction of future research.

One participant/researcher mentioned the funding of their research.

> *My own research is piggybacked onto another [industry sponsored]*
> *study because it's easier to get samples that way because there are*
> *more samples. (AP6)*

For expediency and financial reasons, some graduate theses are based upon

industry sponsored studies.   Since each lab's finances and approaches to

industry involvement vary, the conduct and funding of graduate theses depends

significantly on the lab environment, whether or not these graduate students

were first participants. However, I argue that it is significant that participants are

socialized to accept and appreciate the lab's approach to the types of research

questions asked and funding arrangements.

One of my assumptions before embarking on this research was that I

would meet participants who were critical of medical research, more specifically

the financial interests and aspirations of the research. This assumption proved

naïve. Of the asthma and muscle regeneration study participants I met, only one

expressed criticism of the industry, and this was oblique. One asthma study

participant indicated that he did not consent to having a blood sample kept for

15 years because he did not trust that his genetic data would be used

appropriately, and cited how the human genome project has injured indigenous

communities. I asked him if they recorded his ethnicity.

> *They did but I told them I was white. I would never want my*
> *indigenous status to be known or to be used. Unless it's indigenous*
> *research, I will say I am white so they won't use that knowledge in*
> *ways I don't consent to. They (the people who run the trials) all*
> *know. I tell them to write down that I am white. (AP8)*

Interestingly, I had not seriously considered debates about who owns personal

health data and what they do with the information. I was mostly focused on

how sponsors used money to encourage some people to participate in studies to

help them develop overpriced drugs to sell to other people. I did not think about

how sponsors would capitalize on demographic-related personal health

information. This was the only voice critical of the motives of research or

sponsors. Otherwise, participants demonstrated their knowledge of research

funding (the asthma study was funded by industry, which explained the

generous remuneration; the muscle regeneration study was not funded by

industry, explaining the modest remuneration), but no criticism.

H) The Three Bodies

In this chapter I have weaved the relationship between federal research

and economic policies and outlooks, the university (including the REB) and

individual researchers and participants. The body politic – federal vision and

policy - have a significant impact on the organization and types of research

conducted at the university. The federal vision is to create more industry-

academy partnerships to capitalize on academic knowledge and work and funnel

it into productive and commercializable discoveries. The university benefits and

relies on these partnerships because they enable research activities (that

possibly would otherwise not occur) and are sources of income.

At the social level – the research community – the REB also benefits from these partnerships in the form of levies from industry-sponsored research. For its part, the REB does what it can to prevent undue suppression of research findings by industry sponsors. Biomedical researchers are aware of the ethical and scientific risks associated with partnering with industry. These researchers forge partnerships carefully and pragmatically because they enable their own research agenda and allow them to support graduate students and staff. Those researchers who rely fully on government sponsorship feel vulnerable to changes in government trends and fashions. They do what they can to adjust their own research agenda to conform to the government's vision and use economic - not simply scientific - reasoning to justify their work.

At the same time, researchers use the ideals of science to avoid many of the larger issues. If they maintain funding for their research, and they are content that their research methods are appropriate and the results they produce valid, they are satisfied. In a complex environment where research funding is difficult to obtain and the criteria constantly shifting, it is not surprising that few researchers are engaged in the larger issues. It is my perception that only more established researchers feel they are in a position (both socially and economically) to question the funding structures and economic goals of research.

How do these agendas, economic forces, and ways of understanding and justifying research influence research participants and how does their role fit into the larger picture? Participants in many non-therapeutic health studies are offered remuneration for their work. This increases the ease of participant recruitment, although all of the research coordinators I spoke with indicated that participant recruitment was still a challenge. The majority of the participants in the non-therapeutic studies I met were motivated by the remuneration and the opportunity to support scientific progress. They considered helping develop and further scientific knowledge worthwhile and meaningful. In the therapeutic study I followed, participants were motivated by their desire to improve their health and to further scientific knowledge to help future patients. There was little discussion or interest in who would benefit from the knowledge – save future patients. The participants not only trusted that the researchers and research coordinators would ensure their safety; they also trusted that they would pursue reasonable and ethical ends with the acquired knowledge.

The participants in all studies largely felt safe, valued, and enlivened by their participation. They felt they were treated with respect and consideration. This supported their presumption that university-based scientific research was worthwhile and important. However, those who did experience pain expressed disinclination to participate in further research, although they remained in their current study. Those who had an unpleasant experience did not question the tests or openly state their disappointment. In these congenial atmospheres,

participants avoided conflict. They did not challenge an expert and complex

system which they were either invested in (as graduate students or workers) or

alienated from. Thus, they accepted the organization and goals of research. In

the university environment, the research community was highly trusted. If

researchers accepted and managed the commercial orientation and industry

funding of research, so did most participants.

By examining the 3 bodies, we can trace the influence of federal policy on

university-affiliated research labs. We also see a striking corroboration between

the perspectives of the federal government, the research activities of

universities, and the attitudes of research participants. Private interests – the

interests of companies, shareholders, lab employees, and research participants –

have currency and import. Conversely, collective interests have less currency

because they are not clearly articulated, possibly because there is no consistent

understanding of what shared interests are. The federal government sees a

competitive global economic environment, shaped by the policies of the WTO

and G8, and develops research funding policies it feels will increase the country's

economic advantage.   The university communities, likewise, analyse the policies

of the federal government and develop research agendas accordingly. Research

participants, too, see an economic environment, shaped by university-level

policies and funding realities, and function within that environment. On all

levels, dissent is factored out; negotiation, compliance, and pragmatism are in.

I) Discussion

I have traced the perspectives and impacts of the policies, politics, and financial interests of numerous actors in medical trials in Canada. These included the federal government, the pharmaceutical industry (the biggest industry sponsor in health research), health researchers, the university REB, and research participants. The federal government sets policies and priorities and sponsors research. It explicitly emphasizes the need for greater and stronger ties between industry and the university, which it believes will have a positive impact on Canada's economy. The pharmaceutical industry lobbies for higher levels of patent protection and more favourable conditions for industry-sponsored research. Individual researchers negotiate this complicated field, balancing their academic, monetary, and political interests. Human research participants willingly supply commodities to the industry, often with a philosophical commitment to furthering medical research.

My prediction about the future of university-based health research is rather mundane. I predict these trends will continue. Industry has successfully inserted itself into the university campus and university research agenda. Although, there is a significant literature about its negative impacts on the research agenda, research outcomes, intellectual property rights, and participant safety, this trend continues. The universities themselves, starved of funding from the federal and provincial governments (themselves starved by decreased transfers from the federal government), are dependent on industry funding, and

in some cases have given financial concerns priority over ideals such as academic

freedom and the public interest. The university is transitioning into a social

space where public funds and user fees are used for private interests (Giroux and

Giroux 2004). Few health researchers feel they have the power or position to

challenge these trends, and for practical and pragmatic reasons, develop

partnerships with industry.

It is unlikely that a change in government, unless it is a radical change in

Canadian federal politics, will alter the conditions under which university

research is conducted. In terms of sheer numbers, human research participants

have a great deal of power. If the estimates are true - 1 in 10 Canadians

participating in any type of research, and 1 in 20 participating in health research

every year - this is a considerable force.[59] From my interviews with research

participants, I did not gather any resentment towards industry or concern about

research funding. So, although there is potential for research participants to

organize and begin to question the research agendas (Saunders et al. 2007) and

research methods (Ali et al. 2006), none of the people I met showed any interest

in the politics or policies of research.

Nonetheless, there are some interesting trends developing in university-

based health research. Research ethics is developing as a cottage industry,

attracting committed and passionate workers and academics. It employs

academics and non-academics across the country, providing reasonably secure

and well-paying work. Although most of the research ethics work that takes place is voluntary, there is a small but growing community of practice of professionals employed in the industry. Research ethics board members are not impartial. However, the nation's REBs do act as a moral compass and have to date performed adequately enough such that university-based ethics review remains in-house.

With the intensification and growing sponsorship of university-based research, the number of research participants is growing. This is increasing the wider community's knowledge of medical research. My research suggests that this is in general increasing people's interest in and support for medical research. Thus, as the federal government's vision permeates the university, this will influence the wider public. Assumptions such as the goodness of applied research, the importance of knowledge transfer, and the necessity of industry partnerships are beginning to reach Canadians through their participation in research. There is a potential for research participants to become more politicized, demanding public research monies to be allocated according to the overall public good rather than private interests. However, both the public trust in medical research (influenced by largely positive experiences of research participants) and the complexity of medical research and health care are significant impediments for such a turn.

However, there are some promising areas of activity. AIDS research

activists have worked for decades to fight for access to experimental and non-

experimental drugs (Rylko-Bauer and Farmer 2002). They have also influenced

research methodologies, setting their own agenda and values. Also, some cancer

researchers and policy makers in the UK are engaging the public for developing

research agendas and methodologies (Thornton 2002). These types of public

engagement are examples of policy makers, activists, and researchers working to

encourage public input and influence into an arena that is otherwise skewed

towards industry interests. Work in this area is focusing on how successful public

involvement emerges and how it can be fostered (Boote et al. 2002). This work,

too, needs to be heavily informed by public stakeholders. Canada currently lags

behind in these types of initiatives. Advisory panels on policy and research

agendas (for example, the Canadian biotechnology advisory committee) are filled

by academics and industry. Even NCHER and PRE are primarily driven by

university-affiliated members. By expanding the roles of participants and

patients, we can possibly prevent industry from taking over the industry, and

develop a more balanced research agenda.   The academy has been blinded by

industry money; perhaps outside influence will help balance the scales.

_____

[31] I use "universities" and the terms "higher education" and "post-secondary education sector", which is composed of universities, colleges, and technical institutes, interchangeably.

[32] Lewkowicz and Schellenberg (2006) comment that the significant growth in the number of Canada Research Chairs, University Research Chairs, and Internal Research Chairs (which attract high-profile academics and generate significant income) is part of a broader movement which

emphasizes research and research activities, at the expense of teaching and academic leadership. The authors also frame the establishment of research chairs in terms of global competitiveness: "[O]ntario universities have concentrated increasing resources on a small percentage of their faculty in order to stay globally competitive" (Lewkowicz and Schellenberg 2006:22).

[33] Adjusting for inflation and population growth, the federal cash contribution to post-secondary education in 2004 was approximately 40% lower than in 1992/1993. (Canadian Association of University Teachers 2005)

[34] I use the terms "research", "R&D", and "research and development" interchangeably.

[35] Private research includes research conducted by: industry, the non-profit sector, foreign performers, and others. The vast majority of private research is conducted by and for industry.

[36] In 2006 the Conservative Party of Canada won the Canadian federal election with a minority government. Prior to this, the Liberal Party of Canada had been the ruling federal government since 1993. The Conservative Party has dubbed itself "Canada's New Government".

[37] SSHRC is the Social Science and Humanities Research Council. NSERC is the National Science and Engineering Research Council. CIHR is the Canadian Institutes for Health Research. Together they compose the "tri-council" of Canadian research funding bodies. They are all largely funded by the federal government.

[38] Networks of Centres of Excellence are funded by NSERC, SSHRC, CIHR and Industry Canada. In 2005/6 their total budget of $82.3 million was funded primarily by NSERC (49% of total), then CIHR (33% of total), SSHRC (14% of total), and finally Industry Canada (4% of total). Industry contributed approximately $70 million to the Networks of Centres of Excellence (Networks of Centres of Excellence 2006).

[39] I use the term "public" to denote activities funded and/or conducted by federal and provincial government agencies. Because these activities are fuelled by tax dollars, they are commonly denoted as "public". In contrast, "private" refers to activities funded by non-tax dollars, generally private investors and companies. The assumption implicit in this demarcation is that public interests are morally superior to private interests, and that public activities are concerned with the broader social good, whereas private interests are concerned only with the profit generation for a small elite. In practice, private and public domains overlap and there is no neat demarcation. See Atkinson-Grosjean (2006) for a detailed description of the rise of the terminology and the difficulty in applying it to contemporary scientific development in Canada.

[40] The Reagan administration increased federal funding of public research and encouraged private-public partnerships and commercial pursuits within universities through science, education, and patent legislation (Krimsky 2003).

[41] I use the terms "health sciences research", "health research", and "medical research" interchangeably. Statistics Canada uses the term "health sciences research".

[42] Patented drug manufacturers are required to annually report their research and development spending to the national Patented Medicine Prices Review Board. These figures are self-reported and the board does not have the authority to verify them (Kalant and Shrier 2006).

[43] Generic drug manufacturers also contribute to health sciences R&D in Canada. Apotex Inc., Canada's largest generic drug manufacturer reports spending $181 million in R&D in 2006. It is unclear how much of this was spent in Canada (they also have sites in Spain, Belgium and India), and how much of it was invested in university-based R&D.

[44] This example is an American example. The United States was the first to promote the commercialization of university-based research, and Canada has been trying to institute similar policies. The Bayh-Dole act was passed by the U.S. congress in 1980 to increase the commercialization of NIH (National Institutes of Health) research. What it essentially did was allow large drug companies to rely on NIH researchers, academia, and small biotech companies to develop new drug entities (Angell 2004). In 1990 the federal government passed any patents from university-based research that were owned by the federal government to the universities (Noble 2007). This move, along with an increased emphasis on commercialization spurred the growth in university spin-off firms in Canada from 230 between 1981-1990 to 510 in 1991-2001 (Finlayson 2001). In 1999 the Canadian federal government established a committee to make recommendations to increase the commercialization of university research. The committee recommended that universities be enabled to seek commercialization of federally funded research results. The universities should be given ownership of intellectual property and then funded to develop commercialization departments to transfer these innovations to industry, for the financial benefit of the university and ultimately industry (Fortier et al. 1999). This report essentially recommends that Canada develop intellectual property rights policies similar to the American Bayh-Dole Act. Many academics renounced the commission's report, arguing that it aimed to orient academics towards conducting only commercially viable research, at the expense of basic research and research for the public interests (Canadian Association of University Teachers 2007). In 2006 a new commission was appointed to make recommendations about the commercialization of university-based research. More recent reports on commercialization have agreed that universities should stay focused on research and developing research capacity rather than commercialization (Pecaut and Pether 2005) and that commercialization is dependent not on changes to the university, but changes to the industry (Rotman et al. 2006).

[45] In 2006, 99 new drugs were patented in Canada. Of those, 29 were new active substances, the remaining 70 were modifications of existing medications, commonly referred to as "me too" drugs. Only 4 of the 29 new drugs were "Category 2" drugs, which are "breakthrough drugs", or "the first drug to treat effectively a particular illness or which provides a substantial improvement over existing drug products." (Patented Medicine Prices Review Board 2007a)

[46] Funding for research is perennially limited. Even though funding has increased, the perception that funds are limited persists. This perception is reasonable, because according to CIHR's own reports, although its total funding has increased since its inception in 2000, the number of open grant applications has increased from about 2400 to about 3900 and the success rate has decreased from 34% to 22% (based on 2006/2007 statistics) (Canadian Institutes of Health

Research 2008). So, although there is more total funding, there is greater competition, so opportunities for funding are limited.

[47] I think that most research programs (clinical, non-clinical, natural scientific, social scientific) can be described as industries. Knowledge is produced and circulated in research. Sometimes the research is consumed by other researchers and built upon to form larger research projects and initiatives. Sometimes the research is consumed by policy makers, NGO's and the general public. Sometimes it is circulated in research literature and helps form normative approaches and ideas. This is a very unromantic view of research, but important to describe because, by labelling research "industry", I am trying to describe how it is produced and consumed, not how it is funded or its goals (to generate knowledge, to generate prestige, or to generate profit).

[48] Interestingly, treatments using radio, electromagnetic, and electric fields, which "medical quacks" have investigated in the past have recently been lauded in the medical and popular scientific literature (Gannon et al. 2007;Miller 2007). One of these technologies (using a combination of nanoparticles, that selectively enter cancer cells, and radio waves, which cause the nanoparticles to vibrate, thereby heating and eventually destroying the cell) is being developed in conjunction with MD Anderson, one of the top cancer institutes in the United States. Unlike radio waves, electromagnetic fields, or electric fields, nanoparticles can and are being patented (Praetorius and Mandal 2007).

[49] Publication bias describes the systematic difference between all research conducted and that which gets published. Typically, research projects with negative findings have a lower chance of being published. This can have a devastating effect on practice which is informed by the scientific literature (Young et al. 2008). This well-proven publication bias in medicine is one of the drivers for the clinical trials database, an attempt at making data from all clinical trials available.

[50] The authors (Lewis et al. 2001) assert that the university culture is based on scientific dialogue, open debate, and research transparency, while the culture of industry is based on positive research results for their products and, ultimately, sales. Industry sponsors often push to delay or suppress findings in order to increase their profit potential. These activities compromise the activities and reputations of university-based researchers and universities.

[51] Conflicts of interest include industry funding of research, consultancy, stock ownership, patent licensing, and honoraria (Friedman and Richter 2004).

[52] The REBs were the Hamilton Health Sciences REB, the Tri-Hospital REB, and the Ontario Cancer REB.

[53] REB members who are employees of a hospital or university are not strictly volunteers because they attend REB meetings during work hours. They may prepare for meetings during or after work. The community representatives on REBs are the only true volunteers, for they receive no remuneration for meeting attendance or preparation.

[54] This highlights the current lack of REB oversight. REBs use the TCPS as a guideline, but their unique interpretations and policies vary. This flexibility is intended – interpretation of the TCPS allows for appreciation of and appropriateness to the local environment. NCHER is currently looking at possible accreditation systems to standardize REB compositions, polities, and activities. Although there is considerable reluctance from many REB chairs, members, and researchers, I believe that within the next ten years an accreditation system will be in place.

[55] Pulmonary Arterial Hypertension is, according to the online medical resource Medscape, "a rare blood vessel disorder characterized by increased pressure in the pulmonary artery. Management of the condition is particularly important, given that the elevated pulmonary arterial pressure can cause an increased afterload that, if left untreated, can lead to heart failure and subsequent death" (Medscape Today 2009).

[56] CROs have a booming business. Industry is shifting many of its research activities from university-based research labs to CROs. Now, almost 70% of all clinical trials in the US are conducted by CROs. Universities are having to compete with the CROs for business (Mirowski and Van Horn 2005).

[57] I am not including the cancer study participants because they are not paid for their participation.

[58] According to the ethics literature, the hourly wage for an unskilled labourer, $10/hour, is a reasonable and non-coercive remuneration for human research subjects (Grady 2001). It appears strange that any more than $10/hour is deemed coercive to human research subjects, yet the watershed mark for financial conflict of interest is $10,000 for researchers.

[59] It is difficult to obtain a reliable estimate of the number of persons participating in health research in Canada. According to Schuppli and McDonald (2005), this lack of information is but one outcome of the relatively lax governance for human research participation in Canada, as compared to the governance of research done on animals.

CHAPTER 4: RHYTHMS OF RESEARCH

He fled to the street, but there chaos was multiple.
Broken groups of people hurried past, forming
neither stars nor squares. The lamp-posts were
badly spaced and the flagging as of different sizes.
Nor could he do anything with the harsh clanging
sound of street cars and the raw shouts of
hucksters. No repeated group of words would fit
their rhythm and no scale could give them
meaning. From "Miss Lonelyhearts" by Nathanael
West (1962:11)

> *[T]he world is not to be comprehended as a complex of*
> *ready-made things, but as a complex of processes, in*
> *which the things apparently stable no less than their*
> *mind-images in our heads, the concepts, go through an*
> *uninterrupted change of coming into being and passing*
> *away, in which, in spite of all seeming accidents and of*
> *all temporary retrogression, a progressive development*
> *asserts itself in the end...* Frederick Engels, discussing
> Hegel's dialectics, (Engels 1987:100-101)

A) Introduction

During my conversations with study participants, the topic of time kept

emerging. Participants shared their struggles and frustrations with adapting to

the schedules of research, the strict timelines of the tests, and the monotonous

"downtime" of research. I began to wonder if time was a thread, which if

followed, would lead me to understand many aspects of research participation.

The rhythms of research dictate how time is used and frame the experiences of

research participants. Participants are asked to follow the rhythms of research,

which requires social navigation and negotiation. These rhythms are determined by those who write the study protocols – usually a sponsor or a principal investigator. The sponsor or investigator determines the number, duration, and types of tests in order to efficiently collect valid and useful data.

Time is related to both knowledge and power; the scientific knowledge to structure research and the power (and finesse) to guide participants through the research process. To explore these various dimensions of time, I have chosen to structure my analysis using a critical-interpretive approach, examining the individual, social, and political-economic time of research participants. I will show why exploring time helps us understand the motivations, power struggles, subjective experiences, and social dynamics of the social production of knowledge.

B) Anthropology's Contributions to Time

Anthropologists have contributed to the social theory of time through documenting the time reckoning systems in numerous cultures and providing commentary on the meaning and politics of time. Many classic ethnographies contain detailed information about the time of the "Other".[60] Many of these works focus on how the Other perceives, records, names, categorizes, and uses time. Most of these studies employ Newtonian clock time as an "implicit backcloth" of their research (Adam 1990:97); the other's time is explicitly or implicitly compared to standard clock time.

Important classical texts include Malinowski's (1935:53) work on the Trobriand calendar, where gardening activities "constitute[d] the real measure of time". This is a common theme – where the Other's time is closely tied to the rhythms of nature. In his work on the Nuer, Evans-Pritchard (1940), distinguishes between ecological time and structural time. Ecological time, similar to the time recorded by Malinowski during his work in the Trobriand Islands, corresponds to activities such as fishing, cattle, horticulture. Structural time reflects group members' social relations in the social structure. Both of these systems of time are fixed and predictable and allow group members to "ground" themselves.

Clifford Geertz (2000a), in "Person, Time and Conduct in Bali" argues that institutions and practices cannot be understood in and of themselves, but as part of a cultural whole. Geertz demonstrates the similarities between time reckoning and social behaviour, an important contribution to empirical studies of time. The Balinese follow a permutational calendar, which consists of ten different cycles of varying length. These cycles are:

> endless, unanchored, uncountable, and as their internal order has no significance, without climax. They do not accumulate, they do not build, and they are not consumed. They don't tell you what time it is; they tell you what kind of time it is. (Geertz 2000a:393)

For Geertz, this absence of climax reflects the absence of climax in Balinese social behaviour.

Another major contribution to time in the anthropological literature is

Benjamin Lee Whorf's (1988) famous analysis of the Hopi language. Whorf

explains that there are no tenses in the Hopi language. This, he postulates,

prevents the Hopi from understanding time as linear. "Time is not a motion but

a 'getting later' of everything that has ever been done; unvarying repetition is

not wasted but accumulated. It is storing up an invisible charge that holds over

into later events" (Whorf 1988:163). Some critics renounce Whorf's linguistic

determinism and claim that exoticism[61], rather than sound empirical research,

has shaped his conclusions (Adam 1990).

These analyses illuminate other cultures' conceptions of time and what

these notions of time tell us about each culture. In these studies, time is a

marker of difference, a visceral method of communicating just how very

different the Other is. Distancing is a central problem in anthropology, which is

apparent in many of these analyses. In his influential work "Time and the Other:

How Anthropology Makes its Object", Fabian (1983) traces how anthropologists

have used the concept of time as a method of distancing and exoticizing[62] the

people they studied. He argues that there has been a "persistent and systematic

tendency to place the referent(s) of anthropology in a Time other than the

present of the producer of anthropological discourse" (Fabian 1983:91). This

emerges through literary techniques such as removing the ethnographer from

the research, invoking the "ethnographic present", and understanding the

Other's conception of time in terms of the ethnographer's. Fabian challenges us

to think of time, not as a method of distancing, but a method of gaining proximity. Examining time provides an opportunity to bring us closer to (not further from) the people we study by illuminating the intimate details and rhythms of their lives.

More recently, anthropologists have attempted to reorient the discipline's approach to time and save it from this tendency of using time as a tool for distancing. Over a decade ago, Munn wrote a critical review essay on the anthropology of time, where she "sketched a notion of 'temporalization' that views time as a symbolic process continually being produced in everyday practices" (1992:116). Her review of the cultural anthropology of time is an important, if dense, read. It organizes the anthropological literature on time according to its traditional topics, such as time-reckoning, the construction of the past, and how time is used strategically. Right on Munn's footsteps, Gell (1992) penned "The Anthropology of Time: Cultural Constructions of Temporal Maps and Images". This work nicely complements Munn's because it carefully outlines the different theoretical approaches to time and encourages social scientists to focus on how time is used in everyday practice. Such an approach, Gell (1992) argues, will give us insight into how our informants make decisions and shape their futures.

The most recent compilation of anthropological treaties on time is "The Qualities of Time: Anthropological Approaches", edited by James and Mills

(2005). This collection explores "the convergence of symbolic time... and the

social practice of time – how time is produced" (James and Mills 2005:1). Thus it

blends both a symbolic approach and a critical approach to time by focusing on

what time means to people and how time is produced and consumed. It is a

continuation of both Munn's (1992) and Gell's (1992) work, with greater

attention paid to power relations, specifically who has the power to structure

time. They believe that Gell's functionalist approach to time (to plot the choices

people make and the 'opportunity-costs' facing them while they construct their

futures) is too "narrowly a Protestant ethic motif" (James and Mills 2005:4).

They suggest anthropology focus on both action and meaning because they are

mutually constructive (James and Mills 2005:4).

C) Theoretical Background

In this chapter, I build on previous works by examining the meaning,

production, and consumption of the time of human research participants. In

particular, I use a critical-interpretive medical anthropological approach (Lock

and Scheper-Hughes 1990;Scheper-Hughes and Lock 1987) to bridge these

perspectives. For analytical purposes, Lock and Scheper-Hughes propose that

research questions about health and health care examine what they call "the

three bodies": the individual body, the social body, and the body politic.

i)   The individual body

Phenomenological studies have influenced Lock and Scheper-Hughes'

(1987) approach to the individual body. Phenomenology is an attempt to ground

the study of human behaviour and action in lived experience, rather than high

theory. Phenomenological time is the lived flow of time. Time is not the ticking

of the clock, but the trajectory of a life, the embodied, lived experience through

time. In phenomenological time there is no universal time standard because

time is always situated (Adam 1990:41). Lived time constitutes and, in turn, is

constituted by the past and future. Thus, the present is never cut off from, but is

tethered to the past and future (Adam 1990:31-32). As Husserl (1964) would put

it – it is connected by "protensions" and "retensions"[63]. Using this approach we

can ask how research time is experienced by human research participants.

ii)   The social body

Two approaches to time in social theory may be useful to understanding

the time of the social body. The first is a functionalist approach, championed by

Durkheim (1968). Gell (1992:1) claims that the contemporary anthropology of

time can be traced to Durkheim's work. Durkheim thought that time was a

principle for ordering social life. Time itself is inherently a social phenomenon,

one that is defined, ordered, and given meaning by social groups. All social

events are temporally situated by group members – meaning they do not occur

randomly (ex. Birthdays, barbeques). As Durkheim notes "A calendar expresses

the rhythm of collective activities, while at the same time its function is to assure

their regularity... what the category of time expresses is the time common to the

group, a social time, so to speak" (Gell 1992:3-4).

Thompson (1967) expands on this approach, examining and tracing how time was used by British industrial capitalists between the years 1300 and 1650 as a means of disciplining workers. Both the church and the ruling class began to look on idleness (of the lower classes) as shameful and dangerous. In this case, time was an organizing principle for a society, but promoted by a particular class to further its own interests. Applying these approaches to the time of medical research encourages us to examine how time (Newtonian time specifically) is used to enable and control the development of scientific knowledge. It also makes us sensitive to the ways in which time functions to serve the interests of particular groups – in our case, the medical research industry.

Another possibly fruitful approach to understanding the time of the social body borrows from the school of interactionalist time. Interactionalist time concentrates on the ways social relations mark time and are marked by it (Adam 1990). It focuses on how social relations are developed through time and how these relationships influence how time is used and understood. Schieffelin (2002) examines the linguistic innovations that developed in Bosavi, Papua New Guinea through missionization. During this process, numerous "old" words (those that did not integrate into a Christian worldview) were dropped from the lexicon. For example, words that described anger fell out of usage because, as Schieffelin's informants explained, Christians did not get angry. These measures helped people detach themselves from the past, in order to "catch up" (Schieffelin 2002:S9). The past, associated with non-Christian and archaic beliefs,

was erased through these linguistic innovations. In addition, missionization

brought a new concept of the future, one that is certain, for it promises the

second coming of Jesus. Erasure of the past and knowledge of the future reflects

these new relationships and new social understanding of time and salvation.

Similarly, Ramble (2002) examined how people develop concepts of time

in order to maintain social cohesion in Mustang, a settlement in the mountains

of Nepal. According to the Buddhist priests, if a community member dies in their

house, the body must be removed from the house on an auspicious day, as

determined by astrological calculations (usually 1-3 days after the death).

Otherwise, calamity could meet the community. However, traditional beliefs

about the danger of dead bodies make sleeping in the same room as a deceased

relative appalling. To accommodate these discordant beliefs, the locals interpret

the time before the first cock crow (around three o'clock in the morning) as a

time that does not belong to either day. During this "crack" in time, the family

can safely remove the body from the house. This reinterpretation of time helps

maintain social cohesion and avoids a direct confrontation between the Buddhist

authority and local traditions.

iii)   The body politic
Expanding our view to the body politic brings our attention to how bodies

are surveyed and controlled. We do not live in a world purely of metaphors,

symbols, and culturally constructed meanings (Lock and Scheper-Hughes 1990).

However important the raw experience and symbolic nature of the body and

health, most scholars understand the significance of political and economic

policies. By examining how time is organized and who sets the agendas and

timelines, we can learn about power. Disputes over time and scheduling are

disputes over power and resources. Moreover, those who set the pace of work,

the timing of activities, and the consumption of time have power to influence

how people live, what they give their energy to, and how they organize

themselves.

Social theory provides one lens through which to examine the body

politic. Two concepts from social theory that can help us understand the time of

medical research involving humans are (a) *historical time* where "time is intrinsic

to a large-scale, but specific social process, namely the historical trajectory of

capitalism as a whole" and (b) *labour time* where time itself becomes a

commodity and is given an exchange value (Heydebrand 2003:147-8). This

approach to historical time examines the historical conditions under which a

product becomes a commodity (Marx 1999). In the case of medical research

conducted in a university setting, this inevitably leads us to examine the role and

impact of industry funding on how medical trials are conducted and organized.

Addressing labour time, Marx asserts that what the capitalist gains in labour and

capital, the worker loses in substance (Marx 1999). This is especially true for

human research participants because they lose both their time and some of their

physicality – their blood, bone, and muscle.

iv)   Reuniting the three bodies

In order to forge a sensible corpus of data, researchers must explicitly ask

if and how the three bodies are associated. Since time does not reside in three

distinct domains, that this is simply an analytical construct designed to increase

the resolution of particular elements, some reassembling is in order. But how

should we reassemble them? Lock and Scheper-Hughes (1990:69) suggest that

the common link between the three bodies is human emotions:

> Insofar as emotions entail both feelings and cognitive orientations,
> public morality, and cultural ideology, we suggest that they provide
> an important missing link capable of bridging mind and body,
> individual, society, and body politic.

I suggest that a multitude of "missing links" exist to bridge the three bodies

because the individual, social, and political worlds overlap. Employing emotions

as the missing link will accomplish a specific set of goals. The emphasis on

emotions reminds us that it is individuals who participate in medical research

trials, develop research protocols, and set government policies. In addition, it is

possible to empirically determine what emotions are associated with individual

cognitive orientations and (with somewhat more difficulty) public morality and

cultural ideology.

However, since in this chapter I am specifically examining the role of time

in medical research knowledge development, I suggest that the concept of

rhythms would better link the three bodies. I follow Lefebvre's theory of time

and concept of rhythms as a tool to highlight the interconnection between

individual, social, and political time. Lefebvre was an accomplished French philosopher and sociologist. He was a French Marxist intellectual and highly critical of daily life. He felt that by understanding the social production of time and space, we could understand how the ruling class dominates space and time to maintain its hegemonic rule. He was particularly interested in exploring dialectical materialism[64] because it promised a method of understanding change, flux, and possibility (Elden 2004). I feel that this approach fits nicely into a critical-interpretive framework because it is concerned with how power and economics influence and reproduce daily life.

Lefebvre[65] (2004) argues that our rhythms are the sum of social practice, economic necessity, and embodied, lived time.

> Rhythm appears as regulated time, governed by rational laws, but in contact with what is least rational in human beings: the lived, the carnal, the body. Rational, numerical, quantitative and qualitative rhythms superimpose themselves on the multiple natural rhythms of the body, though not without changing them. (Lefebvre 2004:9)

The rhythms of work, social relations, and the body interact. They may conflict with (arrhythmia) or amplify (eurhythmia) each other. Each of the "bodies" has its own rhythm and these rhythms interact.

> [T]here is neither separation nor an abyss between so-called material bodies, living bodies, social bodies and representations, ideologies, traditions, projects and utopias. They are all composed of (reciprocally influential) rhythms in interaction. (Lefebvre 2004:43)

Using rhythms as a bridging tool, we can ask what are the rhythms of each of the

three bodies, and where and how do they interact.

Rhythms are turned outward, as in the rhythms of representation, and

inward, during more private moments. However, these rhythms of self and

other are not cut off from each other, they coexist and change as social roles and

situations change (Gronlund 1998). Moreover, rhythms are always local and are

always associated with a place (Lefebvre 2004:89). Lefebvre does not explain

how to distinguish the rhythms of the self and other in particular social situations

and geographic locations. His development of the concept of rhythm is rather

thin (it was published posthumously and he most likely had intended to develop

it more fully). Rhythmanalysis is a method for examining the everyday as a

portal to understanding the larger world. It is a methodological statement,

opening up 'everything' for examination (Bratsis 2007). This is an ambitious

(and, unfortunately, vague) methodological project. However, it complements a

critical-interpretive framework because using both, we can focus on three bodies

(instead of an infinite number), tracing the rhythms of each.

For Lefebvre, the everyday life enables relations of production, and is in

fact the basis of economic and social conditions (Aronowitz 2007). Today,

relations of domination have more force than relations of production. Aronowitz

explains Lefebvre's stance thus: "when the mode of production successfully

"programs" everyday life, it becomes the base for the reproduction of the

relations of production" (2007:137). The daily rhythms of social life create and

enable larger relations of production. "The everyday is simultaneously the site

of, the theatre for, and what is at stake in a conflict between great indestructible

rhythms and the processes imposed by the socio-economic organization of

production, consumption, circulation and habitat" (Lefebvre 2004:73). Applying

this perspective to medical research, I explore how the rhythms of research form

the basis for the rhythms and the economies (both knowledge and monetary) of

medical research.

I have chosen the concept of rhythms to understand the time of research

participants because it is flexible enough to incorporate individual, social, and

political time. An individual's rhythms are the integration of the individual,

social, and body politic. In some ways, our rhythms are manifestations of our

own tendencies and desires, social expectations, and broader political and

economic conditions. The rhythms of domestic workers, musicians, and

researchers all tell us about their own individual inner and outer worlds.

Examining rhythms also highlights where discord and disjuncture lie. Rhythms

change at sites where time, and thus production and power, are at stake.

D) Data – the time of research participants

i) Individual time: risky futures?
That's the scary part because the actual data doesn't show that it is very
risky but they have only done short-term studies. They haven't been able to
link pancreatic failure in later life with the drug. There's really no long-term
data. So the theoretical impacts are scary for me. So for me not to have

read it that would have been okay. Some people might want to have all of the facts. I'm more of a person who likes not having unhappy news if it isn't impacting me right now. Some people I'm sure want to know all of the possibilities. (AP15, discussing the risks of taking an experimental drug)

Phenomenologists argue that there is no universal time because time is always situated. The present is never cut off from, but tethered to the past and future. I use a phenomenological approach to understand how the concept of risk is used in medical trials because risk always invokes ideas about the future. Decisions made in so-called "real time" are done in the shadow of prior experience, the richness of the present, and the glimmer of an imagined future. Medical studies have risks and benefits; these may occur at the commencement of, during, or long after the study has ended. Thinking about these risks and benefits necessitates thinking about the future and one's future self.

Study participation also provides benefits. Medical research primarily benefits future patients by improving health and pharmacological knowledge and care. Sometimes individual participants also benefit. These benefits may be monetary, therapeutic, intellectual, or personal. The only benefit that is certain is study remuneration (if offered). The others are unknown – whether the participant responds to a potentially therapeutic drug, whether they gain personal satisfaction from furthering research, whether they satisfy their intellectual curiosity, or whether they enjoy working in a research setting. Participants discussed why they decided to enroll in the study and how being in it benefitted them (or would benefit them). However, in this section, I focus on

risk as a method of investigating how participants perceive the future, and thus, I ignore benefit. I do this for two reasons. Firstly, the concept of benefit is often embedded in notions of risk. Benefit is a motivator which sparks us to even consider risk. Secondly, my focus on risk is a reflection of a wider focus on risks (rather than benefits) in research and in daily life. Consent forms may dedicate several pages to the risks, and only a short paragraph to the benefits of research participation. In addition, there is a large and diverse social scientific literature on the risks of everyday life, but no such complementary literature exists on the benefits of everyday life. My focus on risk is in part a bias of my own training as a social scientist.

a) Asthma Study

All studies have risks. Medical trials very often have obvious health risks. The participants with whom I spoke all discussed comparing the potential risks of participating in the study with the potential benefits. The utility of risk, as Reith (2004:394) notes, "lies not in its ability to correctly predict the future outcomes, but rather in its ability to provide a basis for decision making". Participants' interpretations of risk helped them make decisions regarding study participation. In the asthma study, none of the participants felt their participation was particularly 'risky'. They found the risks either extremely unlikely or not alarming. I asked participants about the risks of the study. Some could not recall any.

> *I don't really know the risks. ... I have to commute here, so that's kind of a pain. (AP13)*

This participant emphasized the challenge of adjusting daily schedules to

accommodate the study requirements. For this person, simply immediate

disruptions in daily activities, the pattern of everyday life, is a threat, a risk.

Others downplayed the risks:

> *Big risks, I don't see any. I don't think there are any risks to the*
> *bone marrow or anything like that. (AP5)*

> *To me the risks – I don't look at them that way because when you*
> *know what they're going to do you know your own risks. They have*
> *to write it for liability reasons but the risks are really one in a*
> *million. (AP3)*

> *It's hard for me to say that, because I know all this stuff. But*
> *someone who just started might not know all this. It's like walking*
> *across the street, you could get hit by a car. It's a risk. I look at this*
> *the same way. It's not a big risk for me. (AP8)*

Participants' conception of risk was influenced by both their past experience as a

research participant and their imagined future – "one in a million". Others felt

that the environment mitigated any risks.

> *The one thing that comforts me is that you're in a hospital and if*
> *something happens they can treat you. (AP9)*

> *I don't feel that I'm at that big of a risk. I don't perceive much risk*
> *while I'm here. I'm pretty comfortable here. (AP11)*

Present experience (in this case feeling safe and comfortable) helps predict

future experience. Participants' emphases on what they perceived as risky about

the study varied. Common responses were the bone marrow tests, having their

asthma induced, and taking an experimental drug. The risks they mentioned

were either what they remembered from the consent form or what they

discussed with the study coordinators.

> *According to the consent form, when they did the study on monkeys*
> *they had pancreatic failures. When they did the study on humans*
> *they had pretty much no problems at all. So, I'm just hoping for the*
> *human part. [note: this was intended to be humorous] (AP16)*

> *Obviously there's a risk of getting something in your body. I don't*
> *know, physical discomfort because I am getting bone marrows*
> *done. (AP15)*

Interestingly, risk was not the only factor people used to help them make

decisions. They also relied heavily on their trust of the people running and

overseeing the study, the ethics board, and the research industry in general.

> *I kinda assume that at this stage it's been through a fair amount of*
> *testing and I trust the people. (AP11)*

> *The thing that convinced me is that all the other doctors here do it,*
> *so if actual doctors are doing it I don't think there's anything wrong*
> *with it. Otherwise, when I read it at first I thought I could get*
> *pancreatic failure, heart problems, there's a chance of death. Why*
> *would I do this? (AP16)*

> *I have a certain amount of faith in what people are allowed to do*
> *under ethics review. (AP14)*

> *I'm confident that Dr.X and the staff here that they wouldn't – that*
> *if something were really risky, that they wouldn't do it. (AP2)*

> *I know that all of the studies go through a pretty stringent ethics*
> *board and that kind of thing, so I don't think they would do anything*
> *that was unsafe to begin with. (AP5)*

> *I don't think the study would be legal if they have a feeling it's going*
> *to kill you or have a feeling it's going to do something severe to you.*
> *I think it's pretty safe. (AP16)*

Good (1995b) has coined the term the "political economy of hope" to explain

how hope is used to convince people to seek and remain in allopathic care. In

the case of these participants, trust, rather than hope, encourages compliance

and cooperation. Trust (like hope) produces a certain orientation towards the

future. Here, trust helps people predict a safe and uneventful future. Trust

invokes a rhythm, a rhythm that promises sameness and, thus, security.

Other scholars have also observed and investigated trust in clinical

research (Corrigan 2003;Lowton 2005;McDonald et al. 2008;Miller and Boulton

2007;Sugarman et al. 1998). This approach to trust frames it as an influential

factor participants use to help them make decisions about the future. Trust can

manifest as trust in individuals and trust in the governance system. However, as

participants indicated, trust can also be fostered through social and

environmental familiarity and comfort. Being at ease, relaxed, and comforted by

the social and physical environment, helped participants feel confident about

engaging in risky behaviour.

Reith (2004:392) claims that in the age of risk we have a "heightened

ontological insecurity" and find it more difficult to engage with an unknown

future. Risk decreases our ability to predict the future and makes us more

uncertain. In other words, risk shortens our "protensions". The asthma study

participants with whom I spoke did not seem particularly "risk averse", nor did

they display this "heightened ontological insecurity". It is unclear to what

degree, if at all, remuneration makes them feel more capable and secure about

engaging with an unknown future. Risk is also relative. While volunteering to

have one's airway compromised may seem unfathomable to many people who

do not have asthma, for some asthmatics, this is a fact of daily living and

introduces no more risk for them than they would see every day. One of the

asthma study coordinators described it thus:

> *The risks I just told you about are nothing different than the risks*
> *they have faced. In ragweed season, this is what happens to these*
> *people when they don't take their drug. We're doing it in a*
> *controlled situation. You wouldn't believe some of these things –*
> *we've dropped people 20% to 30% (from their maximum breathing*
> *capacity) and they'll rate their discomfort as very slight. They have*
> *had much worse so it isn't that bad for them. When you get*
> *someone who doesn't know they have asthma and you drop them*
> *10%, they think they're dying. (KI2)*

The daily breathing rhythms for these participants are not very different than the

rhythms in the study. The breathing rhythm of the study – tightness in the chest,

wheezing, difficulty breathing, and taking Salbutamol (a "rescue" medicine for

asthmatics to help them breathe normally after an asthmatic attack), although

induced artificially instead of from the natural environment, is a normal rhythm

for them. Whether a study is tolerable to an individual may depend upon how

different the rhythms of the study are from the rhythms of their everyday life.

Since notions of risk and the future are influenced by perceptions of the

present, it is logical that one's demographics can influence one's interpretation

of risk. The asthma study participants were primarily (12 out of 16) students under 30. They were young university students with mild asthma, but otherwise in good health. No doubt their lack of "ontological insecurity" is in part a reflection of their youth and health. In fact, during my presentation to the asthma lab, several members of the lab attributed this lack of risk aversion to the participants' age and health status. Likewise, during a presentation to a bioethics interest group, the same comment emerged. There is some evidence which suggests that this intuition is true. Tulloch and Lupton (2003) interviewed hundreds of UK and Australian citizens about their notions of risk and found that younger people were less risk averse, some even embracing risk, equating risk with excitement and adventure. Younger people, and particularly males, had greater feelings of control about their lives and their future.

It is interesting that as the duration of one's life increases, confidence about one's future tends to decrease. From a phenomenological perspective, it can be understood in two ways. First, greater confidence at a younger age may be simply due to less experience and less knowledge of adverse events. Second, as we age, we feel our frailty in a more acute way, both because we see our bodies age and weaken, and also because we tend to have a more acute sense of our physical selves.

b) Cancer Study

The future and risk had completely different meanings for the cancer study participants. These people were already "at immediate risk" of dying (two told

me they were "already supposed to be dead"). The cancer study participants

were most concerned with the potential side effects of the drug. As much as

they "had nothing to lose", they were also wary of feeling worse. One person

noted:

> *If I had read anything that would make it a risk for me I wouldn't*
> *have signed up. I wouldn't take any chances because I'm already*
> *sick enough. (P1)*

Most participants showed ambivalence towards the risks. This might be because

thinking about risk necessitates thinking about the future and these people all

felt extreme uncertainty about their futures.

> *Nobody is giving up yet. They didn't give me any promises. This is a*
> *trial, so an improvement is a bonus. (P1)*

> *I just don't know. I still have some hope. I hope the result is good.*
> *Of course I do. I have to hope. (P8)*

> *I can't really say I expect anything from the drug, but maybe good*
> *news, right? Sure a miracle drug would be great so at the end of the*
> *trial the cancer would all be gone. (P4)*

These quotes seem to imply a trepidation towards hoping, almost a fear in

hoping, partly because, as one person put it "nothing has worked so far so you

get tired of being let down." For some participants, having cancer made

planning for an unknown future difficult.

> *You also don't know what's next if this doesn't work. I'm running*
> *out of options. (P4)*

> *Now with the disease you live day by day, not expecting things, just*
> *see whatever that day brings. I've changed that way – expecting...*
> *(P9)*

In her study on people who suffer from chronic pain, Hellstrom (2001) found that

her informants with chronic pain spoke of "frozen futures" – futures that were

unknown and out of their control. The cancer study participants showed a

similar tendency. However, unlike the chronic pain patients, a sense of unknown

did not translate into hopelessness. The participants' hope for the future and

persistence in the present was often influenced by their social relationships.

Participants often mentioned that they were doing it for their family members.

> *This is tough for my wife. I want to do what I can to make her feel*
> *that I haven't given up. (P1)*

> *This is hard when you have kids. I'm trying to do my best to get*
> *better. I try to eat as much as I can. I try to have my normal energy,*
> *so they don't get too worried. (P4)*

These participants' "protensions" into the future were influenced by their social

relationships and their desire to minimize their loved one's current and future

suffering. As we see, the trajectory of a life, the movement forwards and

backwards in imagined time, although unique for us all, does not take place

within a social vacuum. Thus, the phenomenology of time can highlight

important social relations.

With a diagnosis of refractory cancer, patients were confronted with their

acutely uncertain future. Participating in a study was, paradoxically, one method

of securing a safer future. Having an experimental drug administered was an

attempt to secure a healthier and longer future. In Canada, we are socialized to

turn to medical professionals when we are ill. We believe they have the

knowledge, expertise, and materials to heal us. In addition, medical care is fully

or partially paid for by our provincial and federal governments, so it is

economically a viable (sometimes the only viable) choice. All participants were

already in the medical system and themselves had histories of biomedical care,

and for some, extremely positive care within the allopathic medical system. So

this paradoxical method of securing a better future (by taking an experimental,

possibly toxic drug with numerous side effects) could be linked to both our

socialized dependence on biomedicine and personal experience and patterns.

c) Muscle regeneration study
In the muscle regeneration study, participants used a variety of methods

of assessing the risks and imagining their futures. Most people identified risk of

infection and risk of nerve damage as the main risks.

> *What are the risks? Infection from the thingamajig. ...Yeah, the*
> *biopsy. That's pretty much it. (MP2)*

Some individuals understood the risks of an infection or nerve damage through

risk management – assessing the future using tools such as probability and

potential outcome.

> *So that [the risks] made me a little nervous at first. However, when I*
> *looked at it from a different view – how many biopsies are*
> *conducted and how many people actually have this happen it's like a*

fraction of a percentage. I thought oh it's fine. I'm willing to assume that risk. And really, it's localized damage so if anything happened it would not be life threatening or debilitating. I just break it down rationally. If the pros outweigh the cons or the risks are low level or if they've been managed appropriately then it's okay. Risk management. (MP1)

Others felt they were personally responsible for the risks of the study.

There are no obvious risks. I guess there is a risk of infection, but a lot of that is my responsibility to reduce the risk of that. I have to keep it clean. I'm responsible for taking out the stitch and doing it hygienically. Since I have a background in this I'm not too worried. Others may be more ignorant of how to reduce the risk of infection and it may be a bigger deal for them. (MP3)

Internalizing risk made this individual more confident about proceeding with the study. In contrast, externalizing the risk made others feel confident about proceeding with the study.

I'm not afraid. I don't think about the side effects. They know what they're doing and I just leave it to them. (MP4)

These different perspectives and methods of imagining the future reflect very different embodied experiences and perceptions of self. The future may be almost entirely dependent on one's own mastery and abilities or the mastery and abilities of others. In contrast, the future may be conceived as one of many possible futures that, if unfavourable, can be altered. One participant (MP3) felt confident in his own knowledge and mastery of his body. His own embodied experience, his own rhythms and orchestration, would secure his future. Another participant's (MP4) trust in others secured his future. It is interesting

that people with such diverse ways of conceiving the future all come to the same

conclusion – that the risks are not significant enough to dissuade them from

participating in the study.

As we can see, the asthma and metabolic study participants did not seem

terribly risk averse, nor did they demonstrate much anxiety about imagining

their futures. The cancer study participants were already grappling with an

uncertain future and the risk of dying. They were willing to take on what many

would consider greater risks (taking a drug that had not undergone toxicity

testing) than the other participants. Their protensions were stunted because of

their uncertain futures, and perhaps their retentions were elongated because

most had a long history of cancer treatment. For many people, treating cancer is

a struggle to maintain one's "normal" rhythms. Fatigue, loss of appetite and

inability to work disrupt one's "normal" rhythms and are outward manifestations

of sickness. For these cancer patients, their decision to enroll in a study was

influenced by how well they perceived it would prolong their lives, and

hopefully, normalize their rhythms.

ii)   The Social Body: Time Management

*I sometimes bring a crossword. I'm supposed to be here for four hours. I
have to wait sometimes between measurements. I'm supposed to be in the
hospital so they can watch and monitor you. I usually go for a walk. I don't
think I would drive home or anything. That wouldn't be fair… if something
happened to me they would be very worried. I don't mean anything from
the drug, but if I had an accident or something. If you're walking around
the grounds and you break a leg, that's okay, because they'll know that. If I
go back home, I don't think it would be the same. Chances are it wouldn't*

happen, but you don't want to deal with that. The last time I walked around and then I came back… (P8, Cancer study participant, discussing what they do during a 'long day')

We can learn about the social organization and social environments of medical studies by examining how time is used and conceived in these settings. A functionalist approach to the time of medical research focuses on how time is understood and employed to produce what is considered valid scientific data. How people are organized temporally and how time is used to create scientific data tell us about the social relationships within the lab.

a) Asthma study

Clock time plays an important role in organizing medical studies. In the asthma study, participants were required to perform tests in a particular sequence, duration, and period because asthmatic responses are time-dependent. I observed that the study coordinators used multiple time pieces and timers with buzzers to ensure they took the correct measurements at the correct times. The participants understood these time constraints and commented:

Sometimes the days in which you do certain parts of the study are strict because the companies are pretty strict about when people do things. (AP1)

They need the exact spacing between the doses and the tests so there isn't much flexibility. You want to test the drug at the same time for everyone. (AP16)

The rhythms of research in this study appear to be dictated by the protocol, which was developed by the pharmaceutical company sponsoring the research in conjunction with the principal investigator from the university.

The study took a total of 126 days. The majority of the work was within the first six weeks. The first week was screening, where participants completed a number of tests to determine if they were eligible for the study. During the second week, participants underwent baseline testing, to determine their asthmatic responses to allergens and airway irritants. The participants received the drug or placebo immediately following baseline testing. Over the next 4 weeks each participant was required to visit the lab on 12 specific days (3 sets of 4 consecutive days). Three of those days were "long days", where participants arrived at the lab at around 8 a.m. During this "long day" the lab nurse took their blood to measure the drug concentration. Then, participants performed an "allergen challenge", where they inhaled an aerosol of a solution that contained a precise amount of the substance they were allergic to (usually grass or cats). Over the next 7 hours, they performed FEV1 tests at regular intervals.

Following this, they completed a sputum test (inhaling an aspirated saline mixture for seven minutes and then spitting into a jar) and an NO test (exhaling into a tube, which measures the nitric oxide content in the lungs, an indicator for lung inflammation and irritation). Other days consisted of a number of tests, including methacholine challenges (to determine participants' pulmonary

responses to methacholine, an airway irritant), blood draws, FEV1's, NO tests, ECG's, bone marrow extractions, urine analysis, vital sign recordings, and nasal lavages. These tests had to be performed on specific days, and often at precise times. The research coordinators diligently recorded the test start and duration times. They used digital clock alarms, stop watches, and a wall clock (accurate to the tenth of a second) to help them ensure correct testing administration and recording times. There were often long periods (up to 55 minutes) between tests. If participants used that time to attend class or get lunch, they were required to be back in time for the next test.

One of the expectations was for participants to adjust or bend themselves (*dressage*) to the study protocol timeline.

> *LH: Can you tell me why you are a good participant?*
> *P: Because I am fairly reliable. I come on time. (AP11)*

> *LH: What are the challenges for you as a participant?*
> *P: Being here so frigging early in the morning. (AP13)*

Participants noted that scheduling was often the most difficult obstacle to participation.

> *People need to know ahead of time what kind of time commitment it is... how much time it's going to cost them. (AP5)*

> *Just the time. What will it mean in terms of interruption of time?*
> *Some people seem to have more time on their hands, it's not an*
> *issue. (AP9)*

Participants also spoke of the impacts of the study on their own private time, especially with regard to daily physical activity.

> *If I have an allergen challenge and there is a possibility I might have another fall later in the day, then I don't go to the gym that evening. If I'm feeling tired from giving blood and doing methacholines then I do take it easy and rest and I don't push myself so I don't get sick or pass out or have other exacerbations. (AP3)*

> *After the bone marrow, actually I felt weaker, definitely for that day and then a little bit after. I felt a little like I was betraying my body. I was like "body, I'm sorry for doing this, but I'm making money, so you have to understand and deal with it for a few days". I try to stay in pretty good shape so I feel a little like I didn't want to work out or run around, so I didn't feel like myself for a few days. I took a bit of a hit. (AP11)*

Participating in the study required some to change their activity patterns. Some people (like AP11) found that changing their rhythms influenced their self perception. Our rhythms are both reflections of who we are and how we live our lives. In many ways they form our thoughts, actions, and essential selves.

If we look more closely at how time is organized in practice, we can see that the participants' needs set the scheduling and pace more than the "rules" (i.e. protocol) may indicate. The rhythms of research (visiting the asthma lab 4 days a week for 6 weeks) interrupted their normal daily rhythms, to which it was difficult for them to adjust. However, the research coordinators made concerted efforts to adapt the protocol to the participants' schedules.

> *If I get a fulltime job I will probably have to come in here before work. They are flexible and will stay later. It's amazing how much*

> *they sacrifice to get the study done – not just for one particular*
> *study, but for all of them. (AP16)*

> *I had to come during exams, so during that week they were good*
> *about ensuring I had a place to study or made it fit whenever I could*
> *come. So they really try to make sure it's not out of your way at all,*
> *which is nice. (AP5)*

As one study coordinator explained, they did everything they could to make the

study fit within participants' schedules.

> *We always book around our subjects, so the subject comes first and*
> *then everything is fit around. We do bend over backwards for our*
> *subjects. I have started here at 3 in the morning for a subject who*
> *wanted to get out of here by 9. That's the life of research, as far as*
> *I'm concerned. We always tell the subjects, you're here to get an*
> *education, not do research, so don't let this affect your education.*
> *So we will work around them. If they have classes we'll work around*
> *them. I've never stressed for a subject to miss a class. (KI2)*

The study coordinators value the subjects and reiterate that without them, there

would be no research. Being flexible with scheduling is one aspect of making

participation in the study comfortable.

> *I'm out of a job if we don't get students and people to do our*
> *studies. You have to make an environment that's enjoyable to be in.*
> *Word gets out pretty quick and it can get out good or bad. So, if you*
> *don't make it a comfortable environment for these people to come*
> *in and do research, they're not going to come in and they're not*
> *going to recommend it to their friends and I'm going to be out of a*
> *job (quiet chuckle). (KI2)*

Both participants and researchers in these studies bent their rhythms to the

demands of research. Since the research coordinators represented the study

and the sponsor, their flexibility and their willingness to accommodate the

participants was an indication to participants that they were valued and

respected. The lab's success in retaining participants and bringing them back, I

believe, partly lies in the research coordinators' ability to understand that

research is an interruption in participants' normal daily and flexibility helps them

to adapt.

The rhythm of the research is not completely dictated by the protocol.

Participants' needs can influence the scheduling of tests and the research

coordinators then adjust their own schedules. This flexibility helps ensure the

research coordinators' continued employment (they are university workers but

feel as though their continued employment is dependent upon the lab's ability to

procure industry funding, which is directly related to their ability to recruit and

retain participants) and helps foster a good relationships with the participants.

Participants mentioned "doing favours" (which always have some remuneration)

for the research coordinators, such as enrolling in a study when the researchers

were desperate for participants even though they really did not have the time,

and volunteering to test new procedures.

Because many of the tests are time-dependent, the participants spend

the majority of their research time waiting between tests. Despite the scheduling

challenges and the total time commitment, I found that most of these

participants used the time between tests socializing or relaxing. I observed

participants socializing with each other and the study coordinators, surfing the

net together, listening to the study physician tell stories, and listening to music.

Two participants noted the tension between their professed time constraints

and how they use their time.

> *I always tell myself I'm going to get work done, but as you see it*
> *hasn't really happened yet. I tell myself I will get something done*
> *but I never do. (AP15)*

> *Many of the days you sit around for an hour and have one quick*
> *measurement and it's 55 minutes until the next measurement. So it*
> *is a lot of sitting around and doing nothing, or maybe get some work*
> *done. (AP9)*

Participants sometimes used economic metaphors – "spend time", "afford time"

– to describe their relationship with time, and signify its commodification.

Although participants spoke about time as though it was a scarce commodity, in

practice, people used their time engaged in social activities, and developing

relationships with the study coordinators. Only twice did I observe participants

studying or working. So, despite expressed anxiety over the scarcity of time

(partly expressed through linguistic metaphors), I observed that people engaged

in, what I would consider, social rather than commodified time.

This highlights the contradictions between how we discuss and use time.

In speech acts, we borrow from familiar linguistic conventions. In addition, our

speech is often performative (Butler 1997). When speaking, we perform a role.

It may be the role of busy student, or responsible worker. Some scholars (Adam

1993) claim that modern linguistic tendencies to speak about use of time in terms of efficiency and lack of idleness reflect the continued influence of a protestant ethic. I suggest that although these linguistic phrases are well used, they probably reflect participants' anxiety about time rather than their use of it.

By focusing on time, I saw a compromise between participants and research coordinators. Because participants are valued and asthma studies entail long and erratic hours, the research coordinators adjusted their own schedules to accommodate the participants. This is a prime illustration of the power the participants have. They are asked to assume risk and rearrange their schedules, but they are not totally powerless; they are valued and the research coordinators show this through respecting and accommodating their own schedules.

b) Cancer Study

The cancer study participants also found scheduling and time commitments difficult to manage. As participants, they were required to make more frequent visits to the cancer clinic than they did as patients (daily rather than weekly or biweekly). The rhythms of research required them to spend significantly more time in the cancer centre. Participants did not express resentment at this time requirement, something I thought many would find depressing or draining. Being in the centre was not difficult; it was getting to the centre that proved challenging. Arranging time off of work, child care, and transportation were the most common challenges.

I chose to enroll in this trial because it was recommended by the trial's nurse and oncologist and because it would work with my lifestyle. I am going to pick the best drug for me and let the other things in my life fall into place. I have decreased my workload to allow me to come in here. (P3)

It's a lot of time. It's a challenge with my family. One daughter is in JK and I've got a friend who watches her. I think it's something for them to help me out with, something so that they feel they are contributing. (P4)

As this last quote also indicates, social support networks are important for people in cancer studies to enable them to free up their schedules for participation. Unlike the asthma study, scheduling at the cancer clinic was dictated not by the participant's schedule, but by the institution. Participants arrived at 9 am, and when I came into the clinic at 9:30, they would often still be in the waiting area.

Participation was fairly passive. Participants sat in a chair or in a bed, while study nurses and coordinators took measurements, asked questions, and administered the drug. I noticed that participants passed their time either chatting with other participants and family members or relaxing. They did not express any anxiety about "wasting time" while in the study.

What do I do when I'm here? Absolutely nothing. I am the queen here. Everyone does everything for me. They are fabulous, just fabulous people. (P3)

> *I have a fantastic time when I'm here actually – well, other than the*
> *whole cancer bit. I joke with the others. There's a whole crew of us.*
> *Plus, the nurses are great – not straight-laced or anything. (P5)*

> *I just enjoy myself as much as possible. (P9)*

These individuals were by their physicians' standards, "very ill". They could have legitimately taken on what Talcott Parsons (Parsons and Turner 1991) called the "sick role", where it is socially acceptable to not work; productivity is not expected of the very ill.

Participants arrived between 8 and 9 o'clock in the morning. They checked in at the reception desk, got a number, and took a seat in the 60-person capacity waiting room. The wait could last between 5 and 60 minutes. A nurse came out, called their number, and they followed her or him to a bed or chair. The nurse then took blood, blood pressure, temperature, pulse rate and respiratory rate. On certain days, the nurse also weighed them, asked for a urine sample, performed ECG tests, and inquired about any symptoms. After these preliminary measurements the nurse started the drug infusion. The drug infusion usually took about 30 minutes. Participants were required to remain under observation for the next 2 hours to monitor for any adverse reaction. On some days, participants were required to spend an additional 6 hours in the clinic so the nurses could measure how the drug concentration in their blood changed over time. The nurse withdrew blood at 5 minutes before the drug was administered, and then at 5 minutes, 15 minutes, 30 minutes, 45 minutes, 1

hour, 2 hours, 4 hours and 6 hours afterwards. The nurse recorded the time and

value of each test in each participant's chart.

A functionalist conception of time – one that sees time as a tool used to

produce valid scientific data – is less helpful in the cancer study, at least from the

participants' point of view because the study is passive and participants are only

mildly aware of the timeliness of the data collected by the nurses.

> *They take a lot of vitals and blood so it looks like they're getting the*
> *data they need. They do take lots of measurements, but only on*
> *certain days. Taking the measurements at the right time seems to*
> *be important. However, not all of the nurses seem to take them*
> *right on time. They get busy. (P4)*

Here, the participant noticed the timeliness of tests and the difficulty nurses

faced recording the data at the correct times. He observed, rather than

participated in, data production and collection. One participant, in particular,

monitored the tests and data gathering very closely. She kept a log of all drugs

administered and tests taken, and monitoring completed. She commented to

me that it was important to keep track of everything that was going on.

However, in general, participants' and nurses' experiences of the rhythms of

research were quite different. This was not the case in the asthma study

because the participants were keenly aware of time and were required to

respond to the timeliness of the tests.

Perhaps this discrepancy between the rhythms of the participants and the

nurses and coordinators can help us understand why cancer study participants

did not comment on feeling responsible to "produce good data". Their self-identity was first as patients and then as participants. One participant kept referring to himself as a patient. I asked him what the difference between being a cancer patient and being a study participant was.

> *Good participant. Good patient. Same thing. (P4)*

Thus, being a good participant meant being compliant and polite and, essentially, passive.[66]

> *We do what we're told, we show up on time, we're nice to the nurses. We don't sneak off early. (P9)*

Participants' rhythms speak to their role in the research and the relationships with the study coordinators and nurses. They are not collaborators and co-developers, but rather objects of study. One participant likened his role to a "guinea pig".

> *They monitor me more closely. They take more measurements and tests. On my first day, that's when I really felt like a guinea pig. There were doctors and nurses all around me, checking for this, testing for that, poking me and prodding me. It can be a bit too much. (P4)*

When are participants "guinea pigs" and when are they "collaborators"? If we look closely at the rhythms of research we can start to understand how the differences between the rhythms of participants and researchers impact the role and identity of the participant. The cancer study participants had almost no control over the rhythms of the research. There is no brokering with the

research coordinators or research nurses regarding schedules or start times. In addition, cancer study participants had little to "do" during the study. They were essentially passive subjects and learned little about the various tests. Asthma study participants learned how to properly do an FEV1, an NO test, a sputum test, etc. Cancer study participants did not learn how to complete any tests; they learned to tolerate the drug and the schedule. The degree of control over and active engagement in the rhythms of the research could influence the self-perception of research participants. Passivity could turn participants into subjects or "guinea pigs", whereas more active and engaged participation might have a tendency to encourage participants to see themselves as participants or collaborators rather than subjects.

I argue that the nature of the research – the types of tests involved and the nature of the "work" required of participants – has an influence on participant subjectivity. Asthma study participants performed tests, perfected their technique, and were well aware of and influenced by the timing constraints. In contrast, the cancer study participants were passive and showed less awareness of the details of the tests and the testing schedule and rationale. I believe that being more actively involved in the research encouraged the asthma study participants to be more intellectually and emotionally involved in the research as research. The cancer study participants were more passive, partly due to the nature of the testing.

I also wonder if their position as patients rather than participants played a role. In cancer care, the drugs, chemotherapy, radiation, and skills of surgeons heal the cancer, while the patient remains passive. They have minimal role in their own care, except seeking care and maintaining a positive attitude. The passivity of the patient is grounded in the history of western medicine; biomedicine has developed and polices a corpus of knowledge about the body that bestows the practitioner with power and control (Foucault 2003). In contrast, Ayurvedic practitioners, for example, advise patients to change their diets and environments. Their healing necessitates that they actively engage in their own healing and care. Thus, I argue that the passive nature of cancer study participation reflects the passive nature of cancer care throughout North America.

c) Muscle regeneration study

Research study participation is often monotonous and boring. Thus, it is interesting to note the occasions that are particularly memorable for participants, for they may have a social or symbolic significance. In the muscle regeneration study, participants vividly recalled invasive procedures and the pressure to perform for others. Only one of the participants had had a muscle biopsy taken previously. Participants commonly recalled the biopsy as "interesting" and "really cool", and seeing their own muscle as "startling" and "amazing". However, invasive procedures like the biopsy, upon repetition, lose interest and become mundane.

When I first observed the biopsy I found it very interesting, but after a few I didn't learn anything more. It wasn't as interesting. (MP3)

Participants were required to rest for several hours between biopsies. I observed that they used this time watching movies, sleeping, chatting, or studying.

But, it's been a long day. A lot of sitting around. (MP2)

It takes some time. You've got to be prepared for that. (MP5)

It's not easy. It takes 6 hours one day and you have to come in the next day for blood and you have to do that twice. During the school year I may not have time for this. (MP4)

Here, again we see that participants tended to resent "sitting around" and were more interested in and were impressed by the participatory aspects of the study.

Participants were not allowed to eat or drink anything besides water and the occasional nutritional drink. Because they were hungry and possibly caffeine starved, they seemed impatient to finish the study.

I can't wait to eat. I'm so hungry. I have to wait until my last biopsy to eat. 18 hours without food. We get a few Ensures. It's not substance. I need substance. After this we're going out for a big breakfast. (MP2)

The challenge for me is not eating. After 8 p.m. last night I couldn't eat anything. Because I stay up late I usually eat late. So now I'm really hungry. (MP4)

When participants' regular eating rhythms were disrupted, they noticed the timing of the experiments and the new schedule to which they were required to

adhere. If the study was otherwise going well, I noticed that participants were not too concerned with their hunger. For those who were "having a bad day" this became a larger issue and impacted their mood as well as the atmosphere in the lab.

The monotony of research participation was punctuated by memorable experiences, particularly invasive procedures and instances where the subjects became objects (by viewing their own muscle being removed from their body for testing purposes). In addition, participants noticed when their normal eating and sleeping rhythms were disrupted and resented this when it was one of many inconveniences. Although participants had opportunities to "cheat" and eat when they were requested not to, all participants indicated that they wanted to "give the best data possible" and were not willing to "cheat". As such, they showed their displeasure through gruff behaviour (an unhappy disposition, closed body language, a reluctance to follow instructions) and occasional complaints regarding hunger and discomfort. Only two participants complained loudly about their hunger and both of those participants found the procedures and recovery time especially painful.

These participants reacted against the inconveniences of being in a study. They resented having to fast and became bored with the long waits of research. I did not expect that time would prove to be the most difficult or annoying factor of research participation. Participants needed to be flexible and adaptable to

the time and rhythmic requirements of research, and when faced with those

seemingly painless requests, some responded negatively. However, participants'

schedules were accommodated, as was most evident in the asthma study.

Accommodation was more apparent in that study because it was longer and

accommodation was more necessary to retain participants. In addition,

participant drop-out is more expensive in longer studies. These participants

were valued socially and economically and this manifested itself in this give-and-

take. Finally, I argue that there is a relationship between participant

engagement with study time and their subjectivity as participants. The more

engaged in the rhythms of research, the more participants conceived of

themselves as active participants and contributors, and less as guinea pigs.

iii)   The Body Politic: Labour Time

*I think they just want the results. You're talking about drug companies. I
really think that 100% all they want is to make money. I have seen no
evidence that they care. The years I have been here I have never once been
thanked for being a participant, nor have I been told what the results of the
trial were. I have never had the opportunity to ask. Maybe they're not
allowed to do that though, I don't know. (AP8, asthma study participant,
discussing the sponsor's monetary motivation)*

In Marxism and Critical Theory, time is an important feature of relations of

production. Time, in the form of labour is commodified under industrial

capitalism. Labourers exchange their time for money. None of my informants

considered themselves professional research subjects – individuals who earn the

majority of their income through participating in research – even though the

majority had previously participated in research studies. However, all sets of

participants approached the study as "labour time", but in different ways. Using

critical theory to understand the labour aspect of the time of research

participants is useful in some respects.

a) Asthma study

All of the asthma study participants' primary motivation for being in the

study was money. They felt the compensation ($2000) was adequate for their

labour time.

> *The main reason I do this is for the money. There are a lot of other*
> *things I could do for the money but they interrupt with my schedule.*
> *(AP9)*

> *Money. The more the better. Time is very important to people so if*
> *people take time out from their lives they need to be compensated.*
> *Here there are some studies where they do biopsies. They have a*
> *hard time getting participants because it's painful, you have to*
> *exercise for 2 hours, and you only get $60. Only graduate students do*
> *them. What's the point? When it comes to your own body you can't*
> *use the concept of minimum wage. (AP8)*

People spoke of their remuneration in terms of hourly wage. The figure I was

often quoted was $10 per hour. According to my informants, this amount was

appropriate and not unduly coercive from an economic standpoint, according to

the REB. However, this figure was in fact deflated because when participants

came in for a 5 minute test, they were remunerated for one hour's "work". In

order to maximize their income, all participants agreed to an optional portion of

the study, to have a bone marrow sample taken on three separate occasions. In

line with their perceived roles as labourers, some individuals felt there were

"work expectations".

I am expected to be on time and meet time commitments. (AP5)

I'm a good participant because I am fairly reliable. I come on time. I am pretty flexible - I would work with me. (AP11)

I do feel responsibility for giving good data. (AP14)

These individuals indicated that they felt responsible for both their "work" performance by giving good data and adhering to the rhythms of research. They felt they played a vital role in ensuring the accuracy of the data collected. The participants did not indicate that they felt "alienated" from the research process. This may have been due to their interest in science or their connection with the research coordinators.

Why did I sign up? Well I've had asthma since I was a young kid and I've been interested in learning more about it and more about the research that goes into studying it. (AP14)

Why did I sign up? Because I think [names of research coordinators] need people. I don't mind doing it. It's always a lot of fun coming here. They make it really enjoyable. (AP16)

So I do it more now for the science of it. I care about the progression of new medications, although it's still for the money. (AP6)

Mostly when you have to go in and have another allergen challenge done, which is nothing anymore, you look forward to spending the day because those two goofballs are back there and they're going to make you laugh. (AP1)

I think it's important to have people do this kind of research in order to better the medication out there. (AP4)

However, a few participants did indicate their apathy towards the research process and were almost solely interested in the remuneration.

LH: Why do you do this if you don't get any reimbursement?

AP8: Yeah, you do. I am totally money oriented.

LH: So it's not about the science?

AP8: No, it's not one bit about the science for me (laughs).

LH: Is it because you care about future asthma patients?

AP8: No.

LH: What are you getting out of the study?

AP13: The money.

LH: Anything else?

AP13: (long pause) Uh, helping science?

It is interesting and perhaps not surprising that the few participants that showed no interest in the research process were neither researchers nor students in sciences or health sciences. Most of the participants (13/16) were either students or researchers themselves. Students and researchers are the largest pools of participants at most university research facilities. These findings indicate that students and researchers have a greater tendency to feel invested and interested in the research process and participate for more than the remuneration offered. Thus, for them, research time is not the exact equivalent to labour time.

b) Cancer Study

In the cancer study, participants did not receive direct remuneration, but were given access to "expensive drugs". In all cancer drug trials in Canada, the

experimental drug is provided at no charge. Participants felt grateful for having

access to "cutting-edge technology". As one man put it:

> *I feel lucky that they picked me to participate. I feel lucky to be*
> *Canadian. I hear this drug is very expensive and I'm getting it for*
> *free. (P4)*

Thus, receiving free access to experimental drugs where standard treatment had

not worked was considered a privilege for some participants. Another

participant explained that one of the reasons they were participating in the study

was that the only non-experimental drug available was not available in Canada.

The treatment was available in Buffalo and the Ontario provincial government

would have paid for the medical treatment, although he would have had to pay

for his own transportation and accommodation. Choosing an experimental drug

over an approved one was reasonable for him, taking into consideration the life

disruption and cost.

This particular study required daily visits to the cancer clinic, unlike most

regular chemotherapy, which is usually every 2-3 weeks. One participant likened

being part of the study to a job.

> *It feels sort of like I am back at work. I have a routine schedule and*
> *come in everyday and have a routine when I get here. Sometimes by*
> *the end of the week I don't feel like coming in, just like maybe you*
> *would at a job. (P4)*

Comparing research participation to a job was one method for these participants

to normalize a taxing and potentially dangerous activity. To find a parallel

between the rhythms of research and the rhythms of work (an activity healthy,

productive people engage in) is an effective method of adjusting to research

participation.

One of the distinctions between cancer study participation as "work" and

standard employment is that in research participation, "workers" have

heightened anxiety about losing their job.

> *Today I was a bit sore and tired and of course I would have preferred*
> *to stay at home. It's not such a big deal if you take time off work (it*
> *means a loss of pay) but it is more of a big deal if you don't come in*
> *here. (P4)*

> *I think my biggest fear at this stage is not being allowed to continue*
> *– or getting worse. I don't want to be thrown out. I got this spot*
> *because someone else was thrown out. (P3)*

As such, the "labour time" metaphor is only partially useful for people who are

enrolled in cancer studies because they feel that, by participating, they are

increasing their lifespan. They are more willing to tolerate difficult working

conditions if it means an increase in their lifespan or quality of life.

Being in a cancer study provides a routine for patients with end-stage

cancer. They are required to visit the Cancer Centre every weekday. They see

the same nurses and doctors, and perform very similar tasks during each visit.

Some make friends with other participants and develop "working relationships".

It provides stability and routine, which is helpful and encouraging for some

participants. Anxiety about "end of treatment" for cancer patients is well

documented (Byock 2003). Being in a cancer study actually increases treatment and provides a stable and supportive daily routine.

c) Muscle regeneration study

In the muscle regeneration study, participation was described in terms of labour time. However, study participation sometimes conflicted with other labour time. Participants described their remuneration in terms of hourly wage. Again, $10 per hour was a common figure. However, the payment amount was described in competitive market terms. Participants were paid the same hourly rate as other jobs available for students on campuses. According to the principal investigator:

> I try to make it about $10/hour, which is about what they would get
> if they were working a job on campus. So that's what I try to shoot
> for. Because I don't want the money to be a motivator. Money is an
> added bonus for them. If money is the primary motivator you're not
> getting subjects for the right reasons. They would be purely doing it
> for the money and not for the interest in the work. (KI9)

According to this perspective, the participants ought not commodify their time, but rather engage in activities they enjoy. Nonetheless, they were paid for their time. This figure of $10 per hour was low because the total time requirement, according to participants, was 14 hours. With that time commitment we would expect remuneration to be approximately $150, but it was, in fact, $250. The remuneration was also described in terms of piece work - approximately $50 per biopsy (this was the so-called "going rate" according to the research coordinator).

Since the participants were all students and the study ran throughout the summer, getting time off from one's summer job was considered one of the biggest obstacles for participants who were working.

> *None of these are big challenges. They're really no big deal. It would be more of a challenge if I didn't get any money for it. I guess the hardest thing is getting time off work. So, it's difficult to get time off, so it helps that I'm getting paid. (MP2)*

> *I already had tomorrow and the next day off so I had to change my shift with someone to get today off. Then, I've got a couple of days to recover before I have to go back to work, which is good. (MP3)*

> *I get Fridays off, so I can make it in on Fridays. Otherwise I think it would be a problem. (MP5)*

Thus, if taking time off work is required for participation, remuneration is necessary. As such, participation is limited to those with no income or income comparable to the remuneration. The remuneration limits the population of individuals willing to participate. Economic matters influence whose bodies are used to produce research. This is generally true in non-therapeutic studies like the asthma and muscle regeneration studies. However, this is not true for all people. One metabolic study participant (the person quoted at the beginning of this section) explained that he was not solely motivated by the money.

> *If I did it for money I would feel bad. I would feel like I was selling my body. I would feel like a body prostitute, I don't know. Me, I'm of unlimited value and this is my body so I can't put a value on it. (MP4)*

The participation process adjusted his motivation (from monetary at the beginning of the study, to non-monetary during the study), because, to him, to be solely motivated by money symbolized the commodification of his own body. This was an unusual and rather thoughtful perspective, but an interesting one in contrast with the monetary orientation of others.

The biopsy recovery time varied from person to person. If the biopsy required several attempts to get a good sample, the damage to the muscle was greater and the recovery time longer. Participants were told that the recovery time was usually 2-3 days, during which participants could engage in all of their normal activities, except their legs might be sore. However, two participants experienced a much longer and more difficult recovery time than expected, which upset them.

> *A lot of people said don't worry – the recovery is just 1 or 2 days, but it was much longer. (MP3)*

> *LH: What will it (the biopsy site) feel like tomorrow?*
>
> *MP2: Tomorrow? Terrible. You can't walk. You can't touch it.*
>
> *LH: When does it go away?*
>
> *MP2: Never.*
>
> *LH: Never! (laughs)*
>
> *MP2: About two weeks.*

For these individuals, a long recovery time meant that their participation lingered and impacted their normal functioning and comfort for a longer period and to a greater degree than they had anticipated. Both of these individuals indicated they would do it again, but only for twice the remuneration.

> LH: *Would you do it again?*
>
> MP3: *No.*
>
> LH: *For $500?*
>
> MP3: *Yeah, for $500. There's too much time required for recovery.*

> LH: *Would you do it again?*
>
> MP2: *No. (pauses) Not unless I got $500. It's worth $500.*

For these participants, significant disruption in their normal rhythms (in terms of physical state and functioning) was only tolerable if adequate remuneration was received. In addition, when the effects of participation lasted longer than anticipated, participants felt angry and mislead. They seemed to make a clear distinction between research time and their own time, similar to workers in a labour force.

Participants in research studies are often paid by the hour, but this is not always looked upon positively. In the muscle regeneration study, one participant felt uncomfortable with the remuneration because he felt as though he were selling his body to science. In contrast, other participants embraced the remuneration, but thought it fell short. Since research participation can be

difficult and painful, aspects not encountered in most workplaces, $10/hour does not seem appropriate to all participants. For studies that are strenuous and painful, some participants feel that the low payment rate is not adequate compensation for the work required. So, although time is money, so are less concrete factors such as pain and discomfort. In addition, researchers should take into account how participation may influence a participant's normal activities and rhythms, understanding that what takes place in the lab can have extended influence on participants.

F)   Rhythms of Researchers

i) Scenario A

It's about half past nine. It's probably okay to go in now. I could wait a few more minutes, to give them more time to get hooked up and settled, and also I don't want to look too pushy. I should be pushy though. I need to get data – the more the better. I should be getting data right now, instead of reading this magazine or spying on the other people in this beige waiting room. I spend so much time in this blandly comforting room. I find out when a participant is scheduled to come in (usually they tell me, but the receptionist sometimes lets me know). I come in early and wait for participants and then meet them in the chemo area once they're in and hooked up. Sometimes, I see them in the waiting room and I sit with them and talk if they seem talkative, or just sit with them, if they seem less so. When I go in I see if they're ready to talk. Usually they are. If not, I give them a few more minutes. Once I actually missed

someone because they were in and out faster than scheduled and I arrived just

as they were leaving. That's the danger of waiting too long and being too

cautious and non-presumptuous. If I wait too long I miss the interview, or have

to cut it short. Once their treatment is up, they generally want to leave,

although one participant sat and talked with me for an additional 40 minutes.

ii)   Scenario B

It's 1:55 pm. I like to be a bit early. It shows professionalism. Or, at least

lack of unprofessionalism. His administrative assistant asks me to sit and phones

him to let him know that I've arrived. I usually make some sort of half apologetic

remark about being a few minutes early and not to rush. I spend this time taking

in the atmosphere, writing a few quick notes about the setting, the noises, and

the people. This particular location is quietly productive. Here I sit idly, leafing

through Forbes Magazine while others are busy working. I was riding the bus up

here while they were emailing memos and completing reports. In a few hours

they will take their 60 minute lunch break and I will graze at my desk at home. I

interpret my lack of structure as juvenile, and the unimportance of my time as a

reflection of my own worth. I envy their structure, which is interesting, since I

could also interpret my free and flexible time as a luxury, one often afforded the

rich and the entrepreneurial. My informant eventually comes out and apologizes

for running late, and indicates that he only has a few minutes because something

else came up. We get to his office and I quickly (too quickly?) review the

informed consent process, get his signature and commence the interview. The

informant answers my questions rapidly and expands easily and candidly. I opt

for depth and not range and cut my interview guide to a few short questions.

Deciding which questions to narrow down to, keeping up with his rapid speech,

connecting his ideas to the literature and other informants, and parsing his ideas

to determine if I need him to clarify or expand, leaves me a bit frazzled. I leave

30 minutes later wishing I could ask a few more questions, but also happy it's

over.

iii)   Scenario C
The monthly meeting. A long table with chairs oddly perfect for sleeping.

I chat with the woman to my right – a physician of some kind – worried that I

have pineapple between my teeth, stolen from the generous fruit tray, along

with black coffee poured into a paper cup. She explains to me that she loves

being on the REB. The protocols are interesting, the discussions stimulating, and

the chair is excellent, and he "runs a good ship". The only problem is that it is

hard to schedule the work into her day. The protocols she reads in the evenings,

between her kids' soccer games and other commitments. She tries to make it to

each meeting, but some months it's impossible. Plus, she receives no academic

recognition for the work. If she were only career focused she would never do

this work, but she thinks it's important and she enjoys it. We're about to begin

the meeting. The chair introduces me, summarizing my work and indicating that

I will be taking notes. The other members nod and smile at me. Then it starts. I

have the stack of protocols in front of me, about 40 or so. We have two hours to

get through them all. I write frantically, not sure what information is important.

The more detail the better, I think. I write pages and pages of notes.

Afterwards, looking back, I wish I had just sat and listened.

iv)   Overall reflections of the time of the researcher

These vignettes of the time of a qualitative researcher capture the data

collection activities of research. This is the most valued time of research. Other

research activities, such as making phone calls, sending emails, attending

conferences, reading, writing, and ruminating are less interesting to recount.

They are the invisible work of qualitative research, and are rarely discussed,

although they consume a significant amount of a researcher's time. Data

collection in my research consisted of periods of intense activity and periods of

less intense, even no activity. It was disjunctured and unpredictable. Some

activities never produce good data, while others became rich sources of data.

As the researcher it was my responsibility to adapt to the schedules of the

various research sites and informants. I was also expected to use the time I

wasn't collecting data to analyze data and to read the literature. It was difficult

for me to do these because of other commitments, such as teaching

assistantship and union work. Doing this required me to be disciplined and

efficient with my time, which developed in me an even more acute obsession

with time. Moving between different research sites and my academic and union

work, I found I had little coherent rhythm to my life. Each day was different,

filled with a different number and duration of activities.

My own rhythms were influenced by the studies I followed, but because I followed each study sporadically and conducted multi-sited research, the resultant schedule and rhythm were erratic. This was in sharp contrast with the studies I followed, where the activities and data collection were scheduled in detail in advance and more or less ran according to this plan. The attention to scheduling and timing in clinical research reflects the notion that time is an important and - often predictable - factor in data collection. Data collection can and should be temporally controlled and recorded. In contrast, qualitative data emerges and evolves and the researcher has less temporal control over the data collection. Although data is time-sensitive in qualitative research - meaning the quality of data collected is dependent on the order, duration, and timing of collection - it is not often that temporal occurrence invalidates or compromises data. For instance, the order in which I collected the data, how long I spent at each site, and the overall duration of data collection no doubt influenced what information I collected and how I related to and analyzed the data. However, it is not clear what the optimal sequence might have been or whether a particular order would have invalidated the data collection. Time in qualitative research is a mysterious factor and its effect is difficult to test.

Collecting data required me to know when information would be available for me to record. However, things did not always happen as planned and schedules often changed at the last minute and it was easy for me to miss these "windows" of data collection. So, maximizing my data collection required

me to be an organized and effective communicator who was also flexible. I

would often arrive early and stay late, even arrive at days not scheduled just in

case something popped up. Plus, when people changed the time, or forgot that I

was coming to meet them, I had to be flexible and accommodating. I was the

one pestering them for an interview or permission to observe their study, so I

needed to be organized, reliable, *and* flexible. This was an odd experience

because I found myself anxious about being on time, but I also felt I needed to

appear relaxed about time with others when the timing did not work out. I

absolutely felt that my time was the least valuable and the least respected. This

emphasized my own identity as an outsider, but it also attuned me to the politics

of time. I was often able to accurately ascertain an individual's status according

to the speed of their gate and speech, and how difficult they were to meet with.

Typically, the physician-investigators seemed the most pressed for time; the

cancer patients (ironically, considering they had the shortest predicted lifespan)

seemed to be the least.

G)   Discussion
By examining the rhythms of research, I learned about the embodied

experiences, the social relations, and the political economy of medical research.

These rhythms permeate and resonate throughout all aspects of the research

connecting the three bodies. Individual perceptions of self, time and future

emerge by examining how risk is conceived and confronted in medical research.

Asthma study participants' everyday experiences mirrored the risks associated

with the study, so their perceptions of the future were influenced by their experience of living with asthma. Since the rhythms of research were similar to familiar daily rhythms (being exposed to allergens, having an asthmatic response, monitoring one's condition and administering rescue medication as required) the participants did not feel as though the study was "particularly risky", nor did they have difficulty adapting to the effects of the research. This lack of risk aversion could have been due to a number of factors, including: health status, individual psychological makeup, comfort level and experience with the study procedures, and trust of the researchers, the research institution, and medical research in general.

Cancer study participants were not uncomfortable with assuming risk because they were accustomed to facing an uncertain future. Since all cancer treatment has a possibility of detrimental side effects and ineffectiveness, these participants conceived of the study as another treatment option. The primary difference was that they were already sick and generally are not willing to lower their quality of life with this treatment. The present was crucial because the future was so uncertain.

In the muscle regeneration study, participants tried to grasp their future using two primary approaches. Participants felt confident that the risks were negligible due to either their trust of the researchers, or trust of themselves. Some felt that the capabilities and knowledge of the researchers ensured that

their futures were safe, while others felt that through their own knowledge and capabilities, they could minimize and mitigate any risk associated with the study. In these cases subjectivity and social relations influenced participants' approaches to time and perceptions of the future. For them, time influenced, and not simply framed, human action.

Examining the use of time in research gives us insight into the relationships between participants and researchers. We can see whose interests determine the scheduling, to what degree participants are engaged in the progression of the research, and how participants react to altering their rhythms to the requirements of the research. The asthma study required a considerable time commitment from participants, forcing participants to find creative ways of keeping their other commitments while remaining in the study. However, because the participants were considered a valuable resource, research coordinators tried to arrange their own schedules around the participants to ensure they could remain in the study. Both parties collaborated and altered their normal work and life rhythms to accommodate the study protocol.

In contrast, the scheduling for the cancer study was determined entirely by the institution and the protocol. Participants were required to be at the cancer study on specified days, times, and duration. Like patients, they had to wait up to 2 hours before being treated. Participants were also only vaguely aware of the timeliness of the tests and did not produce data, but had it

extracted. For some, this lack of engagement with the rhythms of research contributed to feeling like a "guinea pig". Others, possibly to resist this feeling, closely monitored the process of the study.

For the muscle regeneration study, the schedule demanded an interruption in the participants' daily rhythms. Participants were required to fast for 18 hours. Their reaction to this requirement seemed highly dependent on how they perceived the study overall. If they found the procedures painful then they were less likely to tolerate these other discomforts. I found that participants were vocal in their discomfort and dissatisfaction, but did not drop out of the study because they were "almost done" and felt obligated to complete the study. Those who were dissatisfied indicated that they would have liked the study coordinator to have gone through the procedures because she would then know what the participants were going through. Thus, feeling as though others understood and had shared the rhythms of the research was important to those who were not adjusting to the rigors of the research. Empathy and solidarity may help participants psychologically and physically adjust to the rhythms of research.

At the level of the body politic, a critical analysis of the labour time of research participants reveals economic aspects of time. In the asthma study, participants confessed that their primary motivation was the remuneration. They understood their wage in terms of hourly pay. Generally, students and

other researchers were also motivated by the scientific aspects and were more

interested in participating in scientific knowledge production. In the muscle

regeneration study, participants were also motivated by the remuneration. They

understood their wage either in terms of hourly pay or in terms of piecework –

price per unit (biopsy) produced. Participants' identities shifted, from knowledge

producers, to patients, to workers. As workers, they were different from other

workers. They were asked to assume risks that other most workers are not.

Moreover, they were not protected by WSIB or other private insurance for their

work. They were essentially private contractors with little protection or

knowledge of their rights.

Cancer study participants did not receive remuneration, but sometimes

likened study participation to a job as a means of normalizing a novel and risky

practice. By paralleling the rhythms of research with the rhythms of work,

participants could identify as workers. This identity was not a revolutionary one,

as it did not challenge the relations or modes of production, but normalized

research participation. It was also not used to demand certain rights and

protections. Cancer research participants were satisfied with their work

environments and grateful to have a job (where they received access to

experimental drugs).

By examining the rhythms of research – the perceptions of (a possibly

risky) future, the embodied time of research, the flexibility required of research

participants and coordinators, the labour time of research – we can coalesce

multiple dimensions of research participation to learn how time is understood

and managed in medical research to enable the production of scientific

knowledge. The discordance between rhythms of research and the rhythms of

research participants in their daily lives varies. They are at times in tension

(arrhythmic), sometimes in agreement (eurhythmic), and sometimes dictated

(isorhythmic) (Lefebvre 2004:68).

The body's rhythms are often in tension with the rhythms of research.

This can manifest as food or sleep deprivation, or reduced functioning (for

example, due to decreased lung capacity or biopsy or bone marrow recovery).

This is not always necessarily an unwanted thing. Research can deliberately aim

to alter the internal function and rhythms of participants (like cancer study

participants). As such, the arrhythmia is intentional and may perhaps produce

eurhythmia. However, eurhythmia exists in other dimensions of personal

experience. Only those individuals, who are able to imagine a safe, and

potentially better, future through participation, enroll in these studies. This

perception of the future – as a more harmonious state – corresponds to the

perceptions and interests of the researchers themselves.

The social body of research, when functioning correctly, is eurhythmic.

One of the most difficult aspects of research is producing this eurhythmia.

Scheduling and retention difficulties are challenging, and if not managed,

become costly and can jeopardize the validity and continuation of the research. Remuneration can encourage or allow participants to adapt to the rhythms of research temporarily. Offering a potentially lifesaving drug can also encourage this eurhythmia. A pleasant lab environment and vocal appreciation of the participants also encourages eurhythmia. Research coordinators too adapt their tasks and routines for the research.

The political body of medical research could be described as isorhythmic. The overall timelines, wages and requirements are determined by the protocol. These protocols are written by drug sponsors, university-based investigators, or in collaboration. Participants are not solicited for their feedback. The purpose of the protocol is to outline the steps required to collect the appropriate number, sequence, and type of data needed to produce (ideally) valid and important scientific information. Remuneration is set at "what the market will allow". Participants are essentially contract workers and individually determine whether the risks are reasonable compared with the benefits. Although participants expect the researchers to determine the details of data collection, they sometimes complained that the protocols were not written with the considerations of the people doing the research in mind. Blood was drawn every 15 minutes, multiple muscle biopsies were required in a day, and participants were required to be available every day for five consecutive days.

Research participants interrupt their own rhythms (sometimes happily) to help produce scientific knowledge. This work requires a confidence that the research will not compromise their internal rhythms, an ability to synchronize one's own rhythms with the rhythms of the research, and a willingness to let the payment and administrative schedule be dictated by the investigators and sponsors. Most of the participants I met were interested in helping develop scientific knowledge and took pride in their work. Despite their repeat participation and their common identity as a partner in research, no one commented on this arrangement. Many felt inconvenienced by it, but not enough to challenge it. I believe that is because participants view themselves as fundamentally outsiders in the research process. As such, the rhythms of research are primarily, legitimately but narrowly, determined by scientific paradigms and economic trends.

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[60] The term "the Other" is commonly used in anthropology and denotes a person separate from and presumably different than oneself. The question of how to understand "the Other" and translate their world into one's own has been central to anthropology. Some contemporary anthropologists claim that historically anthropology has created a particular type of "Other" – savage, unhealthy, helpless and irrational - to justify the exploitation of colonized peoples by colonized states. For examples of this critique, see Said (2003) and Kelm (1999).

[61] Said (2003) argues that during the colonial era, the west began to construct the "exotic Other" as an imaginary counterpoint to the western self. This "exotic Other" was the opposite of the "civilized self" and represented the past (as a more primitive, original version of the civilized self) and the future (the hope for progress and development, often through assimilation).

[62] Contemporary anthropology (and other disciplines) is often fascinated by "exotic" cultures, people, locations, and customs. In this sense, exotic refers to mysterious or unfamiliar. Fabian argues that this assumed unfamiliarity is a distancing strategy.

[63] "Protensions" of the present, are our knowledge and beliefs about the future. We often act in accordance to a future we believe exists or with ambitions to generate that future. Gell used an analogy of a roller coaster, in which the memory of a plunge coexists in the present with the anticipation of "the racketing crunch which will occur as one hits the bottom of the slope" (Gell 1996:16-17), cf (Ramble 2002:S76). Today, many Canadians are aware of the dire predictions regarding global climate change. With this knowledge many Canadians are unable to behave as though our present is cut off from our future. This realization impacts individuals variably, ranging from political action, to changing their own consumption behaviours, to paralysis and ennui. Others may have very short protensions, choosing to believe that more research is necessary or that the current changes are not a result of human activity.

[64] Dialectical materialism is a method of understanding how thoughts and matter co-create the world. The material world is not perfectly created by thoughts, as idealism posits. The world is a dynamic product – more correctly a process – of the fluid interactions of thought and matter. The dynamism, in dialectical materialism, emerges from contradictions in the social fabric (O'Laughlin 1975). Thus, modes of social organization, such as capitalism, always arise from a contradiction. In the case of capitalism, the contradiction is that it relies on the exploitation by the ruling class of the working class. This exploitation creates resistance and struggle, which, according to Marx, will lead to the dissolution of capitalism and the emergence of something new. This approach is radical because it challenges the logic of capitalism and associated notions (for example, that accumulation of capital and class exploitation are "natural" and "unavoidable"). It also suggests that there are complicated and mutable relationships between thought and matter.

[65] Lefebvre is not strictly a critical theorist. Compared to the members of the Frankfurt School, his work is focused less on the impacts of technological and environmental domination and is more hopeful and engaged with political activity. Lefebvre was not a member of the Frankfurt school, but members of the Frankfurt school were aware of Lefebvre's work. Lefebvre was politically active throughout his career, at times supportive of the French communist party. Members of the Frankfurt School, however, were typically not politically active (save Marcuse later in his career) (Elden 2004).

[66] Others (Heaven et al. 2007) argue that trial identity falls on a continuum, with patient at one end, who receives individualized care, and medical research volunteer, who engages in research, on the other. I think this is true, however, it is demographically and study dependent (depending upon the study goal and the study environment).

CHAPTER 5: LAUGHTER AND HUMOUR IN RESEARCH

A) Introduction

When I began investigating the experiences of human research

participants I was initially startled by the prevalence of humour and laughter. I

felt thankful to be in these laughing environments, where I felt comfortable.

After some time I began to see that laughter was used in multiple ways to signify

a number of emotions and agendas. We laugh, obviously, when we find

something funny. However, beyond humour, laughter can also signal

discomfort, cynicism, and social incongruity. The research participants I met

with used laughter and humour to signify their solidarity with research

coordinators, their trust in the research enterprise, and their own discomfort

with aspects of being a research participant.

The fact that I noticed and participated in laughter and humour during my

fieldwork and have focused on this, speaks to my own nature and my own

tendencies as a researcher. I found myself laughing and joking with participants,

where instead I could have possibly argued, debated, or cried with them.

Another researcher, less inclined towards joking and laughing, may not have

produced this type of data, or if they had, they may not have focused on it. This

data is also an artefact of my methods of gaining rapport with participants. In

these studies the coordinators and participants created a social environment to

which I wanted to adapt. I was the outsider, and sometimes looked upon with

suspicion and scepticism. I am generally a jovial person and used this quality

instinctively to gain their trust, or at least their tolerance. I also did this, as I

mentioned, instinctively, because I wanted to fit in. I observed close friendly

relationships, which struck me as a core and unifying feature across the studies.

This world was attractive and I wanted to experience it.

The purpose of this chapter is to explore how laughter and humour are

used by medical research participants in order to understand its forms,

functions, and meanings. Focusing on laughter can help those who conduct

medical studies involving humans gauge the mood and perspectives of

participants because laughter is easy to identify and can signify discontinuity.

Perceiving how participants use laughter can help researchers understand the

perspectives and trepidations of research participants. In addition, focusing on

laughter can help researchers identify moments of discomfort to facilitate

continuous informed consent.

B) Literature Review

There are numerous academic definitions of humour, emerging from

diverse disciplines such as evolutionary psychology[67], literary criticism[68], and

social anthropology[69]. There are three major competing theories that explain

why we laugh (Taylor 2005;Toulouse 2005). The first is the *superiority theory* of

laughter, where laughter is a "form of derision and instrument of domination"

(Taylor 2005:2). The second is the *relief theory*, where laughter acts as a relief

valve. This approach is based on Freudian psychoanalysis, which interprets

laughter as "a release of surplus emotional energy" (Taylor 2005:3) and acts as "a guardian against obsessions and mental confinements" (Toulouse 2005:169). The third, and most popular among social scientists, is the notion that *laughter arises from incongruity*. Hollywood has capitalized on this notion, with numerous "fish out of water" comedies. Indeed many humorologists[70] consider humour a response to incongruity or absurdity (Holmes and Marra 2002:92). For example, Veatch (1998) defines humour as the identification and resolution of a "subjective moral violation". A subjective moral violation threatens the arrangement of the natural and social world of the perceiver. According to Veatch (1998), this threat, this absurdity, if resolved, produces a mirthful response. This definition highlights the difficulty in empirically determining humorous occurrences due to the difficulty in establishing a "subjective moral order".

Humour is a subjective experience. We know what is funny to us, but not always to others (as demonstrated by the popularity of Mr. Bean who is, according to my informal survey, decidedly unfunny yet continues to "delight audiences"). Because humour is subjective and not always easy to identify, it is important to focus not just on humour, but also on laughter. However, laughter and humour do not always coincide. Laughter does not always accompany humour (as in the case of satire). Furthermore humour does not always accompany laughter. For example, laughter can occur in response to discomfort or brutality when a person is nervous.

Why explore laughter and humour? Berger (1980) notes that because familiarity with a cultural code is a prerequisite for understanding humour, the study of humour is useful in providing insights into values. Thus, according to Berger, by understanding humour, we can understand cognitive space. Philosopher Alphonso Lingis (Zournazi 2002:30) sees laughter in a more political light. Humour and laughter often signify when something breaks down, marking a discontinuity.[71] This opens up a space for something new to begin; this space connects laughter with hope and change. I am interested in exploring humour because humour is both a medium of critique, an avenue for despair, and additionally provides insight into social relations because, as Alphonso Lingis suggests, we rarely laugh alone. Thus, by studying humour and laughter in medical research, we can learn more about the perspectives of the participants and their relationships with others who assist in the social production of scientific knowledge.

Laughter and humour, for some, signify resistance. Some humorologists have found that laughter and humour are used to bring people together (Astedt-Kurki and Isola 2001), whereas others have noted that laughter and humour can act as subversive devices, creating social distance (Holmes and Marra 2002). Humour in these instances is a mode of social commentary and means of challenging authority. These more provocative uses of humour are interesting and often exciting for social scientists because they threaten the status quo.

However, social commentary and critique exist in tension with and alongside social harmony. Many social scientists and theorists have noted the cohesive elements of humour and laughter. Bergson (1911:6) wrote that laughter "always implies a kind of secret freemasonry, or even complicity, with other laughers". Laughter and humour can foster consensus and social integration (Chapman 1983). Laughing at one another implies a trusting relationship. Moreover, humour and laughter can reduce deviance through the threat of ridicule (Fine 1983). On the other hand, ridicule can also be interpreted as a method of forcing group inclusion. In this way, laughter and humour are types of "centrifugal behaviour that 'reaches out'" to (selected) others (Pollio 1983:219).

Empirical Research on Humour and Laughter

Humour and laughter in health care has been well documented. Health professionals use humour while dealing with difficult and uncomfortable situations (Astedt-Kurki and Isola 2001;Tatano Beck 1997), developing therapeutic communication (Tatano Beck 1997) and providing emotional support (Greenberg 2003). Some researchers believe that humour has therapeutic effects (Miller Van Blerkom 1995). Greenberg (2003) considers humour a non-invasive, non-pharmaceutical and low-risk alternative therapy. Humour can help professionals save face (Astedt-Kurki and Isola 2001;Tatano Beck 1997), while laughter facilitates cooperation and compliance (Polimeni and Reiss 2006). In a study of stroke survivors, Heath and Blonder (2003) found that stroke survivors

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use humour to manoeuvre "social distance by pointing to boundaries and creating, confirming or denying allegiance" (pp. 91).

Medical anthropologist Burson-Tolpin (1989) also suggests that humour is an emotional outlet for physicians and other health care professionals in situations where other emotions such as rage and despair are not acceptable. It is also a medium for "highlighting the contradictions and absurdities of biomedical culture" (Burson-Tolpin 1989:288), for example, in situations where the cure is worse than the illness. Astedi-Kurki and Arja (2001) have documented patients' uses of humour and have found that they use humour for a variety of reasons – to highlight their feelings of anxiety, their current difficulties, and to avoid conflict. They also note that black humour is rare, but more common among terminally ill patients.

Humour in medical trials, although less common, is also documented. In her investigation of a hospital ward dedicated to metabolic research, Fox (1959) found humour common among physicians and patients/participants. The physicians often "joked" about the experimental nature of their work and commented that they were "killing" rather than curing their patients. They also joked about their conflicting roles as physician and researcher. Good humour and a positive outlook were well regarded among physicians and patients/participants. Indeed, many patients and physicians noted a strong camaraderie on the ward and that it had a special atmosphere. Humour helped

create stronger relationships and deepen interpersonal communication.

However, Fox (1959) noted that not all patients/participants fit in or were happy

in the ward. Some could not use socially acceptable tools such as humour to

help them address their suffering and fear. As we can see, humour and laughter

are useful for reinforcing or reshaping social boundaries. They can also either

foster or challenge social intimacy and acceptance.

Humour and laughter in non-medical environments may give insight into

the social dynamics of medical trials. In Porcu's (2007) examination of humour

used by fish sellers in a Sardinian fish market, she shows how humour is used as

a vehicle for enjoyment in a physically demanding work environment that

develops solidarity among the workers.

> In the fish market, jokes are "tactics," part of those minuscule
> everyday procedures which people use to evade the mechanisms
> of power, allowing a fleeting enjoyment and consumption of the
> field of the other. (Porcu 2007:78)

Savvy uses of humour helped fish sellers increase their sales. However, humour

also had the potential to slow work down and decrease productivity. As such, it

was used strategically. In addition, fish sellers used humour to protect their

employers from government officials. This particular use of humour was a

method of strengthening important relationships while allowing the fish sellers

to save face.

In their study of mushroom collectors and professional meteorologists,

Fine and de Soucey (2005) found that joking smoothed group interaction,

reinforced group boundaries and promoted social control. Their informants used

joking as a method of social lubrication.

> Joking constitutes an established frame that rescues interactions
> from friction. It smoothes relationships and causes the flow of
> discourse within the group to become more widely agreeable and
> acceptable. (Fine and de Soucey 2005:9)

They argue that humour and laughter can alleviate social tension and foster

group cohesion. Humour smoothes over awkward moments and diffuses

negative emotions ((Norrick 1993); in (Heath and Blonder 2003:92)). In contrast,

humour and laughter can also be distancing tactics, used to challenge existing

power relationships. Holmes and Marra (2002) found that colleagues at a

business firm used humour as a tool for both challenging and asserting authority.

The authors labelled this "subversive" humour and argued that it was a form of

distancing. Overall, they found that individuals used humour in multiple ways,

including for subversive purposes.

C) Laughter and Humour in Health Research

Below, I discuss the uses of humour and laughter in each of the three

research studies I followed. I discuss them separately because each study had a

different atmosphere; the types and uses of laughter and humour varied. This is

not surprising because each had its own distinctive social make-up and operated

within slightly different social conditions. Each study attracted different demographics of participants, was organized by coordinators with different backgrounds and perspectives, and conducted in particular physical and social environments. Thus, I have chosen to discuss each study separately to highlight the unique comical, jovial, and sarcastic atmospheres of each.

In this chapter I do not formally use the critical-interpretive framework to structure my analysis. Laughter and humour are social phenomena, and much of this material and analysis speaks to the social body. Humour and laughter certainly do influence the embodied experiences of research participants (whether one jokes and laughs or is quiet and calm, creates a very different study experience). In addition, humour and laughter are common and acceptable modes of political commentary and dissent. Though I do not specifically use the "three bodies" framework to structure my analysis, I will, where appropriate, comment on the individual experiences of humour and laughter and their larger political significance.

i)   Asthma study
The asthma study was conducted in a university lab that was adjacent to a university teaching hospital. I conducted most interviews in the lab (with the exception of two follow-up interviews, one of which I conducted over the phone and one over email). This location was most convenient for participants and did not require any additional time commitment. Generally research coordinators, other staff members, or other participants were in the room or in an adjacent

room during the interviews. As such, it is quite likely that participants were less

inclined to disclose any concerns or complaints. Thus, the interview location

most likely altered the participants' responses. However, as I will discuss below,

it did reveal aspects of the relationships between the participants and research

coordinators.

The two research coordinators (pulmonary technicians employed by the

university) quickly made me feel welcome and at ease in the lab by sharing

stories (work and non-work related) and joking with me. They were similarly

welcoming and jovial with the participants. In one of the offices where a number

of breathing tests were taken, the walls were lined with hundreds of pictures of

participants, office parties, and conference trips. Every participant's (from the

last 2-3 years) photo was on the wall, sometimes more than one. One of the

research coordinators even took a photo of me (notebook and audio recorder in

hand) and posted it with the others. The photo collage was a source of

entertainment and topic of conversation. During one of my visits to the office

many of the photos had been temporarily removed to make room for new office

furniture.

> KI2 had moved the hundreds of pictures on the wall around his
> desk. He moved them up a bit and further out because a new desk
> and hutch were to arrive in the next couple of days. Many people
> who came in said "what happened to your pictures?" or "your desk
> looks so sad" and commented on a few of the pictures. [from field
> notes]

The photos were symbolic of the value of the research participants. They also

represented an open and enjoyable working environment. Many participants

described the lab environment as jocular and fun.

> *What makes for a successful study from my perspective? Everyone*
> *getting paid. Everyone being happy together. If [the research*
> *coordinators] were assholes this wouldn't have been nearly as good*
> *because I have to spend so much time here. (AP13)*
>
> *It's always a lot of fun coming here. They make it really enjoyable.*
> *(AP5)*
>
> *I don't know how they found such perfect people (the research*
> *coordinators). I'm sure if they were boring people I wouldn't want to*
> *come back and waste so much time with people you don't enjoy*
> *being around and the day just goes by so slowly. Someone did a*
> *good job in hiring them. (AP16)*
>
> *Mostly when you have to go in and have another allergen challenge*
> *done, which is nothing anymore, you look forward to spending the*
> *day because those two goofballs are back there and they're going to*
> *make you laugh. (AP1)*

The notion that humour and laughter develop social cohesion (Chapman 1983)

seems appropriate in this case. However, it was unclear whether humour and

laughter helped foster this cohesion, or were products of it.

Positive comments about the research coordinators and lab environment

like these were common. Collegial joking relationships in the lab helped foster

this environment. The research coordinators used teasing to indicate group

inclusion. The following excerpt from my field notes describes one teasing

event, where one of the research coordinators was addressing a participant who

was also a colleague. During this conversation, both of the research

coordinators, their colleague, and two other participants were in the lab.

> When KI2 introduced me to AP6 he said that I had been waiting for
> months to meet with him and that I was from the university auditing
> department and had been watching him and had some questions
> for him. I sat silently and watched him for his reaction. He stared at
> me with both trepidation and disbelief. I felt awkward and told him
> I was really there to interview him about his experience. He smiled
> as everyone else in the lab began laughing. [from field notes]

The research coordinators also countered complaints from participants/co-

workers with teasing. The following excerpt from my field notes describes one

such instance.

> During the manitol test, her (AP3) coughing worsened and she said
> she was feeling terrible. KI2 replied "turn off the whine", grinned at
> me and laughed. KI3 continued the testing procedure and her
> complaints became louder. KI3 said that after the tests she could
> do an interview with me and she could tell me about how terrible
> they are to her and how it's in the protocol that they abuse her.
> [from field notes]

Thus, through the use of humour, research coordinators were able to proceed

with the study unhindered and deflect any criticism. This is an example of how

research coordinators' savvy use of humour reframed their position. The

research coordinators used humour as an acceptable method of derision (Taylor

2005). They deflected any insinuation that they were harming the participant,

and recast themselves as workers who must deal with difficult participants.

These joking relationships were primarily between colleagues. Participants who did not work in the lab were not teased in the same manner, nor were their complaints disregarded. Joking and teasing between colleagues is a method of dealing with stress and creating group cohesion (Burson-Tolpin 1989). However, teasing relationships were not *exclusively* between colleagues. One of the participants developed a teasing relationship with the research coordinators, similar to a collegial teasing relationship. The participant was a male in his early 20's. He was quickly able to establish a joking relationship with the research coordinators. The following is an excerpt from my second interview with him. Both research coordinators and two other participants were in the room at the time.

> *LH: There are optional parts to the study – have you signed up for those?*
>
> *AP13: Actually I was going to sell a piece of my lung to them. But, they don't need any in this study. That's what someone told me. (laughing) All parts of me have to go.*
>
> *LH: You're probably sitting on a million bucks right there.*
>
> *AP13: I've got ten toes – who needs all of those?*
>
> *KI3: We're going to do brain core samples later.*
>
> *AP13: You're not going to find much (laughs).*
>
> *LH: You guys probably even pay for stool samples.*
>
> *AP13: Ah no they can get those for free.*
>
> *KI3: I don't put up with that shit.*
>
> *LH: Can't they keep your blood?*

AP13: Yes they took a ¼ cup of it.

AP7: There's an option on the waiver where they can keep some of your blood in a freezer for up to 15 years.

AP13: Are they going to clone me?

KI3: After those comments we're not going to clone you. (group laughter)

The above witty exchange is an example of humour that makes light of the work of human research participants, much of which involves "donating" body fluids and parts.[72] As is evident, the participant picked up on the social use of humour in the lab and used it expertly.

Although laughter was common among research coordinators and participants, not all laughter was a response to humour and a simple marker of mirth. I found that "wisecracks" and laughter were common in response to my questions about the risks of the study. One of the most common questions people have for human research participants is why they are willing to assume risks to help medical research. I asked participants to discuss the risks associated with the study and what they thought of them. Common risks cited were: infection from the bone marrow and blood tests, breathing problems due to overexposure to an allergen and over-irritation to the lungs, and exposure to an experimental drug. However, also common were wisecracks about the risks. Implicit in these wisecracks was a defence of the research coordinators, as though the presence of risk was an indicator of poor or unethical behaviour on

the part of the research coordinators. Furthermore, by making light of my

question, participants were aligning themselves with the research coordinators

(surely, a more lasting and important relationship than the relationship with the

anthropologist). The following are a few examples of this political and social use

of humour and laughter.

> *They're going to take my bone marrow. They're going to make me*
> *breathe really badly. They're going to then pay me. (laughter)*
> *(AP13)*

> *Risks? Dealing with these guys (the whole room starts laughing).*
> *Sitting here for a long time. Listening to them bicker – just joking.*
> *(AP13)*

> *Paralysis is temporary (laughs). (AP8)*

> *There's a risk of being subjected to [staff member]. (AP9)*

By engaging in "trash talking" rather than discussing the risks, participants

demonstrated that they did not consider the risks significant or important.

Through the use of humour, participants implied that the topic of risk was

perhaps "laughable".

In more serious moments, participants reaffirmed this position, clearly

articulating their allegiance to the research coordinators.

> *So just that there's a risk of – I'm not sure what words to use, and I*
> *also don't want to make them look bad, because they do a very*
> *good job. (AP9)*

> *But, I'm confident in [Dr. X] and the staff here that they wouldn't –*
> *that if something were really risky, that they wouldn't do it. (AP2)*

> *Well I really trust the people who run the study, so I can't think of*
> *anything right now. (AP4)*

In these moments, participants were very clear about their trepidation of "saying

negative things" and demonstrated their allegiance to the study, specifically

those who ran the study. I believe that I was initially viewed as an auditor and

participants interpreted my questions as probes to learn about unsafe or

unethical practice. Responding with jokes and laughter then was one method of

neutralizing my presence and displaying allegiance towards the study lab. As

noted in the previous chapter on time, it is possible that as a result of the work

research coordinators did to make participants feel valued, this altered

participants' perceptions of risk, making them feel safe and confident in the

nature of the work. One of the research coordinators spoke to me about how he

valued participants.

> *You have to make an environment that's enjoyable to be in. Word*
> *gets out pretty quick and it can get out good or bad. So, if you don't*
> *make it a comfortable environment for these people to come in and*
> *do research, they're not going to come in and they're not going to*
> *recommend it to their friends and I'm going to be out of a job (quiet*
> *chuckle). I like working with people and that side of things. I'm not*
> *really a pencil pusher. It's fun for them and for us. I think they enjoy*
> *it. I certainly enjoy it. (KI2)*

For both practical and personal reasons the research coordinators endeavoured

to create good relationships with participants to ensure they felt valued and

increased the likelihood of their future participation. These relationships were

formed through posting pictures of participants, being accommodating with

scheduling, and making personal connections, primarily through eliciting

laughter. The participants repeatedly expressed the importance and value of these relationships. However, this may have influenced participants' perceptions of risk, making it seem almost "laughable".

ii)   Muscle Regeneration Study

The metabolic study had a much different social dynamic than the asthma study. Usually, only one participant was in the study on any given day due to the personnel resources required to complete all of the tests. The study alternated between periods of intense activity (either doing exercise or having a biopsy taken) and waiting periods (of an hour or more). During the waiting periods, I observed participants studying, watching movies (the lab had a TV and a small library of VHS tapes), or sleeping. The participants' primary contact was with the research coordinator (a graduate student); on occasion, they also interacted with the doctor performing the biopsy, other staff, and graduate students in the lab who helped draw blood and record measurements. The following excerpt from my field notes describes the lab environment.

> The mood in the lab is busy, but friendly. The research coordinator is friendly and warm, but doesn't have much time to socialize with the participants. When I came in today the research coordinator was speaking with the participant. She asked how they were doing and what flavour of nutritional drink they wanted. They joked about butter pecan – it was tasty, but an "old person's" drink. [from field notes]

Because the participants and researchers had little opportunity to develop a relationship, there was minimal banter and joking. Since the research

coordinator was a graduate student and was not concerned about re-

recruitment, there was less of an imperative to foster a relationship with

participants.

Laughter in the metabolic study was mostly what I would categorize as

uncomfortable laughter in response to particular questions. Participants often

responded with laughter, but this laughter was not accompanied by joking or

humour. I asked participants about the purpose of the study. Few felt

comfortable with their answer.

> *I know it has something about hydrating cells and exercise (laughs)*
> *but I can't articulate it as well as they can (laughs). (MP1)*

> *I think the purpose is to understand how muscle repairs itself*
> *(laughs). I think it's supposed to see muscle repair, right? (MP3)*

I interpret the participants' laughter as an indication of embarrassment

regarding their lack of knowledge of the study. It is possible that they felt

embarrassed that as both participants and university students they should have

known the purpose of the study. It is also possible that they were embarrassed

because the state of ignorance may have shown them to be more of a subject

than a participant. If they did not understand the purpose of the study, their

status as engaged participants was questionable.

I asked participants about their motivations for enrolling in the study.

Participants primarily responded that they were doing it for the remuneration,

although few also spoke of their interest in the science. Some participants

laughed in response to their monetary motivation.

> *They're paying me a lot of money. (laughs) (MP3)*

> *You could market the hell out of that [the results] (loud laughter).*
> *You totally could. It is a huge industry. Oh yeah! So that maybe is a*
> *bit of a personal vested interest. (Note: the participant was a*
> *member of the research group and felt if the study were successful it*
> *would bring financial gain to the research group, himself included).*
> *(MP1)*

> *Positive aspects? Money! (laughs) I don't think there are any others*
> *really. Well, I guess science. Science benefits. Science benefits.*
> *(MP2)*

The laughter in these situations signified both a discomfort in disclosing

monetary motivation and the social stigma associated with their motivation. By

laughing at their lack of knowledge and their monetary motivation, participants

signified that they felt that their responses indicated a less than ideal position.

By laughing at their monetary motivation, they showed they were letting out an

embarrassing little secret; that they were primarily participating for the

monetary reward. In this case, the perspective that laughter acts as an

"emotional relief valve" (Taylor 2005) may apply.

a) Muscle Regeneration Study – Subject/Participant Debate
Who participates in research for (what is considered by REBs as) minimal

remuneration? These students did not simply engage in research because they

were "lab sluts" (as one participant described it to me). They were willing to

forfeit their time, energy and assume risk for remuneration because as students

in an increasingly de-regulated post-secondary educational system (Canadian

Federation of Students 2007), their monetary situation was challenging and

futures uncertain. One could infer that participation is directly related to their

monetary situation, which was a product of increased user fees accompanied by

cutbacks in federal funding for post-secondary education. However, none of the

participants I met articulated this viewpoint. Indeed, all saw their participation

as fully autonomous and influenced by their own personal inclinations and

attitudes, not the economic organization of the university sector.

Laughter in the metabolic study also speaks to the debate about the role

of human research participants. Recently, NCEHR changed their nomenclature

from "research subject" to "research participant". This change reflects a more

"subject-centred" approach (Interagency Secretariat on Research Ethics 2005),

which recognizes the contribution, nature of involvement, and interests of

research participants. The name of the role varies (from human subject to

collaborator), each name inferring a specific type and level of involvement (Cox

2007). The term "research participant" indicates a more active role than

"research subject" and also reminds researchers that participants cannot be

treated "simply as objects" (Interagency Secretariat on Research Ethics 2005).

The term "participant" implies that those "doing" the research have a

vested interest in the research and are active members of the research team.

The term "subject" implies that they are not actively engaged in the research and

are objects of scientific study. Laughing at one's ignorance about the purpose of

the research and one's monetary motivation indicates the tension between

these two roles. Ideally, research subjects are participants, but due to

power/knowledge and monetary reasons, they are often objects of scientific

study, rather than collaborators or co-conspirators who are in it for the love of

science and not the money. One participant articulated this when he discussed

why he changed his motivation from monetary interest to an interest in science

during the study.

> *I'm not just doing this for the money. While they were doing the*
> *incision (for the muscle biopsy) I was thinking if I was doing this just*
> *for the money – going through all of this, I would feel like not a*
> *human, maybe a prostitute or animal because the body is something*
> *you can't charge an amount of money for. If I did it for money I*
> *would feel bad. I would feel like I was selling my body. I would feel*
> *like a body prostitute, I don't know. Me, I'm of unlimited value and*
> *this is my body so I can't put a value on it. (MP4)*

For some, there is something "funny" about participating in experiments –

donating samples of your leg muscles - for remuneration. As the participant

above notes, this is a strange feeling. So, some alter their motivations, while

others laugh at the strangeness. This brings to mind the humour as a marker of

incongruity theory (Holmes and Marra 2002). Laughter arises due to incongruity

between participants' actual motivations and what they see might be more lofty

motivations.

iii)   Cancer Study

The atmosphere was professional and caring. Patients were often referred to as Mrs. or Mr.. The atmosphere was at times very light-hearted and jovial. At other times it was not – understandably so. The staff members accurately gauged the moods of the participants and engaged in light-hearted joking or had more subdued but caring interaction.

Participants often volunteered praise and admiration for the staff – particularly the nurses - at the cancer centre.

> *Every day something happens that makes me just so impressed by what happens around here. It's crazy. (P3)*

> *It is a bit depressing, but the nurses are beautiful. They are wonderful. Very caring, not snobbish at all. Very gentle and kind. (P7)*

> *They're always nice and friendly. (P8)*

> *The nurses are great – not straight-laced or anything. (P5)*

Some participants developed strong relationships with the nurses, fostering close friendships over the course of several months. I witnessed participants and nurses sharing recipes, advice about relationships, showing each other pictures, and keeping each other up to date on family matters. Participants would also praise the nurses. For example, one nurse was able to inject a butterfly needle into a participant who had very scarred and tender arms from years of drug treatment. The participant praised the nurse and was obviously delighted that the procedure was fast and relatively painless.

Laughter in the cancer study was in response to gentle joking and also

what I would call "black humour" – a response to living with and struggling with

cancer. Both forms of laughter were ways of coping with and commenting on

being very ill with cancer. I was surprised by the amount of joking. Some days –

oddly enough - after being at the cancer centre I would come home tired from

laughing. Joking consisted primarily of gentle jabs targeted at the nurse and, at

times, the anthropologist.

> *What's it like to come here five days a week? Oh, horrible. The staff*
> *are very unkind. (laughs) It's a fabulous place, it really is. The staff*
> *are very conscientious. (P2)*
>
> *I have no complaints at all, except that nurse takes too long to do*
> *things. (grins and looks at the nurse sitting beside him) (P2)*
>
> *When I'm here I chat with the nurses, the group. It's not boring by*
> *far (laughs). There's lots of heckling, bribing the nurses, and just*
> *chit-chatting about stuff, life, hockey. (P5)*
>
> *What do I do while I'm here? Try not to make the nurses laugh too*
> *much! Enjoy myself as much as possible. (P9)*
>
> Before the interview I sat with P5 and his mom and chatted while
> the nurse hooked him up. They "gave me the gears" and we had a
> good time. They threatened to "sick" me on one of the other
> patients. I pretended to get hurt and P5's mom said "Oh we think
> you're great. That's why we're giving you a hard time." [from field
> notes]

Study participants developed relationships through gentle joking. As the passage

from my field notes suggests, this joking was a sign of acceptance. Like stroke

survivors in Heath and Blonder's study (2003), cancer study participants used

humour as a means of negotiating social distance. This supports Astedt-Kurki

and Isola's (2001) view of humour as a centrifugal force that fosters inclusion.

As my field notes demonstrate, being on the receiving end of sarcastic joking was

a marker of acceptance.

Joking was also a method of coping. Having terminal cancer was

extremely emotionally and physically draining, and sharing laughs distracted

patients from their suffering.

> *Sometimes I can talk to others about how they are dealing with it,*
> *but mostly we just talk about hockey or whatever. I actually prefer*
> *that more. It gets tiring to always talk about it. (P4)*

> *Joking helps calm the nerves. (P2)*

> *My positive attitude has gotten me this far – so I'm just going to*
> *keep going. (P1)*

Joking and laughing had functional (calms the nerves) and symbolic (power of

positive thinking) value for some participants. These uses of humour and

laughter are similar to those Tatano-Beck (1997) documented in her work with

terminally ill patients.

Another method of coping with terminal cancer was through the use of

black humour. Black humour is ironic and macabre humour that is not

sentimental (Polizzotti 1997). I never witnessed a nurse or family member use

black humour. Black humour was an outlet only used by (and perhaps only

acceptable for) cancer patients. Black humour was not common. I only met one

participant who used black humour. I asked this participant why he enrolled in

the study. He replied:

> *Well, I have two choices. Either I die or I keep going, so I'm going to*
> *choose this (laughing). That might be a grim way of looking at it,*
> *but it's exactly the way it is. (P2)*

When I inquired about his response, he retorted:

> *I come off maybe not taking it serious, but I take it very seriously. I*
> *have a lot of respect for these people. I can't do anything. You ask*
> *me what drugs I'm on, I don't even know. I don't care. They tell me*
> *what's the best thing. ... I quip about it but only in jest. (P2)*

For this participant, black humour was one medium for facing a possibly grim

future he felt he had little control over. He was laughing at the ridiculousness of

his choice. When I asked him about his motivations for enrolling in the study and

feelings about it, he no doubt found my questions asinine and naïve. He

responded with black humour, humour which was not intended to elicit laughter,

but to remark on the choice he made. In fact, if I had laughed at his "two

choices", he would have most likely interpreted it as inappropriate and, possibly,

cruel.

Humour and laughter are essential elements for cancer research

participation. They improve the study experience by helping distract participants

from the serious implications of their work. Humour and laughter also help them

maintain a positive outlook, which some believe to be an essential ingredient for

living with and fighting cancer (de Moor et al. 2006). The laughter in cancer trials

also fosters trust and closeness between the participants and study nurses who

are adept at determining when gentle joking and laughter is welcome and

needed. Burson-Tolpin (1989) found that health care providers sometimes use

laughter as an emotional outlet. I found that these very ill but very active

participants also used laughter and humour in this manner. Some evidence

suggests that due to the strict inclusion criteria of clinical trials, usually the

healthiest patients enroll, and those with the poorest prognosis either are not

eligible for the study or feel too ill to participate (Van Spall et al. 2007). I wonder

then, whether the prevalence of laughter and humour was an artefact of not just

the social environment, but also the comparatively healthy physical and mental

states of the participants. These findings are also a testament to the complex

relationship between physical, social, and emotional wellness. In retrospect, I

am not surprised that a "healthy" research population, provided with intensive

care and monitoring, engaged in so much joking and humour.

D) The Three Bodies

Although laughter and humour are inherently social phenomena, they

also inform critical-interpretive theory. On an individual level, laughter and

humour both signify and create enjoyment and comfort. One participant who

found the muscle biopsy especially painful afterwards laughed at his behaviour

during the procedure (he held the research coordinator's hand). Laughing

helped him relieve tension. In addition, laughing about engaging in risky

behaviour, as many participants did, transforms a worried disposition into a carefree one. Laughter and humour also simply made an otherwise boring or tedious day more enjoyable and fruitful. Research was a break from participants' everyday world. Although this was often an inconvenience, it was a disruption in time, where participants were in an environment where they were valued and attended to. Many chose to enjoy this time as much as they could, by engaging in humour and laughter. However, I also saw people laugh at themselves when they could not answer basic questions about the study they were in. In those cases, laughter marked incongruity, and flashes of insight.

As I have shown, at the social level, humour and laughter can have numerous meanings and functions. They primarily create and signify social cohesion. From a researcher's point of view, this comforts participants, and demonstrates to them their value. It helps with participant retention and recruitment. In addition, it can curb dissent. By forming social cohesion, and aligning participants with the study and the study culture, researchers and research coordinators may gain the trust and sympathies of participants. I do not suggest that they do this deliberately, but that this may be one of the outcomes of warm, friendly, joking, and inclusive behaviours. However, humour is also a form of dissent. In the metabolic study, participants complained about the study in snide, sarcastic comments. They never complained directly, but used humour as a medium for voicing their discontent.

Laughter and humour are sometimes vehicles for commentary on the body politic. One participant in the cancer study used black humour to comment on the choice that patients with end stage cancer faced when deliberating whether to enroll in a clinical trial. One participant in the asthma study laughed at the idea of participating to help science or the pharmaceutical sponsor. This was a commentary on the idea, but looking back, I believe, also a commentary on other participants who were excited about the importance of testing new medication. These commentaries on the body politic were uncommon, and as such, striking.

Throughout the individual, social, and political levels, humour and laughter work to lubricate the research process or to critique it. This tension emerged to different degrees in each of the studies. Most commonly, laughter and humour enabled the research process, created social and personal comfort, and helped people reconcile themselves with performing risky work that they did not necessarily understand. It sometimes highlighted discontent, discomfort, and criticism. It may seem odd that laughter and humour were the most common forms of criticism and critique. By laughing at the ridiculousness of something, we simultaneously articulate and soften our criticisms. This is a common technique in North America, as demonstrated by the popular "Daily Show" comedic news program. This is one of the only widely televised news programs which provide any political critique, demonstrating the popularity and cultural salience of satire. Satire is biting criticism, but criticism which simultaneously

entertains and implies a sympathetic listener, or a "secret freemasonry", as

Bergson (1911:6) put it.   By laughing at satire, we situate ourselves as co-

conspirators, but we also predispose ourselves to remembering the critique.

Laughing and joking bring ideas into the mind and body; burrowing them into

our deep recesses.   The guffaws, giggles, and snickers stay with us. Thus, it is

important to pause and examine them to see where they take us.

E) Discussion

As the above data indicate, research participants experience amusement and

develop joking relationships during the research process. Research participation

can be time consuming, repetitive and dull. Laughter and humour can improve

the experience and increase the participant's overall disposition towards the

work. It can also bring enjoyment to an otherwise dull day, or provide an

emotional outlet to help cope with a dismal prognosis.

The participants in the asthma study frequently laughed and used

humour in response to my questions. In many instances, they laughed at my

questions about risk and other instances where they interpreted my questions as

"digging for dirt". This was a method of showing solidarity with and trust in the

research coordinators and the research project. This is similar to Porcu's (2007)

findings where Sardinian fish sellers used humour and laughter to defuse the

inquiries of government officials regarding their bosses' work practices. In both

cases, people used laughter and humour to build and protect important relationships.

These studies provide clues regarding the operation and role of social harmony in medical research. In the asthma study, the participants were forthcoming with accolades of respect and appreciation for the research coordinators – and by association – the research process. They were disinclined to say anything negative or critical about the study. Although, in my opinion, the research coordinators were very knowledgeable and concerned about participant safety and acted with diligence regarding any potential participant safety concerns, the participants took their own safety and risk fairly lightly. In addition, participants were reluctant to look at the study critically, as evidenced by their laughter and evasive responses to my inquiries about risk. The friendly and warm atmosphere in the study lab may have contributed to their desire for harmony. I am not implying that this was the intent of the research coordinators. They fostered an amicable environment to help develop and maintain a participant base and out of genuine caring for the participants. However, all parties contributed to the harmonious atmosphere. In fact, this harmonious atmosphere seemed to be the most striking and important aspect of the study for participants. In these circumstances, individuals may not have had the courage or inclination to raise questions and concerns because they did not want to disrupt social harmony.

Although research participants are allowed to withdraw from the study at any time, there are social and monetary barriers to this option. Research ethics boards perhaps should not assume that emphasizing the voluntary and temporal nature of the participants' consent will remove these barriers. Participants quickly develop a relational - rather than contractual – approach to research. Many become committed to helping the researchers and research coordinators and garner pride and enjoyment from their participation. I believe that participants are very reluctant to withdraw from research. Therefore, a subject-centred approach to research acknowledges this issue and makes efforts to create a dialogue with participants such that their participation is mutually beneficial. I, in fact, witnessed this in the asthma study, where researchers consulted long-term participants when developing protocols to get feedback from their perspective. More of this work should be done before and during studies to accommodate and acknowledge participants' role to build capacity in both the research and research participant communities.

The participants in the muscle regeneration study used laughter and humour differently than other participants. Their laughter often signified discomfort with their subject position. They laughed at their monetary (rather than scientific) motivation and their ignorance regarding the purpose and details of the study. Despite an interest in science (almost all participants were students in the sciences or medical sciences), few could recall many details of the study. The discontinuity participants felt between their positions as educated scientists

or health professionals in training and their actual role as under-informed, money-oriented "guinea pigs" was literally laughable for some participants. The laughter denoted identification of this incongruence.

Researchers can help participants feel more involved in the research process by keeping them informed of the procedures and outcomes throughout the study. There are significant barriers to this, including time, training, and interest. If participants are fundamentally uninterested, educating them about the science can be challenging. However, to quote a principal investigator, the most successful recruiters are those who are "passionate about their research". Participants can and do become excited about medical research. Providing opportunities to engage with participants about the goals, methods, and background of the study may lead to greater excitement, involvement, and possibly compliance, for participants.

A more collaborative approach to research will require more than desire and vision; it will require funding and training. If one of the assumptions and justifications of conducting research involving humans is that participants have some interest in producing science then the industry needs to dedicate more energy into educating and involving participants. This will take additional time and resources and certainly will not grasp the interest of all participants. However, if the industry truly believes that research participants have a social and scientific interest in helping produce scientific knowledge, (some ethicists,

researchers, sponsors, and ethics board members make this argument to help justify the use of human research subjects) explicit work needs to be done in this area to create the right conditions for participant collaboration. Researchers and research assistants need the funding, the time, and the training to engage in these activities. I have few suggestions regarding how researchers might secure additional resources. However, I do suggest that training regarding how to engage and develop relationships with participants would best be done by researchers and research coordinators who have experience and success in the area.

Cancer study participants used laughter to signify group inclusion/acceptance and as a method of coping with a serious illness. Participants engaged in gentle joking with study nurses. This was one of many indicators of the closeness of the relationship between participants and research nurses. Some participants indicated explicitly that joking was a sign of acceptance. They used joking as a way of creating social bonds and communicating comfort. Participants also indicated that their laughter, joking, and "positive attitudes" were methods of coping with a serious illness and unpromising prognosis. For some participants, laughter and humour were important mechanisms for staying positive and, possibly, gaining health.

In this chapter, I have attempted to convey how humour and laughter emerge, are used, and what they might signify in medical research participation.

Humour and laughter can symbolize and communicate a number of social and

psychological phenomena. Laughter and humour are social cues and provide

insights into the worlds and perspectives of research participants. It may be

helpful for researchers to take note of when participants laugh and joke, and

when they themselves follow suit. This may help them understand participants'

motivations and gauge when they are uncomfortable, confused, unappreciative

of the study risks, or enjoying a particular aspect of the experience.

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[67] Polimeni and Reiss (2006) associate humour with laughter. They explain, "exposure to a humorous stimulus induces laughter – a loud multi-second seizure-like signal – that generates a positive emotional state in consepecifics and facilitates further social activity" (pp. 348).

[68] See Breton's (1997) anthology.

[69] Apte (1985) notes a number of definitions of humour, including "a cognitive, often unconscious experience involving internal redefining of sociocultural reality and resulting in a mirthful state of mind" and "the external manifestations of the cognitive experience and the resultant pleasure, expressed through mirthful laughter and smiling". Thus, for Apte, humour may be associated with laughter, but is always a pleasant cognitive experience. This definition, therefore, does not include all forms of humour, specifically black humour, or what Vache describes as "a SENSE… of the theatrical (and joyless) pointlessness of everything" (Polizzotti 1997:vii). Breton himself thought of black humour as the macabre, ironic, absurd enemy of sentimentality (Polizzotti 1997).

[70] Humorologists study the origins, physical response, social meaning, and function of humour. They come from a range of backgrounds – many are linguists, anthropologists, psychologists, nurses, physicians, and historians.

[71] This is most obvious in much physical humour, but also true in joke-telling and other verbal forms of humour.

[72] It was interesting that when discussing the various tests they performed, participants often laughed about producing urine or sputum, but never laughed about giving bone marrow or blood or doing the nasal lavage.

CHAPTER 6: MEDICAL RESEARCH ETHICS

A) Introduction

My goal in this chapter is to touch on a number of key issues and topics, including: risk, informed consent, consent forms, hope, the therapeutic misconception and REBs. Many of these are discussed in other chapters (and in other ways), but here I bring them together to review how my research and my research approach informs the discourses and practices of medical research ethics. In each of these sections I (1) describe how the terms or topics are understood within the discipline of research ethics, (2) provide an overview of how important social science and empirical research has informed or critiqued the topic area, and (3) describe how data from my research inform the topic. My overall goal is to provide a summary of how my data speaks to topical issues in medical research ethics and informs, corroborates, and at times expands the debate. Many of my arguments are informed by literature which provides limited, but significant, empirical data to support my arguments. I also provide commentary on current approaches to research ethics.

In this chapter, I do not use a critical-interpretive framework to organize or inform my analysis. Instead, I address the current ethical debates using empirical data. My goal is not to *reform* research ethics debates, but rather to *inform* them. This is a rather conservative, although pragmatic approach. I found that many people involved in bioethics were interested in empirical ethics and learning about the perspectives of research participants. I believe that

addressing research ethics using a critical-interpretive framework would make

my data and argumentation less accessible and less useful to those in the area.

B) Background

When I began to speak with and listen to people about medical research

ethics, the subject of past unethical research transgressions often came up. I

have come to believe that this history is part of the genealogy and identity of the

field. The stories remind of us the dangers of the power dynamics between

researchers and participants. They also make for a fascinating and colourful

history, simultaneously helping to prevent us from repeating the mistakes of the

past *and* reassuring us through these ghost stories that we have a much clearer

and ethical approach to medical research today.

Research involving human participants has a dark history. Many

atrocities of the past have been well documented: Nazi doctors experimenting

on prisoners (United States Holocaust Memorial Museum 2008), American

researchers observing rather than treating African Americans with syphilis,

known as the "Tuskegee Experiment" (Washington 1995), and prison doctors

experimenting with LSD on inmates in the Kingston penitentiary (Osborne 2008).

It is important to note that in all of these cases the bodies of certain people –

religious and racial minorities, soldiers, and prisoners – were valued as

experimental subjects, but as people they were disregarded.

Rothman (1991) traces modern changes in the relationship between the public and the medical profession. He argues that the public has lost trust in the medical profession because a social gap has developed between physicians and their patients. A number of critical events catalyzed this loss of trust, most critically the 1966 article by Dr. Henry Beecher exposing ethically questionable practices in a number of medical experiments involving humans throughout the United States. In many cases, patients were experimented on without their knowledge, and often these patients were the most vulnerable: the elderly, the mentally disabled, and prisoners and servicemen. There was a public outrage, because these signified the growing rift between medicine and the public.

Prior to World War II, medical experiments were therapeutic and small scale. During World War II, the American government began larger-scale non-therapeutic experiments on people, only sometimes with their consent. The history of medical research ethics also focuses on the medical experiments conducted by the Germans. Doctor Trials at Nuremberg. From 1946 to 1947 trials were held in Nuremberg, Germany to investigate Nazi war crimes, including the atrocities of medical personnel and researchers during the Second World War. Estimates are that hundreds of thousands of prisoners of war died at the hands of these individuals – either killed outright because they were deemed unfit to live, or died during medical experimentation (United States Holocaust Memorial Museum 2008). Many of the doctors tried were found guilty of torturing and mutilating prisoners, a despicable act made all the more gruesome

because the guilty were doctors, the very people we feel are responsible for

caring for us and curing illness. Based on these trials, lawyers and physicians

developed the "Nuremberg Code" to guide medical research and protect human

participants. It emphasizes voluntary and informed consent, minimizing the risks

for participants, and the importance of balancing larger social benefit with

individual well-being (National Institutes of Health 2007a).

After the Nuremberg trials the World Medical Association developed the

Declaration of Helsinki, a document that outlines the principals and ethical

guidelines of medical research. The first draft was developed in 1964 and the

latest revision dates to 2004. Its major principals include: respect for the health,

dignity, and privacy of persons; that the potential benefits of the research

outweigh the risks to participants; free and informed consent. It states clearly

that "considerations of the well-being of the human subject should take

precedence over the interests of science and society" (World Medical

Association 2004).

The next significant milestone was the Belmont Report, developed in the

United States by the National Commission for the Protection of Human Subjects

of Biomedical and Behavioural Research in 1979 (National Institutes of Health

2007b). This report outlines three principals that should inform research

involving humans: respect for persons (through informed consent), beneficence

(through minimizing harms and maximizing benefits), and justice[73] (through

ensuring fair recruitment policies). It was developed in the wake of (and partly as a response to) the outcry about the ethical missteps in the Tuskegee Syphilis Trials conducted by the U.S. Public Health Service from 1932 to 1972.

In Canada, the Tri-Council Policy Statement (TCPS) was developed to guide ethical decision making in research involving humans (Interagency Secretariat on Research Ethics 2005). This document applies to all research in all disciplines involving human research participants in public institutions (universities, hospitals, government). It begins with a statement about the importance of research and then explains how respect for human dignity is a moral imperative in research involving human participants. Its guiding principles include: respect for human dignity, respect for free and informed consent, respect for vulnerable persons, respect for confidentiality and privacy, respect for justice and inclusiveness, and balancing harms and benefits. It details the ethics review process and common concerns such as informed consent and conflict of interest (Interagency Secretariat on Research Ethics 2005). This document guides research ethics review boards and articulates ethical norms for research. It is not absolutely prescriptive; it is built to accommodate the needs of specific localities and disciplines and highlight possible ethical concerns in a number of areas of research.

McDonald (2009) described the development of the TCPS, as a member and deputy chair of the Tri-Council Working Group (TCWG), who developed a

document which informed the TCPS. The TCWG formed to develop an ethics

code that would apply to SSHRC, NSERC, and CIHR (then the Medical Research

Council (MRC)). The MRC had ethical guidelines, as did SSHRC although they

were not well known, and NSERC had no official ethical governance or guidance.

Meanwhile, the National Institutes of Health (NIH), in the United States had

developed guidelines, which stated that research funded by the NIH but

conducted outside of the United States must meet their standards. Canada

needed a unified code to meet the needs of the growing and increasingly

complex research industry (McDonald 2009).

In 1996 the TCWG published their code of ethics. It was intended to instil

trustworthiness and accountability in public research. It was met with resistance

and even hostility from the three councils, the Canadian Association of University

Teachers, university presidents, and individual university researchers, especially

social scientists. The document was shortened and revised and eventually

republished in 2000 as the TCPS. The TCPS had less philosophical reflection,

fewer legalistic wording, and was more generic, in that it was adaptable to

diverse applications. McDonald (2009:19) observes that the changes

demonstrate the community's emphasis on researcher placation, rather than

subject protection.

McDonald's historical recording and analysis are important additions to

the history of Canadian research ethics policy. However, the social and political

process he describes is not commonly recounted. We are fonder of recalling the

atrocities of the Second World War. We can trace our policy back to the

Nuremberg trials and much of the heightened focus on research ethics to the

Tuskegee syphilis studies. This story puts our current policy and practices within

a historical context and keeps us emotionally connected with the transgressions

and crimes of our predecessors. It also highlights the most salient features of

ethical practice in research in North America – primarily the respect for persons

and autonomy.

Alternative histories exist. In particular, some scholars have connected

modern emphasis on individual freedom and autonomy to wider economic and

political trends (Campbell and Pedersen 2001). This emphasis on individual

autonomy and freedom takes place against the background of intensifying global

economic competition, the decline of the Welfare State and the

commercialization of public healthcare (Dubler 2002:363). Individuals as health

consumers who are "obliged to be free" (Rose 1990) and choose (with both

freedom and the responsibility that freedom brings) whether enrolling in a study

is "in their best interests" are a modern social construction (Foucault 1994).

Corrigan (2003) argues that this construction ignores the power and relational

dynamics of medicine and research, to the advantage of researchers and

investigators. The current focus on informed consent narrows the discussion of

research ethics and presumes that if informed consent exists other issues, such

as the organization of research and who forms the research agenda, are not

important, or at least beyond the scope of micro and meta-level actors.

Members of the research ethics community have commented on this myopic

approach to research ethics and suggest that REBs or other governance bodies

refocus on broader issues (Chalmers 2007; Emmanuel et al. 2004; McDonald

2005).

C) Risk

Risk is a commonly used term in research ethics parlance. Social

scientists have been concerned with risk and risk analysis for decades, and this

interest has intensified in the last 20 years. Here I briefly describe how the term

risk is used most commonly in research ethics, the empirical evidence about how

participants understand risk, and discuss how the participants I spoke with

understood risk.

Researchers are asked to minimize risks to participants and maximize

benefits to participants and the wider community. Risk in this way is understood

as the probability that an adverse outcome may occur. Often the probability of

the occurrence of an adverse outcome (such as the occurrence of an infection at

the site of a blood sample) is known. The probability is calculated based on past

practice and varies across time and space. However, this probability is an

average and may be higher or lower for various individuals, depending on age,

disease status, and living conditions. "Acceptable risk" is subjective; it depends

upon the risks encountered in everyday life. People with AIDS, people with

asthma, EMT workers, and warehouse workers all encounter different risks in their daily lives.

Although researchers often see risk as a calculated average, participants have to interpret and apply these averages to help them determine whether they think the adverse event will or will not happen to them.   If the answer is "yes", they must assess whether they are willing to face this outcome (for example, an adverse outcome may be a headache, or it may be a prolonged hospitalisation). Data suggests that how a probability is worded influences how people interpret risk. Gurm and Litaker (2000) found that patients were more likely to consent to a treatment that was framed as "99%" safe than a treatment where the likelihood of complication was framed as "1 in 100". In a study of how people interpreted the risks of causes of death, Yamagishi (1997) found that participants rated cancer as riskier when it was described as 'kills 1,286 out of 10,000 people' than as 'kills 24.14 out of 100 people'. People tended to focus on the total number of deaths. These studies show that something as simple as the numerator can influence how people interpret risk.

Iltis (2006:185) believes that the confusion around risk exists because risk is a "non lay concept" and most of us have a limited capacity to understand and appreciate risk. She believes that we have difficulty with both steps of the risk equation – converting the probability to a "yes" or a "no", and then assessing whether we are willing to assume the harm. Her qualitative research with

research participants lead her to conclude that "what they really wanted to

know in advance was whether they would be harmed" (Iltis 2006:187). Of

course, researchers, REBs and sponsors cannot guarantee the safety of

participants; they can try to reduce risks and ensure that any adverse events are

detected and treated if possible.

In my own research, I found that participants assessed risk through their

knowledge of the research environment and their own sense of resilience and

health. The riskiness of a study depended on the research environment; factors

such as the reliability of the researchers, location of the study, and systems in

place.

> *But, I'm confident in Dr. # and the staff here that they wouldn't –*
> *that if something were really risky, that they wouldn't do it. (AP2)*
>
> *I like to think they're doing a good job to make sure these things*
> *are ethical. (MP5)*
>
> *I trust the people here. (MP4)*
>
> *If it were new people doing it, a new surgeon, new oncologist, if I*
> *had to go to a new centre like [Hospital X] I would be like, "No".*
> *I've been coming here for two years. It's the same people. (P8)*
>
> *They are excellent, just excellent here. (P7)*

Their trust of the research was influenced by their trust in the people who

organized and ran the studies. This is what Geransar (2008) has dubbed "trust

by proxy". In her case, participants trusted the researchers because they

trusted the institution they worked for. The trust they had for the researchers

was due to their proximity to the institution. Here, I believe that trust may

migrate in both directions. Participants may trust the researchers because they

trust the institution. In general, public research is well regarded in Canada and

most Canadians are supportive of medical research.   In contrast, participants

may trust the institution because they trust the individual researchers and

research coordinators.

This type of trust – primarily trust of individuals – seems most apparent. In

my research, many participants commented on the competency of the research

coordinators and nurses and their belief that they would not personally harm

them as participants. Trust of the institution and trust of the governance system

is gained through these trusting personal relationships. MacDonald and

associates (2008) found that the trust participants place in researchers and

research was conditional and dynamic. In my research, I found the trust strong,

although not absolute. However, participants would display distrust in the larger

organization of research, not the individual researchers. For example, the cancer

study participant who thought that the scientific community had already found

the cure for cancer, and the asthma study participant who did not trust that the

sponsor would use his ethnic background data appropriately.

Participants' understanding of themselves also helped them assess risk.

Their own tendencies, bodies, and personalities influenced how they approached

the risks. Interestingly, cancer study participants did not describe how

knowledge of their bodies or certain personal traits or qualities helped them

assess the study risks. The diagnosis of a chronic disease can cause people to

question previously held beliefs about themselves and their bodies (Scheper-

Hughes and Lock 1987). However, participants of the other studies used their

knowledge of themselves to help them assess risk.

> Some people might want to have all of the facts. I'm more of a
> person who likes not having unhappy news if it isn't impacting me
> right now. Some people I'm sure want to know all of the
> possibilities. (AP16)

> To me the risks – I don't look at them the way because when you
> know what they're going to do you know your own risks. (AP3)

> Always being positive. I'm not afraid. I don't think about the side
> effects. (MP4)

> But, I am not a nervous person so I am not worried about these
> things. (MP5)

Finally, participants generally were not overly concerned with the adverse

events. They often described them in minimizing ways, offhandedly, and almost

flippantly.

> For the most part the side effects didn't seem that bad. (AP5)

> As I understand them, I'm not sure if there are any risks that are
> that compelling other than I suppose there is a caution in the
> consent regarding minor side effects. (AP14)

> Inflammation, pain. Seemed [like] minor risks. (MP2)

> And really, it's localized damage so if anything happened it would
> not be life threatening or debilitating. (MP1)

Fatigue. Dry mouth. Nothing serious. (P2)

Just the side effects, that's the risk. (P4)

Participants I met tended to assess risk based on their perception of the

governance in place (influenced by their trust in the researchers and research

coordinators), their own orientation towards risk, and their perceptions of

adverse events, which they felt to be either unlikely or negligible.

What was striking was how local environments, personal relationships,

personal qualities, and perceptions of harm influenced how participants assessed

risk. I believe that these were all intertwined, and that perceptions of safety and

the competence of others, perceptions of the self, and perceptions of adverse

events all influenced each other. For instance, when one asthma study

participant found the bone marrow test painful, her attitude and demeanour

changed and she was more critical of the study. This illustrated the

interrelationships between the above mentioned factors, as well as their

temporality. Thus, risk in medical trials is a complex phenomenon, which is

individual, personal, environmentally dependent, and temporal.

It is my experience that most REBs do not appreciate how relationships

and institutional and professional reputations influence participants' perceptions

of risk, other than in the case of physician-researchers. The inherent trust of

university-based research and researchers makes participants feel safe and well

cared for. They are not the experts, but assume that the experts are following

safe practice guidelines and are themselves risk averse. From my own

observations, I share this belief with participants.

However, that is not the point. The point is that participants behave and

make decisions based, at least in part, on social relations and institutional trust

and not simply on reading the consent form and understanding its statistical or

epidemiological calculation of risk. Although REBs are well aware of the trust

participants have in physicians and how this trust and confusion regarding the

role of the physician-investigator may influence informed consent, I do not think

they appreciate that there is an inherent trust in the system and the sense that

the system will not hurt them. The informed consent process is a social process

and not simply a contractual one.

D) Informed Consent

The TCPS (Interagency Secretariat on Research Ethics 2005) states that "free

and informed consent must be voluntarily given, without manipulation, undue-

influence or coercion". Free and informed consent incorporates many of the

guiding principles in the TCPS, most notably, the imperative of respecting

individual dignity and respect for individual autonomy. When someone consents

to research, they are not required to fulfill any obligations, although the

researchers may ask them to follow a number of directions and instructions.

Providing informed consent means that the participant understands what will be

asked of them and the potential risks and benefits associated with their

participation. What exactly is informed consent? Prominent and influential

bioethicists Beauchamp and Childress (1989) state that informed consent

requires (1) substantial understanding (2) lack of coercion, and (3) intentional

authorization.   It is important to note that informed consent does not imply a

contractual relation.

Many academics have critiqued this notion of informed consent. Corrigan

(2003) found that cultural, social and emotional contexts of participants

influenced their approach to research, complicating the model of informed

consent.

> There needs to be a realisation that the type of illness a patient is
> suffering from, her anxiety about the likely trajectory of her illness,
> her expectations about treatment and, in general, her implicit
> trust in the doctor and medical science mean that 'informed
> choices' based on an adequate understanding of the information
> and on careful consideration of the potential benefits and risks,
> are difficult to achieve in practice. (Corrigan 2003:789)

Fisher (2006) also contends that informed consent is difficult to achieve due to

what she calls "procedural misconception". This is the "tendency for individuals

to make false assumptions about research by responding to what is similar to

other non-research contexts and overlooking what is different" (Fisher 2006:253-

4). Most people are not familiar with the context of a medical study, but they

are familiar with medicine, so they may not pick up on cues about the risks

inherent to the research setting. Epstein contends that informed consent is a

"legal fiction[74]" because "it presupposes a certain degree of autonomy, but

rarely, if ever, reflects it" (Epstein 2007:363). This author's analysis reflects

Fisher's, because he states that the notion of informed consent requires that:

> full responsibility is imposed on patients who are not fully
> responsible for the choices they make. At the same time, the
> fiction exempts society, the state, healthcare institutions and the
> medical-industrial complex from responsibility for the patient's
> choice. (Epstein 2007:363)

The concept of informed consent is founded on respect for persons and personal

autonomy. However, informed consent is a "fiction" because it relies on ideal

autonomy. Sherwin (2000) argues that the purely autonomous subject is a

thought experiment and not grounded in how people live, for they live in webs

of relations and power. When we have the right to make our own decisions

these are heavily influenced by our relationships with others (for example, the

physician-investigator) and our own situations (facing death, economic

hardship). Sherwin's (2000) notion of relational autonomy takes into account

that our autonomy is dependent upon our social and personal contexts, and is

both spatial and temporal. In different places and at different times our personal

autonomy can be shifted, limited, or expanded. This nuanced notion of

autonomy contrasts with how it is used in practice – where it is thought of in

binary terms – either you have it, or you have it taken away.

E) Consent Forms

In most cases the ideal of informed consent manifests itself as a consent

form, which research participants must read and sign prior to engaging in the

study. Although the TCPS contains guidelines regarding what information should be included in the consent form, particular requirements in terms of wording, format, and content vary by institution (which causes many researchers who do multi-sited research enormous frustration).   In more recent years, the consent forms have become more detailed and lengthy (Loverde et al. 1989;Tarnowski et al. 1990), and consent form length tends to increase with the risk of the study (Mader and Playe 1997). The FDA has tried to simplify, shorten, and standardize clinical trial consent forms, and this shortened format may enhance understanding and information retention (Dresden and Levitt 2001). Empirical research suggests that lengthy and complex consent forms are onerous for participants (Cannold 1997;Christopher et al. 2007) and make it difficult for them to assess the risks and the benefits of the study and what is required of them (Dubler 2002;Iltis 2006;Jefford and Moore 2008;Wray et al. 2007).

My own research corroborates these findings. I asked participants to reflect on the consent form, the informed consent process, and to discuss the risks and their reasons for assuming them. The asthma study participants spoke critically of the consent form. They spoke of the consent form as a legal or bureaucratic necessity, conveying pessimism and danger, but not really indicative of the study. Two people referred to its contents as "mumbo jumbo".

> *I guess they have to put all that in, but it's just so much mumbo-jumbo. (AP16)*

> *In the written form they have to have all of the legal wording but if*
> *someone tells me it's shorter and condensed and get rid of all of*
> *the legal medical mumbo-jumbo and get to the important facts.*
> *(AP8)*

For some, the consent form was either only partly applicable, not informative, or

contained too much information.

> *Some of it you have to take with a grain of salt. Not all of that*
> *stuff is necessarily going to happen. Just read it through and*
> *figure out what pertains to you. (AP3)*
>
> *Do I think it was helpful? I don't think it influenced my decision at*
> *all. (AP11)*
>
> *You are monitored closely and there are doctors around so I'm*
> *not really worried about it. (AP4)*
>
> *They give you so much information. I guess they have to for the*
> *ethics. They tell you so many possible things that could go*
> *wrong. (AP16)*
>
> *I didn't read it. I gave it to my parents. They were sceptical.*
> *They didn't think it was a good idea. But, I decided I would do it*
> *anyways. (AP15)*

Participants read parts of the form as not applicable, medical or legal mumbo-

jumbo, or written for the ethics board, and not for participants. Others said it

did not influence their decision making. These findings indicate that a patient-

centred consent form for paid volunteers requires a different format.

I presented these data to the asthma lab. I argued that due to trust in the

researchers, participants' enjoyment in their work, and the details of the consent

form, this form was more of a barrier than a facilitator of informed consent. I

also presented other data about the experiences of their participants. In general, they were happy to learn about the experiences of research participants and learned about aspects of doing research that they had never considered. With regards to my messages on informed consent, however, the researchers wanted to know what they could do to get the participants to read and understand the consent form. The lab members did not (or felt they could not) appreciate that there were good reasons why participants did not read or take the consent form seriously and that this was not necessarily the only measure of informed consent. It became apparent to me that those researchers had been taught that reading and memorizing the consent form was necessary for informed consent. It was difficult for them to consider the social and logistical reasons for not engaging with the consent form due to the 'rule' that the consent form was a necessary instrument for obtaining informed consent.

The cancer study consent form was organized in the same manner as the asthma study consent form, had the same types of information, but was notably shorter (12 vs. 17 pages). This may be the case, comparing Phase 1 and Phase 2 study consent forms, because there is more known about the drug in a Phase 2 study. Therefore, there is more information to communicate to participants. The responses from the cancer study participants were very different, which may be partly explained by the difference in length. They all spoke highly of the informed consent process and indicated that the information was helpful and accessible.

How helpful was it? Very. It helped me make my decision. It explains everything, but [research coordinator] sat down with me and explained everything that was in there and that was helpful. (P5)

Read the consent form thoroughly. I did and it was incredibly helpful. It had all of the information I needed. Don't be afraid to ask questions. They're really good about that here. (P9)

These types of responses are common among Phase 1 cancer study participants. In general, participants of these studies indicated that they found the information they received adequate and helpful. Participants alluded to the role the consent forms played in the entire consent process. It was not the consent form in isolation that was helpful, but the consent form, in conjunction with face-to-face discussions that was helpful. This agrees with Schaeffer and colleagues' (1996) suggestion that in order to improve the informed consent process, researchers should concentrate on more and improved face-to-face discussions. In a study of Phase 1 cancer trial participants, 95% of the 144 respondents said they understood all or most of the consent form and 92% found it very or somewhat helpful (Daugherty et al. 2000). In a similar study, Hutchison (1998) found that of the 24 respondents, 86% indicated that they understood most or all of the consent form. Although participants of Phase 1 cancer trials are generally pleased with the consent process, when quizzed about the methods, purpose, and risks of the study participants often cannot remember the details (Daugherty et al. 1995;Joffe et al. 2001).

Another possible explanation of these participants' positive perceptions

of the consent form is that as cancer patients, these individuals were

accustomed to consent forms. Before receiving radiation or chemotherapy,

patients must read about the risks and benefits of the procedure and provide

written consent to undergo the procedure. Cancer patients become accustomed

to reading about medical procedures and their risks and benefits. They have

become comfortable with the "mumbo-jumbo" of consent forms, understand

the medical vernacular, and are habituated to reading and digesting the

information contained in consent forms.

The TCPS lauds a "subject-centred" approach, but the length and detail of

consent forms seems to be going in the opposite direction. An outspoken lawyer

explains the reason for this trend:

> But something happened to the doctrine of informed consent on
> the way to the ball: it got mugged by the corporate, institutional,
> and administrative risk mangers whose focus is singular and is
> directed at the goal of protecting the entity, whatever its form,
> from possible later liability... This goal – and no other – is reflected
> in "informed consent" documents, which neither inform nor
> empower, but rather dump all of the possibly foreseeable –
> however remote – risks on the patient. (Dubler 2002:567-8)

Moreover, what is written on the consent form does not necessarily related into

practice. Petryna's (2009) informants who were employees of CROs confessed

that how they describe their studies does not necessarily reflect what is written

in the consent form. In addition, in the current regulatory environment

meticulous record keeping proxies for ethical conduct.[75] Michael Burgess has a

less cynical explanation for the format of the consent form – what he labels

"bureaucratic informed consent". He agrees that the consent forms are long and

complicated, but feels that it is informed by respect for participants rather than

risk reduction.

> The substantive notion of informed and voluntary participation
> supports a response that the information could be considered
> important by a research participant, so participation based on less
> information may be uninformed and therefore invalid consent and
> a less respectful relationship. (Burgress 2007:2287)

This debate about whether consent forms should contain less or more

information is interesting, although I confess preference for Dubler's position

because it is more critical. However, both arguments skirt the issue of exactly

what information should be included and why. Certainly consent forms could be

longer. They could also be shorter. Why have certain researchers, sponsors, and

REBs chosen particular formats? Moreover, what kinds of information do

participants want and need to make a so-called informed choice?

Testing the understanding and retention of information contained in a

consent form is one method of determining whether informed consent exists.

However, if a participant cannot recall the information in the consent form or

professes to not having read the form very carefully, this does not prove the

absence of informed consent. The participant may have understood at the time

of giving consent, but subsequently forgot the details. Alternatively, the

participant may not have understood or read the consent form, but heard and understood the information when it was communicated orally. Reliance on a bureaucratic written consent process need not exclude other forms of providing and ensuring informed consent. Therefore, the asthma study participants' dismissal of the consent form is not proof that they did not provide informed consent to participate. Rather, it shows that they found the consent form an obstacle, rather than a tool to understanding the study and providing their informed consent.

I have limited insight regarding what exactly participants need in order to make informed decisions. I feel that from discussing informed consent, consent forms, motivations, and risks with participants in different types of studies, it is clear that informed consent needs differ between studies. Phase 1 participants want to be informed about all that is known regarding the experimental drug, including human tissue studies and animal studies. Phase 2 participants, however, are less interested in animal studies and bench studies since the drug in question has already been tested on humans. Animal study summaries are met with humour and confusion. Thus, certainly different types of studies require different consent form formats.

I also wonder how consent forms can be formatted to engage participants in the research and help them determine what they want from the study and how they would react if the study did not fulfill these wants and

desires. Can they include quotes from participants who have enrolled in similar

studies about their experiences? Can they pose questions to the participant to

help them engage in the study, think about the risks, think about their own

motivations, and the possible motivations of the researchers, institution, and

sponsor? What about a short consent form, with a longer background

document which is optional for participants? These suggestions move away

from information dumping, and move toward creating a more interactive

document. Clearly, more creative thinking and research is needed (with the

involvement of research participants) about what type of information

participants need and want and what format works best for them. However, this

suggestion assumes that consent forms are designed to enhance participant

understanding, engagement, and empowerment. If, in fact, they are primarily to

assuage the risk managers of institutions and sponsors, as Dubler (2002) and

Fisher (2006) suggest, then this approach would be misguided because it would

be a waste of resources and time.

F) Cancer Study

i)　　Motivations of study participants
Phase 1 studies are inherently riskier than Phase 2 or 3 studies because

less is known about the experimental drug's effects on humans. In 2006, we

were reminded of the unpredictability of Phase 1 studies when six Phase 1 study

participants testing the monoclonal antibody[76] TGN-1412 had serious adverse

reactions after one dose of the drug. They were all healthy male volunteers paid

£2000 by a Contract Research Organization (CRO) for their participation. The drug development company TeGenero (TGN-1412 was its first product) hired the CRO Parexel to conduct the clinical trial.

All volunteers received the same dose of the antibody (which was 500 times less than the dose tolerated by monkeys in the animal studies) at the same time and within minutes all complained of pain, excessive heat, and nausea. One newspaper reported that they began "screaming and begging for help" (Leppard 2006). Their heads began to swell and their organs began to shut down. They were all immediately hospitalized and two slipped into a coma. One participant was in a coma for over a month and had several fingers and toes amputated. All are now at increased risk of cancer and other immune-system related diseases (Poses 2006). These men were primarily motivated by the study remuneration, as expected in most CRO-organized studies. In fact, one was a professed regular clinical research participant (Rogers et al. 2006). An interesting and unexpected fallout of this incident was a dramatic increase in the number of volunteers and inquiries into private research studies in the UK (Knight 2006). Because this story became international news, many people who were previously unaware of the income potential of these types of studies became informed and intrigued.

Phase 1 studies in healthy volunteers differ from what are termed "therapeutic" Phase 1 studies, where the experimental drug is tested on people who suffer from the disease it targets. People with refractory cancer and AIDS

sometimes enroll in these "therapeutic" Phase 1 studies. The implication is that

although the Phase 1 study in question is designed to determine toxicity and side

effects, the drug may have some therapeutic benefit so people who may benefit

from drug are sought to participate. In fact, the response rates (partial or

complete shrinkage of tumour[77]) in Phase 1 oncology studies are on average 5%

for single drug studies (Decoster et al. 1990;Horstmann et al. 2005) and up to

18% in combination drug studies (pairing a new drug entity with an approved

anti-cancer drug) (Horstmann et al. 2005). Patients, rather than healthy

volunteers are often sought because some consider the risk/benefit ratio too

high for healthy volunteers (Khandekar and Khandekar 2008).

In Canada, in Phase 1 cancer studies conducted at public institutions,

participants are not provided with remuneration, save to cover any minor costs

related to travelling to the study site. In addition, healthy volunteers are not

eligible. Only cancer patients with cancer which does not respond to standard

treatment are eligible for enrollment. During one of the REB meetings I attended

this issue came up and the board wanted to ensure that participants were not

receiving the experimental treatment of a Phase 1 cancer study in lieu of

standard therapy. After the meeting, one of the board members asked me if I

understood why that was the case. They explained to me that Phase 1 studies

are not treatment, but research, and if participants can be treated, they should

be treated using standard therapy. Only those who can no longer be treated by

known therapies should enroll in a Phase 1 study.

If not for money, why do people enroll in these studies? According to the literature, they enroll for altruistic purposes, to help other people with cancer, or to help their relatives who may one day get the same form of cancer (Burnet et al. 2004;Cox 1999;Daugherty et al. 1995;Daugherty et al. 2000). They also enroll to help medical science, as a thank you for years of care and nurturing (Hutchison 1998;Miller 2000). Some also participate in studies to try to extract some meaning and purpose from their illness (Cox 1999;Moore 2001).

However, many studies have concluded that the vast majority of participants enroll in Phase 1 oncology studies primarily in hopes of receiving some medical benefit (Cox 1999;Daugherty et al. 1995;Daugherty et al. 2000;Daugherty et al. 2008;Hutchison 1998;Moore 2001;Sessa and Cavalli 1990). The most commonly anticipated medical benefit, is tumour response; a shrinkage or disappearance of the tumour (Cox 1999;Daugherty et al. 1995;Daugherty et al. 2000;Hutchison 1998). The medical benefit can be psychological; studies suggest that the end of treatment can be devastating to some cancer patients. Continuing treatment, in the form of an experimental drug, postpones the end of treatment and helps the patient (and care providers) maintain hope (Cox 2000;Miller 2000;Moore 2001). Others enter studies with the belief that they will have access to the best and brightest oncologists and will receive excellent care (Moore 2001). Indeed, some research suggests that being in a study is in itself therapeutic because patients receive more care (more tests performed, more frequent monitoring), although arguably not better care (Braunholtz et al.

2001). However, this so-called 'trial effect' is inconclusive (Peppercorn et al.

2004).[78]

In line with other study findings, the Phase 1 cancer study participants

indicated that they enrolled in the study primarily for medical benefit –

specifically, to shrink, or at least, halt the growth of the tumour. Participants

spoke of the imperative they felt to continue treatment, to continue fighting.

The "end of treatment" was frightening for many people with progressive and

life-threatening diseases. Enrollment in a study prolonged the participant's fight

against cancer and ensured continued health care and treatment. A cure may

not have been possible, but continued care was, through Phase 1 study

enrollment.

Participants' discussion of their desire for further treatment is presented in

the chapter "Rhythms of Research" where I discuss how participants spoke of

their imagined future by assessing risk. From this data, we see that participants'

primary motivation was to continue treatment. However, a significant secondary

motivation arose concerning the desire to help others.

> *To be truthful, all other medicines have been exhausted. I talked*
> *with my wife and we thought, at least with this trial there is*
> *something there, we are still trying. I can't give up hope. It is*
> *important to continue to do something. This could help somebody*
> *else hopefully. Whatever comes from this somebody will help from*
> *it. (P1)*
>
> *I had no choice when the other chemo didn't work. They gave me*
> *the option of going in this study. Doing nothing wasn't an option*

> *for me. It also feels good to still try and to help out. (P 7 from field notes)*

> *Why did I decide to sign up? To stay alive. And to help others. Eventually. (P9)*

> *I hope to help others, but I am mostly here to get more time. (P4)*

I include these data because I want to show that some people may participate in Phase 1 cancer studies even if they do not believe them to be therapeutic. One method of finding meaning in the suffering is through working on studies to help the prevention and treatment of cancer for future patients (Moore 2001).

Some research suggests that providers encourage potential participants to think of Phase 1 research as therapy in subtle, yet pervasive ways. Sankar (2004) observed informed consent meetings between research coordinators, physicians and potential Phase 1 cancer study participants. During an informed consent meeting, a study coordinator, study educator, and/or investigator explain the study to a potential participant, review information in the consent form, and answer any questions. Sankar (2004) found that care providers gave potential participants verbal cues that the study may give them some medical benefit. Since there is no direct evidence regarding the drug's anticancer properties in humans, care providers are discouraged from implying medical benefit to potential participants (Glannon 2008). This is delicate, because although the field does not genuinely know whether an experimental drug will be of benefit, individual researchers may feel less uncertain (Freedman 1987).

I did not witness informed consent meetings and, thus, I have no firsthand data to suggest that care providers led participants to believe that the study may be medically beneficial to them. However, research coordinators and investigators did seem to understand that participants were motivated by potential therapy. The following quote illustrates the awareness one physician had of their patient's motivations.

> *My oncologist approached me and asked me if I would be interested. I think that they looked into it first to see if any openings were available before approaching me so I wouldn't get my hopes up and then not have any clinical trial openings available, or I would not qualify for them, which was good. Why get your hopes up? (P3)*

Indeed, health care professionals are aware that participants enroll in the hopes of gaining medical benefit. One research coordinator who I asked why people participated in clinical trials responded:

> *To benefit themselves and – I probably see it more in the oncology population and probably more in the Phase 1 population because they know there isn't much left for them - if they can help someone else. (KI11)*

A principal investigator echoed this.

> *Anecdotally I can tell you that some people approach trials in terms of access to a new drug. In Phase 1 and 2 the person gets the drug and you monitor their response – toxicity, side effects, tumour size. The person wants access to a new drug and they work on determining which one would work best. (KI10)*

Thus, at least some care providers are consciously aware that patients participate for medical benefit.

Due to the fact that participants may be interested in a Phase 1 study because they want to continue receiving treatment when standard treatment is no longer an option, a research coordinator stressed that they were going to start mandating to referring physicians that when patients get referred for a Phase 1 study they also get referred to palliative care.

> *[The referring physician needs to] have that discussion with the patient – I have nothing for you, your disease is not responding. You need to broach that with the patient because we get these patients who are referred and they think we're going to give them some kind of magic cure and that's not true. We find that patients are referred and then we're dealing with end of life issues.... They at least need to plant that seed, because then we're stuck planting the seed and it's very hard.... And it's not fair to the patients because they haven't had that opportunity then to do the things that they want to do and to tie up the things they want to tie up. (KI6)*

Referring patients to palliative care sends a clear message that they do not have a good prognosis. It also provides patients with an alternative to further radiation therapy, genetic therapy, or chemotherapy (Byock 2003). Although no study participants mentioned being referred to palliative care, or palliative care as an option, participants seemed keenly aware that their chance of recovery was low and their prognosis bleak.

> *They didn't give me any promises. This is a trial, so an improvement is a bonus. I guess the main concern I have is that nobody knows what's going to work. (P1)*
>
> *You also don't know what's next if this doesn't work. I'm running out of options. (P4)*

The study represented another chance to continue treatment. However, for

some participants this hope for remission or improvement was not without

precedent. Some had had excellent and encouraging experiences with

treatment in the past.

> *Don't hesitate [in enrolling in a study]. It could save your life, or*
> *someone else's. This is it. You have no other choice. If you're*
> *down to a trial of some sort, I say go. I could have died – the first*
> *time I had cancer, if they hadn't have caught it I would have been*
> *dead over a year ago. It was that close. (P9)*

> *I was on a trial once before. I did well for one year and then I*
> *broke out into hives…. It was devastating to be taken off the drug*
> *because it shrank the tumour in half. (P1)*

In summary, participants' primary motivation for enrolling in the study was to

experience medical benefit. Some people indicated a secondary benefit, to help

others. Participants themselves expressed a strong desire to continue treatment

and a strong desire to shrink or halt the growth of their tumour. From where

does this hope emerge? As we saw above, hope can come from previous

positive experiences battling cancer. It also emerges from encouragement from

and concern for family and friends.

> *I have to say I initially felt guilty when I was first diagnosed with*
> *cancer. The support for people with cancer, especially breast*
> *cancer, is so much greater than for other diseases. Cancer is*
> *difficult, but day-to-day not as gruelling as many other diseases.*
> *When I got cancer, people baked me cookies, went on walks, runs,*
> *wore ribbons, everything. (P6)*

> *This is tough for my wife. I want to do what I can to make her feel*
> *that I haven't given up. (P1)*

My wife has helped enormously. She is remarkable. I can't believe the things she can do. She just knows when I need something. (P9)

I spend time here so hopefully I have more time to spend with my family. Why else would I come here? (P4)

Spirituality is also a source of support and encouragement.

I have faith. I can't imagine doing this without faith. It would be so difficult. I have faith and it's not to say that I'm going to sit back and do nothing. Of course not. Otherwise I wouldn't be here. But having faith helps you get through these difficult times and when things seem bleak you are okay with it. You can persevere. (P8)

This informant's faith allowed her to continue to fight the disease. Others have studied the influence of faith on study experience. Weinfurt and associates (2008) found that greater expectations of trial benefit were associated with religious belief.

ii)   Hope
In their work on American oncology and hope, Good and colleagues (1990) argue that cancer research is dependent on popular American narratives of hope. In this framework, a cure for cancer is possible only if patients and physicians maintain hope and perseverance. Medical research can fuel hope and channel perseverance for patients and physicians alike. The authors argue that the American discourse on hope makes cancer research reasonable, in what they coin 'the political economy of hope'.

The funding of cancer research both depends on and promotes a vision of cancer as curable. Thus, research and treatment

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> institutions, together with patterns of availability and promotion
> of particular anti-cancer therapies, search for treatments and cure
> by patients and their families, and norms of disclosure are linked
> in what we have chosen to call "the political economy of hope."
> (Good et al. 1990:60)

Since the 1960's, physician disclosure of a cancer diagnosis has become standard. Previously, physicians felt reluctant to diagnose patients with cancer, but today they feel that this is both necessary and appropriate. However, disclosure is an ongoing process, which occurs not just at diagnosis, but during discussions of prognosis and treatment. Although disclosure is the norm, oncologists tend to avoid full disclosure. They gauge how much information to provide the patient by evaluating the patient's demeanour and emotional status. Good et al. (1990) found that almost all oncologists attempted to instil a positive outlook in their patients; they felt a duty to provide hope. For many of these practitioners, hope was grounded in biomedical advancement and technology. The practitioners themselves hoped that through advancing technology and biomedical knowledge, and working at the cutting-edge of cancer treatment, they could prolong the lives of their patients (Good et al. 1990).

Although participants' individual experiences, perspectives, and traits influenced their reasons for participating as well as their expectations, they acted within a social and economic environment that enabled their hope. Study personnel may not have encouraged participants to enroll for medical benefit, but they were aware of their motivations, and, in that way, were possibly

complicit. From my observations of the interactions between the study

personnel and participants, the personnel closely monitored the participants and

developed close relationships with them and were very aware of their

motivations and feelings. Although study personnel may not have shared

participants' view that the study could be therapeutic, they shared their hope. I

found that I even wished participants "luck" in their studies and hoped that I

would later see them at the cancer centre, in their second or third round of the

study, indicating the study had some therapeutic benefit. I hoped what they

hoped – that they could continue treatment. Perhaps, even I contributed to their

hope. I know I certainly responded positively (with awe actually) to their

determination and positive outlook.

We receive many cultural and social cues to hope.[79] Hope is practically

synonymous with cancer. Whether it is the "Walk for the Cure", purchasing pink

waffle irons to "help fight breast cancer", or hospital banners promoting "hope"

and "excellence", we are taught to fight, to hope. However, this phenomenon is

not confined to cancer care; hope in general has particular cultural salience in

North America.   It is a modern form of settler optimism, peppered with faith in

the strength of individual will, with a hefty side order of belief in miracle cures.

These ideas have penetrated our economies, our relationships, and our hospitals.

I believe that the hope for a cure for cancer discourse distracts us from the

causes of cancer and the economic injustices of cancer drug development and

use. However, I do not want to be too cynical about hope. I want to recognize

its beauty and value. Although hope has been captured by late capitalism, which

masquerades loss of economic and social protections with freedom from

constraints and hope for an economic and personal "jackpot", hope is a healthy

social ingredient. Hage (2003), in his work on nationalism explains:

> [S]ocieties are mechanisms for the distribution of hope, and that
> the kind of affective attachment (worrying or caring) that a society
> creates among its citizens is intimately connected to its capacity to
> distribute hope. The caring society is essentially an embracing
> society that generates hope among its citizens and induces them
> to care for it. The defensive society... suffers from a scarcity of
> hope and creates citizens who see threats everywhere. (Hage
> 2003:3)

The hope of cancer study participants and study personnel is remarkable. It does

not come out of what came before, but in spite of it (Zournazi 2002:24). This

hope draws people together and can transform them, giving them new outlooks

and ideas for ways of engaging with the world. These are the two sides of hope –

hope as a fantasy which prevents us from engaging in the business of preventing

cancer, and hope as a catalyst for bringing people together and transforming

what is possible. I believe that there is a place for hope in medical research and

in cancer research in particular. I do think that much can be learned about how

hope is generated and used by participants to help us rethink our larger

approach to research and cancer care.

iii)   The Therapeutic Misconception
Some bioethicists find using Phase 1 trials as vehicles for hope problematic.

Many bioethicists use the term "therapeutic misconception" to describe a

participant's lack of understanding that the purpose of the study is to inform

research, not provide therapy. Applebaum et al. (1982) first coined the term

"therapeutic misconception", particularly in relation to placebo-controlled trials.

If participants' goals are to receive therapy, one of the risks of a placebo-

controlled trial is that participants will not receive a drug, but rather a placebo.

The authors explain:

> Their reasons for joining the study are solely to receive additional
> help, but they are unable to identify and take into consideration
> those aspects of the research design that might interfere with that
> goal. Their underlying "trust" that the investigator will act in their
> best interests, often based on a positive interpersonal relationship
> with the investigator, hampers their ability to pursue their
> interests effectively. (Applebaum et al. 1982:327)

This "therapeutic misconception" – that there are elements of the study that

may interfere with their own therapeutic goals – Applebaum et al. (1982) suggest

hinders participants' ability to appropriately evaluate the risk/potential benefit

ratio. As Applebaum et al. later wrote, "to maintain a therapeutic misconception

is to deny the possibility that there may be major disadvantages to participating

in clinical research that stem from the nature of the research process itself"

(Applebaum et al. 1987:20).

In Phase 1 cancer studies, this therapeutic misconception is common –

participants commonly enroll because they hope that the study will be of

therapeutic benefit. However, the purpose of the study is to determine toxicity,

not to treat patients. In this way, the goals of participants are not congruent

with the goals of the researchers. Some believe that it is the duty of researchers

to indicate explicitly that their Phase 1 study is not therapeutic:

> We cannot continue to claim that, since the novel agents under
> investigation have never before been used in humans, any dose is
> potentially therapeutic. The opposite is true. Unless and until we
> know whether a given drug is effective, under what conditions, for
> which malignancies, and at what dose, these trials remain non-
> therapeutic and ought to be spoken of as such. (Glannon
> 2008:253)

Glannon (2008) suggests that consent forms explicitly indicate that the Phase 1

study is non-therapeutic and that a neutral non-physician educator complete the

informed consent process with potential participants and focus on the aspects of

the research that may be obstacles to the patient's own goals. However, neither

Applebaum and colleagues nor Glannon are optimistic that these steps will

eliminate the therapeutic misconception. Participants may understand the

methods and goals of the research very well, yet maintain the belief that it may

help them, either because of their hope for a cure or trust in the therapeutic

value and goals of medicine (Kass et al. 1996). Others have suggested that since

participants do have therapeutic goals, that these goals should be acknowledged

and accommodations made. For instance, researchers ought to make efforts to

ensure participants receive what researchers believe to be the most effective

dose, rather than an assigned dose – which may be too low as to be ineffective or

too high as to be toxic (Miller 2000).

The debate, then, seems to be whether continuing to enroll participants in Phase 1 studies, who enroll because they are seeking medical benefits, is ethical. For some, it is a question of informed consent. If participants believe they will receive medical benefit then perhaps they are not fully informed and, thus, their consent is not valid (Daugherty et al. 1995). There is evidence that suggests that participants are not fully informed because they cannot recall the purpose or risks of the study. One study that surveyed 144 participants of Phase 1 cancer studies found that 61% of participants thought the purpose of the study was to determine drug effectiveness, and only 27% thought (correctly) that it was to determine dose/toxicity (Daugherty et al. 2000). In another study, 155 clinical trial participants were surveyed about the disadvantages and risks of the study they were enrolled in and 24% could not list any risks or disadvantages, 46% mentioned side effects associated with the experimental therapy, and only 14% mentioned risks or disadvantages associated with the study's design itself (Lidz et al. 2004). Investigators surveyed 207 participants enrolled in cancer clinical trials and noted flaws in their understanding of the purposes and designs of the studies. Seventy percent did not understand the unproven nature of the research, 74% did not recognize non-standard treatment, and 63% did not understand the incremental risk of participation (Joffe et al. 2001).

Some researchers have found that participants are not the only ones who misunderstand the goals of clinical research. In their study, Joffe et al. (2001) surveyed 61 physician/investigators of cancer study patients (in Phase 1, 2, and 3

trials) from three hospitals. They found that less than half (46%) of the

physician/investigators recognized that the purpose of clinical trials was to help

future patients. Thus, physician/investigators can also be vulnerable to their own

therapeutic misconceptions. This reflects their dual role as both a health

provider and researcher and their honest desire to provide their patients with

the most and the best options. The research team concludes:

> How best to reconcile legitimate hopes for benefit with the need
> to help research participants understand central concepts of
> clinical research remains an essential unanswered question in
> research ethics. (Joffe et al. 2001:1776)

In a later study, Joffe and Weeks (2002) mailed surveys to 1120 American

oncology specialists to learn about their reasons for enrolling patients into

clinical trials and their thoughts about the purposes of clinical trials. Of those

surveyed, 547 responded. The results reflected the previous study.

> Many respondents viewed the main society purpose of clinical
> trials as benefiting the participants rather than as creating
> generalizable knowledge to advance future therapy. This view,
> which was more prevalent among specialists such as pediatric
> oncologists that enrolled greater proportions of patients in trials,
> *conflicts with established principles of research ethics.* (Joffe and
> Weeks 2002:1846) (emphasis added)

The authors suggest that supplemental provider education, in addition to patient

education, is needed to help reduce the therapeutic misconception of all parties.

I am doubtful that hope can or should be a target for re-education.

Kimmelman (2007) highlights how the interpretation of therapeutic misconception has changed in the more than 25 years since it was originally formulated and suggests that the modern interpretation is overly restrictive and myopic. According to Kimmelman, the original term referred to patients' lack of appreciation of how the constraints of research could conflict with traditional medical practices; whereas the more modern version refers to "the mistaken belief of research participants that the research project will directly benefit them" (Kimmelman 2007:37). Some ethicists have created a binary division between research and care and, thus, to partake in research with the goal of care is misguided. Indeed, to partake in research for therapeutic purposes when only a very small percentage of participants is likely to receive any response from the drug, has been interpreted as an "unrealistic expectation of medical benefit" (Henderson et al. 2006).

> The idea that subjects misconceive trials because they overestimate benefits or underestimate risks implies that some perceptions of risk and benefit are "correct" and others are "incorrect" and that ethicists and clinicians are well positioned (or at least better positioned) for deciding which perceptions are appropriate. (Kimmelman 2007:38)

To demand that participants have the same goals as researchers (to increase knowledge, forward research and practice) or ethicists is unsympathetic to the needs of cancer patients and contradictory to the practice of Phase 1 cancer trials.

Some have argued that cancer patients are, in general, less risk averse than those who are not facing a terminal illness. Thus, for them, a rational or reasonable decision takes place in a very different physical and emotional milieu. Slevin et al. (1990) surveyed 100 newly diagnosed patients in a cancer ward, matched healthy controls from the community, oncologists, general practitioners, and cancer clinic nurses. They asked them about what minimal benefit would be necessary to deem two different types of hypothetical chemotherapy regimens – an intensive regime and a much milder program - acceptable. The required benefits for the regimes were lowest for cancer patients, then oncologists, and highest for the healthy controls. The authors conclude:

> Patients with cancer are much more likely to opt for radical
> treatment with minimal chance of benefit than people who do not
> have cancer, including medical and nursing professionals. This
> should be taken into account when discussing treatment options
> with patients and their relatives. (Slevin et al. 1990:1458)

What I find interesting about this study, are the radically different responses between cancer patients and healthy controls. Cancer patients required a 1% chance of cure, an additional 12 months of life, or a 10% relief of symptoms to enroll in the intensive regime. Healthy controls required a 50% chance of cure, 24-60 months of additional life expectancy, or 75% relief of symptoms to enroll. These findings help describe the vast differences in perspective and assessment of risk/potential benefit between the populations. A principal investigator,

reflecting on his own observation that cancer study patients seem much less risk

averse than healthy persons, astutely remarked:

> *Part of it is how people conceptualize risk. If you're thinking about*
> *it from a frame of being healthy, but those individuals have a*
> *different frame of reference which makes them think in a very*
> *different way. It may not be that astonishing or daring because*
> *the day to day really isn't acceptable. I guess we're all going to*
> *have to face that some day. (KI10)*

Some authors writing about the therapeutic misconception cite such findings to

argue that we must understand that cancer patients are willing to assume

considerable risk for a small chance of benefit (Kurzrock and Benjamin 2005).

Perceptions of risk are related to therapeutic misconception because patients

may enroll in a study knowing that it is research and not therapy, knowing that

there is only a 5% chance of response, yet they still enroll because they want to

continue treatment, they want to explore another avenue.

The pervasive concern about the therapeutic misconception in Phase 1

studies – that participants enroll for therapy when the purpose of the study is

not to provide therapy but to learn about drug toxicity and side effects – is

divorced from the reality of cancer patients and forces the goals of researchers

onto participants. I believe participants should understand that studies are

research and not therapy and there are aspects to a Phase 1 study that may

frustrate participants' therapeutic goals. They are accustomed to uncertainty, to

low probabilities, and to hardship and numerous tests. In these ways, research is

very similar to treatment. Certainly, there are some very distinct differences

between the two, but their striking similarities should make us feel more secure

that participants have a good idea of what they are agreeing to. Unlike healthy

volunteers who volunteer for the first time, these participants have a very good

idea of what the study will be like for them, possibly producing some of the most

"informed" consent in medical research.

G) REBs and the Therapeutic Misconception

There may be cases where, because patient and practitioner both hope for a

medical benefit for the patient, the study is oversold, and not presented as

research, but as a "new, experimental treatment". In these cases, if the patient

does not understand that the primary goal of the study is to help future patients

by learning about the toxicity and side effects of the drug, then they (and

perhaps their practitioners) I believe, suffer from a therapeutic misconception.

Some argue that these situations, although not ideal, are nonetheless not

unethical. Sreenivasan (2003) argues that a therapeutic misconception is

allowable because it does not change the risk/benefit ratio.

> If reliable independent judgment of a trial's risk-direct benefit
> ratio is favourable, an individual's ignorant decision to participate
> should not be treated any differently from an ignorant decision
> not to participate. (Sreenivasan 2003:2017)

The argument here is not whether the participants are adequately informed, but

whether the absolute risk/benefit ratio (as determined by a "reliable

independent" source) is reasonable, or "favourable". This is a compelling argument because it assumes that there is a method of determining absolute risk and assessing whether it is favourable. This is an attractive assumption, because it allows us to sidestep the central issue – the desperation of cancer patients and how this desperation can aid cancer research and cancer researchers. The conflicting actors and motivations can be ignored through the magic of risk assessment.

However, this assumption is not reasonable because there is no neutral position from which to assess whether a risk/benefit ratio is favourable. Risk and benefit are inherently subjective assessments as they rely on the interpretation of outcomes. At the same time, to say that an independent assessment of the risk/benefit ratio has no place in research ethics is also false because this is exactly what REBs attempt to do when they determine whether a study is allowable based on its risk/potential benefit. This can be difficult for REBs to assess because on the one hand, their duty is to protect research participants, and on the other hand they are hesitant to be "paternalistic" and are inclined to respect participant autonomy. The following are quotes from REB members.

> *We can't actually say a certain perspective is right or wrong for*
> *people – they decide that for themselves. All we can say is that it's*
> *important that you are properly informed so you can make the*
> *best decision for yourself. You can look at it from two totally*
> *different ways. It's the role of the board not to play Solomon but*
> *to ensure you have enough information to allow you to make that*
> *decision. (KI14)*

REBs have a duty to protect participants, but within limits. This seems like a

difficult position. Protect participants, yet respect their autonomy and do not be

paternalistic. Reduce risk, yet promote research. This is why informed consent is

so crucial in research ethics; these difficult decisions are delegated to (informed,

capable) participants. This is why the therapeutic misconception raises so many

eyebrows from REB members and research ethicists. If the cornerstone of

research ethics is informed consent, then it is extremely worrisome when

participants do not appreciate that they are participating in research when

research differs from therapy in important ways which may hinder their

therapeutic goals.[80]

At a recent conference I presented data summarizing the vast differences

between how the cancer study participants and the asthma study participants

reflected on their respective study's consent form (see section above entitled

Informed Consent). The cancer study participants all indicated that they found

the form readable and helpful. In fact, some read it over several times and

referred to it during the study. They could not all recount the risks of the study

or the exact details, but they unanimously described the informed consent

process as helpful and important. As we saw, in the asthma study, participants

found the consent form unhelpful, too detailed, and simply a bureaucratic

hurdle. My purpose in presenting this information at the conference was to

argue that different types of research and different participant populations

require different amounts and types of information in the consent forms. The standard format for consent forms for all studies does not take this into account and can overburden some participant populations, causing them to ignore rather than engage with the risks.

The audience, consisting primarily of bioethicists, were shocked and concerned about the therapeutic misconception the cancer study participants displayed. No one seemed particularly interested in discussing the format of consent forms. I was surprised by their reaction (I thought, from reading the literature, that the therapeutic misconception was common, complex, and, perhaps, unavoidable), but have since begun to understand more clearly why the therapeutic misconception is so concerning. In research ethics there are many unanswered questions, difficult situations, and competing interests. REBs protect participants, but are also agents of an institution and even promoters of research. REBs protect participants, but in a society where protectionism is often suspect. Where reasonable people cannot agree on something (e.g. whether participants should be able to enroll in a study), individuals simply decide for themselves. This libertarian attitude exists in environments, such as universities and hospitals, that the public generally trusts (Fisher 2006;Miller and Boulton 2007). Libertarianism and protectionism, in the case of university-based medical research, depend upon each other. In an environment where the conditions of research are heavily monitored and restricted, decisions regarding whether

participation is reasonable or not, are left to potential participants to deliberate. This requires informed consent.

Research ethics would be simpler if participants had the same goals as researchers, to produce reliable data to contribute to the development of scientific knowledge. Some participants have the same goals as researchers, although most either have additional or completely different goals (to earn money, to obtain access to novel therapies, to learn about a disease, to network, to help those doing the research). In Phase 1 cancer studies this divergence of goals can manifest as what many interpret as a therapeutic misconception. The therapeutic misconception would disappear if participants shared the goals of the research community.

In the other studies I followed, I found that researchers were amazed and encouraged when participants were motivated by the idea of helping research and pushing scientific discovery.

> *I think some people think they're giving back to society in some ways. It's almost like a public service. Some people volunteer at the local homeless shelter. Other people are involved in clinical trials. (KI9)*

> *You wouldn't believe the number who phone who want to learn more about their asthma or they would like to help asthma research. (KI3)*

> *I think some of it is altruism. I think the decision is not so much that I am going to participate in a randomized clinical trial, it is more that I'm going to help society, I'm going to help the doctors, the medical system figure out what the best treatment is. I may*

> *not benefit from it directly, but I'm going to somehow contribute*
> *by participating in research.... Something about how a human*
> *being does that amazes me. (KI10)*

To participate in research for the good of research, for the good of possible future findings is an altruistic act. Participants do it to accommodate individual researchers (as I saw in my own study, participants gladly and repeatedly gave of their time and thoughts) and for the greater good. Participants give of their time and assume some additional risk, or at least inconvenience, to participate. If participants were motivated *solely* to learn and to contribute to society and research, rather than for therapeutic or monetary reasons questions of coercion would shrink. We value altruism, but certainly do not expect it. Rather our reaction is often one of awe. The quotes above imply that the altruistic act is special and laudable.

Research participation in many ways is a beautiful act. It is courageous and altruistic. Medical research is a growing field and depends upon the willingness, trust, and courage of millions of people worldwide. These people have shown me that, despite my cynicism, altruism is alive and well. However, as I have shown, altruism usually is not a participant's only motivator. Participants often have multiple goals and these goals can change during the study. It is unreasonable and unsympathetic for REBs to wish that participants always have the same goals as researchers.

H) Discussion

My data suggest that research participation is social, trusting, hopeful, and at times altruistic. In general, the research ethics literature and the REBs I have had the opportunity to observe do not appreciate these elements of research participation. For historical, philosophical, and bureaucratic reasons, these elements are rarely unpacked. The issues are framed in terms of personal rights, understanding, and motivations. The community dynamics of research institutions, researchers, research coordinators, and participants are rarely appreciated. The focus is primarily on risk reduction, not benefit maximization, and on individuals, rather than communities.

Researchers, research coordinators, and imagined actors such as the institution and future patients, all influence participants' perceptions of risk, motivations, and behaviour in studies. These influences are complex and unavoidable. By learning more about these relationships and influences, REBs and ethics scholars can expand their questions about research ethics. This would necessitate REBs to consider questions of who benefits from research, what kinds of research seem reasonable, and how assumptions about research and research participants frame their evaluations of research proposals. Individual REBs are reluctant to ask these questions because they are extremely complex, most likely difficult to navigate, and more basically, perceived to be outside their institutional mandate.

A participant-centred approach requires us to acknowledge that participants have a more diverse set of interests and motivations than researchers. They share some of the motivations and interests of the research community, but also face more pressing issues such as sickness and financial instability. However, the interests of researchers and institutions influence the interests of participants. It seems bizarre to suspect health and financial motivations, while not questioning the fact that participants often agree with and even share the interests of the research community. Hegemony is a phenomena in which working class people come to believe that the interests of the ruling class are their own interests, and, thus, provide their consent and support (Baer et al. 2003).

A good example of this is the belief amongst some Canadians that private health care is more efficient than public health care and by this virtue would be a better alternative to public health care. In fact, evidence shows that public administration and organization of health care is more efficient than private (Hollingsworth et al. 1999). Yet, somehow, this myth lingers in the Canadian political landscape. In research, the fact that many participants eagerly and comfortably participate in medical (and anthropological) research speaks to the power of the interests of universities and research communities.[81] This hegemony, combined with close relationships that develop in research, and the monetary and health benefits of some research, foster an environment in which

participants are rarely critical of the organization, function, or activities of

research.

If participants are rarely critical (and, moreover, do not have a collective

voice) who's role is it to be critical? Presumably, institutional REBs have some

role. However, they largely do not question the role of research, the good of

research, research agendas, and the assumptions and interests of participants.

This is not surprising because they are comprised primarily of researchers and

academics who do not necessarily feel empowered or inclined to broaden the

scope of the REB or take a more critical view of the organization of research.

These larger questions remain unanswered while the minutia of participant

autonomy, the therapeutic misconception, and risk education continue to

consume institutions, REBs, and researchers.

My data have a number of implications for REBs. Firstly, REBs need to

focus on reducing the length of consent forms and resist thinking of informed

consent from the researcher's perspective. Understanding the science and

methods of a study is not proof of informed consent. Participants want to know

what is required of them, what bad and good things could happen, and what

they should expect to happen to them in the study. They should not have to

wade through animal study data and statistics to obtain this information,

although it should be available for those who want it. Secondly, in therapeutic

cancer studies, participants are aware that Phase 1 studies have low therapeutic

probability, but participate anyway because they want to continue fighting their disease. Thus, a greater focus on what the research team *can* do for them, in terms of medical and emotional support, is appropriate. REBs need to focus more on the relationships between researchers and participants. Doing so will help them encourage researchers to look not just at reducing the risk of Phase 1 studies, but increasing their benefit.

Finally, REBs need to be less afraid of the influence of researchers on research participants. I believe that it is not possible to have a study that is free of influence. Research participants can experience social, economic, and medical benefit from their work in medical studies. These benefits, these friendships, these hopes implied by research (either hope for themselves or others) are the currencies of medical research participation. Yes, remuneration, hope for better medical care, and a desire to help researchers, can influence or even coerce participants. However, lack of influence implies lack of benefit. It also implies an absence of social contracts, public awareness, monetary realities, and trusting relationships. I believe that reducing risks while increasing benefits will engage participants more in research and create stronger ties between researchers and participants. It may also help researchers think about the social good of their research in new ways.

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[73] The report concentrates on the notion that there must be fair methods of determining who is and is not eligible to participate in research. Questions such as who benefits from research, controls research knowledge, and influences research questions are ignored.

[74] A legal fiction is a resort to pretence in the process of common law reasoning (Epstein 2007:362). It often involves using a legal rule out of context, to benefit one's particular position.

[75] Several authors have documented the lack of oversight for research involving humans. The reliance on the bureaucratic processing of research protocols and consent forms is not sufficient ethical governance (Schuppli and McDonald 2005:7). There are no systematic methods of controlling for REB conflicts of ethics, there are no mechanisms to measure the effectiveness of REBs, there is little coordinated follow-up, and there are no effective mechanisms for addressing fundamental, recurring issues, like participant remuneration (Brown 1998; Emanuel et al. 2004; McDonald 2001; McDonald 2005). These authors have delineated the broader and more fundamental under-governance which plagues research ethics, describing more fully what I refer to as "bureaucratic measures".

[76] Monoclonal antibodies are antibodies which have been artificially produced (not produced in the body) which bind to specific cells and can be used to block or encourage specific immune system responses. In the case of TGN-1412, it was designed to enhance T-cell expression and response, essentially resetting the immune system's response. Several experts have commented that these types of antibodies are unpredictable and dangerous to test. TGN-1412 was thought to have potential therapeutic benefit against leukemia and rheumatoid arthritis.

[77] Reduction of tumour size does not always correlate to clinical benefit, for example, reduction in pain, or increase in daily activity. A smaller number of people experience clinical benefit than those who experience tumour regression (Markmann 2006).

[78] One oncology PI also explained the numerous "biases" which contribute to the "trial effect". *"There's some data out there that suggests that people on Phase 1 studies have better outcomes than those who don't, but there's a huge bias there. To actually come on to a Phase 1 trial you have to have a quite good phenotype. You have to have decent health, good performance status; you have to be able to really care for yourself. They tend to be a bit more educated and knowledgeable so their outlook and mechanisms to get supportive care, eating well and exercising, they tend to do that a bit more. So there are probably enough biases to explain that."*

[79] Miyazaki (2004) defines hope as the "reorientation of knowledge". In end-stage cancer care, a very small chance at survival can be reoriented to mean a chance at survival, or conversely, imminent death.

[80] Pullman (2002) proposes a method which recognizes that the REB is asked to balance the interests of multiple stakeholders, not simply the interests of research participants, while protecting participants. He acknowledges that REBs recognize the interests of multiple stakeholders (universities, researchers, funders, participants) and from a social justice perspective argues that this is reasonable and advantageous. He then suggests that when REBs review protocols, they deliberate whether they are willing to provide provisional proxy consent. REBs understand research much better than most potential participants and if the REB feels that it would consent to a research protocol, the protocol is at that point in a form which is suitable for potential participants who can deliberate whether they will provide their own personal consent. I think that this would increase the scrutiny of the REB and provide them a platform and

mechanism from which to balance the interests of multiple stakeholders. However, I think that many patient-advocates would not approve of this process because it would reduce the risk (and therefore potential risks) of research overall. However, this is only an opinion and it would be an interesting experiment.

[81] Those who are most critical of research and academic activities presumably rarely participate in research. Those who trust the academy, science, and medicine might be the least critical, explaining why I found that they were generally excited about the research and trusting of the process and governance system.

CHAPTER 7: AUTOETHNOGRAPHY OF A RESEARCH PARTICIPANT

A) Introduction

Autoethnography is a method of both inquiry and writing. In autoethnography, the researcher's own experience is the source of inquiry. Ellis and Bochner define autoethnography as "an autobiographical genre of writing and research that displays multiple layers of consciousness, connecting the personal to the cultural" (2000:739).[82] This approach is a reaction to mainstream forms of scientific writing and inquiry where the "scholar is seen (in the credits) but not heard (in the text)" (Sparkes 2001:213). The researcher is a critical element of ethnographic inquiry and fieldwork and is never outside of it (Hastrup 1992:119). Autoethnography faces this reality head on by exploring the researcher's subject position, bringing to light what is deliberately or unconsciously hidden from view.

Autoethnography is in many ways a product of the postmodern and post-structural turn. A modern representation of research hides the author and researcher in a veil of neutrality and objectivity, claiming a disembodied truth (Lincoln 1997). Autoethnography can make explicit that the knowledge claims of the author are situated, temporal, and partial. Greenhalgh explains:

> In an effort to reduce power hierarchies and to scale back claims to authoritative knowledge, a new generation of critical anthropologists has turned to alternative forms of ethnography in which to do their work. Although its use remains rare in anthropology at large, and rarer still in medical anthropology, the auto-ethnography is a promising means by which to pursue these political and intellectual ends. (Greenhalgh 2001:54)

Autoethnography can encourage the reader to question the author's knowledge claims by undermining the assumed power of the standard distant authorial voice. This distant, rational voice is the voice of the colonial project (Gandhi 1998). Autoethnography is also sometimes used as a method for deeply exploring a particular phenomenon, but in this situation it is the ethnographer's own story (Greenhalgh 2001). Often these experiences are very difficult, complex, and emotional. The authors often use their own experiences to comment on, explore, or expand theory. For example, Greenhalgh (2001) uses her experience suffering from chronic fatigue syndrome to comment on medical authority, connecting her own data to those of other scholars. Rapport (1992) uses his experience doing fieldwork in a rural area in England to discuss how class and background can limit the type and amount of data collected and understood. Mykhalovskiy (1996) wrote about his experience of having his autoethnography peer reviewed to remark on the field's continued discomfort with autoethnography, regarding it as narcissistic, irrelevant, unscientific, and biased.

Readers and writers of autoethnography have suggested novel (and more appropriate) methods of judging its academic merit, which are different than the methods used to evaluate other forms of ethnographic inquiry. Ellis suggests its validity should be judged on whether readers feel it is "lifelike, believable, and possible" (2004:124). She also believes that an autoethnography's validity lies partly in its communicative power, opening up new avenues of understanding

between the author and reader. Richardson (2000:254) outlines five criteria she

uses to evaluate this type of writing: (1) substantive contribution, (2) aesthetic

merit, (3) reflexivity, (4) emotional impact, and (5) expresses a reality. Criteria 2-

4 are not commonly used to evaluate qualitative research and thus, it is these

that reviewers may find the most difficult to use in practice.

Rather than explaining how autoethnography should be evaluated, most

adherents describe what good autoethnography is. Ellis explains that writing

autoethnography is:

> amazingly difficult. It's certainly not something that most
> people can do well. Most social scientists don't write well
> enough to carry it off. Or they're not sufficiently
> introspective about their feelings or motives or the
> contradictions they experience.... The self-questioning
> autoethnography demands is extremely difficult. So is
> confronting things about yourself that are less than
> flattering. (Ellis 1999:671)[83]

A good autoethnography is often in the form of a story with characters, a plot,

and a timeline. It often highlights emotional experiences. In fact, good

autoethnographic writing is "truthful, vulnerable, evocative, and therapeutic"

(Ellis 2004:124). Moreover, it is "the celebration of concrete experience and

intimate detail" and connects "the practices of social science with the living of

life" (Sparkes 2001:210).

These sweeping descriptions, high literary standards, and moral

imperatives are intimidating to me. I am uncertain whether autoethnography as

a genre demands better writing. However, like all good writing,

autoethnography requires practice and dedicated study. Although I leave it up

to the reader to determine the artistic merits of this chapter, as in the other chapters, I believe it has a number of functional merits. It is an opportunity to explore my own physical, intellectual, and emotional experience, adding depth of analysis to breadth. I can also relate these experiences and reflections to the larger culture of medical research involving human participants. Finally, this approach will help the reader to gain an understanding of who I am as a writer (and a researcher, and a research participant), my motivations, perspectives, and biases.

In this chapter, I focus on my own individual experience as a research participant. I try to describe the sensations I have experienced and my own subjective reality of being a research participant. However, I also describe the social environment of research and remark on larger questions of research data ownership and how narratives of risk frame participant experience. This chapter, the final analytic chapter, spans all three bodies and in it, I try to demonstrate the fluidity of these bodies. Although I am aware of where my body ends and other bodies begin, these bodies (other individual bodies, the social body, and the body politic) influence my own subjective experience, which allows me to reflect on all three bodies. Autoethnography is a powerful tool for demonstrating the interactions of the three bodies and clarifying that there is only one body and a critical-interpretive approach is a powerful, yet limited method of analyzing phenomena.

B) Entry into the field

As mentioned in the methods section, it was difficult for me to find a study to enroll in. Few studies seemed to require healthy female volunteers over 30. I would often scour the hallways and billboards in the hospital and university looking for advertisements for research volunteers. One day I came across a study poster asking "Do you worry?" I did, in fact, worry. I worried about never completing my fieldwork. I worried about school, finances, and my future. Every day I was less sure about what I was doing, why I had decided to pursue a doctoral degree, and what my goals were. Graduate school was teaching me discipline and tenacity. It was also teaching me about who I was (although I wondered if my personality was simply a product of the institution – irreverent, critical, and indecisive). But, I was not learning what I wanted, other than to generally fit in and succeed. It had not made me more resilient either. Instead, I had become paranoid and jumpy, on guard for my next inevitable screw up. So, in short, I did worry.

The poster indicated they were testing an anti-anxiety drug against an anti-depressant on people with anxiety to see if one was better than the other. I initially did not like the idea of taking one of those drugs, but I thought that if I could feel a bit better for a while, and do some fieldwork, it would be alright. I knew that my worrying was connected to the emotional and financial precariousness of graduate school. Meanwhile, what sort of toll was this experience taking on my mental and emotional wellbeing, my personal relationships, and my personality? Maybe medicalizing my condition was the

best I could do at that time. It might get me through the rough spot, and, not inconsequentially, help me complete my degree. Millions of Canadians have taken or are taking medication for anxiety and depression. I felt comforted that these drugs were "normal". My partner Shane, however, was not. He was worried that the drug would have a negative impact on my cognitive functioning and mood. I think he used the terms "zombie" and "drone". I guess it was one thing to live with an anxious graduate student, another thing to live with a zombie.

I phoned the study coordinator, who asked me a few screening questions (age, medical history, medications) and then asked me to come in for an assessment to determine if I was eligible for the study. I visited the clinic about a week later. I was nervous. I wanted to be "crazy" because then I could get into the study, get some drugs and, perhaps, data. At the same time, I did not really want to be "crazy". Even in a culture that celebrates uniqueness and individuality, I did not want to be off the scale. This was the contradiction of social critique. We can criticize these normalizing processes, on paper resist their homogenizing effects, but in practice we are not immune to them and, in times of weakness, are whole heartedly influenced by them.

I arrived at the study office. I was told to sit in the waiting area (mint green walls, rounded corners, ugly still life silkscreens on the walls, and filled primarily with parents waiting for their children) and fill out a form with demographic questions. The intake person (a young attractive reserved woman

in casual clothing) greeted me and led me to her office. I sat down in the chair

closest to the door, hands in my lap, poker face on. She asked me what seemed

like hundreds of questions, questions about medical history, family health

history, medications, phobias, compulsions, anxieties, abuse, and substance use.

She did not appear to react to any of my answers. She simply asked each

question in the same detached voice and expressionless face. I interpreted this

as disinterest and not detachment. It made me feel rushed, although it did not

make me feel uncomfortable.

I did not answer all of the questions honestly. I under-reported my

alcohol consumption, how often I cried, and failed to admit to past psychiatric

diagnoses. I believe if we had not been rifling through so many questions so

quickly I would have given her the correct (and not the *corrected*) answers. I lied

because I was embarrassed of the truth, and worried about being judged by this

stranger with a pencil. It is curious that I lied about these topics. There is a

social stigma regarding drinking, mental illness, and emotional distress.

However, I do not think I would have lied about these topics in different

circumstances. For example, if it were a less clinical interview and a more

narrative-based interview, I believe I would have felt more comfortable telling

the truth as I would have had trust and connection with the interviewer. I also

believe that if the questions were asked outside of an institutional setting, I may

have been more honest. It was my experience that the interview structure and

setting facilitated psychiatric diagnosis, but discouraged full disclosure.

The cold rationality, quick succession of questions, and structured nature of the interview, reflected a medical-scientific approach to reducing confounding factors and illuminating the truth. The interviewer was to come across as "neutral" so as not to influence the participant. Neutrality is subjective, and in my case, I interpreted her demeanour as cold and judgemental rather than neutral. For me, this was a barrier to truth telling. I thought about correcting myself but I felt rushed and embarrassed. I can only assume that others are not truthful because they are reluctant to disclose personal information in that setting, or possibly at all. I believe that I would have been more honest if I had to personally fill out the form because I would have gone through it at a slower pace and I would have felt less embarrassment writing it down.

Being on the "other side" of the interview questions was a strange experience and I felt a mixture of emotions. I was decidedly uncomfortable talking about myself. As an anthropologist, I have learned to question others and ponder the experiences of others. I less often think about my own experience or interpret or analyze my own world. In my social life, I have adopted the interviewer's stance. I ask questions of others, probe their answers, and express interest in their perspectives. This accomplishes two things. First, others often interpret this move as friendliness and openness, to which they usually respond positively. I am genuinely interested in others and worry that we do not listen to each other enough, so I feel that this approach is not just a strategy to make friends and become accepted. It is a quasi-political strategy

which fits with my own inclinations. Second, as an interviewer, I do not have to

reveal much of myself. I do not have to show my worries, my weaknesses, my

radical ideals or my poorly formed theories. So, by being the perennial

interviewer I can avoid conflict and judgment. I also avoid intimacy and

closeness. I do have close friends, but very few. As a PhD student I have formed

very few close friendships, most likely because I am in a vulnerable and

especially unhappy phase of my life. I believe playing the role of the interviewer

is my method of coping with my uncertainty and lack of self esteem.

This experience of anxiety and emotional distress is not unusual for an

anthropology graduate student. Several friends and acquaintances in the

discipline have labelled my condition 'the doctoral student blues' and have

expressed understanding or, at least, lack of surprise. Presumably graduate

students in other programs also struggle and the phenomenon is not restricted

to anthropology. However, here, I reflect on what conditions produce these

"blues" while enrolled in a graduate anthropology program. Graduate training in

anthropology can encourage feelings of isolation and insecurity. Graduate field

work is generally not team based and graduate students must do the majority of

the work themselves, with committee guidance and oversight. The purpose of

this is to train learners to develop their own research questions, troubleshooting

skills, and to apply methodological and analytic techniques to practice. This

approach is very different than those I observed in the studies I followed. I

observed graduate students working in teams and working closely with other

students, staff, and supervisors. Graduate students in these labs tended to work in close proximity – physically and theoretically – with other researchers. Their work was tied into a larger research vision and purpose. In anthropology, graduate students may work closely with their advisors on similar aspects of the same broad research question. They may also, as in my case, work on unique topics, outside of the interests of others in their department. In hindsight, I regret this decision to work outside of the interests and research agenda of my supervisor and believe it has played some role in my emotional trajectory during this training program.

Returning to the psychiatric interview, I was, indeed, uncomfortable and unaccustomed to being interviewed. It was an odd sort of interview because, although it was about very personal aspects of my life, since the questions were closed (I was asked to respond yes or no, give a frequency, or give a numerical response to intensity or importance) the interview felt dry and unemotional. So, even though I disclosed a number of personal things about myself, I was never asked to *talk* about myself. I never felt emotional or especially engaged in the questions or the progression of the interview.

Even though I was uncomfortable providing answers instead of posing questions, I enjoyed being the object of inquiry in some ways. I enjoyed the freedom of simply answering questions, of not probing, or building a relationship. I did not have to concentrate as much, or have to think about a number of things concurrently (the content of the speaker's story, the speaker's

mood and reaction, my personal reaction, my own understanding, possible

probes for clarity) as is required of a qualitative interviewer. I also found that I

enjoyed talking about myself while (mostly) ignoring my desire to create myself

using ideas, words, and gestures, manufacturing a public self, a well-intentioned

fantasy. In addition, there was no ambiguity of judgment. I was absolutely and

voluntarily being evaluated, and in that evaluation there was an implicit

judgment.

After the interview, the intake person said that if I did not make it past

the inclusion criteria (which I was never clear about) and if I wanted help I could

still become a patient. The disadvantage to that, she said, was that there was a

long waiting list for new patients. Study patients would not have to wait for

treatment and would possibly have more frequent access to the psychiatrist, as

well as free medications (but perhaps not the best medication for them). For

someone who is desperate to get help, the preferential treatment obtained

through study participation is a significant factor. It also indicates to study

participants that they are valued, or valued more than those who are simply

using health care services and not contributing to research. I was willing to take

a drug when a safer non-drug intervention might have worked. I was also willing

to take a randomly assigned drug, not a drug the physician would prescribe to

best suit me.

A week later the intake person phoned me to tell me that I did not qualify

for the study. She did not indicate why, nor did I ask. I considered seeking

treatment at the centre outside of a study, but thought against it because I felt I did not have time for therapy if it was not part of my research. I honestly wanted a quick fix, a magic bullet, which is ridiculous, because I could have received a medication that was not good for me. I was disappointed personally and professionally. I had been looking forward to feeling better and getting help. Once I was rejected from the study, I was unsure whether I had the time to seek help, where I would go, or what I would do. I felt that seeking mental health care was an indulgence that I could not afford in terms of the time commitment if it was in addition to, not supplemental to my research. I was also disappointed because I thought it would have been very interesting data and fascinating to medicalize my personal struggles. It also meant that I still had to find a study that would enroll me. Shane, however, was pleased that I was rejected.

C) Finding a study and losing it

I eventually did find a study I was eligible for. I talked to a research coordinator about why I wanted to enroll (for my thesis) and that I would write about my experience. The research coordinator (who I originally thought was in charge of the study) agreed to having me participate. On the final day of participation I learned that someone other than the research coordinator was in charge of the study. I submitted my autoethnography of participation in the study to this person for reasons of transparency. They did not feel that my experience was accurate. Since they had not consented to my involvement in the study they did not consent to my use of the experience as data. I offered to

fictionalize the story, add their comments, and to make any necessary changes. However, they found none of those options were acceptable. Therefore, I agreed to withdraw the experience from my dissertation. Afterwards, I met with a representative from the REB to discuss the event and was told that withdrawing the data was the most appropriate response as I had not obtained consent from the appropriate person.

Looking back on it, I of course regret not being attentive and gaining consent from the correct person. I also feel unease because the correct individual was upset that I did the work without their consent. In their own work they diligently obtained consent from all participants and were confused and upset that I apparently did not follow the same requirements. They also felt my description was "inaccurate and misleading". Presumably, had that not been the case, gaining post-factum consent would have been possible. Until that point, all researchers I had spoken with were very welcoming of and interested in my research. The key differences in this case were that I failed to obtain appropriate consent before conducting the research, and that I studied my own experience rather than others'.

I made an amateur error - not following the correct consent procedure – but also misrepresented and angered others. This is one of the dangers of ethnography, but I feel the danger is heightened in autoethnography. The imperative in autoethnography is to be graphic, critical, and open. Although as

an ethnographer I am willing to be self critical, others may not be open to criticism and critique. By laying open my own experience, I exposed myself and others and presumed that since I was critical of my own reactions during the study, that others would be tolerant of an overall critical stance. I wonder if there is something inherently threatening about autoethnography. It does not claim universality or objectivity, but rather delves into subjective and emotional experience. Perhaps my autoethnography was read as a personal attack, rather than a personal narrative, as an opportunity to complain or vent without bothering to obtain external verification or alternative perspectives, one of the standard techniques of qualitative research. The manner in which this transpired was extremely unfortunate for both the researcher in charge and me. The researcher felt betrayed and attacked. I felt badly for creating such ill will, and angry for having my personal experience disregarded. This experience reminded me that when we talk about our own experiences, others evaluate them according to their own knowledge and beliefs. As an anthropologist, it was informative, although initially confusing and difficult, to have my personal experience externally evaluated for its accuracy and truthfulness.

This experience raised the issue of who we ought to obtain consent from to write about our own experience. I think the current standard is based on both spatial and temporal factors. If I occupy another person's world or environment, I think the general agreement (and I mean very general – because there is no consensus) is that I ought to obtain their consent. Occupying public space (and

thus experiencing public events) may not require such consent. However, like in other forms of ethnography, the writer ought to be careful about anonymity and may choose a number of literary techniques to hide individual identities. However, not all people agree with this. At the NCHER conference I attended, some attendees argued that all people who could potentially be harmed by an autoethnographic story ought to give their consent. To me, this seems impractical, requiring paranoia and clairvoyance. Consent is also temporal. If my intent is to record and publish my experience while I enter the field or are in the field, gaining consent may be appropriate. However, reflections on past experiences tend to migrate into the biographical genre and there is less (although it exists) of an imperative to obtain consent. These notions are conservative ones and more radical approaches (like from some of the members of a qualitative health research group I attended) declare that the necessity of obtaining consent to write my own story is censorship and limits the scope of research. Like most debates, I can see both sides. However, I ultimately think that if actors (and possibly settings) can be safety disguised (which is not always possible), informed consent should not be required. If REBs adopts this approach they must be prepared to support researchers if they are challenged.

Although I am not permitted to write about my experience, I think I am free to write about what I learned from the experience and how it relates to how I perceive motivation, risk, and informed consent. Of course, these reflections are more meaningful when tethered to the events of the study, but in and of

themselves they remain informative and interesting. First of all, my primary

motivation for enrolling was to learn more about being a research participant.

However, like most other participants, I had secondary motivations. I essentially

wanted to show myself that I could undergo the study without any substantial

pain or discomfort. Like all studies, this one contained risks, which were

communicated to me in terms of (a) their probability of occurrence based on

past practice and (b) their permanence. If the probabilities of an adverse event

were significantly higher, I still would have agreed to do the procedure because I

was a healthy person. I had very little experience being sick or injured so I found

it difficult to internalize what that would have meant to me and did not feel

physically vulnerable.

I remember a cancer study participant telling me that they required the

risks of their study to be low because they would not have agreed to do anything

risky since they were already sick enough. This reflection really resonated with

me, except the opposite applied. I was not sick or injured, nor had I really had

much experience with that, so I felt more confident "taking on risk" because an

adverse event was a non-reality to me, and also because I felt that the

probability that I *personally* would have had an adverse reaction was practically

zero. Because of this risk hubris, if I were to have an adverse reaction I would

have responded quite negatively. It would have been a shock.

One of the risks was pain. I was convinced that it was not a risk I would

have to face and I identified and internalized all possible cues from the consent

form and the research assistant regarding the possibility that pain would not be a risk for *me*. When I listened to the explanation about the risks and benefits and asked questions, I primarily wanted to hear that these would not have been risks for me. I was convinced that they would not be. In fact, I did experience pain and beyond the unpleasantness of pain, I felt confusion and betrayal. In retrospect, my reaction was naive, but at the time acutely unpleasant.

It is odd that I have imagined my body as a strong fortress, able to hold back any invaders with ease and dignity. As I write these words, I am suffering from a terrible cold and I have broken out into hives (due to chronic stress – this sometimes happens to me). So, my imagination of my body is different than the one that drags me along with it. This cognitive dissonance actually delights me because I think that it is fascinating and adaptive. I wonder what brings it on. Is it an internalization of the American "can-do attitude"? As an anthropologist I wonder if I have a colonial view of my body. I wonder if I have internalized the myth of the white hero, the strong champion who braves invading forces and is immune to their attacks and threats. Maybe I can even blame my mother. She used to say "Haydens don't get sick" as a normative statement about both Haydens and non-Haydens. When I did get sick it was conceived as both an unusual event that required sleuthing (usually the trail of clues terminated at a character flaw) and as betrayal to the family. For these reasons (and possibly more) I was not prepared for an adverse event.

Also, I learned what it was like for me to be observed. In some circumstances men observed and measured me. In these situations, I felt uncomfortable being measured, observed, and evaluated by men. I was always treated with camaraderie, respect, and appreciation. However, I felt especially self-conscious and uneasy. Generally, researchers, research coordinators, and research nurses are women and many participants are men, so the men-observing-women scenario was not typical. In other ways, however, I enjoyed being observed. I was often the centre of attention, which I quite liked. I liked feeling that I was contributing to something. I liked feeling appreciated and I only realized this once the study was over and I was no longer the centre of attention. I felt it odd that I enjoyed that aspect of participation to such an extent and wondered why I was so starved for appreciation and needed to feel that I was contributing to something. All of the research coordinators, technicians, and principal investigators I met valued their participants and mentioned that they wanted them to feel valued. I personally found that aspect both satisfying and essential. I suspect that my experience was somewhat exaggerated. I do not doubt that my discomfort with being observed was heightened because I was studying my own experience as a research participant.

At no time did I think about my contribution to science, but only about my contribution to particular scientists. I am happy that I contributed to university-based research. I did not feel pride as such, but more camaraderie, a sense of within-group altruism. Despite being a research participant and not a

peer, I felt a connection to them because, as a researcher, I supported research and I was happy to support others' work. I believe this is a common reaction among researchers. In other, unrelated work, when I asked other academics about their motivation to participate in a qualitative study I was coordinating, they replied that as researchers they simply wanted to support research.

From this experience I learned more about consent. Although the consent form was not a legal contract, it had the same flavour. Both a legal contract and a consent form contain detailed information which one is expected to read and understand its content and implications. They both require a signature and a date. Because of these similarities, the consent form format gave me impression that I had to carefully read and understand it to ensure I was not being taken advantage of. It also gave me the impression that if anything went wrong, I was responsible (or at least implicated) because I signed the form. I am not suggesting that the research coordinator or the others running the study were implying any of these things. I am, however, suggesting that the consent form format gives participants the impression that it is a legal document and that once they sign it they have some responsibility to the researchers, the research, and for any adverse events they may experience. Some REBs are reconsidering the requirement for a witness's signature on the consent form because this also gives the false impression of a legal document (McDonald 2007).

I believe that REBs should also reconsider requiring participants to sign the consent form. It is my suspicion that this signature is required to protect the university and is not for the benefit of participants. Dubler (2002) argues that written consent is primarily for institutional risk management purposes and institutions are not inclined to simplify or eliminate them (in favour of other method of obtaining informed consent) because this would expose them to more risk. One of my informants complained that the consent forms have become longer and more complex in recent years because "lawyers have gotten a hold of them". Reflecting more on what I perceive as a conflict between the needs of participants and those of the institutions, I think that it is fascinating that there is an enormous literature on what risk means to individuals, but a dearth of critical scholarship on how institutions interpret risk.

Through my participation, I also learned about continuous consent. I found many of the tests unpleasant and was often tempted to drop out of the study. I felt some compulsion to complete the test because I wanted to be in a study, but mostly I felt it necessary to continue because I wanted to keep my word. I always wondered how people could predict how they might respond to study procedures before they did them. How could they know if they would be able to tolerate them if they had never done them before? Now I believe that one cannot really know, but only know whether one is willing to find out. The descriptions of the procedures cannot predict response. Moreover, I feel that it would take extreme discomfort for me to drop out of a study, especially if the

procedures were short in duration. It felt bad to find something painful, but it would have felt worse to quit half-way through. It would have been helpful for me to have had a better idea of what I could and could not tolerate before entering the study. This would have helped me prepare for the experience. I found myself in a situation where I was uncomfortable and unhappy about continuing, but even more uncomfortable about speaking up. I enjoyed the atmosphere and the company of those doing the research. I was pleased to feel connection to the researchers, which made the experience more interesting and meaningful. At the same time, this connection made me reluctant and embarrassed to withdraw.

D) Autoethnography as method

Although I was not able to use my autoethnographic experience in the way that I had hoped, and although I cannot publish my experience, I am glad to have gone through the exercise of writing about my experience, exploring and critiquing my emotions. I learned more about myself (my risk hubris, how influenced I am by social pressure, and my discomfort and pleasure in being observed) and I learned more about my writing style. I write the way I think; choppy and concerned with trivialities, but occasionally more reflective and analytical. I learned that my standard, terse writing style, with its bulldog rhythm and muted cynicism, is safe for me. When I stray from this, my writing becomes humour writing, tangential, bizarre; essentially unfit for any academic format. I love humour. I love laughing at things. I laugh sometimes cynically,

sometimes gleefully, and sometimes mischievously. However, my humour

writing is self-conscious and I feel that it creates a barrier between me and the

reader. Some autoethnographic writing may integrate humour successfully, but

mine did not.

I found writing "emotionally and evocatively" extremely difficult. I fear

that my "emotional" voice comes across strained and melodramatic. It is

interesting, and moderately depressing, that I have found it so hard to write

emotionally, and that an emotionless, objective-sounding voice is easier for me

both stylistically and cognitively. The truth is that I do not experience life with

much heartfelt emotion. I experience life with humour, cynicism, and curiosity;

the attributes of an observer, not an actor. I mentioned this conundrum to Dr.

Tom O'Neil (2008) and he was not surprised. He thought that, as

anthropologists, we are taught to be analytic and not emotional. He believes

that it is difficult to do both simultaneously or to find the balance between the

two. I found this to be a convincing explanation. I was also reminded of

something my boss once told me "oh you WASPs are just like that – you bury

your emotions". I certainly do, but I had never thought of it as a cultural trait;

simply an odd personal quirk. Understanding my lack of connection with my

emotions as a cultural trait is both comforting and depressing. It is comforting

because I do not have to think of it as pathological or maladaptive, but as a

learned behaviour that connects me to my family and culture. It is depressing

because, if I think of it as a cultural trait, I feel powerless to change it.

i)   Knowledge Ownership

What does it mean that I cannot write about my experience? I cannot write about my experience, but I can write about my experience not being able to write about my experience. To write about this critically is not to imply that I do not have responsibility for what happened or that I did not make any errors. I am also worried that analyzing the situation sounds like sour grapes or a method of constructing myself as a victim. Thus, I want to think more broadly about what autoethnographic knowledge is; who owns it, and how it is produced.

Autoethnography is a study of one's own experience. The purpose is to explore first-hand knowledge and embodied experience. It exposes the researcher to a phenomenon and sharing the experience exposes it to others. Since our personal experiences almost always involve other people (otherwise they would probably not be of anthropological interest), writing about our experiences and ourselves implicates others. If we do not obtain consent from others who share (or in my case facilitate) our experiences, can we use the knowledge? Who owns it? Do we all own our thoughts and experiences and in as much as they influence others, and can we claim dominion over them? Why are our experiences and thoughts so precious? Why is the idea that we may be misrepresented or misunderstood so terrible? I believe the answer involves control. Concern regarding who does what with our images, ideas, and activities in many ways is positive. It presumes to allow for individual autonomy and rights. But, what if one person's individuality and rights infringes on another's?

One person's story impinges upon another's? Whose story, whose experience, whose knowledge gets preference? In my case, the knowledge of the researcher and the researcher's story did not get preference. There is logic to this because the researcher is the interloper; to maintain trust researchers must put the needs of the public and informants before their own. In addition, as I will explain below, autoethnographic knowledge is different from other forms of qualitative inquiry, and challenges and confuses ideas about knowledge ownership.

Why is autoethnographic knowledge so difficult to capture, control and understand? In autoethnography there is no knowledge exchange – it is shared knowledge production. In the interviews I conducted, informants shared their experiences and ideas with me, knowing that I would use them as research data. It was a form of data transfer.   I significantly influenced what kind of knowledge was transferred and how I interpreted it, and so the process was more interactive and interpretive than a unidirectional transfer of knowledge. However, I conducted those interviews based on that knowledge transfer model. In autoethnography, the researcher produces the knowledge (or co-produces it), and so the means of production are contested. Autoethnography is not direct exchange. It is a co-production of knowledge. The issue is whether others involved need to be informed that the experience will be used for research (and indirectly career) purposes. Traditionally, ethnographers have tried to get around this by "anonymizing" or fictionalizing the data. These are attempts to protect the identities of others involved. In my case, this was not acceptable. I

could not use the data, even if fictionalized, in any circumstance. This decision

was based on the fact that I did not acquire informed consent from a person who

had "rights" to the experience. There was no formal exchange, no agreement.

How does that differ from other circumstances where knowledge is

produced and published? In journalism, journalists are free to partake in social

and economic activities without the knowledge or consent of others involved.

Journalists sometimes access gatekeepers, depending upon whether it is

necessary to gain access to an event or area, or whether it will help them answer

their questions. By journalistic standards, they are not expected to do so. If they

publish material about others that others do not like, the publishing companies

and journalists are sometimes faced with a court action. This was the case with

Harpers' when they published one of Robert Helms' "report cards" about a

medical research facility. Robert Helms contributes to and edits a magazine

called "Guinea Pig Zero" where medical research participants (many of whom

used "guinea pigging" as their main source of income), share their stories and

experiences. Robert Helms sometimes publishes his "report cards" about

research facilities he has recently worked at to educate other "guinea pigs"

about the pay, study environment, and other working conditions. In 1997,

Harper's Magazine ran one of his report cards on the Allegheny-Medical College

of Pennsylvania. He gave them "a big, fat F", due to sloppy blood draws, long

wait times for volunteers, and not providing extra copies of the consent form

unless asked. The institution filed a libel suit against Harper's, which was settled

out of court, as well as Helms, which the institution dropped the day before

Helms was set to appear in court.

The issue of libel and ownership of data (both public and private) is

counter to many modern trends in public disclosure. Sharing personal and

intimate information with strangers via networking websites such as Facebook

and Myspace and video documentation of events, vlogs[84], and interviews is

common. Moreover, offensive messages and personal attacks are also common

on internet communication platforms such as forums.

Publishing accounts that other people do not agree with or find exception

to and publishing private information about oneself and others are not

intolerable or unusual in our modern "information society". However, research

is an exceptional activity because it relies on a contract. This contract can be

formal or informal, but it indicates that researchers have permission to collect

and publish the data (although some industry sponsors, such as pharmaceutical

companies, put limitations on researchers in terms of their rights to publish).

However, this contract is shallow. I cannot publish my experience as a human

research participant without the consent of the study PI. However, I could relay

my story to another researcher and they could publish my story if I give them

consent to do so. So, when we ask who owns the data, who owns the

experience, it is *not* the property of those who publish it, even if it was their own

firsthand experience. Unless, of course, there was no one else who could have

claim to the data.   I could post my story on Facebook (as could any participant) including names and location, but I cannot, as a researcher, for research purposes, or for career gain, publish the data.

This situation, where researchers must gain the consent of others in order to discuss their own experiences, reinforces the traditional position of the ethnographer as one who collects and interprets knowledge but does not actively co-create it. It also limits the kinds of knowledge that research can produce. Although the TCPS states that there are instances where research may be collected without the consent of certain people (such as public figures), it is a murky area, and many researchers are uncomfortable with such a scenario. At one NCEHR conference I attended, the keynote speaker delivered an address on research ethics and the arts and the pragmatic and theoretical drawbacks of the standard consent process. The audience (of researchers, policy makers, and ethicists) seemed uncomfortable with not obtaining consent from individuals in public or semi-private settings, especially if they might consider the findings of the work objectionable. The message I took away from the discussion that followed was that this type of research should be avoided because it was ethically suspect and potentially risky. It was a quagmire researchers ought to avoid.

There seemed to have been two objections. First, people must always give their consent to participate in research, no matter how obliquely, because

not obtaining consent is a personal violation. Secondly, people should never be

hurt by research or feel that their voluntary or involuntary involvement was a

negative experience. I wonder if this perspective is motivated by the desire to

maintain the credibility and trust of academic institutions. Without credibility

and trust, academic researchers would find recruitment even more challenging.

Certainly, these perspectives and trends are obstacles to more critical social

science research. Furthermore, the ethics regarding autoethnographic research

and the challenges of obtaining informed consent are obstacles to more personal

social science research. These factors make certain types of research activities

and questions more accessible than others, influencing academic activities and

knowledge production.

This experience also highlighted the tension inherent in researching other

researchers. As a junior researcher, I understand the academic and financial

pressures of the work. I also understand the challenges of recruitment, the

practical and optical importance of following research ethics protocols, and the

emotional and research demands of developing rapport with informants. I

wonder if, as a researcher studying research (and implicitly other researchers),

the PIs of the studies I followed assumed I was "on their side", a sympathetic

witness to the challenges and joys of research. I do indeed sympathize with the

challenges of medical research. I also fundamentally think that medical research

is important, so I am critical of its organization and funding. However, my

position (as outlined in the third chapter) is not particularly unusual in the

academy. Those who do not share this perspective simply consider it naïve, and therefore unthreatening. My analysis of the studies I followed was not terribly critical of researchers or the research environment. This is a product of: (a) my own trepidation to be overly critical of those who have enabled my research (without their consent and support I would have no project), (b) my inherent sympathy of the researcher's position, and (c) my methodology – I spoke with most participants at their research site, and rarely in private.

In contrast, my analysis of my own experience as a research participant was critical. This was partly because I had access to more visceral and real-time data. I tried to record and capture my actual experience of the procedure, not my reflections on it, or my edited and rose-coloured public narrative. I did not reveal my pain, my complaints, or my critical attitude to the researchers during the procedure because I felt it was socially unacceptable and childish to complain or show my discomfort. I had, after all, been informed of the risks, and had gladly agreed to the procedure. Today I do not reflect on the procedure with the same negative emotions or memories. So, the reactions I had during the procedure were both very private and very temporal. This was because they undermined my self-identity and my relationships with the researchers. Autoethnography can be threatening. It exposes emotions and criticisms we would otherwise censor or forget. Moreover, as I found, autoethnography can create enemies, and if the autoethnographer's experiences do not correspond with others' viewpoints, they are easily disregarded. After capturing my

immediate experiences, I reflected on them to understand more broadly what they said about me as a researcher, the relationships between participants and researchers, and the organization of research. So, even though I critiqued my own experience, the researcher was more interested in my account of my "negative" experience, and its implied critique of their own research.

E) The Three Bodies

Here I want to briefly reflect on how autoethnography is a tool for examining interactions between the three bodies. I believe that one of the most important contributions of autoethnography is connecting personal experience to a broader culture. When autoethnography can successfully do this, it shows the interconnectedness of the three bodies. However, I also believe it highlights the differences between the three bodies and helps us understand how and why we do things that do not seem to benefit us or reflect our intent.

How does my experience reflect on the social body and the body politic? My own experience as a research participant was situated within a Canadian context where healthcare is a "social good", a laudable goal, a worthwhile endeavour, and a trusted sector. I, like other research participants, fundamentally trusted that I would not be significantly harmed by the investigators (by virtue of their position and location). Otherwise I would never have done the work. I also reinforced the justification of and approach to participant remuneration. I gladly took the $100, but when I received it I felt

that I did not deserve it, that, somehow, I was taking money from the individual researchers. I mistook the world of research and the financing of research with the worlds of the individual researchers and their own personal finances. Nonetheless, I took the money, felt it adequate, and bought Shane dinner. This is a telling example of where the three bodies collapse. My own feelings of inadequacy, combined with my affinity with the researchers, prevented me from seriously questioning the payment system. In fact, I thought the remuneration was generous. The relationship also moved in the opposite direction; no doubt the formal payment and governance system in place discouraged me from questioning its function, and challenging its assumptions and operations. In addition, the impersonal and opaque nature of the larger body politic – the systems and structures in place which organize medical research – made it easy for me to ignore the body politic and simply assume that the social body (the friendly and capable natures of the researchers) was a reflection of the body politic. If I could trust them, I could trust the system.

My experience was also situated within a university, where both critique and academic position are tools used to circulate and accumulate power. I believe that my narrative reflects the awkward position of a novice autoethnographer. There is both a hunger for critique within academia, but also a discomfort with criticism, unless it means criticizing *structures* or *systems,* but not *individuals* (unless they are obvious targets such as the head of the CIA). My knowledge of academia is mostly informed by the other graduate students in my

program, the faculty who have taught and supervised me, and, to a lesser degree, other anthropologists and social scientists I have met at academic conferences. Over the years I have learned that in anthropology, critiquing people in power or structures of power is a valued activity. Through my experience doing autoethnography, I have learned that this critique, although valued by anthropological communities, is not well received by others. I am not suggesting that in anthropology, critique is valued, whereas in other disciplines it is not. I am suggesting that critique is less welcome when it is directed at you. I certainly did not appreciate the critique of my own original autoethnography. Here, again, I see how things change. In a larger academic setting, critiquing systems of power is valued and can further a researcher's career. In actuality, this critique is often not welcomed when it is directed at individuals and programs within a university. This critique is not interpreted as academic, but personal. While I was surprised by this reaction, I also felt rage and hurt when my own program of research was censored.

I highlight these two examples of relationships between the three bodies which emerged in my autoethnography because they show discontinuity. In Scheper-Hughes and Lock's work, their analysis and discussion of the critical-interpretive theory tends to emphasize the similarities and the isomorphism of the three bodies. When this works it is incredibly satisfying. It also tends to support the efficacy and utility of the framework. However, in my own experience as a research participant, I found difference and discontinuity. The

realities, assumptions, and logic of each of the bodies often vary drastically. This

divide, perhaps, explains why people sell their bodies to science, why people

take experimental drugs for a small possibility of benefit, and why other people

approve this kind of work. The critical-interpretive framework can help identify

discontinuity between the three bodies. This incongruence can be one

important aspect of the complex and confusing relationships between personal

experiences, social behaviours and knowledge, and political economic discourse

and policy.

F) Discussion

Much of anthropological work is based on writing; whether it is writing

down field notes, writing *up* findings, writing *for* sponsors, or occasionally writing

with colleagues and participants. Writing seems to be our main form of

communication. We rely on writing to capture our observations and experiences

and to help us process them. In many cases - although not always - writing is a

solitary activity, one which is reflective, introspective and analytical. Writing is a

way of making sense of information, ideas, and intuitions. Through writing,

these various features can coalesce. I found that writing about and analysing my

experience helped me learn more about my own motivations and thought

processes. It helped me build my reflexive and analytical skills. Because

anthropological inquiry is so heavily influenced by the inclinations, assumptions,

fears, and passions of the researcher, doing autoethnography has made me a

better researcher. It has forced me to think more critically about my motivations

and it has highlighted many of my weaknesses and fears. In addition, thinking

critically about myself, increased my curiosity about and empathy for others.

Having to understand my feelings enough to articulate them was extremely

difficult. Perhaps this experience will help me build tools to assist informants in

articulating their own experiences. I found that, in my research, participants

often found it difficult to explain what something felt like, how they weighed the

study's risks and benefits, and other emotional, physical, and cognitive

processes. I hope that continuing to force myself to articulate these processes

will provide me with more insight regarding how we can mine our largely

subconscious knowledge.

For some people, writing also has therapeutic value. I did not find writing

about my experience as a research participant therapeutic, but I *did* find writing

about and reflecting on my mistakes and the impasse of my research

therapeutic. I learned that I am extremely sensitive to personal criticism. The

knowledge that I hurt and misled someone produced in me great anxiety and

shame.[85] As a medical anthropologist, it was informative to experience my first

anxiety attack. As a graduate student, it was horrifying. I felt like my body was

coming apart; I could not think or breathe. Still today, when I think about it, I get

shaky and upset. Anxiety is a somatic state of emergency. It is a chaotic storm of

fear and confusion. Writing about that fear was my method of controlling the

storm, organizing the chaos. My therapeutic needs influenced my analysis,

laying a cold hard hand of forced rationality and maturity on a traumatic

experience. In this, I learned that when backed into a corner, I fight as an

anthropologist, using analytic and narrative tools of the trade. Until that point, I

had never thought of myself as an anthropologist. This was because I do not

have an undergraduate degree in anthropology, have difficulty parsing much of

its literature, and do not mirror the disciplinary zealotry of many of my

colleagues. I find it delightful and odd that through making ethical and

procedural errors, I have found myself at home in my anthropological skin.

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[82] There are many differing definitions of autoethnography. The Ellis and Bochner definition fits best with how I understand and use autoethnography, although many scholars have their own interpretations. Certainly, Ellis and Bochner did not define autoethnography to enforce an orthodoxy, but rather to clarify the term. Reed-Danahay (Reed-Danahay 1997)explains that autoethnography can vary in its emphasis on auto (the self), ethnos (culture), or graphy (the research process). This emphasizes that autoethnography, but nature, has diverse interpretations. Muncey writes that autoethnography is an "ethnography that includes the researcher's vulnerable self, emotions, body and spirit, and produces evocative stories that create the effect of reality and seeks fusion between social science and literature" (Muncey 2006). Pratt, using the term for something like "native narrative", indicates that autoethnography "refers to instances in which colonized subjects undertake to represent themselves in ways that engage with the colonizer's own terms" (Pratt 1992). This type of autoenthography engages informants on their own terms and in their own words and directly addresses concerns of the crisis of representation in the human sciences (Marcus and Fischer 1998).

[83] Ellis suggests that the primary reason for autoethnography's failure to grip the discipline is because it is too challenging a genre. However, here she does not address the stigma of autoethnography within anthropology. Because autoethnography is not objective, explores a singular case, and exposes the ethnographer, many consider the genre self-indulgent and unscientific (Mykhalvoskiy 1996).

[84] Vlogs are video-recorded blogs, web-based commentaries.

[85] My first reaction was to blame myself, apologize, and immediately offer to retract the data. Mine was a typical flight reaction, and for the sake of pushing academic inquiry, I wish I had more fight in me.

CHAPTER 8: SUMMARY

A) Introduction

This chapter has four main segments. In the first segment, I return to my research questions in order to specifically address why people participate in health research despite its risks, why people are asked to do this work, and what happens in the research lab. I will do this by reassembling the themes laid out in the body of this paper and demonstrate how the themes help us understand and appreciate these phenomena. In the second segment, I will address the critical-interpretive framework, commenting on its strengths and weaknesses for multi-sited research. Then, in the third segment I will discuss the limitations of my research, summarizing how I thought my methods and approach influenced the data collection and analysis. Finally, in the fourth and final segment, I will list a few practical implications from my work.

B) Research Questions Revisited

My research questions are:

1. Why do people participate in health research, despite its risks?

2. Why are people asked to participate in health research?

3. What is the research environment like? What factors influence this environment?

These questions are interrelated. I found that participation was informed by participants' perceptions of researchers and research coordinators and the

governance system. It was also informed by the perceived comfort and safety of

the lab and broader ideals about science and medicine. I think that the most

fruitful method of addressing this conglomerate of questions is through

travelling between the three bodies, to learn about the factors which influence

participant motivation. I do this with each study in isolation and then comment

on all of the studies as a collection.

i)   The cancer study

Motivations are heavily dependent on an individual's health status. For

Phase 1 studies, cancer patients enroll because they want to continue to treat

and fight their cancer. A secondary motivation may be to help others, but this

seemed to be a contingent motivation; if they did not personally experience

benefit, at least others might. These studies provide one last hope for cancer

patients. Although they are designed to test toxicity, not effectiveness, patients

enroll for the very small possibility of benefit. Bioethicists and physician-

investigators both struggle with this discrepancy. However, for cancer patients

who have long-term relationships with their oncologists, and have experienced

good, sometimes excellent care, continuing medical treatment, even if it is in the

form of a Phase 1 study, is reasonable from their perspective. They have

become physically and psychologically dependent on medicine, and when

bioethicists and practitioners confront participants' complex motivations, they

sometimes become concerned.

Continuing treatment does three things for a cancer patient. First, it ensures a supportive group of practitioners. As research participants, patients have more practitioners involved in their care, and are more intensely monitored. In addition, because researchers and research coordinators are worried about "killing" participants, they rally around them, ever vigilant. Second, being in a study gives participants structure, which is comforting. The rhythms of research mirror the rhythms of the workplace, where temporal and spatial familiarity bring normality and comfort. Finally, it enables participants and their families to continue to hope.

Hope[86] is complex and highlights complex relationships and attitudes regarding biomedicine. I heard participants refer to the so-called healing powers of positive thinking. This was a form of folk-medicine, but also a moral imperative. Those patients who did not have hope were not administering to their duties. Hope was not only directed inwards, but outwards. Hope summoned a patient's trusted medical team, who also hoped for the cancer to remit. Hope was hinged to hope in medical progress and the scientific method. They hoped that the newest drug would be the one that will work, and simultaneously hope that the drug has gone through adequate testing and will not be given in lethal concentration. Good and associates (Good 1991;Good et al. 1990) argue that the political economy of hope fuels cancer treatment. Without the hope for a cure and the hope in medical progress, cancer treatment would be a much more modest enterprise today. I believe that this is also the

case for cancer research; however, I do not believe that there exists much

sustainable hope for a cure. Physician-investigators revealed that they were not

hopeful for a cure, but for better care. Even participants spoke of extra time,

rather than a cure. One participant even thought that the medical establishment

had buried the cure for cancer. Although "hope for a cure" is a common

message communicated through print and broadcast media, this message is

primarily for external audiences in order to help increase donations for cancer

care and research. The internal message is more modest, at least for end-stage

cancer patients. They hope for a little more time, better care, and a reason not

to despair.

The research atmosphere encouraged participants to foster hope. The

study environment was friendly and warm. Nurses, oncologists, chaplains,

volunteers and research coordinators dropped by, chatted with participants,

inquired about how they were doing, and maybe offered some advice, a blanket

or a cookie. As one participant put it, "it's great coming here, except for the

whole cancer thing". Over time, these figures became friends, but friends who

were always supportive, always caring, and incredibly reliable. The environment

was comforting due to the perceived competency of the workers and also the

normality of cancer. Participants were reminded that they were not alone in

their suffering (the cancer clinic was a shockingly busy place).

Patients were invited to participate in Phase 1 oncology studies because

they had a good risk profile (they were already at risk of dying), were accessible

(they are already patients), accustomed to oncology treatment, and arguably motivated to furthering cancer treatment. This explains why particular people are invited, but does not address why human research participation in early-phase oncology studies is considered ethical or necessary. Using human participants to test the toxicity of new drugs is necessary in the clinical research framework. First, the principal of unique response necessitates that interventions for humans be tested on humans. Ideally, the human testing population mirrors the target population. Second, the principal of response amplitude dictates that researchers must first determine the maximum tolerable dose before determining effectiveness. The maximum tolerable dose is also presumably the most effective dose, so this information is necessary to design a study which will show the maximum possible effectiveness.

This logic of Phase 1 clinical research makes human research participation necessary. The logic of altruism, however, makes it possible. Many participants are secondarily motivated by altruism. Since the research is not designed to test effectiveness, altruism is the only acceptable motivation. Investigators and REBs need to believe that Phase 1 participants are motivated by altruism, at least partly. Just as participants and REBs need to believe that investigators are motivated by desire for knowledge and compassion for cancer patients.

The interconnectedness of the three bodies I think enables cancer study participation. As patients facing a terminal illness, participants desire to continue treatment, even when all approved treatment has been exhausted.

They look to medical research because the environment is familiar, the

personnel trusted, and because they may have had previous (although

temporary) success with allopathic cancer treatment. The research lab provides

support, caring, and stability. Past success and present stability and familiarity

help participants face an uncertain and risky future. The laughter in the research

lab help participants feel comforted and welcome, while providing a medium to

comment on the experience of having cancer and the "choice" of enrolling in a

Phase 1 study. Although cancer funding drives rely on the hope for "a cure" for

cancer, the hope participants and practitioners have is more modest.

ii)   The asthma study

The asthma study participants had mild asthma and allergies but were

otherwise healthy and relatively young. They were not in the study to seek

medical treatment, but to earn money. Secondary motivations included helping

out the research coordinators, learning about asthma and science, and having

fun. Being in the asthma lab was an enjoyable experience. The research

coordinators entertained, counselled, taught, and complimented the

participants. Participants usually met other participants, employees, and

graduate students in the lab, so the environment was highly social; the asthma

lab was the hub of jokes, stories, and personalities in the area. Being in an

asthma study was taxing for some participants. The bone marrow test could be

painful, and the repeated breathing tests hard on the lungs. Primarily however,

participation was inconvenient, rather than painful. It required frequent visits to

the asthma lab and some days participants were required to perform tests throughout the day. Daily life was interrupted, daily activities and responsibilities put on hold. Participation could also spark participants' interest. Their engagement and cooperation was essential for the study and participants responded by picking up the language, and inquiring about the study. They were required to complete and master a number of breathing tests. Through their enrollment, they learned about breathing mechanics, the logic of the study methodology, and the function of each of the various tests.

The lab environment made these challenges more surmountable for participants. The risks seemed unlikely because participants felt that the researchers and research coordinators would not ask them to complete any risky procedures and carefully monitor their performance. They also felt safe by virtue of being in a university-based hospital where there were trained professionals in the building to care for them if they experienced an acute adverse event. Participants were also vaguely aware of a governance system and assumed that it functioned adequately and appropriately safeguards participants. New participants relied on the veteran participants, who also worked in the lab, to quell their fears about the bone marrow procedure, and relied on the study physician to advise them if they found the testing too hard on their breathing. In terms of timing and scheduling, the research coordinators tried to work around participants' schedules as much as possible. Finally, the

time in the lab was a break from their normal routines and commitments, a time where participants socialized and relaxed.

Participants mostly did this work for the money. They used this money to pay for tuition, pay bills, donate to hurricane Katrina disaster efforts, and other charity efforts. The remuneration was provided by the sponsor; non-industry sponsored studies are much less profitable. The remuneration was (generously) calculated on an hourly wage basis. The involvement of industry sponsors in university-based research is accepted practice and justified based on limited and restrictive government funding. The provincial and federal governments themselves encourage industry partnerships. They argue that these partnerships encourage university-based researchers to funnel their time and expertise into useful and profitable areas, maximizing the benefits of university-based research, helping Canada "compete in a global marketplace". At the university, industry-sponsored research attracts money, for the university, research labs, individual researchers, and participants alike.

iii)   The metabolic study
The metabolic study was the least time consuming and most physically demanding study. Participants were young healthy males who enrolled for the remuneration, an interest in science, and a desire to help the research coordinator. Participants did not develop much of a relationship with the research coordinator due to the low time commitments and how the research was organized. During the study, the research coordinator was busy organizing

tests and collecting data and did not spend an extended amount of time with the

participants. Despite this, participants indicated their respect, trust, and

appreciation of the research coordinator.

The muscle biopsy test can be very painful, although this is not always the

case. The presence of pain is dependent on a number of factors, including:

participant physiology, biopsy technique, and participant tension (the tenser the

muscles, the more difficult and painful the procedure). When it was painful, the

embodied experience of the study changed for them and the jovial and relaxed

atmosphere changed as well. Participants reacted through the use of sarcastic

humour, body language, and complaints about inadequate remuneration. The

social environment and the participants' perspectives on the economic

relationship morphed. In addition, those participants who felt pain said they

would not do the work again, unless paid considerably more. In contrast, the

majority of participants with whom I spoke indicated that they would enroll in

another study in the future. This study helped identify a critical aspect in

research participation – discomfort. Acute discomfort changes how cooperative

people are and how well treated they feel. As I found in my own experience as a

participant, when a study does not go as expected (even if the expectation you

have as a participant is based on wishful thinking and not the information the

research team communicated) your own allegiance to the research can change

significantly. Feelings of betrayal and hurt can emerge. If researchers learn

about these reactions they can address them through interpersonal and

instrumental means.

C) Research limitations

My study had several limitations. I spoke with a limited number of

participants at university-based research labs. Although I tried to find studies

with different requirements, tests, and goals, a great many of my informants

were students, participating primarily for remuneration. This population was

most likely more trusting and supportive of university-based research and

research in general than many other populations of research participants. In

addition, the cancer patients, although not students, were highly socialized to

medical treatment. It is not surprising that these sets of populations were not

risk-averse.

My recruitment and interviewing methods also influenced my data

collection. As mentioned, the research coordinators recruited from their studies

for my research. Relying on people who were not responsible for my study and

busy with their own work limited my recruitment. This was most apparent in the

cancer study, where the research coordinator worked 10-12 hour days,

coordinating multiple studies for numerous PIs. I also relied on the research

coordinators to inform me of when participants were set to arrive so I could

schedule interviews. This was only partially successful, as schedules sometimes

changed and I was rarely (understandably) notified.   I then chose to interview

participants at their study sites. This increased my recruitment and made double

enrollment (participating in two studies at a time) less onerous. It also is likely that being interviewed in the lab encouraged the participants to censor their responses.

Selection bias influenced my research findings. I observed studies where the principal investigator was welcoming of my presence.   It is not surprising then, that I generally found that the participants reported positive experiences and orientations to research. Some cancer study participants did not agree to meet with me. I do not know why they declined, but I wonder if their experience was significantly different from those who did speak with me. I wonder if they experienced more side effects and found less satisfaction in their study participation.

I observed three different REBs. My data collection during these meetings was suboptimal for two reasons. First, since I was once an REB member several years ago, I take much of the logic and operation of REBs for granted. As a participant observer, I found it difficult to observe carefully. In addition, during these meetings I focused on the content of the meetings. In hindsight, I believe that a greater focus on process, relationships, and tenor would have been more fruitful. As a result, my understanding and observations of REBs has been limited.

D) Overall insights

In health research, the three bodies are intimately connected. A comforting social body and trusted body politic can influence individual embodied experience, making participants feel safe, cared for, and even appreciative. The body politic – representing access to experimental medication and remuneration – can motivate individuals to participate in research and assume new risks. University-based medical research is entrenched and participants willingly engage in these studies and serve as commodities to industry because they trust the researchers. In fact, this activity can be exciting, fulfilling, and increase one's sense of altruism and social contribution. I think that many of the motivations of participants – the desire to further research, the desire to help others, the desire to push themselves – are admirable.

However, I do feel that it is unfortunate that these desires and motivations are funnelled into activities which primarily benefit shareholders and universities. One of my most exciting findings is that participants want to see improvements in the health of Canadians and are willing to assume risk, inconvenience, and discomfort for this goal. I believe that the organization of health studies provides a framework in which participants can engage, contribute, and become involved in something larger than themselves. This means that given structure, organization, purpose, and opportunity, people are willing to give of themselves and work towards the greater good. Currently, this

level of organization is most commonly achieved by those with resources, which

often equates to industry sponsorship and vision.

Taking on risk can in turn increase a participant's trust in their own bodies

and sometimes even trust in the researchers. If the experience of research

participation does not go well, this can alter a participant's perspective

significantly. They can become more critical of research, of the remuneration,

and of their own relationships with the research team. If the experience is not

unpleasant, participants often take for granted the organization and funding of

research and the investigator-driven nature of the research agenda. I found that

participants were readily co-opted by the research agenda and their positive

experiences with the individuals they worked with made them sympathetic to

and advocates of the research programme. This cooptation is a major factor

which prevents participants from organizing. Participants relate to the research

labs and feel perhaps a sense of loyalty to them. They do not identify as having

much commonality with participants in other studies. This contributes to

research participant protectionism and governance remaining in the hands of

REBs and researchers. These boards and individuals take these responsibilities

very seriously, although their perspectives are necessarily limited.

Another major finding is that REBs and researchers concentrate primarily

on risk reduction and are less focused on increasing benefit. This is for historical

and practical reasons. Harming research participants is part of the history of

health research, thus prevention of harms has become a creed in health research

today. In addition, institutions and individuals are more likely to be criticized or

disciplined for causing harm rather than providing inadequate benefit. However,

participants enter studies assuming the risk for them is low (which REBs and

researchers ought to continue to concentrate on), and are essentially motivated

by potential benefit. These benefits range from health improvements,

remuneration, and contributing to knowledge production.

When striving to increase benefit, REBs and investigators ought to consult

past and potential participants. This will help them think in new ways about

their own research. For example, researchers in all disciplines sometimes work

with participants and communities to share the results of their research. This is

admirable and often extremely helpful. However, from my own experience in

this work and other research initiatives, participants very rarely are interested in

the research results. Their interests are different than those of the researchers

and if researchers and REBs want to increase benefit, they ought to learn from

participants rather than assume what activities would benefit them. Research

ethics is becoming a cottage industry, which is increasing the visibility and

circulation of research ethics. However, this industry is currently most

influenced by academic and research perspectives (due to its proximity to

academic and research institutions). This industry could benefit from closer

consultation with research participants.

The time of health research demonstrates the subjective nature of risk

and modern pressures of time. According to the TCPS, risk is relative to one's

daily activities. This is an important insight because this is how participants described their risk. They were not concerned about procedures or events they were familiar with and mirrored their own daily rhythms. Restricted breathing for asthmatics and cancer treatment for cancer patients is "normal". However, participants are generally less comfortable with alterations in rhythms of daily schedules, and foreign treatments. Familiarity creates a sense of safety and security. However, this familiarity can easily be established and participants quickly become veterans at procedures such as bone marrow extractions and muscle biopsies. Another striking finding is how unproductive time is for research participants. This can be a source of stress or an obstacle to one's normal workday. It can also be time away from one's normal world, a break to socialize and relax. The cancer study participants seemed the least worried about time. This is odd considering they probably had the least amount of time.

E) Critical-interpretive medical anthropology

I used a critical-interpretive framework to inform my field work and analysis, and this approach had both strengths and weaknesses. Critical-interpretive medical anthropology as a theoretical orientation and framework encourages a breadth of analysis. It attunes the researcher to a range of phenomena, experiences, and influences. It also equips the researcher with a number of theoretical approaches, ranging from phenomenology, interpretive anthropology, to critical theory. The framework provides flexibility and allows for creativity. I found that it guided my exploration of themes and events.

However, it gave me little analytic direction. Because the theoretical schools

from which it borrows are numerous and the goals of critical-interpretive

medical anthropology are vague, I felt I had little guidance regarding analytic and

critical tone. In contrast, if I had used a critical medical anthropological

framework, my analysis and purpose would have been clearer. My goal might

have been to examine how economic and social power controls research and

uses medical hegemony to convince people to participate in medical studies.

However, with a critical-interpretive approach, such a goal appears

presumptuous and may ignore the visceral experience of being a research

participant. With a critical-interpretive approach, my goal was to understand

this experience in light of a larger social organization and political and economic

forces to "give voice" to the participants. This is a much more elusive goal and as

such, less satisfying.

The obvious difficulty of employing the critical-interpretive framework is

reuniting the three bodies. In my work, in some instances I avoided this problem

because I took phenomena that encompassed the three bodies (for example,

laughter and time) and disassembled them. Reassembling was not necessarily

required, although tracing the links between the three bodies was. This

illuminates one of the weaknesses of the framework. The three bodies are

connected in numerous ways. I chose to explore them using a few different

approaches, opening multiple windows into the world of health research

participation. This approach provides different kinds of insights, but ultimately feels fractured.

I explored the time of research to illuminate the experience of research participation. I found the concept of rhythmanalysis helpful to tie together the different times of research. This concept was never well developed, but as I understand it, it is a method of exploring how day to day rhythms create a larger whole. I found it was also a helpful method of locating the challenges and exploring the reciprocity of research. I believe that this concept is beneficial for studying multi-layered experience and aids investigation into the interactions between the three bodies. It is a useful tool because with rhythmanalysis, we can explore action and meaning, cohesion and contradiction. In contrast, by using emotions to tie the three bodies, as Scheper-Hughes and Lock (1987) suggest, the analysis requires considerably more interpretation. Although interpretation is inevitable in anthropology, if our analysis incorporates not only what we think people mean, but what we think they do and say, then this is potentially a more fruitful approach.

At times, for example, in my autoethnography, I found it difficult to reunite the three bodies. Disjuncture and discontinuity were more apparent than commonality and linkages. This is an important finding because the critical-interpretive approach does assume that the three bodies combine to form a unity. The approach encourages the researcher to develop a cohesive narrative, a theme which ties the three bodies together. I found that the framework can

just as easily highlight contradictions and incoherencies. Although this makes for

a less satisfying narrative, I think it exposes an important aspect of the

framework, its flexibility to identify not only cohesion, but disjuncture. This is

perhaps why phenomena are frustrating, curious, and interesting; logic breaks

down and the experiences and realities on the different levels are extremely

different and disparate.

F) Suggestions for Research Ethics Boards and Researchers

My goal has not been specifically to inform the research community

about how best to incorporate the needs and perspectives of participants. I

believe that there are ample opportunities while conducting research for

investigators to listen to and learn from their participants. Sometimes

researchers ask participants to advise them on the research protocol, to help

them determine what types, combinations, and numbers of tests are tolerable.

Other times they help them when they are afraid or distressed. Overall, the

researchers who I had an opportunity to meet with and observe made

participants feel valued and protected. However, I do have a few

recommendations.

1. One method of respecting, engaging, and valuing participants is through

    sharing research findings with them. Although this is an admirable activity,

    most participants are not interested in future research publications.

    Although providing this information to participants should be encouraged,

    researchers and REBs should think of additional methods of involving and

valuing participants. I propose that focusing on maximizing participant benefit would improve the experience of research participation. This may be in the form of additional health care, more substantive remuneration, or increasing the convenience of participation, for example, by providing transportation.

2. Participants often forget the information in the consent form. Researchers can engage participants by teaching them about the tests and purposes of the research throughout the study. This will improve their understanding and possibly their enjoyment.

3. Researchers ought to minimize data triangulation where possible. For example, in the asthma study, participant antibody response was determined by testing the antibody count in the mucus, blood, nasal fluid, and bone marrow of participants. The nasal lavage test (which obtained nasal fluid samples) was universally hated, and possibly redundant. In cases where the scientific merit is minor and the discomfort significant, researchers should consider giving greater priority to the participants' experience.

4. Laughter may signify participant discontent. Participants are generally reluctant to complain about certain procedures or timing. Sarcastic remarks may veil unease or dissatisfaction. Researchers may wish to note these occurrences and pursue them with participants to determine how they are feeling and whether they would like to continue with the study or make any changes.

5. For many participants, schedule interruption is the most challenging aspect

    of research participation. If researchers want to reduce the impact on

    participants or improve recruitment, they should consider ways to reduce or

    soften time requirements of participants.

G) Suggestions for Future Research

I had opportunities to observe studies at university-based research labs

where the principal investigators were open and welcoming to have me observe

their work. In the future, it may be fruitful to learn about the experiences of

participants in different settings. Although approval may be difficult, observing

CRO-based research studies would be worthwhile. The general assumption is

that they aren't as safe as university-based studies and the participants are only

motivated by remuneration. It would be interesting to test these assumptions

and do to a comparative study. In addition, it might be helpful to investigate a

random selection of studies, instead of study labs which are especially amenable

to being observed.

I think that future research could focus on how participants define risk

and benefit, with an emphasis on the latter. Understanding just what benefits

participants find agreeable and motivating would be helpful for REBs. REBs could

provide researchers with this information and encourage them to consider more

carefully how they can not only reduce risk, but increase benefit. More applied

research may investigate how organized, or how willing to organize, participants

are. By organizing, participants can advocate for themselves and inform REBs

and research communities about research agendas, research methods, and

research remuneration. Some participants, primarily in HIV research, are

organized and do advocacy work within the research ethics communities.

However, in my research I did not find evidence of organization or even identity

as a participant. I believe that participants first need to identity *as* participants

and *with* other participants for them to begin to organize. I do not believe this

will be spontaneous. Thus, other approaches may be more fruitful.

I believe that like ensuring public input into the organization and funding

of research, ensuring research participant input into the health research requires

leadership. This leadership can originate at governmental and institutional

levels. Possible ideas include: increasing the number, representativeness, and

influence of community representatives on REBs; establishing ombudspeople to

advocate for research participants at policy, governance, and practice levels; to

developing an NCHER advisory board (with real influence) comprised of only

participants and patients. Such measures may enhance research experiences,

and possibly simplify governance.

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[86] Here I deliberately use the term hope rather than trust to describe faith and confidence. In the literature, patients are described as having hope for a cure, but trust in research. The term trust implies reasonableness, whereas hope implies some degree of fantasy. It is curious that hope is used in relation to patient outcomes, but trust is used in relation to scientific methods, the medical establishment, and a health team's proficiency. Here, I use the term hope to signify the subtle but significant distinction between trust and hope.

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APPENDIX A – INFORMANT LIST

Research participants

Code	Study	Sex	Age	Previous participant?	Number of interviews
P1	Cancer	M	82	Yes	3
P2	Cancer	M	65	Yes	3
P3	Cancer	F	34	Yes	1
P4	Cancer	M	46	No	2
P5	Cancer	M	32	No	2
P6	Cancer	M	69	No	1
P7	Cancer	F	68	Yes	2
P8	Cancer	F	58	Yes	3
P9	Cancer	M	62	Yes	1
AP1	Asthma	F	19	No	3
AP2	Asthma	F	30	Yes	3
AP3	Asthma	F	26	Yes	3
AP4	Asthma	F	32	No	1
AP5	Asthma	F	22	Yes	3
AP6	Asthma	M	28	Yes	1
AP7	Asthma	F	23	Yes	3
AP8	Asthma	M	38	Yes	3
AP9	Asthma	M	41	Yes	3
AP10	Asthma	M	22	Yes	3
AP11	Asthma	M	21	No	3
AP12	Asthma	F	21	Yes	3
AP13	Asthma	M	19	No	3
AP14	Asthma	M	20	Yes	3
AP15	Asthma	F	19	No	3
AP16	Asthma	F	21	Yes	3
MP1	Muscle	M	24	Yes	1
MP2	Muscle	M	22	No	2
MP3	Muscle	M	23	No	2
MP4	Muscle	M	20	No	2
MP5	Muscle	M	22	Yes	2

Key Informants

Code	Position	Sex	Age
KI1	Research coordinator	F	28
KI2	Research coordinator	M	47
KI3	Research coordinator	M	49
KI4	Research coordinator	F	25
KI5	Research coordinator	M	28
KI6	Research coordinator	F	46
KI7	Principal investigator	F	42
KI8	Principal investigator	M	44
KI9	Principal investigator	M	51
KI10	Principal investigator	M	42
KI11	Principal investigator/REB	M	55
KI12	REB	M	63
KI13	REB	M	65
KI14	REB	M	58

APPENDIX B - INTERVIEW GUIDES

1) Questions for participants:
   a. After recruitment
      i. How did you learn about this trial?
      ii. Why were you approached?
      iii. Why did you decide to participate? (probe for any online searches or support group involvement, in addition to influence of family, friends, and health care providers)
      iv. What is expected of you as a research participant?
      v. What do you expect will happen during the trial?
      vi. What are the risks for you?* Why are you willing to assume those?*
      vii. What will happen with the information gathered from this trial?
      viii. Self-declared demographic information (age, education, occupation, residence, health status)
   b. During the trial
      i. How is the trial going?
      ii. What stage are you at in the trial?
      iii. Have there been any surprises?
      iv. Can you tell me about the procedures?*
      v. What kind of information do you think they are collecting?
      vi. How do you feel about continuing to participate in the trial?
      vii. What is it like to come here?*
      viii. What are you getting out of this?*
   c. Post trial
      i. How would you describe your experience?
      ii. What recommendations would you make to someone who is considering participating in a similar trial?
      iii. What recommendations would you make regarding the conduct of the clinical trial?
      iv. Could you see yourself participating in another clinical trial in the future?
      v. What has it been like to speak with me about your experience?*

2) Questions for clinical trial researchers and research coordinators:
   a. What is the purpose of the trial?
   b. What kinds of research participants are you looking for?
   c. What are your recruitment techniques?
   d. What is required of participants? Is it difficult to find people who are willing to do this?
   e. Please describe your informed consent process.
   f. Briefly describe the research protocol. Who developed this?
   g. What will happen with the information gathered from this trial?
   h. Can you please describe a typical day? (for research coordinators)
   i. Have you ever participated in a research trial yourself?
   j. What do you want to know about the experiences of research participants?*
   k. What are the challenges of running these studies?*

3) Questions for experts on human research participants and clinical trials:
   a. Why do people participate in clinical trials?
   b. Have you ever participated in a clinical trial yourself?
   c. What are the risks and benefits of participating in these trials?
   d. How is research ethics changing?*
   e. To what extent are research participants collaborators in research?
   f. What are the biggest issues in research ethics?*
   g. Other questions specific to their areas of expertise.