

M.A. Thesis – J. Vaters; McMaster University – Philosophy.

A COMBINED APPROACH TO VULNERABILITY IN RESEARCH ETHICS

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A COMBINED APPROACH TO VULNERABILITY IN RESEARCH ETHICS

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for the Degree Master of Arts

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### **Lays Abstract**

Vulnerability as a concept is thoroughly debated in the field of research ethics. Some argue that the concept is useless, while others argue that the concept of vulnerability needs to be more specific about who it applies to and why. This thesis situates itself within the latter side of the debate. The Combined approach to vulnerability is my answer to this question. The Combined approach defines vulnerability as an increased likelihood to incur additional or greater wrongs. The Combined approach functions like a taxonomy and categorizes vulnerability into three groups (inherent layers, contextual layers, cascade layers) with the use of the metaphor of layers and restricts the application of these layers with its formal the definition of vulnerability. The main contributions of this approach are its novel combination as well as its new approach to the duties owed to the vulnerable.

### **Abstract**

There is a problem associated with the concept of vulnerability for research ethics. This problem is that we must identify populations in need of additional protections while also delineating these protections. Some have argued that the concept is too nebulous to warrant use since an increasing number of individuals may be deemed vulnerable such that virtually everyone is vulnerable in some way. In opposition to this, many have argued that that the concept of vulnerability needs to be more specific. In this thesis, I evaluate the concept of vulnerability in a number of ways. I touch on rejections of the concept, the history of the concept though both research guidelines and research ethics and seek to explore a way forward to a more useable account of vulnerability. I argue that no current account of vulnerability is adequately able to address the challenging questions posed by research trials involving human participants.

A persuasive account of vulnerability should (1) have a plausible/persuasive definition of vulnerability; (2) figure out what the application of a theory of vulnerability looks like; and (3) what obligations or duties are owed to the vulnerable (and who is responsible for fulfilling these duties). In order to address this, I propose the Combined approach to vulnerability. This approach defines vulnerability as an increased likelihood to incur additional or greater wrongs. The Combined approach functions like a taxonomy and categorizes vulnerability into three groups with the use of layers and restricts the application of these layers with its formal definition of vulnerability.

This thesis marks a new novel contribution to the field of research ethics, in the way of a new theory to vulnerability that emerges from the current literature and makes progress towards

a more useful concept of duties and obligations owed to the vulnerable grounded communal engagement.

### **Acknowledgements**

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This thesis is dedicated to my parents Kathy and Les Vaters and my grandparents Lynda and Bert Robinson. This would not have been possible without your unwavering support.

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**List of Abbreviations**

Research Ethics Boards (REBs)

Council for International Organizations of Medical Sciences (CIOMS)

Tri-council Policy Statement (TCPS)

**Declaration of Academic Achievement**

I, Jordan Vaters, declare this thesis to be my own work. I am the sole author of this document. No part of this work has been published or submitted for publication or for a higher degree at another institution.

To the best of my knowledge, the content of this document does not infringe on anyone's copyright.

My supervisor, Dr. Ariella Binik, and second-reader, Dr. Mark Johnstone, have provided guidance and support at all stages of this project. I completed all of the research work.

## **Introduction**

What makes someone vulnerable? Broadly understood, vulnerability is connected to a number of conditions, such as the inability to provide informed consent or protect one's interests, the lack of access to resources, sickness that impairs the normal functioning of the body, the susceptibility to exploitation, a likelihood of incurring harm, or even the lack of access or enjoyment of rights such as reproductive rights. However, should vulnerability be understood as the presence of all of these conditions, only some of them, or none of them? This question only becomes more challenging when we begin to consider vulnerability in relation to research ethics. Consider the use of child participants in COVID-19 vaccine trials. Children generally are unable to give informed consent, they generally lack a sense of autonomy, and they may be more susceptible to exploitation as a result. In response to this, children have been excluded from clinical trials like the ones for the COVID-19 vaccine, and also from research trials with human participants more broadly. This exclusion appears to make sense, since, even if some children can meet the threshold of participation, their inclusion could set a risky precedent for other children who do not. However, the worry with excluding children from these trials is that we cannot safely recommend things like the COVID-19 vaccine to them because of this exclusion. If there is a lack of testing on children, medical decisions move risk away from a heavily controlled trial and into a doctor's office and may further exacerbate the children's vulnerability. This is just one example that illustrates the problems faced when trying to develop a theory of vulnerability.

There is a problem associated with the concept of vulnerability in relation to research ethics, this problem being that we must identify populations in need of additional protections while also delineating these protections. In other words, we must outline not only who is vulnerable, but why they are vulnerable, and how we might ameliorate this worry. This is not a straightforward task, and, since a lot hangs in the balance, it is really challenging to get right. On one hand, failing to provide the right definition of vulnerability carries the risk of overprotecting potential participants. Wrongfully overprotecting a certain population may exacerbate their situation, perhaps even rendering them vulnerable when they need not be. For example, pregnant women have historically been considered vulnerable, and are therefore excluded from most clinical research trails. Vulnerability in this instance is understood as an increased risk or likelihood to incur harm.<sup>1</sup> This exclusion leads to a lack of treatments or medicine that have been tested on pregnant women and can be safely recommended to them. Because of this, pregnant women have their vulnerability exacerbated.

The wrong kind of definition of vulnerability risks under-protecting or failing to encompass those who should rightfully be included in these protections. Consider the elderly participating in a research trial. The elderly may be considered vulnerable due to age, disposition towards certain degenerative brain disorders, or their frailty. Unlike children though, the elderly are largely able to give informed consent and express their

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<sup>1</sup> Angela Ballantyne and Wendy Rogers, “Pregnancy, Vulnerability, and the Risk of Exploitation in Clinical Research,” In *Clinical Research Involving Pregnant Women* (Switzerland: Springer international publishing, 2016), 139

autonomy. However, because of this they may be included in trials that they ought not to be. For example, someone with a degenerative brain disorder may go through periods where they are lucid. What this means is they may be deemed able to provide informed consent in their lucid state. However, once this state passes, they may no longer be able to provide the same consent. Similarly, their condition may be such that the disorder progresses in such a way that they are able to consent one week but unable to the next week or two weeks from the original date. If we do not have the right type of definition of vulnerability, these individuals may be included in research on the basis that they can provide informed consent, when in fact their ability to provide this consent does not remain constant. Thus, their inclusion may risk exploiting them if we cannot recognize this fact and either accommodate it or exclude these individuals from participation. This example illustrates how the wrong kind of definition can cause the under protection of people and thus result in the occurrence of harm.

Getting the definition of vulnerability wrong therefore potentially results in the over protection or under protection of research participants, and thus may cause harm to those who need the most help. Over or under protection here relates to research ethics regulations that often restrict degrees of risk, add additional safety protocols, or even insert exclusionary clauses for inclusion in research trials.<sup>2</sup> My thesis will argue that there is a need for a more persuasive account of vulnerability than currently exists. More work is needed to create a theory of vulnerability that is properly situated to handle the

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<sup>2</sup> Samia A. Hurst, "Vulnerability in Research Ethics and Health Care; Describing the Elephant in the Room," *Bioethics* 22, no. 4 (2008): 191-202

troublesome questions raised in research ethics. I will propose that no existing conceptual account of vulnerability can adequately address concerns about the inclusion of vulnerable populations in research, but that, by drawing on successful elements of existing theories, it is possible to develop a novel and more successful theory of vulnerability. For example, the lack of action guidance and clear obligations for the vulnerable, or unfairly attaching the label of vulnerable to those whose situation or circumstances do not warrant it. My aim is to produce a nuanced hybrid theory of vulnerability that is flexible in application I call this account the Combined approach to vulnerability. A lot of excellent work on this topic been done in an attempt to solve these problems, but there remain problems that warrant attention. My account of vulnerability will aim to resolve these problems by drawing upon the theories of vulnerability that have fallen short.

The first section of this project will focus on addressing an important challenge to the concept of vulnerability. This challenge is to determine whether vulnerability should be considered a universal condition for all of us, or if the concept should work to identify specific groups or individuals who require special protection in research trials. There is a history of this debate that can be traced through ethics codes and research guidelines such as The Declaration of Helsinki, The Council for International Organizations of Medical Science (CIOMS), the Belmont Report, the U.S. Federal Code, and The Tri-council Policy Statement (TCPS). We also see this debate take place at the same time in the field of research ethics, where a lot of conceptual work has been done to elaborate on these



issues. This problem has further driven some to suggest that we ought to reject the concept of vulnerability entirely.

From the literature reviewed in the first chapter, a few central themes will emerge. The main theses that emerge will be the fluid, dynamic and relational nature of vulnerability, a focus on wrongs and how they might render someone vulnerable, and finally the idea of a taxonomy to classify the different sources of vulnerability. With these themes in mind, the second chapter of this project will aim to explicate three prominent theories of vulnerability applicable to research ethics that illustrate these themes best. These will be the Layers Approach, The Greater than Usual Wrongs account, the taxonomy. The section will begin by explaining why I have selected these three theories for more careful attention. I will Consider whether these theories might be best developed for research ethics, have been adopted in recent ethics codes, are most fit for purpose, or are simply the most practical. I will then proceed to provide a deeper explanation of the fundamental elements of each theory and discuss their chief advantages before moving on to critique each. The analysis throughout this chapter will help to identify challenging aspects of each theory that may need further revision or might need to be abandoned altogether.

After identifying the thematic overlap between these theories of vulnerability, in addition to their shortcomings, the third and final section will propose a novel Combined account of vulnerability that attempts to overcome these concerns and to make progress towards a more useful approach to vulnerability. This section will begin by reviewing the

conclusions from the previous chapter and will then move on to pitch a novel theory of vulnerability that is built out of the three main theories considered. The authors of these three accounts make a lot of progress, and yet there are several questions left unanswered by their accounts. It is my view that these worries make all their accounts inadequate and unable to handle the unique questions born out of the context of research trials with human participants. This Combined approach will seek to merge parts of The Layers Account to vulnerability with The Greater than Usual Wrongs account, and the taxonomy. More specifically, I propose that using the Greater than Usual Wrongs accounts' thesis of an identifiably increased likelihood to incur additional harms or greater wrongs as a threshold within the fluid approach to vulnerability found in the Layers can help address the concerns surrounding vulnerability in research ethics. In addition to this, I will also use the taxonomy to provide clear categories of vulnerability that will afford researchers and REBs the ability to more easily consider the obligations that they may have towards the vulnerable. This new Combined approach to vulnerability will make progress towards clarifying the duties owed to the vulnerable, while also expanding work already done up and to this point on the concept. I am not attempting to solve all the issues present here, but instead I aim to ameliorate some of the most pressing concerns found in the current vulnerability literature

## **1.0 Chapter 1: Tracking Vulnerability**

### 1.1 Introduction

This chapter will track vulnerability throughout both research ethics guidelines and the conceptual work done on the concept. This will be done by first addressing a challenge to the concept of vulnerability. This challenge being to determine whether vulnerability should be considered a universal condition for all of us, meaning that everyone could be considered vulnerable because of a growing number of categories or situations, and as a result the concept adds little to our understanding of the world. Or if the concept should work to identify specific groups or individuals who require special protection in research trials and then make progress towards delineating what these protections look like. The first section of this chapter, entitled framing the debate, will introduce the two sides of this debate before moving on to consider one proponent of the universal or rejection side of the debate. To further illustrate this debates place within the field, I will proceed to track the usage of the concept of vulnerability throughout the history of research ethics guidelines. These documents all understand vulnerability in different ways, and in light of this leave room for a lot of ambiguity surrounding the concept of vulnerability and its application. After discussing the importance of vulnerability in research ethics guidelines, this chapter will conclude by reviewing the conceptual work done in the research ethics sphere. What we see here is an emergence of themes mainly a focus on the dynamic nature of vulnerability, a consideration of wrongs or transgressions that may occur during research trials, and the use of a taxonomy as a way to organize and situate the concept of vulnerability.

## 1.2 Framing the Debate

There is a central challenge one must address when attempting to think about what is meant by the concept of vulnerability for research ethics. The problem is that the concept can be broadly understood as applicable to all or in a much more specific way. In other words, vulnerability may be defined as “a universal ontological condition of humanity inherent in human embodiment and our social life”.<sup>3</sup> This is challenging because if everyone is vulnerable, then the concept becomes superfluous and loses its force. Every human being is vulnerable due to their frailty, which is to say the possibility of harm or injury, whether a result of something intentional or accidental.<sup>4</sup> This innate vulnerability is only exacerbated when we consider our natural dependency on others. This innate vulnerability is then added to all the other possible instances that may make someone vulnerable. This is a problem because if a growing number of individuals and groups can be labeled as vulnerable, the special protections for the genuinely vulnerable may be lost.<sup>5</sup> An implication of this is the complete rejection of the concept all together.

In contrast to the universal side of the debate, attempting to be very particular about what is meant by vulnerability requires the consideration of a complex web of concerns. Mainly, who the concept of vulnerability encompasses and why, and how to address those who require special protections during research trials. We need to avoid

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<sup>3</sup> Anthony Wrigley, “An Eliminativist Approach to Vulnerability,” *Bioethics* 29, no. 7 (2014): 481

<sup>4</sup> Martha A. Fineman, “The Vulnerable Subject: Anchoring Equality in the Human Condition,” *20 Yale J.L. & Feminism* (2008): 9

<sup>5</sup> Doris Schroeder and Eugenijus Gefenas, “Vulnerability: Too Vague and Too Broad?” *Cambridge Quarterly of Healthcare Ethics* 18, no. 2 (2009): 113

Heidi P Forester, Ezekiel Emanuel, and Christine Grady, “The 2000 Revision of the Declaration of Helsinki: A Step Forward or More Confusion?” *The lancet* 358, no. 9291 (2001): 1449-53

being overly vague about what is meant by vulnerability. This entails a move towards defining the concept instead of leaving it as another unanswered question. In other words, there is a broad problem with the concept of vulnerability being considered a universal condition for all of us, rather than identifying specific groups or individuals that may require special protections in research. My contribution fits within the particular side of the challenge to vulnerability and will attempt to get very specific about what the concept entails and requires of us. However, it is important to understand the key points of the universal challenge before moving on.

### 1.3 Framing the Debate: Rejections of the Concept of Vulnerability

Vulnerability understood in the universal way will consider all of humanity as vulnerable. This is because, as the concept grows, there are a multitude of different reasons or situations that may render someone vulnerable. In light of this, almost everyone could be considered vulnerable for some reason or another. If this is the case, vulnerability adds little to our understanding of the world, and that it may be better understood in terms of other ethical challenges such as the avoidances or minimization of harm or the promotion of autonomy. This worry has led some authors such as Anthony Wrigley to argue for the abandonment of the concept all together. Anthony Wrigley argues for the rejection of the concept of vulnerability. Wrigley holds that the concept of vulnerability has been open to many interpretations that have resulted in its definition being criticized for being too narrow, too general, or too vague.<sup>6</sup> Wrigley understands

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<sup>6</sup> Wrigley, 478

vulnerability as a special status that an individual or group has that creates an obligation to pay special attention to their wellbeing.<sup>7</sup> He argues that attempts to define vulnerability suffer from two major problems. The first of these is the lack of a coherent account that can adequately define vulnerability in a way that also avoids contentious classification of individuals or groups as vulnerable.<sup>8</sup> Wrigley thinks the difficulty of defining and categorizing vulnerability has resulted in the addition of more and more groups of people being classified as vulnerable in an increasing number of situations.<sup>9</sup> If this is the case, then virtually everyone is vulnerable in some instances, and thus an increasing number of activities will require special attention, so much so that the concept becomes useless as a way of identifying special status.<sup>10</sup> Simply put, if everyone is vulnerable, the concept loses its force and usefulness because attempting to delineate protections based on a condition experienced by everyone will only produce redundant and unhelpful results. A profuse number of categories of people are now considered vulnerable, such that virtually all of humanity could be included.<sup>11</sup> Considering this, they argue that the concept of vulnerability has simply become too nebulous to be useful.

A problem with this argument against the usefulness of the concept of vulnerability is that it fails to understand that vulnerability is both a fluid and dynamic

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<sup>7</sup> Wrigley, 478

<sup>8</sup> Wrigley, 478

<sup>9</sup> Wrigley, 478

<sup>10</sup> Wrigley, 478

<sup>11</sup> Schroeder and Gefenas, 113

Carol Levine, Ruth Faden, Christine Grady, Dale Hammerschmidt, Lisa Eckenwiler, and Jeremy Sugarman, "The Limitations of 'Vulnerability' as a protection for Human Research Participants," *The American Journal of Bioethics* 4, no. 3 (2004): 45

concept. That many of us may be vulnerable in a given situation does not make the concept useless or vacuous. Just because someone is vulnerable in one situation does not mean they will be vulnerable in all situations or even in the same situation in a different circumstance. This also means that the obligations towards them are different. Some of these obligations will have more requirements than others, and yet, this seems like an advantage to the concept and not the detriment that Wrigley and others think it is. The fact that more and more people might be considered vulnerable does not reflect badly on the concept itself, but instead may point to the need for a more nuanced theory of vulnerability. The failures of many of the current theories of vulnerability should not negate the concept's usefulness.

Wrigley's second concern is that the concept of vulnerability does not serve any real explanatory role since it fails to add to our understanding of the world in a way that is not previously captured by other concepts.<sup>12</sup> If this is in fact the case, then vulnerability serves little purpose outside of a mere signal term towards scenarios that may require special attention. The worry here is that vulnerability adds nothing, since we appeal to other concepts and background ethical theory when appealing to it anyway.<sup>13</sup> However, I argue that the concept can still be of use. In particular, vulnerability is useful in the context of research trials, as it can help decide what research is needed, who we should allow to take part in said research, how we might go about selecting participants, and how

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<sup>12</sup> Wrigley, 478

<sup>13</sup> Wrigley, 479

the research should be designed in the first place.<sup>14</sup> The concept of vulnerability seems more useful than a simple signal term.

If vulnerability is not a universal condition for all humanity, then we need to be specific about which groups or individuals might require special protections. We are left to define vulnerability in a way that is not overly broad or overly restrictive. A definition of vulnerability cannot be too broad as to encompass groups that are not necessarily vulnerable and should also not be so narrow that it misses people who should rightfully be considered vulnerable. Thus, in order to take defining vulnerability seriously, a definition must avoid treating the concept as a universal human condition, while also remaining broad enough to ensure it encompasses everyone who should rightfully be considered vulnerable. This is no small task, and there is a lot at stake when attempting to define vulnerability. Getting the definition wrong can exacerbate harm already experienced by certain groups, and furthermore risks exploiting and disrespecting groups either over or under protected by these definitions. The challenge of getting the definition of vulnerability right and the issue of whether it constitutes a universal condition can be traced throughout research guidelines, as well as the field of research ethics itself. To further illustrate this debate, I will now consider how the concept of vulnerability has been used within research guidelines.

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<sup>14</sup> Margret Meek Lange, Wendy Rogers, and Susan Dodds, “Vulnerability in Research Ethics: A Way Forward,” *Bioethics* 27, no. 6 (2013): 334



#### 1.4 Vulnerability in Ethical Guidelines

This section will consider research ethics guidelines and the role they have played in coming up with a suitable definition of vulnerability. Mainly, I will consider the Council for International Organizations of Medical Sciences (CIOMS), the Declaration of Helsinki, The Belmont Report, and the Tri-Council Policy Statement (TCPS). I will also briefly touch on the United States Federal Code of Regulations. Ethics guidelines have played an important role in the development of the concept of vulnerability for research ethics in particular. The problems of addressing and understanding vulnerability are well documented throughout these guidelines. Additionally, vulnerability has been a central concept in all of these guidelines. The interpretation of vulnerability differs between them, and in many cases changes to the understanding of vulnerability has also contributed to the revisions of these guideline<sup>15</sup> as I will now go onto explain, beginning with the example of CIOMS.

CIOMS focuses on identifying the vulnerable by focusing on the ability to consent. I will be considering multiple iterations of this guidelines and how CIOMS understanding of vulnerability has changed through these various versions. The 2002 iteration of CIOMS defines the vulnerable as those who are relatively (or absolutely) incapable of protecting their own interests.<sup>16</sup> They then go on to list groups that may be considered vulnerable, such as those who have a limited capacity for consent, the elderly,

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<sup>15</sup> See CIOMS 2016 and The Declaration of Helsinki 2013

<sup>16</sup> CIOMS, 2002, International Ethical Guidelines for Biomedical Research Involving Human Subjects, Geneva Switzerland: (CIOMS)

the unemployed, homeless people, prisoners, and those with terminal illness.<sup>17</sup> Here, CIOMS are targeting subpopulations and affixing the label of “vulnerable” to them. This approach shifts in the 2016 iteration of the guidelines. Guideline 15 of the 2016 document aims to avoid labelling and instead seeks to identify characteristics that may render someone vulnerable.<sup>18</sup> They attempt to do this by seeking to identify groups that may require special protections because they have an increased likelihood of incurring additional harm.<sup>19</sup> We are still given a list of those who may be considered vulnerable, although this is not a new approach from what is seen in the first iteration of the CIOMS document. This list includes those with a diminished capacity to consent, women (sometimes), pregnant women (in situationally specific instances) and the institutionalized. However, CIOMS 2016 takes it one step further, as they start to specify what protections might look like for these groups. One example of this is that research on vulnerable groups or people must only have minimal risk for procedures that offer no direct benefit to participants.<sup>20</sup>

The Declaration of Helsinki from 2000 defines the vulnerable as incompetent people who are susceptible to coercion, those who do not get direct benefit from research, and those who experience research mixed with clinical care.<sup>21</sup> For example, a cancer patient whose oncologist recommends they enroll in a study that aims to discover a

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<sup>17</sup> CIOMS 2002

<sup>18</sup> CIOMS, 2016, *International Ethical Guidelines for Health-related Research Involving Humans*, Fourth Edition, Geneva, Council for International Organizations of Medical Sciences (CIOMS)

<sup>19</sup> CIOMS 2016

<sup>20</sup> CIOMS 2016

<sup>21</sup> “World Medical Association Declaration of Helsinki: Ethical principles for Medical Research Involving Human Subjects” Helsinki, Finland, (2000)

treatment for their condition would be considered vulnerable. This becomes an issue because of the therapeutic misconception. A therapeutic misconception is when the patient misunderstands the purpose of research and joins for personal benefit, when the primary goal of research is generalizable knowledge.<sup>22</sup> However, in 2013 there was a revision that follows the lead of the CIOMS 2016 guidelines by recognizing that vulnerable people may have an increased likelihood of being wronged or incurring additional harm.<sup>23</sup> The 2016 document also states that research may only be done on the vulnerable if the research responds to their needs and if it cannot be done on a non-vulnerable group.<sup>24</sup>

Much like early versions of CIOMS and The Declaration of Helsinki, the Belmont Report attempts to define vulnerability based on consent. It defines vulnerability with a focus on the dependent status of those who are vulnerable, as well as a reduced capacity for consent (Belmont Report, 1979).<sup>25</sup> Again, we are met with a list, which this time includes racial minorities, the economically disadvantaged, the very sick, and the institutionalized. The Belmont report fails to explain vulnerability or how a group or individual might become vulnerable. Instead, it simply mentions the concept and lists

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<sup>22</sup> Rebecca D Pentz, Margaret White, R. Donald Harvey, Zachary Luke Farmer, Yuan Liu, Colleen Lewis, Olga Dashevskaya, Taofeek Owonikoko, and Fadlo R. Khuri, “Therapeutic Misconception, Misestimation, and Optimism in PARTICIPANTS Enrolled in Phase 1 Trials,” *Cancer* 118, no. 18 (2012): 1

<sup>23</sup>“World Medical Association Declaration of Helsinki.” *JAMA* 310, no. 20 (2016): 2191

<sup>24</sup> World Medical Association Declaration of Helsinki

<sup>25</sup> The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. 1979. *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research*. Washington D.C.: Department of Health, Education, and Welfare.

various groups that should be labeled as vulnerable. The problem with these approaches is that they assume a paradigmatic example of a vulnerable individual or group. This is worrying because every individual is different and just because someone falls into a vulnerable group i.e., the elderly, does not mean they are vulnerable solely because they belong to that group. In other words, while some elderly people may be vulnerable, some will not be, or at the very least may not be in the same ways as others who also fit into this group. It would be a mistake then to assume every single elderly person is vulnerable because some elderly people are vulnerable. This inductive reasoning creates unhelpful and problematic stereotypes and offers a simple answer to the question of who is vulnerable, when in fact a much more complex response is required.

The TCPS defines vulnerability as “A diminished capacity to fully safeguard one’s own interests in the context of a specific research project”.<sup>26</sup> This definition is very similar to the other guidelines, especially the CIOMS guideline of 2002. The focus here is seemingly on the ability to consent and protect one’s own interests. The TCPS guideline also provides a list of groups historically considered to be vulnerable. The examples provided are children, the elderly, pregnant women, prisoners, etc. However, interestingly, TCPS recognizes that individuals should not be considered vulnerable simply because they belong to a certain group that has historically been assumed to be vulnerable.<sup>27</sup> Along with this, the TCPS recognizes that vulnerability is fluid and how the

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<sup>26</sup> Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council, Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, December 2018.

<sup>27</sup> Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, December 2018.

historical exclusion of these groups that are considered vulnerable can actually make things worse for them.

It seems that guidelines show significant variation and some remaining ambiguity about what it means to be vulnerable, how one might become vulnerable, and what is owed to the vulnerable. However, maybe holding these guidelines to such high expectations is unfair. The guidelines reflect the difficulties in both understanding and applying the concept of vulnerability to research ethics. While vulnerability is a central idea in all the guidelines, it has been understood differently and has in fact necessitated change within the guidelines themselves. Should we expect guidelines to do all the work for us? I think not: the fact that there are various interpretations of vulnerability over the multitude of guidelines means there is a lot of room for inconsistency amongst them. This possibility of inconsistency in both application and interpretation means there is still a lot of conceptual work to be done to realize a useful theory of vulnerability. This will ideally fall upon the field of research ethics itself. A further implication of the ethics guidelines is the emergence of various themes throughout. There is a trend of the use of consent-based theories of vulnerability in early iterations of some of these documents, mainly CIOMS, The Declaration of Helsinki, and The Belmont Report. All these documents make some use of a labelled approach or system, for example, the variety of lists given to exemplify and denote the concept of vulnerability and who it might encompass. This relates to the consent-based definitions found in these guidelines because those who are unable to

provide informed consent get added to said lists. And finally, in later iterations<sup>28</sup> we see a focus on harm based or even comprehensive based approaches to vulnerability. Ethics guidelines alone cannot answer all the complex questions brought up by research trails, and we should not expect them to. Guidelines like CIOMS and TCPS are only meant to serve as chaperons for research trials and IRBs. We should look to the field of research ethics to do some of the heavy lifting and theoretical work to ameliorate the concerns surrounding vulnerability in research trials. I will now consider some of the prominent general approaches to vulnerability, these being consent-based approaches, harm-based approaches, comprehensive approaches, and the labels approach.

### 1.5 Prominent Approaches to Vulnerability

An important aspect to note about this literature is that it is complex. As such, I will follow the loose organization that Samia Hurst provides because it provides what I think is a fairly clear way of organizing the terrain.<sup>29</sup> Hurst begins with consent-based definitions of vulnerability. Consent-based definitions can be found in guidelines such as CIOMS and the Belmont Report, they focus on the participants' inability to provide informed consent.<sup>30</sup> One notable population that has historically fallen into this category is children. Children generally lack the ability to express their autonomy and as a result are unable to provide valid consent. While researchers may rely on an adult's ability to

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<sup>28</sup> CIOMS 2016

Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, December 2018.

<sup>29</sup> Hurst, "Vulnerability in Research Ethics and Health Care; Describing the Elephant in the Room,"

<sup>30</sup> CIOMS 2002

The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research 1979

provide informed consent to undertake the risks associated with a particular trial, they cannot do the same for children, and therefore children are often excluded in light of this.<sup>31</sup> The problem with this is that it is not clear that vulnerability should be understood as merely an inability to provide valid consent. There may in fact be instances where we do not want, nor should we expect consent to do all the heavy lifting. While consent may be a necessary condition for participation in a trial, it cannot be a sufficient one.<sup>32</sup> Due to the complex nature of research trials, I as a participant may lack crucial information, or at least a proper understanding of that information. In these instances, I would rely on the researcher to have my best interests in mind. Making decisions in research trials may take the shape of the prisoner's dilemma, where the participant needs to be confident that other participants will make the same choice as them.<sup>33</sup> For example, if everyone chooses the still medically effective but less convenient generic drug, the extra resources will ideally benefit everyone, especially those who may require the most assistance.<sup>34</sup> However, if significantly fewer participants opt to take the less convenient option, then the overall benefit is lost and only they lose out. While the inability to provide valid consent may be a necessary condition to be considered vulnerable, it cannot and should not be considered a sufficient one. The main point here is that focusing squarely on the inability to consent misses the point that consent itself should not be the primary motivating force behind a

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<sup>31</sup> Ariella Binik, "Does Benefit Justify Research with Children?" *Bioethics* 32, no.1 (2017): 27

<sup>32</sup> E.J Emanuel, D Wendler, C Grady, "What Makes Clinical Research Ethical," *JAMA*, 283, no. 20 (2000): 2701-2711

<sup>33</sup> Hurst, 193

<sup>34</sup> Samia Hurst, J Russel Teagarden, Elizabeth Garrett, and Ezikeil J. Emmanuel, "Conserving Scarce Resources: Willingness of Health Insurance Enrollees to Choose Cheaper Options," *Journal of Law, Medicine & Ethics* 32, no. 3 (2004): 498

useful theory of vulnerability. Consent should play a role, but it cannot and should not be the only factor present.<sup>35</sup>

After discussing consent-based definitions of vulnerability, Hurst then moves on to mention harm-based definitions of vulnerability. Harm-based definitions of vulnerability focus on the participants' susceptibility to exploitation. What these definitions mean can change drastically depending on how exploitation is defined. For example, if we define exploitation as treating someone as a mere means instead of an end in themselves,<sup>36</sup> which is to say in a way they could not possibly consent to, we gain a more useful definition than we would have if we were to understand exploitation as simply including harm and injustice.<sup>37</sup> We may want to further define harm-based accounts based on our natural frailty and susceptibility to compound additional harms.<sup>38</sup> However, neither of these definitions moves very far beyond what can be found in consent-based definitions. This leaves us with a consent-based definition of exploitation, and therefore would fall victim to the same critiques. Again, it seems that exploitation cannot cover the multitude of wrongs or harms that may be experienced within the research setting. Being denied participation in a trial may constitute a harm, for example,

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<sup>35</sup> An alteration of consent-based accounts can be found in: Emanuel, Ezekiel J, Xolani E Currie, and Allen Herman, "Undue Inducement in Clinical Research in Developing Countries: Is It a Worry?" *The Lancet* 366, no. 9482 (2005): 336–40.

<sup>36</sup> Immanuel Kant, *Groundwork of the Metaphysics of Morals*, Edited by Mary J. Gregor and Jens Timmermann, (Cambridge: Cambridge Univ. Press, 2012)

<sup>37</sup> Hurst, 194

<sup>38</sup> Michael H Kottow, "The Vulnerable and the Susceptible," *Bioethics* 17, no. 5-6 (2003): 460-7  
Kottow starts with the definition of vulnerability as a universal human condition and then argues that the concept of susceptibility to compound harms may be of more use for research ethics. Research ethics mistakes its participants for vulnerable (a condition common to everyone) when they are in-fact susceptible.



the wrongful historical exclusion of pregnant women. However, it cannot be said that this is an example of exploitation. Therefore, harm-based definitions seem to be insufficiently comprehensive.

Finally, comprehensive accounts of vulnerability seek to encompass a variety of definitions into one theory. These theories attempt to define the vulnerability as: (1) the inability to provide valid informed consent or the inability to protect one's interests; (2) susceptibility to incur an unfair share of the burdens in research trials; and (3) Proneness to not experience the benefit or participation in research trials because of some shared feature.<sup>39</sup> Ruth Macklin differentiates between intrinsic vulnerability (due to age, reduced cognitive ability etc.) and extrinsic vulnerability (due to hospitalization, imprisonment, financial capacity) and states that even if we presume intrinsic vulnerability, a situation can render an individual more or less vulnerable.<sup>40</sup> Starting with a basic idea of vulnerability as the relative inability to protect one's interests, she argues that a theory of vulnerability should identify individuals who are vulnerable, drawing on empirical facts and circumstances to help explain why that group may be worse off, and should also say something about preventing harms.<sup>41</sup> In a similar vein, Philip Nickel argues that the principles of respect for persons and fairness found in the Belmont Report contain overlapping senses of vulnerability related to them in the research context.<sup>42</sup>

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<sup>39</sup> Philip J Nickel, "Vulnerable Populations in Research: The Case of the Seriously Ill," *Theoretical Medicine and Bioethics* 27, no. 3 (2006): 245-264 Ruth Macklin, "Bioethics, Vulnerability, and Protection," *Bioethics* 17, no. 5-6 (2003): 472-486

<sup>40</sup> Ruth Macklin, "A Global Ethics Approach to Vulnerability," *IJFAB: International Journal of Feminist Approaches to Bioethics* 5, no. 2 (2012): 68

<sup>41</sup> Macklin, "A Global Ethics Approach to Vulnerability," 71

<sup>42</sup> Nickel, op. cit. note 31

Nickel concludes that there will then be fairness and consent-based explanations for why a group is considered vulnerable. When people cannot protect their own interests, they ought to be given special protections.<sup>43</sup> A lot of the time this is expressed in a weakened sense of autonomy, as would be the case for children. In contrast, principles of fairness can help explain the vulnerability of groups at risk on an undue inducement whereby they are presented with an offer of compensation in return for participation in a trial aimed at improving an illness. Vulnerability on these two accounts is predicated on both consent and fairness. However, the existence of wrongs that transgress things other than consent or fairness means comprehensive approaches like this one also are insufficient.<sup>44</sup> If a participant is at risk of having their confidential information released, a comprehensive approach like this one would not consider them vulnerable when perhaps they should be.<sup>45</sup> Thus, comprehensive approaches are not able to sufficiently handle the complexities found within the concept of vulnerability. This is mainly because they are far too rigid in what they are looking for.

Along with these three approaches to vulnerability, there is a fourth approach which may be taken up at the same time or exist within any of these other approaches: the labels approach. Vulnerability understood under the labels approach involves necessary and sufficient conditions that groups must meet to be considered vulnerable.<sup>46</sup> Simply put, the labels approach puts forward certain conditions that, if met by a group or individual,

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<sup>43</sup> Nickel, op. cit. note 31

<sup>44</sup> Hurst, 194

<sup>45</sup> Hurst, 195

<sup>46</sup> Florencia Luna, "Elucidating the Concept of Vulnerability: Layers Not Labels," *International Journal of Feminist Approaches to Bioethics* 2, no. 1 (2009): 123

labels that person or group as vulnerable merely because they fit in the category. We get a very simple answer to the question of who is vulnerable under this approach (for example, the inability to provide informed consent). Groups that then exhibit this condition, whether by a circumstance of their situation or a reality of their existence, would be labeled vulnerable. A prominent example of a group traditionally viewed as being unable to provide consent would be children, however, this could also be the case for the elderly in certain instances.

### 1.6 Implications of Being Labeled Vulnerable

Now that we have considered what vulnerability looks like in both research ethics guidelines and some of the conceptual work done in the field of research ethics, it is crucial to fully understand why getting these definitions right matters. This can be done by examining some of the implications that being labeled as vulnerable creates. When an individual or group is labeled as vulnerable, they then require special protection during the research trial. This additional protection may include but is not limited to certain safeguards such as a risk threshold, which aims to limit the amount of acceptable risk these individuals are allowed to incur. Another potential implication of being labeled vulnerable is the outright exclusion from the research trial altogether. While sometimes this exclusion will be warranted, other times it may not be. Unwarranted exclusion from research can have a profuse and lasting impact on the populations that are excluded. Three examples of populations that have historically been excluded from research trials are: pregnant women, children, and the elderly. Each of the guidelines would consider the elderly and children to be vulnerable, and while the same cannot be said for pregnant

women in these specific guidelines, this is not always the case. While the US federal code of regulations does not necessarily delineate what vulnerability is or might entail, it motions towards pregnant women constituting a vulnerable group.<sup>47</sup> All of these groups have often been continually excluded from research because of the perception that they will incur more than their fair share of the burden: pregnant women because of the risk to their fetuses; the elderly because of their age, disposition to certain degenerative neurological diseases, and their frailty; and children because of their inability to consent and lack of autonomy. However, by excluding these groups, we end up with a lack of research showing what treatments are suitable and safe for use on them. The result is a medication or vaccine that cannot be recommended to these groups. A very recent example of this is the COVID-19 vaccine. confusion surrounding the safe usage of the Pfizer and Moderna vaccines for pregnant women and children due to lack of testing is just one example. These groups then would initially have the decision between taking a vaccine that has not been tested on them or risking infection from the virus. Essentially, exclusion of them (especially of pregnant women) moves the risk from the controlled clinical trial to the private doctor's office.<sup>48</sup> This is merely one example; we can also look to the fact that around 70% of the drugs used on children have not been tested on them.<sup>49</sup> Or the fact that even though the elderly make up the majority of patients that receive

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<sup>47</sup> DHHS (US Department of Health and Human Services), 2009, Code of Federal Regulations: Title 45, Part 46 Protection of Human Subjects

<sup>48</sup> Angela Ballantyne and Françoise Baylis, "Excluding Pregnant Women from COVID-19 Vaccine Trials puts their Health at Risk," [https://theconversation.com/excluding-pregnant-women-from-covid-19-vaccine-trials-puts-their-health-at-risk-147414?utm\\_source=citynews%20ottawa&utm\\_campaign=citynews%20ottawa&utm\\_medium=referral](https://theconversation.com/excluding-pregnant-women-from-covid-19-vaccine-trials-puts-their-health-at-risk-147414?utm_source=citynews%20ottawa&utm_campaign=citynews%20ottawa&utm_medium=referral)

<sup>49</sup> Committee on Drugs, "Off-Label Use of Drugs in Children," *Pediatrics* 133, no. 3 (2014): 563-567

medications for the treatment chronic conditions, clinical trials are typically conducted only on participants between the ages of 18-64.<sup>50</sup> This leaves out a large portion of the senior population, resulting in the same type of worries that face both children and pregnant women.

### 1.7 Where Are We Now, and What is Left to be Done

Some of the approaches considered in this chapter will be useful for further consideration. Examples include the idea of the importance of context and the understanding of how vulnerability may change because of various contextual or situational changes. Consider that it is possible to be rendered vulnerable because of a situation, when otherwise that person may not be considered vulnerable; for example, illness may render someone vulnerable who otherwise would not be. The idea of a taxonomy and classification of vulnerability in different categories for a more detailed explanation of what the concept might entail may be useful in getting very specific about what we mean by the concept and what it entails. Kenneth Kipnis, for example, develops an analytical approach to vulnerability which involves a taxonomy of six potential sources of vulnerability (cognitive, juridic, deferential, medical, allocational, and infrastructural).<sup>51</sup> Each one of these six sources of vulnerability shows how someone may become vulnerable, and therefore requires special attention from researchers. Kipnis

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<sup>50</sup> Premnath Shenoy and Anand Harugeri “Elderly Patients' Participation in Clinical Trials,” *Perspectives in Clinical Research* 6, no. 4 (2015): 184

<sup>51</sup> Kenneth Kipnis, “Vulnerability in Research Subjects: A Bioethical Taxonomy,” in *Ethical and Policy Issues in Research Involving Human Research Participants*, National Bioethics Advisory Commission, ed, Bethesda, MD While Kipnis provides a taxonomy of vulnerability, I will later be focusing on another taxonomy that is better suited for application to research ethics. Kipnis’ taxonomy lacks duties for researchers, and as such is closer to a list making it less useful for the type of inquiry I intend to engage in.

argues that informed consent is in most cases the remedy for these issues, eventually giving a list of sorts that may deem certain research impermissible.<sup>52</sup> Finally, the focus on wrongs and how they may render someone vulnerable before, throughout, and after the research trial. Three notable accounts in particular develop these ideas into separate theories that attempt to answer the complex set of worries found in clinical trials. These three theories are the Layers approach, the Greater than Usual Wrongs approach, and the taxonomy.

These theories will be explored in further detail in the following chapter. The primary reason for a closer consideration of these three theories is that both Layers approach and to a greater extent the Greater than Usual Wrongs approach have been adopted by the ethical guidelines such as CIOMS and TCPS. CIOMS more specifically uses the Greater than Usual Wrongs special protection thesis directly in Guideline 16, where they aim to identify groups that may require special protections because of having an increased likelihood of incurring additional harm.<sup>53</sup> On the other hand, TCPS borrows from the Layers account by recognizing the fluid and dynamic nature of vulnerability and directly seeking to avoid labels. The taxonomy on the flip side intends to encompass ideas from both the Greater than Usual Wrongs and Layers accounts. The taxonomy shares the view that research ethics needs a more throughout account of vulnerability, and they intend to create such an account that pays special attention to layers.<sup>54</sup> Along with the

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<sup>52</sup> Kipnis, *op. cit.* note 51

<sup>53</sup> CIOMS 2016

<sup>54</sup> Lange et al. 336

adoption into research ethics guidelines, each of the three theories is in my view best developed for research ethics. All three attempt to create duties and obligations that seek to guide the action of researchers towards the vulnerable. How successfully they do this will be considered in the next chapter. And finally, it is my view that these three theories are the most practical of the existing theories on this topic and provide the best attempt to date at creating a theory of vulnerability sensitive to the issues the problems they attempt to ameliorate.

Having more fully discussed the history of vulnerability throughout both research guidelines and the more conceptual work in the research ethics field we can take stock of where we are at. In terms of the debate over universal versus particular approaches to vulnerability, a universal approach simply will not work. This is because vulnerability is useful in the context of research trials by helping pick out what research is needed, who should be allowed to take participate in said research, how these participants will be selected, and finally the overall design of the research. We are then left with the particular approach; a lot of work has been done that makes progress towards improving our understanding of the concept of vulnerability. Something more than a consent-based, harm-based, or comprehensive account is needed that can properly pick out reasons for special protection in order to avoid some of the worrisome implications that may come from being labeled vulnerable. The three theories covered in the next chapter have stepped in to fill some of the gaps, but there is still much work to be done.

## **2.0 Chapter 2: Layers, Wrongs, and Taxonomies**

### 2.1 Introduction

This chapter will provide a more in-depth look at the three theories I have picked out from the vulnerability literature for further review. The chapter will be organized as follows. The three theories in question – The Layers account, The Greater than Usual Wrongs account and The Taxonomy – will each be explained in greater detail. After each explanation, I will summarize the chief advantages of the theory, and then critique it. The Layers account provides a lot of flexibility and can account for circumstances outside of the research protocol. However, The Layers account provides no guidance on how or when these layers should be applied. The Greater than Usual Wrongs account can easily point out where transgressions may occur in a research trial, but it fails to provide a baseline of harm. The Taxonomy on the other hand, provides a straightforward way to identify harms and their sources. Nevertheless, it fails to function as a proper taxonomy, meaning it does not go much further than merely providing a list. The goal of this chapter as a whole is not only to provide an understanding of the theories that will be central to my own view in the next chapter, but also to illustrate some answers and some problems that have already been addressed. I will conclude that while each theory makes progress towards solving the complex questions associated with research trials involving human participants, much work is still needed to create a persuasive account of vulnerability.

### 2.2 Layers Approach to Vulnerability

In a series of recent publications, Florencia Luna has developed a theory of vulnerability that she calls the Layers approach. The Layers approach is put forth as a



response to what she viewed as the leading approach to vulnerability, mainly the labels approach. The labels approach to vulnerability has a long history in research ethics guidelines, providing a simple answer to a very complex question. The labels approach puts forward conditions that if met by an individual or group label them as vulnerable. Under this approach we might consider all pregnant women vulnerable because they fit a paradigmatic example of a vulnerable person, even if this is not actually the case. Vulnerability, as understood in the labels approach, involves necessary and sufficient conditions that must be fulfilled for a person or group to be considered vulnerable.<sup>55</sup> Groups the labels approach may consider vulnerable include, but are not limited to, pregnant women, children, the elderly, prisoners, etc. This subpopulation approach assumes a baseline of the paradigmatic research subject (a mature, educated person), and then assumes identifying vulnerabilities in subpopulations is merely a matter of identifying variations from the paradigm.<sup>56</sup> This approach seems to assume that what it means to be vulnerable looks the same for everyone, essentially meaning that groups are heterogeneous, and every member is the same. This is plainly not the case. Consider the elderly, a population historically considered to be vulnerable. Each individual member may be vulnerable in separate ways to separate things, and some may not be vulnerable at all. For example, an elderly person with a degenerative brain disorder may not have the ability to provide informed consent, and this may make them vulnerable, but this does not mean every single elderly person is vulnerable. To give an example, the current

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<sup>55</sup> Luna, "Elucidating the Concept of Vulnerability: Layers Not Labels."123

<sup>56</sup> Florencia Luna and Sheryl Vanderpoel, "Not the Usual Suspects: Addressing Layers of Vulnerability," *Bioethics* 27, no. 6 (2013): 325-332

President of the United States Joe Biden would be someone who falls into the category of elderly without being clearly vulnerable. The subpopulation or labels approach assumes this similarity between groups by setting out conditions that, if met by a certain person or group, labels certain groups as vulnerable simply because they fit the category. According to Luna, there are a few worries associated with this approach. One worry is that the baseline would need to be continually adjusted to fit populations that fall outside the baseline or paradigm, while another is that people often will suffer from varying types of vulnerability and could experience these different types at the same time as the others.<sup>57</sup> If we are to label groups as vulnerable, there is no space at all to accommodate these worries. Thus, the labels or subpopulation approach looks to address a complex issue with a simple response, while also assuming that vulnerability is a permanent and categorical condition.<sup>58</sup>

The goal of the Layers approach is to provide an account of vulnerability that overcomes these worries about the label approach and more accurately embodies what Luna understands the concept of vulnerability to mean. She wants to create “an account that does not render vulnerability vacuous, rescues its force and importance, and allows us to avoid labelling entire groups”.<sup>59</sup> Luna posits that we may understand the concept of vulnerability by using what she calls “layers.” As I understand it, a layer for Luna is simply an instance of potential vulnerability. For example, someone with a terminal

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<sup>57</sup> Luna, “Elucidating the Concept of Vulnerability: Layers Not Labels.”123

<sup>58</sup> Luna, “Elucidating the Concept of Vulnerability: Layers Not Labels.” 123, 129

<sup>59</sup> Luna, “Elucidating the Concept of Vulnerability: Layers Not Labels.” 128

illness who is also economically disadvantaged could be assessed using two separate layers as a result of their situation. She argues that “the metaphor of layers gives the idea of something ‘softer,’ something that may be multiple and different, and may be removed layer by layer”.<sup>60</sup> It is important to note that Luna thinks her account of layers is not overly rigid and therefore does not exhaust the category; the layers may result from different vulnerabilities, and the layers may overlap. We may relate some layers to problems concerning informed consent, while others may concern social relations.<sup>61</sup> This metaphor is not Luna’s definition of vulnerability per se. In fact, the lack of a precise definition of vulnerability is a tension that is present throughout Luna’s account. I will address this worry later in the chapter when I consider critiques of the various theories covered here.

To illustrate what Luna is thinking of here, consider an economically disadvantaged individual in a risky clinical trial that offers a cash incentive for participation. This person would be given a layer of vulnerability because their social position makes them more at risk of suffering the harms that may follow from participating in the trial because they need the money to live. On top of this, the individual in question may be illiterate, making it much harder for researchers to obtain informed consent from this person; again, this would add another layer on top of the previous one. Not only can these layers be added one-by-one, but they may also be

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<sup>60</sup> Luna, “Elucidating the Concept of Vulnerability: Layers Not Labels.”128

<sup>61</sup> Luna, “Elucidating the Concept of Vulnerability: Layers Not Labels.”128

removed one-by-one as well.<sup>62</sup> For example, we might remove the illiteracy layer by verbally communicating the necessary information to the person instead of making them read the consent form by themselves. This action alone may not fully remove this person's vulnerability, but it can remove at least one of their layers, with similar actions being taken to remove other layers that they might experience.

Luna thinks that the idea of layers gives the concept of vulnerability flexibility. The way the layers approach does this is by recognizing that there is no single condition that counts as making someone vulnerable. Instead, layers of vulnerability are multifaceted and diverse. Luna believes that the layers approach solves the problem presented by the labels approach because it allows vulnerability to be a more nuanced concept. Instead of simply looking to a list and then attributing the label of vulnerability to all who fit the description denoted on the list, we can think about why a certain situation may create vulnerability for an individual. We are then able to apply various layers to that person, and then they may also be removed one by one. The label approach provides a simple answer to a complex question because it assumes that everyone individual that fits under a specific label is the same. For example, the labels approach would assume that a group like the elderly are all vulnerable for the same reasons, and that they all experience their vulnerability in the same ways. Luna's layered approach recognizes this worry and aims to provide complex answers to these complex questions.

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<sup>62</sup> Florencia Luna, "identifying and Evaluating Layers of Vulnerability – A Way Forward," *Bioethics* (2019):88

Luna argues that vulnerability is a contextual condition. In other words, if a person's situation changes, they may no longer be considered vulnerable, if a feature of their situation rendered them vulnerable in the first place.<sup>63</sup> For example, people who work in mines may be vulnerable to cave-ins during their shifts (this would add a layer). However, after leaving the mine shaft at the end of their shift, this layer is removed since the vulnerability is no longer present because of a change in situation. We would not say that a miner at home eating dinner is still vulnerable to a cave in. Here, the Layers approach is recognizing that the person themselves is not vulnerable; instead, it is characteristics of their given situation that make them vulnerable. In other words, for Luna, a person's situation is what creates vulnerability, not the person themselves. It therefore appears at first glance that vulnerability in the Layers approach cannot be a permanent condition of an agent, because if layers are tied to one's situation, they also go away when that situation changes.

Luna sets out a way in which we might go about identifying and prioritizing layers. The first consideration one must account for when attempting to think about prioritizing certain layers over others is that we must first identify the layers. What this means is that we must look at what makes up the varying layers of vulnerability that someone might have. In other words, we must look at the content of the layers. For example, we could look at how consent is given and whether a person's social status is being exploited. Luna thinks layers are dispositional, and therefore that we must also

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<sup>63</sup> Luna, "Identifying and evaluating layers of vulnerability—a way forward," 88

consider the structure and relevant characteristics of people's dispositions.<sup>64</sup> Someone who has a genetic predisposition to breast cancer may be given a layer as a result. For Luna, it is the emphasis on the potential of being harmed or exploited that is relevant to determining vulnerability. If a person has already been harmed or exploited, Luna believes they are no longer vulnerable, because they have already been harmed or exploited.<sup>65</sup> For example, if a participant in a research trial is harmed or exploited by some characteristic of the trial, on Luna's account we would not say that person is still vulnerable to these characteristics because they have already been harmed or exploited by them.

Dispositions on Luna's account are important as they relate to stimulus conditions. A stimulus condition is simply the event that will cause the disposition to actualize. For example, the socio-economically disadvantaged person may have a disposition to being exploited in trials which offer monetary incentives for participation. However, this would not be the case if the trial offered no incentive at all for participation. In this example, the incentive acts as the stimulus condition that actuates the disposition. In other words, the disposition is dormant until the specific stimulus condition (the incentive) triggers it.<sup>66</sup> If the incentive is not there, then it does not actuate the layer.<sup>67</sup> It is then crucial to identify any potential stimulus conditions present in research trials. Luna thinks that if we can identify the stimulus conditions that trigger the various layers of vulnerability, and if we

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<sup>64</sup> Luna, "Identifying and evaluating layers of vulnerability—a way forward," 91

<sup>65</sup> Luna, "Identifying and evaluating layers of vulnerability—a way forward," 91

<sup>66</sup> Luna, "Identifying and evaluating layers of vulnerability—a way forward," 91

<sup>67</sup> Luna, "Identifying and evaluating layers of vulnerability—a way forward," 91

can also remove them, we could avoid the harmful consequences of those layers.<sup>68</sup> What is important to note is that even if the stimulus condition does not occur or is sufficiently unlikely to occur, that person must still have a layer.<sup>69</sup> This layer will simply not be given priority, but it is still important that it is there, so that we are aware of the potential for the actuating of that layer.

The second consideration one must contemplate when thinking about prioritizing certain layers over others concerns what Luna refers to as cascade layers. In plain terms, we can think about a cascade layer as a layer that acts like a domino might when struck by another domino. This is to say that a layer cascades, causing more layers to actuate and thus exacerbate a person's vulnerability because of the cascade layers being triggered.<sup>70</sup> There are two features of these types of layers that are important to focus on: the first is its origin and the second is its effects. The origin of the layer looks at the generation of this type of layer "by morally dysfunctional interpersonal and social relationships," while its effect looks at "the consequences this kind of layer entails".<sup>71</sup> Luna focuses more squarely on the cascade layers effect. An example of a cascade layer would be the lack of an early diagnosis of a disease like cancer. This then leads to various other complications such as the stage and severity of the cancer progressing, causing more harm which could have potentially been avoided had the person been diagnosed earlier. In sum, cascade layers differ from normal layers since if the stimulus condition is triggered for a cascade

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<sup>68</sup> Luna, "Identifying and evaluating layers of vulnerability—a way forward," 91

<sup>69</sup> Luna, "Identifying and evaluating layers of vulnerability—a way forward," 91

<sup>70</sup> Luna, "Identifying and evaluating layers of vulnerability—a way forward," 92

<sup>71</sup> Luna, "Identifying and evaluating layers of vulnerability—a way forward," 91-2

layer, that layer then triggers another layer and on and on. The actuation of a cascade layer also acts as the stimulus condition for another layer. The first step in Luna's account, then, is to identify the content of the layers, identify any stimulus conditions, and also ascertain whether there are any cascade layers.

The second step in Luna's account is to evaluate the given layers and lay out obligations. Evaluating the layers allows us to rank them, giving the most harmful layers priority. Cascade layers tend to be the most harmful, given their domino-like effect. We should give priority to these layers, considering their unique potential to exacerbate harm.<sup>72</sup> During the ranking of the layers, we must give focus to the potential harm that they will cause, while also paying attention to the probability that they will actuate.<sup>73</sup> Luna gives layers with stimulus conditions that are more likely to occur higher priority. What we end up with then is a ranking that looks something like this: (1) cascade layers, (2) very harmful layers, (3) very probable layers. These three factors (harm, probability, and potential to cascade) together help to determine the priority ordering of potential layers of vulnerability. Luna notes that ordering the layers in this way will not always be possible since reality can influence the ability to follow such a strict ranking.<sup>74</sup>

This brings us back to the question mentioned earlier in the chapter: does having additional layers lead to increased vulnerability on Luna's account? This is a central question for Luna's account because if certain layers have priority over others, is

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<sup>72</sup> Luna, "Identifying and evaluating layers of vulnerability—a way forward," 92

<sup>73</sup> Luna, "Identifying and evaluating layers of vulnerability—a way forward," 92

<sup>74</sup> Luna, "Identifying and evaluating layers of vulnerability—a way forward," 93



someone with two high priority layers more vulnerable than someone who maybe has five layers of less priority? Or is everyone attributed the same level of vulnerability regardless? Given the ranking and what Luna thinks about the various layers, it seems clear that additional layers do not necessarily equal increased vulnerability – but they might. What I mean by this is that if we accept Luna’s ranking, the level of vulnerability would depend on what type of layers they were (cascade/ normal), how harmful they were, and how probable they are. If someone has a multitude of layers but these layers are not very probable or harmful, this person may does not seem to be additionally vulnerable because of the number of layers they have alone. If this person also had a few cascade layers and very harmful layers on top of this, we might say that they are additionally vulnerable. At least, it seems useful to Luna’s account to allow the possibility of this.

In sum, Luna puts forth an account of vulnerability that attempts to be relational, flexible, and dynamic. She thinks that the metaphor of layers helps to achieve these goals by considering that vulnerability may arise because of certain circumstances or situations one might find themselves in. Tied up within this understanding is the idea that a person may be vulnerable to multiple different things at the same time and may experience these layers to differing extents and lengths. Along with her layered approach to vulnerability, Luna also attempts to attach or tie three types of obligations to her theory that fall upon those responsible for the vulnerable. For example, in a research trial the responsibility to uphold these obligations would fall on the IRB overseeing the trial and the researchers themselves. The first is the obligation to avoid exacerbating layers. In other words, we

should not make a person's or group's vulnerability worse.<sup>75</sup> Second, we have an obligation to eradicate the layers of vulnerability. What is important here is that we can only require this to a certain extent when possible.<sup>76</sup> Finally, we have an obligation to minimize layers. Essentially, this obligation connects to the second obligation, in that if we could not eradicate the layers, we should aim to minimize them as much as possible. Luna thinks this can help research boards in the evaluation of protocol to analyze, evaluate, minimize, and remove the layers of vulnerability. The scope of these duties or obligations and whether they create any sort of action guidance is a problem faced by Luna's account.

The chief advantages to Luna's account are its flexibility and its relational and dynamic nature. One of the biggest strengths of Luna's account is that it is not overly restrictive. Her account recognizes that vulnerability is not a permanent or categorical condition, and that people may suffer from varying types of vulnerability at the same time. This allows Luna's approach to take a nuanced view of vulnerability and to strip it back layer by layer. This could be useful in a research context, since it would allow researchers to take a microscope to each individual aspect of the research design and protocol to see what might create a layer of vulnerability. If we consider the miner example from earlier, they may be vulnerable to cave ins at work, but perhaps they also have lung issues due to the conditions at their work, and they may also be hard of hearing due to the constant noise. We could assess the miner a layer for each of these separate

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<sup>75</sup> Luna, "Identifying and evaluating layers of vulnerability—a way forward," 93

<sup>76</sup> Luna, "Identifying and evaluating layers of vulnerability—a way forward," 93

circumstances. After this is done, researchers can look at the research protocol and figure out of anything in particular may exacerbate or cause harm as a result of these layers. For example, because the miner has issues with their lungs, the researchers must avoid enrolling them in research that may exacerbate this issue because of some feature of the research trial.

### 2.3 Critiquing the Layers Account

Luna's account, while being relational and dynamic, is far too broad to handle the specific vulnerabilities found within research trials on human subjects. Luna claims that her account does not have a single standard or ideal for what it means to be vulnerable; instead, there are multiple factors involved.<sup>77</sup> However, Luna is not explicitly clear here about these other sources, nor is she clear about defining what the concept of vulnerability means. While Luna could argue that this is a strength of her account because it avoids any rigidity by not specifically naming these sources or defining the concept, I think that in certain contexts, it acts as a detriment to her theory. This is because it seems that Luna's account cannot work efficiently when we talk about extremely limited or specific cases. For example, when we talk about pregnant women, Luna's account may identify some as vulnerable when they are not. This is because layers, while contextual, do not seem to have a limit in their application. Or at least, Luna is not clear about when we should and should not apply layers to a person. Consider a pregnant woman who along with her pregnancy is economically disadvantaged. While she may have a layer

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<sup>77</sup> Luna, "Identifying and evaluating layers of vulnerability—a way forward," 88

added because of her disadvantage, this layer does not necessarily matter if the research does not provide an undue inducement. She may also have a layer added if she lives in an area where there is a lack of free access to health care, perhaps she broke her leg and is less mobile, maybe she suffers from chronic migraines, maybe she was just rejected by her partner. We could add a layer for all these separate instances, but it is not immediately clear that each of them makes her vulnerable or which ones we should care about. When Luna states that layers are contextual, I assume she means the person's context and not the context of the research trial itself. The reason for this assumption is that Luna herself states that a person's vulnerability can change if their situation changes such that they are no longer vulnerable.<sup>78</sup> And yet, I think one implication of Luna's theory is that it can add these layers for just about anything which could negatively affect someone.

In addition, Luna's account is also not adequately able to handle the research sphere. Luna claims that her account provides a fine-toothed comb for the research context, allowing researchers to view the various layers present within their protocol and address them as needed. However, she does a poor job of explaining how researchers ought to handle the various possible layers. For example, Luna claims that there is a duty to not exacerbate layers, to eradicate them, and to minimize them.<sup>79</sup> But Luna does not say how any of this will be done, nor is she very clear on who has these obligations in the first place. Do they fall upon the REB, perhaps the government, or even public health policy? Luna does note that the strategies involved to work on removing layers will be different,

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<sup>78</sup> Luna, "Elucidating the Concept of Vulnerability: Layers Not Labels," 129

<sup>79</sup> Luna "Identifying and evaluating layers of vulnerability—a way forward" 93

but she is unclear exactly what this entails. If we consider who should be allowed to participate in research, I am unsure if Luna's account will be able to identify who has what obligation here and what that obligation looks like aside from avoiding, eradicating, and minimizing layers. If we consider this along with the fact that the Layers account has a hard time identifying layers (and to a greater extent limiting their identification) the issue of attaching obligations to these layers is only further complicated. This ambiguity takes away from her theory's ability to properly apply these obligations to research trials. Luna might say that this is a benefit of her account since it would be hard to determine in every single instance who is responsible for the vulnerable. Perhaps, those who already have an obligation towards them will hold these responsibilities. If this is the case, much of the responsibility will fall upon researchers and REBs. However, should these groups be responsible for ameliorating layers of vulnerability that fall outside the research context? Luna's account relies on some level of ambiguity that creates a scenario where it is almost impossible to assign responsibility for the care of the vulnerable aside from those who may be responsible for them in other instances. This is worrisome because if we are not only unsure about when or how layers apply but are also unable to properly assign or motivate obligations towards the vulnerable, we are left with an account that assigns layers for a lot of things it probably should not, and can only tell us to avoid, eradicate, and minimize them. All of this is to say that Luna's account is neither conceptually clear enough nor action-guiding enough to handle a research context well.

#### 2.4 The Greater than Usual Wrongs Account

In her 2008 article, *Vulnerability in Research Ethics and Health Care; Describing the Elephant in the Room*, Samia Hurst advances an approach to vulnerability focused on wrongs. I will refer to this account as the Greater than Usual Wrongs account. The Greater than Usual Wrongs account differs from the broader Layers approach, instead opting to focus on wrongs and one's potentially increased susceptibility to them. This approach focuses on the likelihood of incurring additional or greater wrong.<sup>80</sup> Hurst argues that the restrictive nature of her account is necessary because any account of vulnerability on which every member of humanity turns out to be vulnerable cannot provide any reason for special protection.<sup>81</sup> On the whole, Hurst's goal is to develop an account of vulnerability that is restrictive enough that it allows vulnerability as a concept to not become naturalized or seen as a universal human condition, while remaining broad enough that it is able to rightfully capture everyone who should be considered vulnerable. Hurst positions her theory as an answer to some of the main issues that face three of the most prominent approaches to vulnerability (the consent, harm, and comprehensive approaches). All three of these accounts suffer from the same or similar issues, according to Hurst, in that they are too broad or insufficiently comprehensive. This is to say that each of the three accounts only covers one aspect that is important to a concept of

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<sup>80</sup> Hurst, 197

<sup>81</sup> Hurst, 192

vulnerability, but crucially leaves out others. In short, Hurst’s account aims to provide a definition of vulnerability that is both comprehensive and useable.<sup>82</sup>

The Greater than Usual Wrings account offers a definition of what it means to be vulnerable. Hurst argues that vulnerability should be understood as a claim to special protection. The claim to special protection can be understood as “an identifiably increased likelihood of incurring additional or greater wrong”.<sup>83</sup> It is important to note that Hurst thinks that there are situations in which we should neither expect nor require a patient to protect every single one of their own interests.<sup>84</sup> Certain interests are harder to protect than others, especially in a clinical setting. For example, someone who is able to fully consent and protect their own interests normally could still incur a greater or additional wrong in a clinical research setting.<sup>85</sup> Considering this, we cannot rely upon an account solely based upon consent or the ability to protect one’s interests, since these accounts will be insufficient in examples like the one just mentioned. Hurst’s account then aims to create an understanding of the concept of vulnerability that is not restricted to the ability to protect one’s interest or to give valid consent.

Hurst’s definition of vulnerability as an identifiably increased likelihood to incur additional or greater wrongs is connected to certain valid claims that we have. However, it is unclear what exactly Hurst means by a “valid claim” in a research setting. Elsewhere, Hurst and several colleagues discuss what a valid claim might look like in a health care

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<sup>82</sup> Hurst, 192

<sup>83</sup> Hurst, 196

<sup>84</sup> Hurst, 196

<sup>85</sup> Hurst, 196

setting.<sup>86</sup> However, they are silent as to what these claims might look like when considering research involving human participants. They do provide some insight into what a valid claim might look like in other settings, though. An identifiably increased likelihood to incur additional or greater wrongs equates to the thought that someone is being denied adequate access or satisfaction of certain legitimate claims that they have.<sup>87</sup> Claims are something that imposes a duty onto someone else. We can logically state this as follows: “X has a claim that Y does not infringe upon X’s physical integrity — where Y refers to everyone. Most importantly, it is conditional upon Y having a correlative duty of the form Y has a duty to X not to infringe upon X’s physical integrity”.<sup>88</sup> For example, if we assume that health care is a right, then I have a right to satisfactory access to health care, which correlates to a duty that someone (most likely the government) must provide me with satisfactory access to health care. My claim to healthcare is violated then if the government transgresses their duty. In sum, I have a claim that you do something or refrain from doing something, which implies that you have a duty to me to do or not do that very thing.

The specific claims we are concerned with will mostly be morally protected needs, for example, the right to autonomy or self-determination. The problem arises when we then attempt to decide what constitutes a valid claim in a research setting. This is because reasonable people will disagree on what should and should not count as a valid

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<sup>86</sup> Nicolas Tavaglione, Angela K Martin, Nathalie Mezger, Sophie Durieux-Paillard, Anne Francois, Yves Jackson, Samia Hurst, “Fleshing out Vulnerability,” *Bioethics* 29, no. 2 (2013): 98-107

<sup>87</sup> Tavaglione et al, 98

<sup>88</sup> Tavaglione et al, 99



claim. We know this to be the case because many reasonable people disagree about the right way to live or what makes someone's life go well. Examples of potential valid claims in the research setting might be a claim to autonomy, equal participation in clinical trials, or a claim to not being enrolled in research without my consent. Thus, if any of these duties were transgressed by researchers, for example, I would be at risk of incurring additional wrongs as result of this.

Hurst's definition of vulnerability is connected to these types of valid claims, and this is important because they restrict her account's focus. The special protection thesis is "restricted to wrongs, including wrongful harms that we incur when something we have a valid claim to is denied [to] us".<sup>89</sup> Therefore, the definition cannot include a harm of interests that are sufficiently hard to protect. We simply do not have, nor can we have, a duty to protect every single interest that someone might have. Suppose that someone was to enroll in a research study, and this research does not lead to any meaningful contribution or outcome. We cannot say that their interest in not having their time wasted is something that an IRB should protect them from. This is not possible and should not be a goal of a theory of vulnerability since it risks making the theory far too broad. Hurst thinks that her approach to vulnerability will require starting from the types of wrongs likely to occur.<sup>90</sup> No single transgression may be linked to vulnerability on this account. Instead, the wrongs suffered can be varied and multifaceted, while also being experienced

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<sup>89</sup> Hurst, 196

<sup>90</sup> Hurst, 196

in different ways by different individuals or groups.<sup>91</sup> Additionally, Hurst's account does not try to recognize all forms of vulnerability. In other words, it will not identify vulnerability that is associated with the morality of the human condition or our natural culpability.<sup>92</sup> Instead, the focus will be on picking out the types of wrongs or vulnerabilities what require special attention in research trials. Once this is done, there can be a comparison to the approaches normally taken to avoid perpetuating these wrongs.

The application of Hurst's theory takes the form of a four-step approach. These steps are:

“(1) is there an identifiable potential wrong; (2) if yes, are some people identifiably more likely than others to incur this wrong or likely to incur it to a greater degree; (3) who shares in the duty to minimize, or avoid this wrong, and does it include us in any way; (4) and what should we do to minimize, or avoid, this likelihood or degree, or compensate for it in ethically justifiable ways”.<sup>93</sup>

It is crucial to note that Hurst's definition of vulnerability is silent as to who will have a share in the duty to protect the vulnerable. I will return to this critique later in the chapter. Bearing this in mind, Hurst adds a third step that shows that since the wrongs likely to occur are multifaced, it is unreasonable to point the finger at a single agent or group who might be responsible for ameliorating these wrongs. The type of wrong that occurs will

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<sup>91</sup> Hurst, 196-7

<sup>92</sup> Hurst, 197

<sup>93</sup> Hurst, 197

determine who has a responsibility or duty to prevent them. However, this makes it extremely challenging for Hurst's account to define vulnerability.<sup>94</sup> This is because vulnerability is "as multiple as potential wrongs and as sources of greater likelihood of suffering them".<sup>95</sup> Nevertheless, this does not void the concept of its usefulness, since even though we may disagree "in the grey zone," differences in the likelihood of suffering wrongs will most of the time be sufficiently marked and uncontroversial.

The key advantage of the Greater than Usual Wrongs account is that it restricts Hurst's account to deal only with certain wrongs and wrongful harms that may occur when a valid claim is denied to us.<sup>96</sup> This allows her account to focus on the types of claims participants might have in the research context. With this in mind, she can then point out where transgressions could occur. She then provides a rubric of potential research related wrongs that could occur. This helps her account clearly lay out the potential concerns for IRBs. Finally, Hurst's account has a narrower focus on research, ideally making it equipped to deal with uniquely research related wrongs.

### 2.5 Critiquing the Greater than Usual Wrongs Account

Hurst's account, unlike Luna's account, can be critiqued for being too narrow. Hurst's account is too narrow because it only focuses on or applies specially to the context of research and clinical care. Hurst's account then cannot address possible circumstances which may affect someone outside of this context.<sup>97</sup> Hurst takes wrongs to

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<sup>94</sup> Hurst, 196

<sup>95</sup> Hurst, 197

<sup>96</sup> Hurst, 195

<sup>97</sup> Macklin, "A Global Ethics Approach to Vulnerability" 69

be multiple and varied. However, this only appears to be the case within the research or clinical context. Hurst claims that her theory must focus on the research protocol and environment instead of being restricted to the characteristics of the potential subjects.<sup>98</sup> However, this may end up being problematic when we consider some of the complex concerns related to research trials. One of these concerns is the effect on those outside the trial and potential participants' circumstances outside the trial. Hurst's account will not be able to consider someone's situation before they enter clinical care or a research trial. Another way to phrase this critique would be that it may be hard to determine when a claim is valid or under what circumstances might it become valid. For example, women may experience a variety of harms or wrongs outside the context of research. This may be the case because of societal and patriarchal norms that treat gender, sex, or race as important or salient characteristics.<sup>99</sup> It does not appear that women who experience these harms have a valid claim denied to them in the research context, and yet these harms and wrongs do not simply disappear upon taking up the mantle of a research participant. Instead, this is something they come into the research trial with because it is an unfortunate reality of their existence within these societies. The Greater than Usual Wrongs account will not be able to handle this because of the narrow focus of the account. It would then seem that this person could be admitted research or deemed to not need special care or attention, when in fact they might. Now what this special care or attention might look like is still an unanswered avenue. What is important, though, is that

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<sup>98</sup> Hurst, 196

<sup>99</sup> Macklin, "A Global Ethics Approach to Vulnerability" 69

The Greater than Usual Wrongs account is unable to deal with these types of circumstances, since the account does not appear to consider the characteristics of the person before they enter research or clinical care and is instead focused upon the possible wrongs they may incur when in these different contexts presented by research trials.

A second critique that can be leveled at the Greater than Usual Wrongs account concerns how we might identify, track, and apply these wrongs. Another way to phrase this would be to say that the Greater than Usual Wrongs account suffers from a specificity problem. This concern arises because it is never clear what exactly constitutes an additional or greater wrong, or a valid claim for that matter. Hurst is clear that she is only concerned with wrongs, wrongful harms, and the wrongs we incur when a valid claim is denied to us.<sup>100</sup> However, she never explains what constitutes a valid claim. Hurst's special protection thesis, which is central to her argument and theory about research, is only applied to clinical care. What this means is that what constitutes a legitimate claim here is largely unanswered. This is problematic because, if we cannot identify what a legitimate claim is, then the entire theory loses a lot of its potential use. If we cannot identify what legitimate claims someone may have in relation to research trials with human subjects, then we become stuck on how to address them. It is exceedingly hard to address something when you cannot identify it in the first place. Not only that, but how should we be tracking the types of wrongs possible in these contexts? It is already clear that the Greater than Usual Wrongs accounts ability to identify and apply these wrongs

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<sup>100</sup> Hurst, 196

may be limited due to a lack of specificity, but this seems to be the result of an inability to track them in the first place.

A related problem for the Greater than Usual Wrongs account is that Hurst specifies no baseline amount of harm. If there is no baseline to go off, then it becomes increasingly difficult to assess what we might mean by “greater” or “additional”. In other words, if we want to say that vulnerability is an increased likelihood of incurring greater or additional wrongs, and there is no baseline to go off, who or what are we basing the idea of an increased likelihood on? There needs to be a proper baseline here: we cannot assess increased likelihood without first figuring out what exactly it is that makes something a greater or additional harm. The words “greater” and “additional” must relate to something, otherwise, what differentiates between harms? Thus far it seems that the answer is nothing, and this is unsatisfactory and worrisome if we want to become specific about the types of wrongs and harms present in research trials. This is because there could be differing levels of harm experienced and the same wrong or harm may impact separate individuals in vastly disparate ways. If we add on top of this the fact that the Greater than Usual Wrongs account is generally silent about who has a share in the duty to protect the vulnerable, there is a major concern as to not only what counts as an additional or greater wrong, but also whose responsibility it is to ameliorate it. In sum, the Greater than Usual wrongs account can then be critiqued in three main ways (1) the person’s circumstances outside of the trial; (2) a specificity problem that impacts the accounts ability identify, track, and apply the types of wrongs it is concerned with and; (3) the lack of a baseline of harm.

## 2.6 The Taxonomy

In their 2013 article, *Vulnerability in Research Ethics: A Way Forward*, Margaret Meek Lange, Wendy Rogers, and Susan Dodds aim to provide a typology of vulnerability that will (1) accurately describe and define a broad range of vulnerabilities, and (2) identify the moral duties for researchers that emerge from the differing types of vulnerability.<sup>101</sup> Lange and colleagues propose their taxonomy as a way to overcome shortcomings they find in both the Greater than Usual Wrongs and Layers accounts. They share the opinion of Hurst and Luna that vulnerability requires more careful attention and seek to put forward an account that “captures Luna’s insight that vulnerable research participants inhabit a context generated by the coming together of layers of vulnerability”.<sup>102</sup> However, Lange and colleagues hope to make progress towards naming and classifying the layers, while also remaining vigilant to the layers’ potential interactions.<sup>103</sup> Tied up within this, they attempt to construct an account of the duties involved in answering the questions posed by vulnerability “that avoids stereotyping and paternalism and is also consistent with the principle of respect for individual autonomy”.<sup>104</sup> The taxonomy recognizes the contributions made by Luna and believe that an account of vulnerability must capture Luna’s argument that vulnerable research participants inhabit a space that is created by the coming together of the layers of vulnerability.<sup>105</sup> Lange, Rogers, and Dodds’ continue by stating that this approach to

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<sup>101</sup> Lange et al, 334

<sup>102</sup> Lange et al, 336

<sup>103</sup> Lange et al, 336

<sup>104</sup> Lange et al, 334

<sup>105</sup> Lange et al, 335

vulnerability must make progress towards naming and classifying the layers of vulnerability, while recognizing the interactions between these layers and accounting for certain duties related to or owed to the vulnerable.<sup>106</sup> This is their starting point. From there, they aim to provide an account of vulnerability that fits into a taxonomy aimed at understanding more than ordinary vulnerability.

When Lange, Rogers, and Dodds talk about vulnerability, most of the time they are referring to more than ordinary vulnerability. They believe that this type of vulnerability entails an increased risk of incurring harms or wrongs.<sup>107</sup> Here it seems that Lange, Rogers, and Dodds' are incorporating the definition found in the Greater than Usual Wrongs account. The authors think that more than ordinary vulnerability also recognizes that people and groups will vary in their exposure to risks and also in the resources that they have available to them to help mitigate or counter these risks.<sup>108</sup> They classify the unique sources of vulnerability into three categories that may overlap and two states that these sources could be experienced as. These sources or categories are inherent, situational, and pathogenic, while the two states they may be experienced as are occurrent (immediate and present) or dispositional (latent and background). For example, while everyone experiences dispositional vulnerability to hunger, most people in an affluent country do not experience an occurrent sense of vulnerability to death because of a lack of secure continual access to food. They believe that these three sources and two

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<sup>106</sup> Lange et al, 226

<sup>107</sup> Lange et al, 336

<sup>108</sup> Wendy Rogers, Catriona Mackenzie, and Susan Dodds, "Why Bioethics Needs a Concept of Vulnerability," *IJFAB: International Journal of Feminist Approaches to Bioethics* 5, no. 2 (2012): 12



states can “explain an individual’s susceptibility to harms or wrongs”.<sup>109</sup> Additionally, if a particular risk is due mostly to a single source of vulnerability, they refer to that vulnerability as inherent, situational, or pathogenic.

Inherent sources of vulnerability are those which are innate to the human condition. In other words, they are “our corporeality, our neediness, our dependence on others, and our affective and social natures”.<sup>110</sup> An important aspect of inherent sources of vulnerability is that they are inescapable because of the very nature of the human condition. Inherent sources of vulnerability may produce risks or wrongs associated with health, age, gender, disability, one’s ability to cope, and the social structure that they live in, and the supports available to them.<sup>111</sup> The extent to which inherent sources of vulnerability impact someone may change in relation to the scope of support that is available to them.<sup>112</sup> For example, a research participant who identifies as non-binary could be inherently vulnerable because of this. This vulnerability could be occurrent if they live somewhere where this gender identity is not widely accepted. In contrast, if they live somewhere their gender identity is accepted, this vulnerability would instead be dispositional.

The second source of vulnerability Lange, Rogers, and Dodds account for is what they refer to as “situational.” Situational sources of vulnerability are context specific and

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<sup>109</sup> Lange et al, 336

<sup>110</sup> Lange et al, 336

<sup>111</sup> Lange et al, 336

<sup>112</sup> Rogers et al, 24

include the personal, social, political, and environmental or economic.<sup>113</sup> Situational sources of vulnerability could be experienced intermittently or have a more enduring impact upon a person or group. For example, working in a care home for the elderly during a pandemic will render the support staff vulnerable because of their situation. However, if they are given proper personal protective equipment and rotate out on shifts, then this vulnerability will be more intermittent. However, the residents of this care home may experience a more permanent and enduring vulnerability since they cannot leave the care home and therefore may have an enduring risk to becoming infected with a virus (especially if other residents become infected).

The last source of vulnerability is what Lange, Rogers, and Dodds refer to as pathogenic. Pathogenic sources of vulnerability are a subtype of situational sources. They arise from dysfunctional relationships that are often characterized by things such as abuse, prejudice, disrespect, or from unjust or violent political situations.<sup>114</sup> For example, a person who has a cognitive disability and is occurrently vulnerable because of their care needs may be especially at risk to pathogenic sources of vulnerability such as sexual abuse by the person who cares for them.<sup>115</sup> Pathogenic sources of vulnerability may also arise from social policies aimed at ameliorating situational vulnerabilities that have the perverse effect of creating new vulnerabilities.<sup>116</sup> A prominent illustration of this is a policy that excludes pregnant women from clinical trials. While this policy is attempting

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<sup>113</sup> Lange et al, 336

<sup>114</sup> Lange et al, 336

<sup>115</sup> Rogers et al, 25

<sup>116</sup> Lange et al, 336

to protect pregnant women or their fetuses, the inadvertent side effect is the general lack of approved or safe medicine that can be used during pregnancy. Overall, this creates an increased amount vulnerability for every pregnant woman. Consider the fact that pregnant women were by and in large excluded from clinical trials for the COVID-19 vaccine. They may have been excluded in order to protect them or their fetuses from potential harms, but as a result of the lack of inclusion, we do not have enough information about whether the vaccine will be safe and effective for pregnant women. In light of this, individuals are left with the burden of deciding for themselves whether they want to take an unknown risk. This outcome is a poor one but may have been (at least partially) the result of a regard for protecting the interests of pregnant women.

Lange, Rogers, and Dodds believe that this typology of the sources of vulnerability provides not only a classification scheme, but also gives rise to certain duties that aim to ameliorate or redress vulnerabilities. The first set of duties they illustrate are aimed at providing an understanding of the harm's researchers should avoid concerning the different sources of vulnerability. Researchers have a duty to avoid exacerbating occurrent vulnerability and/or making dispositional vulnerability occurrent in their research design.<sup>117</sup> They can do this by paying special attention to the circumstances facing research participants and their inherent, situational, and pathogenic vulnerabilities. Next, researchers have a duty to:

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<sup>117</sup> Lange et al, 336

“avoid or minimize risks specifically attributable to the trial intervention... not to risk participants’ health, capacity to work or maintain social activities, or to provide care and well-being of those who depend on the participants”.<sup>118</sup>

To illustrate what this might look like, consider a trial for any type of drug. Researchers must consider how potential side-effects will affect the participants’ ability to continue to work or their ability to care for those who depend on them. If this drug potentially risks depression, insomnia, or aggression, for example, these side-effects could negatively affect that person’s ability to carry out the previously mentioned tasks.

Next, Lange, Rogers, and Dodds contend that researchers have a duty not to exacerbate participants’ dependency on others. This duty is especially important for those who can withhold support from the participant.<sup>119</sup> The worry associated with this duty is that if participants are made more dependent upon others, there may be an increased risk of exploitation or abuse. A further worry associated with this duty is that it could also be attributed to a loss of the sense of control or a feeling of powerlessness.<sup>120</sup>

A fourth duty that Lange, Rogers, and Dodds put forth is the duty to foster the autonomy of participants. They frame this duty in two separate ways. First, researchers are obligated to foster the autonomy of participants for instrumental reasons. This is because participants who can recognize their autonomy may be more resilient compared

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<sup>118</sup> Lange et al, 336

<sup>119</sup> Lange et al, 337

<sup>120</sup> Lange et al, 337

to those with a weakened sense of agency.<sup>121</sup> They also claim that researchers have a duty to promote autonomy or agency for intrinsic reasons. The reason for this is that autonomy has intrinsic value to human life. This duty to promote autonomy or agency can take multiple different forms and may require different things from researchers. It may require that researchers ensure an participants understand the condition that the trial aims to improve and potential alternative forms of treatment for that condition.<sup>122</sup> Ameliorating the concern brought up by this duty could also look more like collaboration between researchers and the target populations that seek to identify aspects of their conditions they believe warrant research focus.<sup>123</sup> Lange and Colleagues put a large focus on the fostering of autonomy and agency because all three sources could potentially propagate a sense of powerlessness and a loss of agency or control.<sup>124</sup> And while this may not always be remedied, it is important to ensure that participants do not suffer from a loss of agency or feelings of powerlessness, especially when these conditions could further exacerbate the risks and harms already present in research trials.

Lange, Rogers, and Dodds continue their list of duties researchers have towards vulnerable participants by claiming that researchers have a duty to ensure that well-intended protections do not exacerbate or create new vulnerabilities. This duty is akin to their understanding of pathogenic sources of vulnerability, where something put in place to protect a vulnerable person ends up creating a new vulnerability for that person. For

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<sup>121</sup> Lange et al, 337

<sup>122</sup> Lange et al, 337

<sup>123</sup> Lange et al, 337

<sup>124</sup> Rogers et al, 25

example, consider a trial for a new cancer treatment that requires daily treatment under close observation. While this is aimed at observing whether the treatment is causing adverse effects and thus improving public health outcomes, it also may reduce a participant's autonomy, and could sometimes (especially if the patient is economically disadvantaged) negatively impact their social standing or amplify their disadvantage.

Besides the previously mentioned duties, Lange, Rogers, and Dodds' taxonomy can frame the duty to not exacerbate or create new types of vulnerability in a fresh way. This is to say that there is a duty "to avoid generating pathogenic vulnerabilities through the design and conduct of research trials".<sup>125</sup> In order to explain this further, consider the fact that research trials aim to reduce the inherent vulnerabilities of a population. However, if the research increases the target population's vulnerability, this is the type of vulnerability pathogenic sources attempt to pick out.<sup>126</sup> For example, consider research about HIV with only queer male populations. The reason this type of research might increase that population's vulnerability is that the target population of the research has historically been stereotyped because of the condition the research aims to help improve. Therefore, if that is the only population included in research into that condition, the research may further stereotype or harm those individuals.

After Lange and Colleagues put forward their set of duties, they move on to one final important consideration for their taxonomy. This consideration is that researchers

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<sup>125</sup> Lange et al, 337

<sup>126</sup> Lange et al, 337

themselves are a potential source of vulnerability.<sup>127</sup> In other words, researchers themselves, because of their connection to participants and the design of these trials, are themselves a potential source of new or increased vulnerability.<sup>128</sup> For example, researchers might neglect to respect the autonomy of an elderly person or a pregnant woman because these groups have historically been viewed as weak or powerless, this fact creates an implicit bias for researchers that must be overcome.

The chief advantages of the Taxonomy are that it provides a straightforward way to identify potential wrongs and their sources. This is important because it helps in naming and identifying the different instances of vulnerability. However, where the taxonomy really differs is in its ascription and linking of duties to these sources. Some of these duties are more persuasive and demanding than others, for example, the duty to seek to redress the circumstances of all outside the trial and find additional funding in comparison to the duty to avoid exacerbating current participants circumstances. Nevertheless, Lange, Rogers, and Dodds can ascribe a variety of duties to researchers connected to the wrongs likely to occur. They also put a large focus on fostering autonomy of the research participants. Ideally, their taxonomy can not only identify potential sources of vulnerability and their potential interactions, but also articulate the types of duties or obligations owed to the vulnerable.

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<sup>127</sup>Lange et al, 337

<sup>128</sup> Lange et al, 337

## 2.7 Critiquing the Taxonomy

Lange and Colleagues' taxonomy aims to provide a typology of the sources of vulnerability that can both pick out and define a wide range of vulnerability and identify moral duties for researchers that emerge from these differing sources of vulnerability.<sup>129</sup> The Taxonomy is unable to meet both of these goals. They provide three separate sources (inherent, situational, and pathogenic), but seem to recognize that these categories may overlap. For example, if we consider the elderly, they will most certainly have a physical layer related to the decline in physical capabilities.<sup>130</sup> This layer is categorized by a seemingly inherent aspect of this stage of life. For example, the elderly has a heightened vulnerability to falls because of the higher risks of bone fractures and breaks. At first glance, this would count as an inherent source of vulnerability. However, if we consider that the condition of sidewalks and the accessibility of buildings can go a long way to either alleviate or exacerbate this layer, we can see that it also seems to fit into the situational sources of vulnerability. This overlap can make it so that the taxonomy is difficult to implement. While this worry does not by itself make the taxonomy unusable, it makes the second goal much harder to achieve.

The Taxonomy's second goal is to connect duties to the separate sources of vulnerability. As I have already mentioned the sources themselves can be hard to separate

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<sup>129</sup> Lange et al, 334

<sup>130</sup> Florencia Luna, "Vulnerability', an Interesting Concept for Public Health: The Case of Older Persons," *Public Health Ethics* 7, no. 2 (2014): 186



from each other, and while this alone may not pose a large issue, it may make it harder to accurately connect a set of duties to each source. The duties themselves only add to this confusion further. Lange and colleagues claim researchers must: (1) avoid harms related to the three sources of vulnerability; (2) avoid exacerbating occurrent vulnerability and/or make dispositional vulnerability occurrent; (3) minimize risk concerning the trial intervention; (4) avoid exacerbating or increasing participants dependency on others (avoid generating pathogenic vulnerabilities); and (5) promote autonomy for its own sake.<sup>131</sup> It is unclear how any of these duties directly connect to the three separate sources of vulnerability that Lange and colleagues explicate in their paper. In fact, all of these duties come across as connecting to either all of the sources at the same time or just the pathogenic sources.<sup>132</sup> The taxonomy therefore fails to accurately connect a set of obligations and moral duties for researchers that are clearly connected to each of the three sources of vulnerability.

Some of the duties are more persuasive or demanding than others. Consider the duty to seek to redress the circumstances of all outside the trial or the duty to find additional funding. These duties are going to require a lot more from researchers than the duty to avoid exacerbating current participants circumstances. The duties themselves rely on other concepts to do the work for them. In other words, all these duties really do is say that we must avoid causing harm, promote autonomy, and avoid or minimize risks

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<sup>131</sup> Lange et al, 336

<sup>132</sup> Florencia Luna, “Rubens, Corsets, and Taxonomies: A Response to Meek Lange, Rogers, and Dodds,” *Bioethics* 29, NO. 6 (2014): 449

associated with the trial intervention. This makes some of them more persuasive than others, again if we consider the duty to redress the circumstances of all outside the trial or find additional funding, this seems to be more persuasive than the duty to avoid exacerbating current participants circumstances. We already have normative concepts that aim to avoid exacerbating participants vulnerabilities. However, the duty to remedy everyone's circumstances outside the trial is really strong because researchers must actively ensure that they are not causing or exacerbating a large number or individuals' vulnerabilities. For example, undertaking research with a population that ends up perpetuating a stereotype about that population. All of this is to say, that the Taxonomy duties generally rely upon other normative concepts to do the work for them, and as a result do little more than provide a list with a list set of overarching duties attributable to research ethics in general.

## 2.8 Summary of the Main Advantages and Disadvantages of Each Account

Each of the three theories presented here has stepped in to fill some of the gaps in the vulnerability literature. The Layers account helps further our understanding of what exactly vulnerability is or tangibly might look like. It can recognize that vulnerability is not one single condition or blanket statement about a specific person or group. Instead, vulnerability should be understood as a condition that can be experienced in a multitude of different ways or layers, and that these can be removed one by one. This intersectional understanding of vulnerability adds a lot of nuances to the overall concept. This is useful because it allows for the recognition that there will not be a one size fits all solution to the

problem of vulnerability. While The Layers account may fail to provide a clear and concise way apply these layers and account for them, it expands our understanding of the concept and provides a good foundation to start from.

The Greater than Usual Wrongs account provides some progress towards defining the concept of vulnerability, this is not easy task, the Layers account for example does not attempt to do this at all. The Greater than Usual Wrongs account provides a focus on the types of wrongs that are likely to occur in a research trial. This tighter focus may be useful because it can help take a fine-tooth comb to the research protocol and point out where transgressions are likely to occur. It does this by narrowing its focus to the types of wrongs that occur when valid claims are denied to us. This is important because the theory can recognize that not all claims a person has need to be addressed by the researchers. This is useful because it works as a mechanism to ensure we are not excluding people form research trials for the wrong reasons. Ideally, the Greater than Usual Wrongs account affords researchers the ability to identify where potential wrongs may occur and makes the task of addressing them a little easier. The account also provides a rubric of what these wrongs might look, providing further guidance on what we might be looking for. However, it makes little progress towards how we should address these concerns and at times may have problems specifying the wrongs.

The taxonomy provides straight forward ways to identify not only the harms but also their sources. It does this by creating a language and a few signifying terms that help point at exactly what we are looking for. The Greater than Usual wrongs approach

attempts this with its rubric, but the taxonomy provides a much more refined way to organize an approach to vulnerability. The taxonomy also attempts link a set of duties that arises from the different sources of vulnerability, this is useful because both The Layers account and the Greater than Usual Wrongs account fail to make much progress here, only providing free standing lists that lack organization or connections to the main theory. However, these duties are not always clear and do little beyond account for the minimization of harm and promotion of autonomy.

Some conclusions we can take from this is that a lot of progress has been made in different areas to help improve the usefulness of an approach to vulnerability, however, there are still some major areas of concerns that these accounts are unable to address on their own. In my eyes, there are at least three major concerns that need to be addressed to create a more feasible singular theory of vulnerability. These are (1) The definition of the concept of vulnerability and what the application of this looks like; (2) how we prioritize certain instances of vulnerability over others; and (3) what obligations or responsibilities are owed to the vulnerable. The answers are for the most part here, some of them are just separated amongst the theories.

	Layers	Greater than Usual Wrongs	Taxonomy
Advantages	<ul style="list-style-type: none"> <li>• Flexibility</li> <li>• Can account for a person’s circumstances outside a trial</li> <li>• Recognizes that vulnerability is not a permanent condition, and that people may suffer from varying types of vulnerability at the same time</li> </ul>	<ul style="list-style-type: none"> <li>• Only deals with wrongs and harms that may occur when a valid claim is denied to us</li> <li>• Easily able to point out where transgressions may occur in the research trial</li> <li>• Rubric of the potential wrongs that might come up</li> <li>• Narrow focus on research trials</li> </ul>	<ul style="list-style-type: none"> <li>• Provides a straightforward way to identify harms and their sources</li> <li>• Can name and identify instances and sources of vulnerability</li> <li>• Attempts to link duties to the different sources of vulnerability</li> </ul>
Disadvantages	<ul style="list-style-type: none"> <li>• Unclear about how or when layers should be applied</li> <li>• Fails to be action guiding enough for research</li> <li>• Does not define vulnerability</li> <li>• A lot of ambiguity relating to application of theory</li> </ul>	<ul style="list-style-type: none"> <li>• Cannot/ does not account for peoples circumstances outside of the research trials</li> <li>• No baseline of harm (greater or more likely than who?)</li> <li>• Silent as to who has an obligation towards the vulnerable</li> </ul>	<ul style="list-style-type: none"> <li>• Fails to function as a proper taxonomy, meaning it essentially is a list</li> <li>• The three sources of vulnerability are not easily separable</li> <li>• The duties and obligations have no tangible connection to each separate source and do little beyond avoiding harm/risk, and promoting autonomy</li> </ul>

Figure 1. chart of advantages and disadvantages

### **3.0 Chapter 3 A Combined Approach to Vulnerability in Research Ethics**

#### 3.1 Introduction

This chapter will focus on developing my own novel theory of vulnerability. I am calling this theory the Combined approach to vulnerability. The Combined approach emerges from and builds upon the literature analyzed in the previous chapters. In particular, the Combined approach combines aspects of the Layers account, Greater than Usual Wrongs account, and the taxonomy. In previous chapters, I have argued that at least three challenges with theories of vulnerability need further work. The major challenges left unanswered concern (1) a plausible/persuasive definition of vulnerability; (2) what the application of a theory of vulnerability looks like; and (3) what obligations or duties are owed to the vulnerable (and who is responsible for fulfilling these duties). These three concerns represent what needs to be resolved in order to progress further in creating an adequate theory of vulnerability for application in research ethics. The Layers, Greater than Usual Wrongs, and the taxonomy make considerable progress towards solving some of the issues, however, none of these theories alone can adequately address each of the challenges faced when attempting to create a nuanced theory of vulnerability. My contribution seeks to get more specific about what we mean by a theory of vulnerability and what the theory might entail and/or require of us. The Combined approach specifically adds (1) a better understanding of vulnerability through the use of layers organized into groups to point out where these layers come from; (2) communal engagement to better understand which layers should have priority and what duties and obligations may be owed to the vulnerable; and (3) the combination of the three theories

themselves in a way that helps overcome some of the disadvantages of the singular theories.

### 3.2 Setting the Stage

The previous chapter drew out some of the main advantages and disadvantages of the Layers account, the Greater than Usual Wrongs account, and the taxonomy. These three theories each agree vulnerability is a concept that should not be abandoned and instead attempt to reinforce its significance and practicality. They each go about getting to this answer in different and yet connecting ways, with the taxonomy attempting to take in considerations from both the Layers and Greater than Usual Wrongs approaches. I will briefly recap where each theory left us in terms of becoming more particular about what a theory of vulnerability ought to entail before moving on to explain the Combined approach to vulnerability.

The main advantage of the Layers account is its *flexibility*. The Layers account is fluid and dynamic, allowing for a lot of flexibility in its application, while also recognizing that vulnerability is not, nor should it be seen as, a permanent condition. A central contribution that can be linked to this advantage is that the Layers account recognizes that individuals may experience vulnerability to different degrees, at different times, and may experience multiple instances at once. However, the layers account suffers from *practicality* concerns and *ambiguity* issues. Particularly, it fails to provide a definition of the vulnerability and contains a lot of ambiguity concerning both its application and action guidance.

In contrast, the Greater than Usual Wrongs account defines vulnerability as a likelihood to incur greater or additional wrongs. An advantage to this approach, aside from its more formal definition of vulnerability, is that it is also very specific. However, the account has trouble accommodating for peoples' circumstances outside of a clinical trial, meaning that it needs to be a little more specific than it already is. The Greater than Usual Wrongs account makes it easy to point to where transgressions might occur if or when a valid claim is denied to us. However, like the Layers account, the Greater than Usual Wrongs account suffers from ambiguity issues, because it fails to create a baseline of harm. This account also lacks clarity about the types of obligations owed to the vulnerable, creating further issues of ambiguity.

The taxonomy's main advantage is its *structure*: it makes progress towards naming what the layers of vulnerability might be, while providing a straightforward categorization for identifying harms and their sources (inherent, situational, and pathogenic). However, the taxonomy suffers from specificity issues, it attempts to connect duties to each of the three sources, but does not do so convincingly, leaving no tangible connection between each separate source and the corresponding duty. These duties also do not go much further beyond the obligations to avoid risk or harm and the promotion of autonomy, meaning the taxonomy fails to make a meaningful contribution in this area. In sum, the strengths present in the various theories are their *specificity, flexibility, and structure*. However, there remain concerns relating to their *practicality and ambiguity*. These four aspects specificity, flexibility, structure, and practicality are the



criteria that a persuasive account of vulnerability must meet. The Combined approach to vulnerability aims to better meet these criteria.

### 3.3 The Combined Approach to Vulnerability

The Combined approach to vulnerability defines vulnerability as an increased likelihood to incur additional or greater wrongs. The Combined approach functions like a taxonomy. It categorizes vulnerability into three groups (inherent layers, contextual layers, cascade layers) with the use of the metaphor of layers and restricts the application of these layers with its formal definition of vulnerability. We can begin to think about the Combined approach to vulnerability in terms of a house. A house requires a strong foundation and general structure, materials to reinforce the structure of the house, and fixtures and appliances that make it liveable. Without a strong foundation the house is destined to collapse. The foundation of the Combined approach is a formal definition of vulnerability. Vulnerability on this account is understood as an identifiably increased likelihood to incur additional or greater wrongs.<sup>133</sup> This will act as a threshold of sorts to restrict the account and to make up the foundation of our house. The important aspects then will be the ones that make an individual more likely to incur greater or additional wrongs. For example, an elderly person's increased risk of degenerative brain disorders may not put them at risk of incurring greater or additional wrongs in a research trial testing a COVID-19 vaccine. But since a lot of elderly people in their sixties risk reduced income due to the inability to work, they may incur greater or additional wrongs if the

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<sup>133</sup> Hurst, 195

trial offers compensation in exchange for participation.<sup>134</sup> In this instance this person may be liable to experience greater or additional wrongs because of this compensation.

The first part of the materials needed to reenforce this structure of our house will be the Combined approach's use of the layers of vulnerability. These layers will function similarly to those found in the Layers account. However, they will be categorized into groups. These groups will be called inherent, contextual, and cascade layers. Inherent layers constitute vulnerabilities connected to the innate vulnerabilities of the human condition, for example, our frailty and our dependency on others. An elderly person's vulnerability to falls because of an increased risk of broken or fractured bones would be one instance of inherent vulnerability. Contextual layers are vulnerabilities relating to our political, economic, and social context. For example, a pregnant woman who lives somewhere that does not provide access to abortions would have a contextual layer of vulnerability. Cascade layers of vulnerability are those that come about because of dysfunctional relationships. These layers have the unique ability to create a domino effect wherein they create new layers of vulnerability or further exacerbate existing ones. For example, the exclusion of pregnant women, the elderly, and children from research trials may add new layers of vulnerability to these groups because a large majority of medications and treatments have not been tested on them, and therefore their safety for use on them is unknown.

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<sup>134</sup> Elisabeth Schroder-Butterfill and Ruly Marianti, "A Framework for Understanding Old-Age Vulnerabilities," *Ageing and Society* 26, no. 1 (2006): 2

The flexibility of the layers allows for an intersectional understanding of vulnerability since we can view each layer as a different instance of vulnerability. Organizing these layers into separate groups allows for REBs to specifically point out where each layer of vulnerability comes from, which can ideally help in addressing the issue more quickly. In other words, this organization helps to create a language that can act as a signpost or signifier for REBs. This is helpful because it clarifies what exactly we are looking for and where we might find it. The Layers and their categorization into the three different groups creates a strong foundation to build our house of vulnerability upon. Broadly constituted, this step can ideally pick out a wide variety of vulnerabilities that an individual might experience. Consider a middle-aged man who works in a mine. He may be vulnerable to cave-ins at work, and this would add a contextual layer of vulnerability. Perhaps, he is illiterate having dropped out of school at a young age to support his family. This would add a further layer of vulnerability to this person. If his boss is abusive, this may add a cascade layer because this abuse may cause further issues for him, for example, fear of being fired (income security), mental illness, increased dependency on others. This would count as a cascade layer of vulnerability because of the multitude of other vulnerabilities it may create in light of the domino effect. While these materials may be a strong, by itself it is not enough to stop the house from collapsing.

The materials used to reenforce the foundation and general structure build upon the foundation to create a functional house that will not collapse. The foundation (the Combined approaches formal definition of vulnerability) alone is far too narrow in its reach and may not pick out all the layers of vulnerability needed, whereas the materials

and general structure (the layers) will pick out every single instance of vulnerability. This is an issue because it may lead to identifying someone as vulnerable when they are in fact not. Consider the miner who is vulnerable to cave-ins. An REB should not be considering this vulnerability when they are looking to enroll people in a trial testing for a new vaccine. Nevertheless, we could add a layer of vulnerability here because we are considering that person's circumstances fully. In order for the Combined approach to vulnerability to be useful then, it needs to be restricted in a way that only picks out the relevant layers of vulnerability. This is not to say that someone's circumstances or situational characteristics outside of a trial have no place at all in a theory of vulnerability for research ethics. Rather, we need to be careful about analysing which of these characteristics might impact the specific trial being undertaken. Even though we should not focus on the miner's risk to cave-ins, we should pay attention to his illiteracy and abusive relationship with his boss. This is because these layers may affect his ability to enroll in a research trial. For example, if he is illiterate, he will have issues fully understanding the risks associated with the trial if they are only written out. This will impair his ability to give informed consent to participate in the trial. To overcome this worry, we can use our foundation and formal definition of vulnerability to restrict the types of vulnerabilities we are looking for by narrowing in on those liable to make an individual more likely to incur greater or additional wrongs. The Combined approach to vulnerability is then able to differentiate between the types of layers that might require special attention from REBs.

The overall application of these layers will remain quite flexible within the Combined approach. Flexibility is important, but too much flexibility will create a theory of vulnerability that will be ever expanding, including everyone within its definition.<sup>135</sup> This constrained flexibility is important because no two research trials are alike and the same can be said about research participants. In light of this, the consideration of which outside aspects will require special attention will vary greatly between research trials, but also between participants. It may be the case that two participants in the same trial who share similar backgrounds and therefore outside aspects with one another will require different treatment and consideration of which aspects require special attention for that specific individual.

The second part of the materials required to reenforce the foundation and general structure is a way to go about prioritizing the various layers of vulnerability. At this point the Combined approach can pick out the various layers and consider only the ones that will be relevant to the particular research trial. Now, we must figure out which of these layers will be most important or which ones will require more attention. Some layers are going to require more attention than others due to their potential to cause significant harm to the research participant or their potential to create further layers. The ordering of the layers is an important task to provide practical guidance to REBs and yet, due to the complex nature of research participants, it is hard to create a single order of what will have lexical priority. I do however share the opinion that layers that cause a chain

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<sup>135</sup> This may open the theory up to the universal critiques covered in the first chapter by Wrigley and Levine et al.

reaction, whether we want to refer to them as cascade layers or pathogenic vulnerabilities, should be given priority. Other than that, it would be more beneficial to think about prioritizing layers based on the individual research participants. This may take the shape of a collaborative process between the participants and the researcher: the researcher being aware of the risks the trial poses, and the participant being intimately familiar with the context they exist within. If a research participant thinks that one aspect of their situation requires more attention than another and the researcher fails to allow for that, the researcher is disrespecting the patient's ability to express their own autonomy. It remains important to differentiate between less harmful and more harmful layers; however, this cannot be done solely by the researchers or REB's. An implication of this is more input from the community or participants about the research being done, which may help to improve research further. However, this is not my focus here. The prioritization of the layers along with specifically pointing out what layers are relevant (those that create an increased likelihood to incur greater or additional wrongs) act as the materials that reinforce the general structure of our house. Our house then will not fall over. However, it is not yet livable. The next step then is adding in the fixtures and appliances needed to make the house liveable and therefore useful.

The Combined approach must make progress towards clarifying the duties and obligations owed to the vulnerable. These duties and obligations will act as our fixtures and appliances that make our house liveable. When thinking about the duties and obligations owed to the vulnerable, we do not want to create a new system of research ethics out of vulnerability as this will only further complicate any theory of vulnerability.

Instead, we should aim to work with what we currently have. It would be an impossible and frivolous task to create a list of duties that will cover every possible transgression that may occur in a research trial. To do so would only limit a theory of vulnerability because it assumes a finite number of ways vulnerability can be experienced. It is possible that we are not going to be able to address every single transgression, but this should not be the Achilles heel of a concept of vulnerability.

Perhaps, the way forward is to think about the types of transgressions that may occur, which claims these transgressions deny, and then how can we ameliorate these concerns. The answer then is most likely found in the origin of the transgression themselves. In other words, we can begin to think about the obligations owed to the vulnerable by considering what we ought to avoid and what we ought to actively do for them. A research participant will have a variety of positive and negative claims on researchers, where positive claims require the researcher to do something, and negative claims require them to refrain from doing something. These claims are arrived at by thinking about the type of responsibilities owed to people more generally. For example, a research participant may have a positive claim to physical integrity, meaning the researchers must actively aid them in avoiding harm. They may also have a negative claim to physical integrity requiring the researcher to avoid harming them. Anything that transgresses these claims has wronged them and may require reparation. The researcher cannot take away the fact that I have been wronged and will not always be able to compensate for it. However, they should be able to make progress towards mitigating any damage done by it.

In other words, researchers, REBs, governments, and society at large will have positive and negative duties towards vulnerable people and groups. It is not reasonable to expect researchers and REBs to address every single concern a potential participant may have. For these reasons, researchers will have a duty not to allow anyone to participate in the research trial who may experience wrongs that they cannot ameliorate or ethically compensate for. Some of these duties may include duties toward the avoidance of harm, the promotion of autonomy, or ensuring one's basic needs are met. Along with these considerations, there must be collaboration with research participants about what is owed to them. The participants themselves may have a more informed opinion about what is owed to them than the researchers or REBs will. We should think about the duties or obligations towards the vulnerable as a cooperative process whereby there is room for dialogue between both parties. Not only will this aid in the active promotion of autonomy, but it also allows the research participant to take a functional role in their participation and protection before, during, and after the research trial. We normally train workers who undertake large risks during their jobs, and by incorporating more cooperative aspects we may be able to do similar things for research participants. For these reasons, it would be superfluous to attempt to list a simple set of duties or obligations because they will change with each person and there needs to be some form of collaboration to solve these unique problems.

#### 3.4 How the Combined Approach Emerges from and Improves Upon the Layers Account, the Greater than Usual Wrongs Account, and the Taxonomy



The Combined approach to vulnerability emerges from and improves upon the three central accounts considered in the previous chapter. A simple way to put it is that the Combined approach to vulnerability seeks to use the Greater than Usual Wrongs account's special protection thesis as a threshold within the Layers account, while using the taxonomy to organize the theory. This inclusion or combination of these accounts overcomes the worries that they individually cannot solve. We can assess the success of the Combined approach by thinking about whether it meets the four criteria of a persuasive account of vulnerability (specificity, flexibility, structure, and practicality).

The Layers approach is extremely fluid and dynamic, however, a side effect of this is that it lacks a proper focus. In other words, the Layers approach suffers from practicality or ambiguity concerns. The Layers account considers the person and their circumstances fully, and therefore constraint is needed to only consider the Layers that are relevant to the research trial. The Combined approach overcomes this worry by restricting the types of layers REBs are looking for. Essentially, what they should be concerned with are the layers that create a greater likelihood of incurring additional or greater wrongs. The Combined approach's inclusion of the layers account allows it to meet the flexibility criteria. However, it must overcome some of the practicality and ambiguity issues.

The Combined approach overcomes the Layers approach's lack of practicality and ambiguity by directing its application in a more focused way that is centered upon the research protocol. In the same way, this addition also benefits the Greater than Usual Wrongs approach by adding a situational and relational aspect to the account. This opens

up the account to possible vulnerabilities it may not otherwise consider due to its narrower focus. Consider a healthy person (person x), who is in routine contact with someone who is vulnerable to a viral disease because of an underlying health condition (person y). The Greater than Usual Wrongs account may not consider this person vulnerable because it is unclear how person x has had a valid claim denied to them. Therefore, we might allow person x into a challenge study<sup>136</sup> testing a vaccine for COVID-19 when in fact they ought to be excluded due to their close contact with a vulnerable third-party. In this instance person y has a valid claim denied to them. This valid claim might look like a claim to not be exposed to a disease that may pose a threat to my life. By adding in the focus on context that the layers account has, we can alleviate this worry. This person's context (their close contact with person y) necessitates a layer of vulnerability. Even though person x would not automatically have a valid claim denied to them, their participation denies person y of their valid claim and therefore they ought to not participate. Both the layers and the transgressions of claims are doing important work here. First, the layers point out the potential instances of vulnerability one might have, then these layers are looked at in relation to the research trial to see if they create any transgressions. In this example, the contextual layer of person x's close contact with person y creates a transgression of person y's claim. This is where the transgressions of claims does the work, because here we recognize that person x should not be allowed into this particular trial.

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<sup>136</sup> A challenge study is a trial where participants are given an intervention, for example, a vaccine and then are directly challenged with the disease the vaccine is aiming to prevent (See Euzebiusz Jamrozik, and Michael J. Selgelid, "Ethical Issues Surrounding Controlled Human Infection Challenge Studies in Endemic Low-and Middle-Income Countries," *Bioethics* 34, no. 8 (2020): 797–808)

Now someone may rightfully ask why person x is vulnerable if in reality person y is the vulnerable one. Due to the interconnected nature of human beings, it would be a mistake to not consider the relationships they have. Also, if person y is dependent on person x for care, this only further confirms that person ought to be excluded from participation. We may be able to remove this layer if person x agrees to isolate away from person y for the duration of the trial. In this instance person x is no longer considered vulnerable and may be allowed to participate in the trial barring any other potential issues. Therefore, the layers account is able to meet the specificity criteria by overcoming some of the ambiguity concerns found in the individual accounts.

Finally, the Combined approach to vulnerability makes use of the organization of the taxonomy to situate the various layers of vulnerability. The Combined approach separates the layers of vulnerability into three categories: inherent layers, contextual layers, and cascade layers. This is much like the three sources of vulnerability proposed by the taxonomy, which are inherent, situational, and pathogenic. For the most part, the different grouping of layers in the Combined approach is meant to function like the taxonomy. I have chosen to keep inherent layers the same since this adequately describes what constitute these layers. I have chosen to rename both the situational and pathogenic sources. The reason for this is that I think the labels “contextual” and “cascade” layers are clearer than the ones proposed in the taxonomy.

The taxonomy uses situational sources of vulnerability to describe context specific instances that relate to our personal, social, political, environmental, and

economic vulnerabilities.<sup>137</sup> I, however, think that a simple name change here can be beneficial. The Layers account, the Greater than Usual Wrongs account, and the taxonomy all place a large focus on context, whether it is the context of the research protocol or the context of the research participants themselves. If we are going to place such a large focus on the context, then in my mind it makes more sense to call these layers the contextual ones instead of the situational ones. This change is an improvement because it creates a more consistent language for REBs that can aid in looking for the types of vulnerabilities they are looking for or trying to address. For example, an elderly person may be vulnerable because of mobility issues. As a result of this, a sidewalk that is not properly maintained may create a contextual layer of vulnerability. The same could be said for a building that did not have a ramp or elevator. These layers are related to the context of that person's circumstance. The main reason for this change in terminology is so that we can be consistent when thinking about how the Combined approach incorporates aspects of the three other theories.

The taxonomy understands pathogenic sources of vulnerability as those that arise from dysfunctional relationships characterized by abuse, prejudice, disrespect, or unjust and/or violent political situations.<sup>138</sup> These layers may also create a domino-effect where a policy intended to address someone's vulnerability has the unintended consequence of exacerbating and creating further instances of vulnerability. The taxonomy refers to these as pathogenic sources of vulnerability. The word pathogenic is more closely tied to the

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<sup>137</sup> Lange et al, 336

<sup>138</sup> Lange et al, 336

causation of disease than it is to vulnerability. Naming these sources pathogenic only hinders the theory's ability to act as an effective organization tool. Therefore, I propose renaming these layers or sources of vulnerability "cascade layers" in the same vein as the Layers approach. This more accurately represents that these layers are instances of vulnerability that result due to a chain-reaction of various other contextual or inherent layers. This differs from the context layer because it is only focused on those layers that may exacerbate or create further layers of vulnerability. This is a useful distinction because various aspects of someone's context or their inherent characteristic may cause this domino effect. However, it is my view that it would be confusing to start differentiating within these categories themselves. What differentiates the cascade layers from the other layers is the potential to cause greater amounts of harm because of the domino effect these layers produce. Therefore, it is useful to provide a specific signal term for these specific layers. The overall organization of the Combined approach then allows it to meet the structure criteria required for a persuasive account of vulnerability. The Combined approach has met three of the four criteria these being specificity, flexibility, and structure. All that remains is practicality, I believe that the Combined approach's more nuanced understanding of the duties owed to vulnerable people allows it to meet this criterion.

### 3.5 A Potential Objection and Response

I will now consider a potential counterargument to the usefulness of the Combined approach to vulnerability. The claim could be made that organizing a theory of vulnerability like this provides no meaningful difference from what the layers account

already provides, and that the combination itself as a result is not useful. In other words, even if it is compatible, it simply collapses back into all the other accounts. The first issue here is the inclusion of the taxonomy within a Combined approach to vulnerability. The Layers account itself does not contradict other accounts of vulnerability, and instead may be able to include and compliment them.<sup>139</sup> While it is not clear how the Layers account does this, the possibility suggests an opening for a Combined approach to vulnerability. This is because it creates the possibility to include the Greater than Usual Wrongs account within the Layers approach. However, the same cannot necessarily be said for the taxonomy. In fact, the Layers account may have issues incorporating the taxonomy within itself.<sup>140</sup> Taxonomies have been argued to be too rigid for the concept of vulnerability in that they simply do not work within the complex nature of ever-changing systems.<sup>141</sup> Since the relations of human beings represent a very complex and ever-changing system, perhaps the taxonomy does not have a place here. In other words, the rigid nature of a taxonomy may pigeonhole the concept of vulnerability, making it harder to apply or practically use. However, I think that while we may worry about restricting an account of vulnerability more generally, this may serve some use when applying the concept purely to research trials that involve human participants.

The second issue then is that even if we can show that the taxonomy is not at odds with the Layers approach, it does not add anything new either way and organizing it this way simply collapses back to layers. While this is a concern that merits attention, I do

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<sup>139</sup> Luna, “Identifying and Evaluating Layers of Vulnerability–A Way Forward.” 90

<sup>140</sup> Luna, *op. cit.* note 132

<sup>141</sup> Luna “Identifying and evaluating layers of vulnerability–a way forward.” 90-1

not believe it is enough to warrant the removal of these categories as a way to organize a Combined approach to vulnerability. One of the problems with the Layers account is that it is silent towards naming the layers of vulnerability, and instead merely provides examples of what they might look like. By making progress towards naming the layers of vulnerability, this new Combined approach can aid researchers and REBs by providing a language that helps signify what they are looking for. This will also help with the process of ameliorating the concerns the layers of vulnerability create. This form of labeling is useful because it creates a very clear and concise way to think about the different layers of vulnerability and their causes. By organizing the theory in this way, the Combined approach to vulnerability can move from simply treating the symptoms of one's vulnerability to treating the root causes. Categorizing an individual's vulnerability can be beneficial in the same way that diagnosing someone with cancer is beneficial to their treatment. Simply put, organizing a theory of vulnerability in this way provides clearer language than is found in the layers account. By providing clearer language, less time can be spent arguing about where each layer fits into the picture and more time can be spent addressing the layers and their causes.

## Conclusion

The concept of vulnerability occupies a complex position in research ethics. It is a long-standing fixture of ethics codes and regulations but has also been criticized for being unhelpful, superfluous, and nebulous. The concept has also been viewed as something that requires further explanation and focus on who is vulnerable and for what reasons. I have presented a novel account of vulnerability, one that builds upon and expands the work already done to retain the concept's strength and usefulness. The result of this endeavour is a Combined account of vulnerability that takes aspects of the Layers account, Greater than Usual Wrongs account, and the taxonomy and molds them together to improve upon their various faults while also making helpful novel additions to make a more rounded and helpful approach to vulnerability.

Through a critical analysis of the current field of research ethics and the ethics guidelines issued by various institutions, I have argued that the concept of vulnerability has a long history of confusion and ambiguity surrounding its definition and overall practicality or usefulness. This literature review helps to establish the problem of identifying populations that are in need of special protections, and also the problem of delineating these protections. Creating a theory of vulnerability that does this is crucial because failing to do so risks either overprotecting or in some cases, disrespecting certain individuals or groups, especially those that have historically been viewed as vulnerable. While getting the definition wrong may underprotect them, and risks exploitation and harm for these people. Throughout this section certain themes emerged that lead to the consideration of the three main theories this project engages with.



The exploration of the Layers account, the Greater than Usual Wrongs account, and the taxonomy provides a useful starting point for the Combined approach by considering the pieces to the puzzle that we already have. Each of these accounts provides movement towards a more through and thought-out theory of vulnerability, however, each fails to make it all the way. This inability to make it all the way to a useful theory can be attributed to a failure to be specific, practical, flexible, and structurally sound. Not all is lost though, because these theories leave the potential for a combination to ameliorate these concerns and as a result improving upon our understanding of the concept of vulnerability. This takes the shape of a Combined approach to vulnerability.

The Combined approach understands vulnerability as an increased likelihood to incur additional or greater wrongs. It practically functions as a taxonomy that categorizes vulnerability into three groups (inherent layers, contextual layers, and cascade layers) with the use of the metaphor of layers. The account further restricts the application of these layers with its formal definition and only considers those layers that put an individual or group at risk of incurring greater or additional wrongs. The Combined approach puts stock into communal engagement to create a better understanding of the types of responsibilities owed to the vulnerable. The combination of these theories along with the ascription of the duties make up the chief contributions of this new novel account of vulnerability.

The Combined approach is a new and novel account that emerges from and builds upon the current vulnerability literature. Nevertheless, this does not mean that all the current or future problems associated with vulnerability have been or that no further work

will be needed in the future. The ever-changing nature of people, technology, and the world necessitates continual critical engagement with the concept of vulnerability. And while the Combined approach makes advances in the research ethics sphere, vulnerability exists in all aspects of human relations and therefore the concept should remain prominent and important in all of these spheres.

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