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Kathryn Wright

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Date

Improving the Interpretation of Vulnerability in IRB Review of Research Involving Asylum
Seekers

By

Kathryn D. Wright

Master of Arts

Bioethics

James V. Lavery

Advisor

Margo A. Bagley

Committee Member

Amy J. Zeidan

Committee Member

Accepted:

Lisa A. Tedesco, Ph.D.

Dean of the James T. Laney Graduate School of Graduate Studies

Date

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Kathryn D. Wright
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Abstract

Vulnerability is a complex term that is commonly used but rarely defined. Research institutions including but not limited to the Office for Human Research Protection (OHRP) and Institutional Review Boards (IRBs) have exclusive lists of populations that are considered vulnerable. This is problematic for populations that may experience vulnerabilities but are not included in the list, such as asylum seekers. This paper aims to demonstrate how a novel approach to conceptualizing *vulnerability*—Luna’s “layered approach”—can improve the interpretation of the U.S. regulations governing research with human subjects (i.e., the “Common Rule” regulations) for research involving asylum seekers in the United States. It will then critique existing various conceptions of vulnerability and ultimately argue that the layered approach can best aid researcher’s attempts to interpret the Common Rule in research involving asylum seekers.

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PURPOSE

In this thesis I aim to demonstrate how a novel approach to conceptualizing *vulnerability*—Luna’s “layered approach”—can improve the way Institutional Review Board (IRB) members interpret and implement the U.S. regulations governing research with human subjects (i.e., the “Common Rule” regulations) while reviewing research proposals involving asylum-seeking populations.

INTRODUCTION

Who Is an Asylum Seeker?

The Immigration and Nationality Act of 1952 permits individuals to legally seek asylum in the United States if they are fleeing persecution (or fear of persecution) due to their race, religion, nationality, membership in a social group, or political opinion.¹ If an asylum seeker is granted asylum, they are provided with protections and rights similar to individuals with refugee status. However, refugees and asylum seekers are two different populations. Refugees file for protection before fleeing their home country and are provided with certain accommodations upon entering the US such as resettlement/housing assistance and work

1. Immigration and Nationality Act, 8 U.S.C. § 1158 *et seq.* 1952, <https://uscode.house.gov/view.xhtml?req=granuleid:USC-prelim-title8-section1158&num=0&edition=prelim>.

authorization.^{2,3} An asylum seeker cannot initiate an asylum claim until they enter the US, and their cases can take months to years to be processed. They cannot receive legal provisions (work authorization, housing resettlement assistance, etc.) until their case has been approved. Despite various nuances between cases, all asylum claims can be divided into two main categories: affirmative and defensive.

The Asylum Process

An affirmative claim occurs when an individual initiates the legal process of claiming asylum within one year of entering the US.⁴ A defensive claim occurs when an individual initiates the legal asylum process after being subjected to removal proceedings (also known as the deportation process).⁵ Individuals can file a defensive asylum claim if their affirmative claim was denied. They could also initiate this process if they are apprehended by border patrol. Finally, individuals fleeing persecution may file for a defensive asylum claim if they remain in the US with an expired visa. In both affirmative and defensive asylum cases, asylum seekers are responsible (with the representation of their lawyers, if they have one) for providing evidence indicating “credible fear” or proof that that asylum seeker is at significant risk of persecution, harm, or abuse in their country of origin. The process for determining credibility in both types

2. USCIS, “Refugees and Asylees,” [uscis.gov](https://www.uscis.gov), U.S. Citizenship and Immigration Services, April 27, 2020, <https://www.uscis.gov/i-9-central/form-i-9-resources/handbook-for-employers-m-274/60-evidence-of-status-for-certain-categories/63-refugees-and-asylees>.

3. American Immigration Council. 2020. “An Overview of U.S. Refugee Law and Policy,” January 8, Accessed July 2, 2021.

<https://www.americanimmigrationcouncil.org/research/overview-us-refugee-law-and-policy>.

4. U.S. Library of Congress, Congressional Research Service, *Asylum and “Credible Fear” Issues in U.S. Immigration Policy*, by Ruth Ellen Wasem, R41753 (2011), 1-36.

5. U.S. Library of Congress, *Asylum and “Credible Fear” Issues in U.S. Immigration Policy*, 8.

of claims is complex and involves a number of legal documents, court dates, and participation in a 'credible fear' interview, during which an asylum seeker must answer questions regarding why they are seeking asylum, any persecution they have endured, any crimes they may have committed in their home country, etc.

There are many challenges associated with the asylum process. Because a ruling can take months to years, asylum seekers may reside within the US for long periods of time while being uncertain about their legal status.⁶ During this time, they are not authorized to work for a certain time period (usually 150 days) or file for social security.⁷ Some may be confined to a detention center during this time until their case has been processed. Unlike defendants in other legal scenarios, asylum seekers are not provided with legal counsel.⁸ An asylum seeker is therefore responsible for locating legal aid on their own, or risk going through the process without legal representation. There are many barriers associated with seeking counsel including but not limited to language barriers, lack of familiarity with the US legal system, and financial challenges. While several law firms do provide *pro bono* services, the asylum seeker is burdened with locating these facilities/services. While some non-profit organizations are geared towards connecting individuals seeking asylum with legal representation and other accommodations, the asylum seeker is ultimately responsible for locating these services.

6. National Immigration Forum, 2019, "Fact Sheet: U.S. Asylum Process". Jan 10. Accessed May 25, 2021. <https://immigrationforum.org/article/fact-sheet-u-s-asylum-process/>.

7. National Immigration Forum, "Fact Sheet: U.S. Asylum Process."

8. U.S. Library of Congress, *Asylum and "Credible Fear" Issues in U.S. Immigration Policy*, 31.

The Benefits of Asylum

Asylum status provides individuals with a variety of benefits.⁹ It protects them from being deported to their country of origin. Additionally, it allows them to legally reside in the US and access resettlement services (similar to refugees who are resettled in the US). Finally, individuals with asylum status can travel outside the US and file for legal protection of their family, who may also be at risk of persecution. After holding asylum status for a year, individuals can apply for a green card.¹⁰

Asylum Seekers in Research

Research involving asylum seekers and refugees tends to lump these populations together.^{11,12,13} This is likely due to the similarities these groups share. Both asylum seekers and refugees have experienced persecution due to their race, religion, nationality, social identity, or political opinion. Both refugees and asylum seekers are pursuing a new life in a new country. They both are also susceptible to being re-traumatized or re-experiencing negative

9. The Advocates for Human Rights, "What is Asylum?" Accessed June 7, 2021, https://www.theadvocatesforhumanrights.org/what_is_asylum_2.

10. National Immigration Forum, "Fact Sheet: U.S. Asylum Process."

11. Kenneth Carswell, Pennie Blackburn, and Chris Barker, "The Relationship Between Trauma, Post-migration Problems and the Psychological Well-being of Refugees and Asylum Seekers," *International Journal of Social Psychiatry* 57, no. 2 (2011): 107-119.

12. Giulia Turrini, Marianna Purgato, Francesca Ballette, Michela Nosè, Giovanni Ostuzzi, and Corrado Barbui, "Common Mental Disorders in Asylum Seekers and Refugees: Umbrella Review of Prevalence and Intervention Studies," *International Journal of Mental Health Systems* 11, no. 1 (2017): 1-14.

13. Cécile Rousseau and Laurence J. Kirmayer, "From Complicity to Advocacy: The Necessity of Refugee research," *The American Journal of Bioethics* 10, no. 2 (2010): 65-67.

emotions/memories associated with past instances of persecution.¹⁴ However, synonymizing these populations may lead to the misconception that both refugees and asylum seekers have similar needs and vulnerabilities. Asylum seekers face legal uncertainty upon entering the US. Confinement to a detention center puts them at a greater risk of re-traumatization and psychiatric disease.^{15,16}

Goals of Research Involving Asylum Seekers

Research involving asylum-seeking populations can provide profound insight. First, research can help investigators assess the efficacy of existing services offered to asylum seekers. For example, some organizations provide forensic evaluations for asylum seekers to accompany their legal case as a way of documenting the prior trauma/torture they endured. Preliminary research suggests these forensic evaluations improve an individual's chance of being granted asylum.^{17,18} However, further investigation is necessary to confirm this

14. Lisa D. Butler, Eugene Maguin, and Janice Carello. "Retraumatization Mediates the Effect of Adverse Childhood Experiences on Clinical Training-related Secondary Traumatic Stress Symptoms," *Journal of Trauma & Dissociation* 19, no. 1 (2018): 25-38.

15. Trine Filges, Edith Montgomery, and Marianne Kastrup, "The Impact of Detention on the Health of Asylum Seekers: a Systematic Review," *Research on Social Work Practice* 28, no. 4 (2018): 399-414.

16. Diana Vega German, "Retraumatization in Detention: An Interpreter's Perspective" (Bachelor's thesis, University of Arizona, 2020), 29-30.

17. Dabney P. Evans, Caitlin E. Donato, Bridget A. Malewezi, Anyie J. Li, Mario J. Corea, and Andrew B. Mitchell, "Outcomes Among Asylum Seekers in Atlanta, Georgia, 2003-2012," *MEDICC review* 17 (2015): 12-17.

18. Stuart L. Lustig, Sarah Kureshi, Kevin L. Delucchi, Vincent Iacopino, and Samantha C. Morse, "Asylum Grant Rates Following Medical Evaluations of Maltreatment Among Political Asylum Applicants in the United States," *Journal of immigrant and minority health* 10, no. 1 (2008): 7-15.

conclusion and to determine what components of the evaluation are associated with an increased chance of being granted asylum.

Research can help investigators identify efficient protocols for identifying physical evidence of trauma. For example, a recent study identified plantar hyperpigmentation as an indicator of Falanga, a type of torture that involves consistent blunt force to the soles of the feet.¹⁹ There is a lack of published guidance outlining symptoms that are consistent with specific types of torture.²⁰ Such insight could help clinicians clearly document evidence of torture in asylum seekers. This would perhaps serve as strong evidence supporting an asylum seeker's case.

Research could also help investigators determine appropriate methods for psychological evaluations of asylum seekers. Many of the psychiatric inventories that are currently implemented in forensic evaluations are designed for western, English-speaking populations. Some asylum seekers may come from cultures that have conceptualizations of mental health that are not compatible with the existing inventories.²¹ The traditional inventories also neglect temporal circumstances specific to asylum seekers. Months or even years have likely elapsed between the time an asylum seeker endured persecution and the time when they participate in

19. George F. Longstreth, Lydia Grypma, Brittney A. Willis, and Kathi C. Anderson, "Foot Torture (Falanga): Ten Victims With Chronic Plantar Hyperpigmentation," *The American Journal of Medicine* 134, no. 2 (2021): 278-281.

20. Amy Zeidan (Co-Director of Human Rights/Asylum Clinic at Emory University School of Medicine), "Goals of Research Involving Asylum Seekers," Interview by Kathryn Wright, April 18, 2021.

21. Zeidan, Interview, April 2021.

a forensic evaluation. This can make it difficult for an evaluator to detect signs of mental illness since the questions are designed to detect present symptoms.²²

Asylum seekers tend to experience barriers to receiving sufficient healthcare, even after being granted asylum.²³ Research can further elucidate these barriers and measure the success of interventions intended to minimize them. It can also be used to gather evidence documenting the quality of care (or the lack thereof) for asylum seekers in detention centers. This information could be used to either discourage detention of asylum seekers or encourage standardized medical treatment across centers.²⁴

BACKGROUND

Research Protections: The Common Rule

The Office for Human Research Protections (OHRP) aims to help research institutions preserve the rights and welfare of human subjects involved in biomedical/socio-behavioral research. It provides regulatory advice for Institutional Review Boards (IRBs), which must assess the benefits and consequences of approving research proposals involving human subjects. IRBs are also responsible for interpreting and implementing OHRP provisions into their ethical analysis. Several of these provisions are outlined in subpart A of title 45, part 46 of the Code of Federal Regulations (45 CFR 56), also known as the “Common Rule”. Originally established in

22. Zeidan, Interview, April 2021.

23. Ramin Asgary and Nora Segar, "Barriers to Health Care Access Among Refugee Asylum Seekers," *Journal of health care for the poor and underserved* 22, no. 2 (2011): 506-522.

24. Zeidan, Interview, April 2021.

1981 (and revised in 2018), the Common Rule outlines various procedures intended to protect research participants and emphasizes the protection of “vulnerable populations”:

...If an IRB regularly reviews research that involves a category of subjects that is vulnerable to coercion or undue influence such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these categories of subjects.²⁵

Based on the excerpt from the Common Rule mentioned above, IRBs could potentially develop specialized safeguards for asylum-seeking participants if they incorporated one or more professionals who are “knowledgeable” about this population into the IRB. These professionals would either become permanent members of the IRB or serve as special consultants for review of research involving asylum-seeking populations. The number of professionals included could depend on the volume of research proposals involving asylum seekers (i.e., IRBs with more proposals would incorporate more professionals).

Research Protections for Asylum Seekers: Limitations

Though instructive, I am doubtful that incorporating professionals who work with asylum seekers into the IRB would yield sufficient protection for asylum-seeking participants. This provision would be contingent on the IRB “...regularly review[ing]” research involving asylum seekers. In other words, an IRB would not be obligated to implement this provision if researchers within its institution are not conducting studies involving asylum seekers on a regular basis. It is not clear how often research of this nature would need to be conducted to be

25. Common Rule, 45 C.F.R. § 46 *et seq.* 2018.

deemed “regular”. My concern is that asylum seekers may not have any specialized safeguards if they are participating in studies under an institution that does not frequently oversee investigations involving this population.

Professionals who work with these individuals typically have expertise that is specific to one aspect of the asylum process. For example, a lawyer who has represented asylum seekers may be competent in the legal process but know little about detecting signs and symptoms of trauma. Conversely, a healthcare professional might know how to detect and address asylum seeker sequelae but be less aware of the legal challenges asylum seekers face. In sum, there is no single “expert” who could elucidate all the vulnerabilities asylum seekers experience.

Since there is no clear definition of what it means to be vulnerable, it is unclear how an IRB would determine if asylum seekers were vulnerable to coercion or undue influence. Even if they were able to do so, how can IRBs be sure they are not ignoring other relevant vulnerabilities of this population? Surely there are things one can be vulnerable to other than undue influence and coercion. IRBs might be able to identify asylum seekers as vulnerable because they would likely be economically advantaged since they do not have work authorization, and therefore, no source of income. Some asylum seekers may be considered a type of “prisoner” if they are confined to a detention center. There may be unaccompanied minors, or pregnant women seeking asylum. However, there are no subparts that explicitly address the unique vulnerabilities asylum seekers face.

Even if IRBs were able to gather enough experts to provide sufficient insight, there is no guarantee that identifying what asylum seekers are vulnerable to will also reveal the source of

those vulnerabilities or what provisions IRBs might implement during the review process. For example, simply stating that pregnant women are vulnerable to coercion or undue influence does not explain *why* they should be deemed a “vulnerable” population. Using this label can lead to the misconception that being pregnant makes one inherently vulnerable. This claim can be stigmatizing and ignores external factors that may contribute to a population’s vulnerabilities (e.g., people’s attitudes towards pregnant women).

While there are subparts that outline safeguards for certain “vulnerable” populations, the Common Rule does not provide IRBs with regulations explicitly designed for research involving asylum seekers. It also fails to explain what makes a population “vulnerable” or how IRBs can identify vulnerable populations outside of those listed in the 45 CFR 46. It is unlikely that IRBs have a default model of vulnerability that encompasses the vulnerabilities experienced by asylum seekers. These discrepancies raise several questions. How can IRBs develop a functional account of vulnerability based on the Common Rule? How can they identify the vulnerabilities specific to asylum seekers? Furthermore, how can IRBs create safeguards that will provide asylum seeker with appropriate protection while participating in research?

IRBs need a framework that provides a clear conceptual understanding of vulnerability. This would help them identify what asylum seekers are vulnerable to in addition to the cause of these vulnerabilities. This framework should also posit a way to ameliorate vulnerabilities within the context of research (when possible). This would ideally help IRBs identify which safeguards are appropriate for research involving asylum-seeking populations.

Vulnerabilities experienced by Asylum Seekers

Vulnerability is a complex term that is commonly used but rarely defined. In the passage above, the Common Rule uses the word “vulnerable” without providing a clear definition. It is described as a trait that is inherent to certain populations, specifically those that may be coerced or inappropriately influenced into participating in a research study. Though IRB members tend to synonymize coercion with undue influence, it is important to understand the difference between these two terms.²⁶ In the realm of research, individuals can feel coerced into participating in a study if they believe they will be harmed for failing to do so.²⁷ In this case, individuals are presented with a scenario where the only logical solution is to participate in a study they would not take part in under normal circumstances.²⁸ For example, an individual might feel coerced into participating in a study if it provides them with a medication they would not otherwise be able to afford. Individuals may experience undue influence (or undue inducement) if they are offered benefits that they cannot refuse.²⁹ For example, someone might volunteer for a study that offers substantial compensation and their desire to be compensated overshadows their ability to appreciate the risks associated with the study.

26. Robert Klitzman, "How IRBs View and Make Decisions About Coercion and Undue Influence," *Journal of Medical Ethics* 39, no. 4 (2013): 224-229.

27. Department of Health, Education, and Welfare, "The Belmont Report. Ethical Principles and Guidelines for the Protection of Human Subjects of Research," *The Journal of the American College of Dentists* 81, no. 3 (2014): 4-13.

28. Jennifer S. Hawkins and Ezekiel J. Emmanuel. 2005, "Clarifying Confusions about Coercion," *Hastings Center Report*, 16-19.

29. Department of Health, Education, and Welfare, "The Belmont Report. Ethical Principles and Guidelines for the Protection of Human Subjects of Research," 4-13.

Pregnant women, fetuses/neonates, prisoners, and children are all identified as “vulnerable” populations under subpart B-D of the 45 CFR 46. These subparts outline protections that should be implemented in research involving vulnerable populations in addition to those outlined in the Common Rule, which refers specifically to subpart A of the 45 CFR 46 and applies to all human research subjects.

There is a twofold challenge with interpreting and applying the Common Rule’s conceptualization of vulnerability to research involving asylum-seeking populations. First, IRB members need to identify what asylum seekers are vulnerable *to*. The mere concept of vulnerability makes little sense unless the specific thing the individual is vulnerable *to* is mentioned. When it is not explicitly stated, people are likely to make stigmatizing misconceptions. For example, simply saying that asylum seekers belong to a vulnerable population may make them seem inherently weak or fragile. The Common Rule focusses on populations who are vulnerable *to* coercion and undue influence/inducement. This raises two main questions. First, do asylum seekers experience unique circumstances that render them vulnerable to coercion or undue influence? Secondly, are asylum seekers vulnerable to anything else that IRB members should consider when reviewing research proposals involving this population? IRBs must also understand the source of vulnerabilities asylum seekers experience. In understanding both what asylum seeker are vulnerable to and the sources of these vulnerabilities, IRBs would theoretically be able to create safeguards specific to their review of studies involving asylum-seeking populations.

Asylum seekers have at least two unique sources of vulnerability. The first source is an asylum seeker’s legal status. Because they are often desperate for asylum, they may participate

in research if they think doing so will positively impact their case.³⁰ An asylum seekers' legal status can make them vulnerable to coercion if they believe refusing to participate in a study will decrease their chances of being granted asylum. Their legal status can also be a source of undue influence if they believe participating in a study will increase their chances of being granted asylum. It is common for asylum seekers to falsely associate their participation in research with the asylum process and these misconceptions may persist despite researchers telling them otherwise.³¹

Asylum seekers are also vulnerable to re-traumatization. This is because they have likely endured persecution/torture before fleeing their home country, which puts them at risk of re-experiencing the negative feelings they had during this time if so triggered. This process involves hypersensitivity to threats to safety, becoming triggered, post-traumatic stress reactions, and avoidant coping techniques.³² While re-traumatization can be understood as a vulnerability separate from coercion and undue influence, it also functions as a consequence of coercion and undue influence. For example, providing novel forensic data in a study might re-traumatize asylum seeking participants if they reluctantly agreed to participate and never really wanted to in the first place.

30. Amy Zeidan (Co-Director of Human Rights/Asylum Clinic at Emory University School of Medicine), "Barriers to Conducting Research with Asylum Seekers," Interview by Kathryn Wright, June 16, 2021.

31. Zeidan, Interview, June 2021.

32. Ana Carla S.P. Schippert, Ellen Karine Grov, and Ann Kristin Bjørnnes, "Uncovering Re-traumatization Experiences of Torture Survivors in Somatic Health Care: A Qualitative Systematic Review," *PloS one* 16, no. 2 (2021): e0246074.

SIGNIFICANCE

To interpret the Common Rule during the review of research involving asylum seekers, an IRB must be able to identify this population as “...vulnerable to coercion or undue inducement.”³³ This would involve understanding the unique circumstances (e.g., legal status) of this population that renders them vulnerable to coercion/undue inducement. IRBs would also need to identify additional vulnerabilities unique to asylum seekers that might exacerbate their vulnerability to coercion/undue influence or put them at risk of being harmed while participating in research. These steps would ideally help an IRB justify incorporating specialized safeguards into their review of research proposals involving asylum-seeking participants. To successfully implement the Common Rule into their review of research involving this population, IRBs would also need to develop specialized safeguards that address the sources of vulnerability unique to asylum seekers.

It is important that IRBs have a clear model of vulnerability. Such a model would help IRBs pinpoint *why* certain individuals are “vulnerable” to coercion, undue inducement, and more while participating in research, especially those that are not explicitly mentioned in the Common Rule and subparts B-D of the 45 CFR 46. IRBs could use this model to disapprove research proposals that involve vulnerable populations but do not explicitly state how the researchers intend to protect these populations. IRBs could also use this model to help researchers develop appropriate safeguards for vulnerable participants.

33. Common Rule, 45 C.F.R. § 46 *et seq.* 2018.

A pertinent model of vulnerability would ideally help IRBs know how to appropriately protect the welfare of asylum seekers. It would propose a method they could use to appreciate the vulnerabilities experienced by asylum seekers including but not limited to coercion, and undue influence, and re-traumatization. It would also help IRB members understand how they might implement certain safeguards to ameliorate research participants' vulnerabilities when possible.

Failing to have an appropriate model of vulnerability may result in a lack of proper safeguards which can ultimately cause a great deal of harm to asylum-seeking participants. The lack of tailored regulations for this realm of inquiry may also discourage investigators from conducting research with asylum seekers because there is so much at stake and no standard for minimizing potential harm.³⁴ This can lead to asylum seekers being excluded from research studies that could yield knowledge that could ultimately improve the quality of their experiences. Finally, a lack of specialized safeguards for asylum seekers may reinforce the gross misconception that conducting research on this population is not worth the risk.

METHODS

I first encountered Luna's layered approach to vulnerability during the spring of 2021 when I was completing my bioethics practicum with the Atlanta Asylum Network. My duties began with reviewing literature recommended to me by my supervisor to better understand the asylum process and identify ethical concerns related to seeking asylum. I was tasked with

34. Zeidan, Interview, June 2021.

drafting ethics guidelines for research involving asylum seekers. I reviewed a total of 29 papers and vulnerability was a recurring theme throughout several of the articles. Exactly 21 of the 29 articles mentioned the word “vulnerable”, “vulnerability,” or “vulnerabilities,” usually in reference to participants involved in research. Most of the articles either mentioned vulnerability without explaining what it was, or highlighted discrepancies between different accounts of vulnerability. One article posited a framework – the layered approach- to conceptualizing vulnerability within the realm of research ethics. It also critiqued three other approaches to conceptualizing vulnerability that I will analyze in my findings.

In the findings section below, I will assess how an IRB might use different vulnerability frameworks to interpret and implement the Common Rule while reviewing research proposals involving asylum-seeking populations. This will involve discussing how each framework could be used to recognize vulnerabilities relevant to asylum seekers. I will also analyze how an IRB might use each framework to find the underlying sources of these vulnerabilities. To assess how an IRB could use the vulnerability frameworks to implement provisions, I will identify potential safeguards/provisions IRBs could develop based on that framework.

Because this is a conceptually focused bioethics thesis, my findings will represent an interaction between my analysis and conceptual critique. There may not be a clear distinction between the different steps I outlined above in my findings section below. For example, some of my analysis will include the authors’ critiques of the existing paradigm of conceptualizing vulnerability in the Common Rule. This is meant to provide context and ideally demonstrate the logic behind the authors’ proposed models of vulnerability. I will also mention instances where

the authors critique each other. This is meant to show how nuanced differences in conceptualizing vulnerability can lead to drastically different implications for an IRB.

FINDINGS

In this section I will discuss my findings using the process I described above. Each subsection will be dedicated to one of the four frameworks I discovered during my literature review. The first two models posit novel concepts that might exist alongside the Common Rule's framing of vulnerability. I will begin by introducing Levine et al.'s "special scrutiny"³⁵ framework followed by Kottow's "susceptibility"³⁶ model. Next, I will analyze two distinct approaches to understanding vulnerability. First, I will discuss Kipnis' proposal to create a vulnerability taxonomy.³⁷ I will conclude with Luna's layered approach to vulnerability.³⁸ I have chosen to end with Luna's framework so I can first demonstrate the limitations of the other frameworks before explaining how Luna's model addresses these concerns. Her layered approach also builds upon certain aspects of the other models, so I believe it is fitting to discuss those first. Luna also engages with two of the other frameworks in her articles. I incorporated a fourth framework in my analysis to get a balanced perspective (i.e., two frameworks proposing novel concepts and two focused on unpacking vulnerability). Because I believe they represent

35. Carol Levine, Ruth Faden, Christine Grady, Dale Hammerschmidt, Lisa Eckenwiler, and Jeremy Sugarman, "'Special Scrutiny': a Targeted Form of Research Protocol Review," (2004): 221-223.

36. Michael H. Kottow, "The Vulnerable and the Susceptible," *Bioethics* 17, no. 5-6 (2003): 460-471.

37. Kenneth Kipnis, "Vulnerability in Research Subjects: A Bioethical Taxonomy," *Ethical and Policy Issues in Research Involving Human Participants* 2 (2001).

38. Florencia Luna, "Elucidating the Concept of Vulnerability: Layers not Labels," *IJFAB: International Journal of Feminist Approaches to Bioethics* 2, no. 1 (2009): 121-139.

diverse viewpoints that provide well-rounded insight into the complexities of understanding vulnerability in the realm of research ethics, I limited my analysis to four frameworks (plus the existing framework of the Common Rule).

Special Scrutiny

Levine et al., are concerned that any account of vulnerability will ultimately be either too broad or too narrow.³⁹ They fear IRBs will be perpetually debating if another population should be added to the list of protected groups. As more populations are deemed “vulnerable”, the label will become increasingly normalized until it is too broad to have any meaning. The authors believe extensive analysis will likely reveal that nearly every population under review is vulnerable in some way. Eventually, the term “vulnerability” will be rendered obsolete such that everyone eventually requires special protection(s) in research studies.

Conversely, Levine et al., argue that having a list of rigid criteria an individual needs to meet to be deemed “vulnerable” is too narrow.⁴⁰ This approach makes the false assumption that all existing vulnerabilities can be identified and listed. Furthermore, the authors are concerned that this approach will lead researchers to make the false assumption that eliminating or accommodating vulnerabilities is congruent with eliminating all avenues of harm that a participant can likely incur during a study.

39. 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): 44-49.

40. Levine et al., "The Limitations of “Vulnerability” as a Protection for Human Research Participants," 46-47.

Levine et al., posits that the use of vulnerability as a criterion for warranting special protections in research should be replaced with “special scrutiny.”^{41,42} This method involves identifying risks inherent to certain research designs/contexts and developing safeguards that would protect all research participants regardless of their background. According to them, IRBs may need to implement additional safeguards if the research meets at least one of the following criteria: 1) it involves implementing novel/irreversible interventions, 2) There is a risk of substantial harm to the participants with no direct medical benefit, or 3) the study’s protocol raises ethical questions/concerns for which there is no consensus.⁴³

The first criterion is the least relevant to research involving asylum seekers. The majority of research involving this population would likely be geared towards identifying existing disparities in asylum-seeking populations rather than implementing cutting edge interventions. Some research involving asylum seekers may meet the second criterion listed above. As I mentioned before, there is a demand from researchers for information regarding clinical outcomes of asylum seekers, the efficacy of procedures for detecting sequelae, the efficacy of forensic evaluations in granting asylum, etc. Investigations of this nature may require the acquisition of novel clinical/forensic data.⁴⁴ It is unlikely that these types of studies would provide any direct medical benefit to participants providing the data. Research involving asylum seekers most readily meets the third criterion. There is an ethical concern that asylum seekers

41. Levine et al., ““Special scrutiny”: a targeted form of research protocol review,” 220-223

42. Levine et al., “The Limitations of “Vulnerability” as a Protection for Human Research Participants,” 48.

43. Levine et al., ““Special scrutiny”: a targeted form of research protocol review,” 221-222.

44. Some investigations may retrospectively review existing medical record, meaning the collection of novel forensic data may not be necessary.

may be harmed, or more specifically, re-traumatized, during a study. There is also a risk of asylum seekers confusing the research process with the legal asylum process. They may feel coerced to participate in a study if they think failing to do so will increase their chances of being deported. Furthermore, they may experience undue inducement if they believe their participation in a study will increase their chances of being granted asylum.

The special scrutiny framework transitions the source of vulnerability from characteristics inherent to certain populations (e.g., economically disadvantaged, impaired decision-making capacity, young age, etc.) and places it on the context created by the research itself. The authors believe this framework would “lower the threshold” for protocols that require “special scrutiny [and IRB review]”⁴⁵ or more frequent reviews with the ultimate goal of providing “appropriate protection for all research participants....”⁴⁶ Implementation of this framework would ideally increase the number of research proposals subjected to detailed IRB review. This, in turn, might increase the number of research participants that are provided with “appropriate” or specialized protections. Through the special scrutiny lens, special protections would apply to many participants, not just to those who are labeled as “vulnerable” by the Common Rule/the 45 CFR 46.

While this framework may help IRBs identify asylum seekers as a population in need of protection, I am still unclear how they would use “special scrutiny” to develop specialized safeguards for research involving asylum seekers. Levine et al.’s paradigm merely creates a new

45. Levine et al., ““Special scrutiny”: a targeted form of research protocol review,” 222.

46. Levine et al., “The Limitations of “Vulnerability” as a Protection for Human Research Participants,” 48.

categorization scheme that is more inclusive than the 45 CFR 46 subparts/the Common Rule. Even though this might provide safeguards for people who would not otherwise be explicitly considered under the Common Rule, implementing “special scrutiny” does not necessarily benefit asylum seekers. Under this framework, asylum seekers are at risk of being lumped into a general category of participants who are participating in a study whose protocol “raises ethical questions...,”⁴⁷ (criterion 3 for special scrutiny). All three of the criteria for special scrutiny are so ambiguous, I am doubtful provisions meant to address them would be nuanced enough to accommodate challenges specific to asylum seekers. For example, the authors discuss “...creating a data safety and monitoring board”⁴⁸ as a potential safeguard. This proposal resembles the provision in the Common Rule about including experts in the IRB. Yet, there is still a lack of guidance for how boards/professionals might develop provisions specific to asylum-seeking populations.

I am also concerned that the special scrutiny framework focuses on ethical concerns that arise exclusively from the nature of research being conducted. This mentality might cause IRBs to neglect harms that originate from contexts outside of the research setting. For example, I have mentioned earlier that asylum seekers are at risk of re-traumatization. Even though a participant may be at risk of becoming re-traumatized during the study, their initial trauma almost certainly originated from instances of torture/persecution that occurred outside the context of research. How can IRBs advise researchers on how to mitigate the risk of re-

47. Levine et al., ““Special scrutiny”: a targeted form of research protocol review,” 221.

48. Levine et al., ““Special scrutiny”: a targeted form of research protocol review,” 222.

traumatization if they do not know what caused the initial trauma? They need to be able to screen research proposals for elements that might trigger asylum-seeking participants. It would also help if IRBs knew about some of the existing disparities in the asylum-seeking community. For example, asylum seekers do not have healthcare coverage while they are waiting for their case to be processed, so they may feel coerced to participate in a study that would grant them access to clinicians. Neglecting to appreciate the harms originating from both the research protocol and the socio-cultural context the participants live in could lead to IRBs inadvertently approving research proposals that exacerbate existing vulnerabilities in asylum-seeking populations.

Susceptibility

In *The Oxford Textbook of Clinical Research Ethics*, Carol Levine authors a chapter entitled "Research Involving Economically Disadvantaged Participants". She enumerates several concerns with defining/conceptualizing vulnerability in a meaningful way and posits potential solutions. Michael Kottow's "susceptibility" approach is described as an alternative to conceptualizing vulnerability.⁴⁹ Kottow argues that "The distinction between vulnerability and susceptibility also marks the difference between being intact but fragile – vulnerable – and being injured and predisposed to compound additional harm – susceptible."⁵⁰ He later

49. Carol Levine, "Research Involving Economically Disadvantaged Participants." In *The Oxford Textbook of Clinical Research Ethics*, eds. Ezekiel J Emanuel, Christine C Grady, Robert A Crouch, Reidar K Lie, Franklin G Miller and David D Wendler (New York: Oxford University Press, Incorporated, 2008), 433.

50. Kottow, "The Vulnerable and the Susceptible," 460.

mentions that vulnerability "...is a human condition from which we all suffer..."⁵¹ According to Kottow, "the State"⁵² grants citizens with certain rights that are meant to protect them against the general vulnerability of being human. For example, he describes the right to healthcare as a protection against general sickness, or "biological vulnerability".⁵³ However, once someone becomes sick or injured, they become *susceptible* to experiencing additional harm and require special protection or treatment. Kottow admits that not all individuals have access to healthcare, especially those who do not have citizenship. He states that individuals in this situation should be especially entitled to special protections while participating in research since they have already been deprived of rights that ought to be universal (e.g., right to healthcare).⁵⁴

Unlike the special scrutiny framework, the susceptibility model takes participants' legal status into consideration. It recognizes that those who do not have citizenship/access to basic rights may have an increased risk of being harmed while participating in research. This feature is extremely relevant to asylum seekers since their legal status makes it difficult for them to access certain services. The susceptibility model also recognizes how a lack of access to certain resources can put an individual at a greater risk of being harmed while participating in research. IRBs might use this framework to identify asylum seekers as susceptible in research studies because they do not have access to healthcare, work authorization, housing resettlement assistance, etc. Additionally, this model captures the fact that asylum seekers have already

51. Kottow, "The Vulnerable and the Susceptible," 461.

52. Kottow, "The Vulnerable and the Susceptible," 461.

53. Kottow, "The Vulnerable and the Susceptible," 464.

54. Kottow, "The Vulnerable and the Susceptible," 463-464.

experienced harm in the form of persecution or profound fear of persecution, which also makes them more susceptible to being harmed (i.e., re-traumatized) in research studies.

Kottow claims that susceptibilities can only be reduced through provisions that are actively applied and tailored to the uniqueness of the susceptibility. IRBs could use this framework to justify the need for specialized safeguards in research involving asylum seekers. The minor critique I have here is that this framework offers no guidance on what safeguards should be implemented, or *how* IRBs might go about developing specialized safeguards to ameliorate relevant susceptibilities. Still, it does provide clear guidance on how an IRB might identify asylum seekers as a “susceptible” population and justify the implementation of specialized safeguards in research involving these individuals.

I am mainly concerned with IRBs’ ability to use this framework in conjunction with the Common Rule. Kottow outlined vulnerability as a fixed characteristic shared by all humans. The Common Rule, on the other hand, grants this label to specific populations (pregnant women, minors, prisoners, etc). Kottow would likely interpret the Common Rule (subpart A of the 45 CFR 46) as protecting general vulnerabilities and label those populations in subparts B-D as provisions for the “susceptible”. Unfortunately, the Common Rule is unlikely to change anytime soon, and using these two frameworks alongside each other would likely cause confusion since they are conceptualizing vulnerability in conflicting manners. Thus, it would be more pragmatic for the IRB to apply a framework that can supplement rather than supersede, the Common Rule.

The Vulnerability Taxonomy

Kenneth Kipnis claims that the current method of deeming entire populations “vulnerable” has little utility since this method does not offer a clear path to protecting the “vulnerable”.⁵⁵ This echoes the concern I mentioned above regarding the reluctance of researchers to conduct investigations with asylum seekers since they do not want to cause undue harm. Kipnis aims to remedy the shortcomings of deeming certain populations “vulnerable” by creating a “vulnerability taxonomy”.⁵⁶ He believes all vulnerabilities can be placed into one of six categories: cognitive, juridic, deferential, medical, allocational, and infrastructural vulnerabilities.⁵⁷ These categories are meant to serve as a checklist for IRBs to identify the sources of vulnerability research participants may be experiencing. If a participant meets the criteria for at least one of the six listed vulnerabilities, they become candidates for receiving specialized safeguards.

Under each category, Kipnis lists a question a researcher might ask to help them determine if a participant is vulnerable. For example, in assessing cognitive vulnerability, IRBs need to ask themselves if the participants have the capacity to decide if they want to participate in the study.⁵⁸ Asylum seekers would likely experience cognitive vulnerability if they were not fluent in English, unfamiliar with the research process, or possess cognitive impairment (could be acquired from torture or congenital). To detect juridic vulnerabilities, IRBs might ask if the participants are “... liable to the authority of others who may have an

55. Kipnis, "Vulnerability in Research Subjects: A Bioethical Taxonomy," G-3-4.

56. Kipnis, "Vulnerability in Research Subjects: A Bioethical Taxonomy," G-3.

57. Kipnis, "Vulnerability in Research Subjects: A Bioethical Taxonomy," G-6.

58. Kipnis, "Vulnerability in Research Subjects: A Bioethical Taxonomy," G-7.

independent interest in that population.”⁵⁹ Deferential vulnerability is similar to juridic vulnerability, but instead looks at individuals who the participant may trust.⁶⁰ For an asylum seeker, this may be a neighbor or friend. There could be some overlap between juridic and deferential vulnerability. For example, an asylum seeker may participate in a study because it was recommended to them by their physician who is both knowledgeable and a trusted member of the asylum seeker’s social network.

Medical vulnerability occurs when the research participants have a medical condition for which they have not been able to find relief.⁶¹ The likelihood of this vulnerability is highly dependent on the nature of research being conducted. For example, research investigating health outcomes in asylum-seeking populations may focus on identifying existing disparities rather than implementing novel interventions. However, if the study is gathering novel forensic evidence it may be worth clarifying in the informed consent process that medical care will not be administered through the study to clarify confusion.

In the case of allocational vulnerability, IRB members would ask themselves if the participants are “... seriously lacking in important social goods that will be provided as a consequence of his or her participation in research?”⁶² If the answer is yes, then additional safeguards may be needed. A participant is subject to allocational vulnerability if the study provides them with a “social” good (other than medical care) that they may not otherwise have access to outside of the study. The presence of this vulnerability again depends on the nature

59. Kipnis, "Vulnerability in Research Subjects: A Bioethical Taxonomy," G-7.

60. Kipnis, "Vulnerability in Research Subjects: A Bioethical Taxonomy," G-8.

61. Kipnis, "Vulnerability in Research Subjects: A Bioethical Taxonomy," G-8.

62. Kipnis, "Vulnerability in Research Subjects: A Bioethical Taxonomy," G-10.

of the research. Asylum seekers may experience allocational vulnerability if the study provides compensation since they cannot receive work authorization until their claim is processed.

Finally, infrastructural vulnerability occurs when research protocols make false assumptions about participants.⁶³ For example, a contact form asking for a participant's telephone number assumes the participant has phone service. Preliminary research has suggested that individuals do not frequently use technology during the resettlement process.⁶⁴ At the macro level, it is important that researchers ensure that proper infrastructure is available to maintain the integrity of the study. For example, it is known that the asylum process can last for years. Researchers may therefore need to create methods to keep updated contact information for asylum-seeking participants on record. This is especially important if the study design is longitudinal, since an asylum seeker's place of residence and contact information may change multiple times before the final data point is collected (case outcome).

This model provides insight to a variety of vulnerabilities that asylum seekers may experience while participating in research studies that extend beyond coercion and undue inducement. It balances vulnerabilities originating from inherent characteristics with external factors. It also acknowledges the interdisciplinary nature of vulnerability by incorporating legal, social, and medical factors into the taxonomy.

63. Kipnis, "Vulnerability in Research Subjects: A Bioethical Taxonomy," G-11.

64. Linda Leung, "Telecommunications Across Borders: Refugees' Technology use During Displacement," *Telecommunications Journal of Australia*, (2010).

In terms of safeguards, Kipnis explains that a list of potential protections could be brainstormed based on the six vulnerability categories. For example, a safeguard for asylum seekers experiencing infrastructural vulnerability could involve a frequent follow-up period where researchers confirm/update participants' contact information. Another safeguard could require contact forms to have a place for asylum seeking participants to provide contact information of someone who they see frequently and has consistent access to technology such as a lawyer, neighbor, or friend.

Most of Kipnis' statements appear to be directed towards researchers. He does not explicitly state the IRB's role in his model. Admittedly, the responsibility of determining vulnerabilities of participants in specific studies may fall on the shoulders of researchers since they are the ones interacting with the participants. However, IRBs could still use the vulnerability taxonomy to develop a general list of safeguards addressing all six of the vulnerabilities illustrated by Kipnis. They could then implement these safeguards into their review of research proposals and provide suggestions for studies involving asylum-seeking populations. This method also promotes accountability between IRB members, researchers, and the institution as a whole. IRBs could have researchers submit a vulnerability taxonomy checklist complete with proposed safeguards as part of the research proposal. Either way, this model provides concrete guidance for individuals to identify vulnerabilities in asylum seekers and brainstorm potential safeguards.

The main question I had after reviewing this framework was, *how did Kipnis come up with these six categories? How did he know there were not more or fewer categories of vulnerability? Two years after proposing his taxonomy of vulnerability, Kipnis published another*

paper outlining the *seven* vulnerabilities pediatric research participants experience: incapacitational, juridic, deferential, social, situational, medical, and allocational.⁶⁵ Note that in this list, infrastructural vulnerability has been removed and situation and social vulnerability has been added. My point is that there is no guarantee that the taxonomy proposed in the initial Kipnis paper included a complete list of all the potential vulnerabilities, and Kipnis proposes no method for identifying new sources. Still, there does not appear to be any drastic changes between the initial taxonomy and the list Kipnis made for pediatric patients. In the worst-case scenario, IRBs might implement this framework and unknowingly ignore another source of vulnerability that Kipnis failed to mention. However, the initial taxonomy appears to be well-rounded, and I suspect it would encompass the majority of the vulnerabilities experienced by asylum seekers.

The Layered Approach to Vulnerability

In 2009, Florencia Luna proposed a novel way to understand vulnerability using the metaphor of layers.⁶⁶ She agrees with Kipnis' preference to focus on the contextual factors rather than claiming entire populations of people are inherently vulnerable. The "subpopulation approach,"⁶⁷ as she calls it, ignores variability within populations. Luna also agrees with Levine et al.'s claim that the current paradigm of vulnerability is futile and ultimately leads to endless debates about adding certain populations to the existing list of

65. Kenneth Kipnis, "Seven Vulnerabilities in the Pediatric Research Subject," *Theoretical Medicine and Bioethics* 24, no. 2 (2003): 107-120.

66. Luna, "Elucidating the Concept of Vulnerability: Layers not Labels," 121-139.

67. Luna, "Elucidating the Concept of Vulnerability: Layers not Labels," 123.

“vulnerable populations.”⁶⁸ However, Luna has some concerns with Levine et al.’s special scrutiny framework. She fears that their paradigm minimizes the importance of vulnerability by “throwing out the baby with the bathwater”⁶⁹ and failing to unpack this concept. She claims that “...it is far more comfortable to deny the idea of vulnerability than to acknowledge it and seriously provide safeguards to avoid the harmful consequences.”⁷⁰

Luna also opposes the use of vulnerability taxonomies. she believes taxonomies are too simplistic. In her view “Taxonomies, like corsets, are not enough to categorize reality! The real world is too complex, layers of vulnerability overlap and the context interacts with them.”⁷¹ She is also concerned that committing to the vulnerability taxonomy discourages researchers/IRBs from appreciating the interaction between different layers of vulnerability. Finally, Luna believes that the vulnerability taxonomy fails to outline how IRBs/researchers might prioritize vulnerabilities that are more relevant.

Because this concept is so complex, Luna does not offer an explicit definition of vulnerability. She claims her model can include and complement existing frameworks.⁷² She loosely identifies a layer of vulnerability as a way of conceptualizing “...the likelihood of harms and wrongs.”⁷³ Her framework has two steps, the first of which involves identifying layers of vulnerability. She claims that IRBs can accomplish this by first identifying “stimulus

68. Luna, "Elucidating the Concept of Vulnerability: Layers not Labels," 127.

69. Luna, "Elucidating the Concept of Vulnerability: Layers not Labels," 128.

70. Luna, "Elucidating the Concept of Vulnerability: Layers not Labels," 128.

71. Florencia Luna, "Identifying and Evaluating Layers of Vulnerability—a way Forward," *Developing world Bioethics* 19, no. 2 (2019): 86-95.

72. Luna, "Identifying and Evaluating Layers of Vulnerability—a way Forward," 89.

73. Luna, "Identifying and Evaluating Layers of Vulnerability—a way Forward," 91.

conditions"⁷⁴ that might render a participant vulnerable. She cites the Kipnis taxonomy questions as an appropriate way to get the conversation started.⁷⁵ For example, an asylum seeker may be rendered vulnerable to re-traumatization when they participate in a study that requires them to recall past instances of persecution. IRBs must also identify "cascade layers" of vulnerability, which arise when two or more layers of vulnerability interact and exacerbate each other.⁷⁶ For example, an asylum seeker may be rendered vulnerable to re-traumatization if they do not really want to participate in a study that requires them to recall traumatic experiences but persist in doing so because they think their participation will increase their chances of being granted asylum. In this instance, the participant's concern about their legal status and exposure to past trauma is increasing their risk of being re-traumatized.

The second step involves ranking and prioritizing the list of vulnerabilities developed in step one.⁷⁷ During this step, IRBs should consider which layers are the most likely to be relevant during implementation of the proposed study in addition to what layers have the greatest potential to harm the participant(s). IRBs should also assess the extent to which they can minimize the stimuli for all the layers they identified. For example, some concerns regarding re-traumatization may be minimized if the IRB requires researchers to have a counselor on site who can talk to participants experiencing traumatic emotional responses. However, there may be other stimulus conditions contributing to this vulnerability that exist beyond the

74. Luna, "Identifying and Evaluating Layers of Vulnerability—a way Forward," 91-94.

75. Luna, "Identifying and Evaluating Layers of Vulnerability—a way Forward," 89.

76. Luna, "Identifying and Evaluating Layers of Vulnerability—a way Forward," 91-94.

77. Luna, "Identifying and Evaluating Layers of Vulnerability—a way Forward," 92-93.

researchers' control. In this case, the research design is putting participants at risk of re-traumatization. To fully ameliorate this vulnerability, IRBs would have to stop the research all together, which would be counterproductive (but might warranted in some circumstances). IRBs cannot ameliorate every situation that might render an asylum seeker vulnerable. The idea is that once IRBs have a list of layers of vulnerabilities and agree upon a ranking system, they should be able to develop specialized safeguards by finding ways to reduce the stimulus conditions within reason. They would still need to weigh the benefits of the proposed study with the risks posed to the asylum-seeking participants. The layered approach is not claiming that all vulnerabilities can be ameliorated. Rather, it is challenging IRBs to see vulnerability as an invitation for further conversation instead of a roadblock to approving a research proposal.

Luna's layered approach to vulnerability challenges researchers/IRBs to assess what contextual elements render research participants vulnerable. She then considers these contexts to be solely responsible for rendering people vulnerable. She rejects the notion that vulnerability is a characteristic inherent to certain populations. She believes the entirety of the concept is relational and contextual. Her framework, she claims, is meant to unpack vulnerability such that it helps others understand the complexities of vulnerabilities experienced by research participants. The framework is also meant to demonstrate its applicability in research settings.

Compared to the taxonomy model, I think the layered approach does a better job at encompassing the vulnerabilities experienced by asylum seeking research participants. This is primarily because Luna accounts for the functional aspects of various models while simultaneously adding unique features. For example, she recommends the guiding questions

proposed by Kipnis as a way to start conversation among IRBs/researchers. However, she ventures a step further by positing that IRBs ought to prioritize which vulnerabilities are the most important/manageable. She also introduces the idea of “cascade layers” without providing a finite list of all the vulnerabilities that exist. This ideally challenges IRBs to see the big picture and assess how vulnerabilities interact with each other. Finally, this model allows room for IRBs and researchers to discover new vulnerabilities in real time. This would likely prevent IRBs from using criteria that do not explicitly apply to asylum seekers, as was the problem with the Common Rule.

DISCUSSION

In this section I will delve into some of the observations I had during my investigation. First, I will discuss the challenges with replacing vulnerability with a novel concept (such as those proposed by Levine et al., and Kottow). Next, I will elaborate on the IRB’s ability to interpret and implement the Common Rule into their review of research involving asylum seekers. I will also discuss the implications my findings have for IRBs. Finally, I will outline some of my personal experiences in conducting this research inquiry.

Replacing Vulnerability is Counterproductive

The two alternatives to vulnerability I presented in my findings section took two distinct approaches to identifying and protecting research participants who are at risk of being substantially harmed. The special scrutiny framework identifies those in need of protections (in addition to those outlined in the Common Rule) based on risks imposed on participants by the research itself. The susceptibility model posits that those in need of specialized safeguards are

likely subject to certain conditions or situations outside the realm of research that puts them at a greater risk of being harmed. Both frameworks highlight the limitations of labeling certain populations as “vulnerable”. The special scrutiny framework could ideally refine IRB members’ interpretation of existing notions of vulnerability and could exist alongside the Common Rule provisions while providing additional protections. The susceptibility framework, in contrast, would need to supersede the existing frameworks to be fully functional. However, I found both models one-sided such that they put a great deal of effort into helping us - and hopefully IRBs – understand what it means to be vulnerable/susceptible, and very little time on how IRBs and similar entities might go about protecting individuals from these harms they are more likely to experience. For these reasons, I was ultimately convinced that replacing or supplementing vulnerability was counterproductive. It seemed more intuitive to find a model that simply gave a clearer account of vulnerability than the Common Rule and posited a method for identifying various vulnerabilities/potential safeguards for asylum seekers. Finally, both the special scrutiny and the susceptibility approaches do not unpack the nuances and complexities of vulnerability. They instead created entirely new concepts, that are ultimately unlikely to help the IRB interpret and build upon the Common Rule in a way that adequately benefits asylum seekers.

Interpreting and Implementing the Common Rule

The main objective of my thesis was to find a model that could help IRBs interpret and implement the Common Rule to research involving asylum seekers. Admittedly, I had to make some assumptions about how IRBs would approach this endeavor. I spent a great deal of time describing how an IRB might be able to identify asylum seekers as vulnerable. To be clear, this is only one step of interpretation. Identifying what asylum seekers are vulnerable to and

unearthing why they possess those vulnerabilities are integral parts of interpreting the Common Rule. Furthermore, there is more to implementing the Common Rule than merely proposing specialized safeguards. The safeguards must specifically address the source of vulnerabilities relevant to asylum seekers. This is contingent on the IRBs ability to identify *why* asylum seekers are rendered vulnerable in certain situation.

The Common Rule is clearly focused on populations that are vulnerable to coercion and undue influence. However, it does not preclude other vulnerabilities from warranting specialized protections during the IRB review process. In my findings I discussed how IRBs might use the four frameworks to conclude that asylum seekers are vulnerable to coercion, undue inducement, re-traumatization, etc. While I do think being vulnerable to re-traumatization is sufficient for requiring specialized safeguards, viewing it as a vulnerability that is independent of coercion/undue inducement oversimplifies the matter. I think it is more appropriate to conceptualize these three vulnerabilities as what Luna called “cascade layers”.⁷⁸ They exacerbate each other and cannot be fully disentangled. An asylum seeker could be simultaneously coerced and unduly influenced into participating in a study. They are at a constant risk of being harmed (i.e., sent back to their home country). Any chance of being granted asylum is an offer they cannot refuse. They could therefore perceive their participation in a study as decreasing their chances of being deported while simultaneously increasing their chances of being granted asylum. While it is unlikely that their participation in research will actually do either of these things, IRBs need to be aware that it is common for asylum seekers

78. Luna, "Identifying and Evaluating Layers of Vulnerability—a way Forward," 91-94.

to make these types of associations.⁷⁹ Furthermore, the risk of re-traumatization compounds the consequences of coercion/undue influence in asylum seekers. If they are pressured to participate against their own will, they may be re-traumatized, and experience negative emotions associated with past instances of persecution/torture. In sum, asylum seekers do not need specialized protections simply because they are vulnerable to coercion/undue influence. They need special provisions because they are vulnerable to an amalgamation of coercion, undue influence, and re-traumatization that is caused by their unique circumstances.

Implications for IRBs

Apart from Kottow's susceptibility model, the vulnerability frameworks mentioned in the findings section could ideally coexist with the Common Rule. I have already explained why I believe Luna's layered approach would be the most helpful for interpreting the provisions outlined in the Common Rule. But is the existing framework of the 45 CFR 46 limiting IRBs from adopting a superior model of vulnerability?

If there was no Common Rule and we were starting from scratch, I could see the benefits of implementing Kottow's susceptibility model as a new paradigm. It would make a clear distinction between protections all research participants are entitled to and those intended for participants that are at a substantial risk of being harmed by the research. This framework also avoids the disaster that ensues from creating an exclusive list of people who are "vulnerable" and in need of special protection.

79. Zeidan, Interview, April 2021.

However, I also think Luna's layered approach to vulnerability would be a viable contender for a new paradigm. The susceptibility model predominately focused on justifying *why* people are deemed "susceptible" and ought to be entitled to certain protections. The layered approach explains the *why* in addition to the *how*, as in, *how* IRBs and researchers might go about creating appropriate safeguards to minimize stimuli that may render participants vulnerable. I also like how this framework integrates other frameworks (e.g., the Kipnis taxonomy) into its paradigm. I think having this type of flexibility in regulations long term encourages collaboration between disciplines and allows space for the framework to be revised in the event someone comes up with a better paradigm in the future. Finally, I think this approach might facilitate more collaboration between researchers and IRBs.

Admittedly, I do not have a lot of experience working with IRBs. The special scrutiny and susceptibility models both seemed to be putting most of the responsibility on IRBs. The layered approach would likely encourage researchers to brainstorm their own protections since they are the ones interacting with the participants. While the IRB would still have to approve the protections proposed by the researchers, the layered approach would ideally make the process less top-down and more of a collaboration where both researchers and IRB members could learn how to implement proper safeguards in research. In sum, I do not think the 45 CFR 46 is limiting IRBs from adopting a superior model of vulnerability because I believe the layered approach is the superior framework that can stand on its own or enhance and IRB's interpretation of the existing paradigm.

Personal Reflections

Perhaps the most frustrating experience of my inquiry was never finding a concrete definition of vulnerability. I spent hours trying to wrap my mind around the intricacies presented in the various frameworks. It felt counterintuitive to dive so deep into a topic and still be unable to define the very thing I was investigating. Most of the authors simply refer to it as a “characteristic” or “trait” that may or may not be a result of who you are (depending on who you ask). Kottow probably came closest to providing us with a definition when he said vulnerability was the state of being “...intact but fragile.”⁸⁰ However, he also used this definition to defend the controversial claim that everyone was equally vulnerable, and those in need of special protections were “susceptible.” While the concept of vulnerability as a universal quality is nothing new, making such a claim would drastically complicate things for IRBs. As Jonathan Moreno puts it, “...if even Superman is at risk the rest of us are toast.”⁸¹ Including everyone in a category meant to offer special protections may further marginalize groups that are rendered more vulnerable than others. IRBs would have to create some sort of ranking system to fully appreciate the heterogeneity of vulnerabilities that exist in our population. In sum, this experience helped me appreciate the sheer complexity of understanding vulnerability and its relevance in the realm of research ethics.

My research also helped me appreciate the countless challenges asylum seekers face. After fleeing their home under extreme duress, they must fashion a new life for themselves in a

80. Kottow, “The Vulnerable and the Susceptible,” 460.

81. Jonathan D Moreno, “The Natural History of Vulnerability.” *The American Journal of Bioethics* 4, no. 3 (2004): 52-53.

new country with minimal assistance from the government. They must fight for their right to remain within the US and live-in constant fear of being returned to their home country. They may go years living in uncertainty without access to basic services/rights such as healthcare, work authorization, ability to travel, etc. Ideally, research could help investigators identify disparities among asylum seekers and eventually identify ways to improve this population's quality of life. Yet, I sympathize with researchers who may feel reluctant to conduct research with asylum seekers. It is incredibly hard to weigh the consequences and benefits of initiating this type of research when it is unclear what protections asylum-seeking participants would be entitled to during the study.

This investigation also exposed me to the shocking shortcomings of the Common Rule's ability to provide clear safeguards for individuals experiencing vulnerability. While Levine et al., Kottow, Kipnis, and Luna had distinct opinions that rarely coincided with each other, they all seemed to agree that the existing paradigm is extremely problematic and in need of replacement or revision. While it was refreshing to see all the authors agree on something, it is extremely concerning that there is an unanimously negative perception of the existing paradigm.

Perhaps the most concerning revelation is the lack of empirical evidence documenting the efficacy of the Common Rule's (and subparts B-D of the 45 CFR 46's) ability to protect vulnerable populations. Most of the research I found simply documented the lack of clarity between what it meant to be vulnerable. One article I found claimed that most IRBs rarely

know the difference between undue influence and coercion.⁸² This is extremely concerning given that the Common Rule has the very narrow scope of vulnerability (it only explicitly mentions those that are vulnerable to undue inducement or coercion). But if IRBs do not even know what it means to be vulnerable to undue influence/coercion, how are they supposed to correctly identify participants that need of special protections? The harsh reality is that the Common Rule needs to be replaced or revised to better protect populations that are not guaranteed special provisions. However, things are unlikely to change until there is empirical evidence demonstrating the 45 CFR 46's shortcomings. Ideally, this would involve evidence documenting both the lack of clarity in IRBs' interpretation of the 45 CFR 46 and feedback from research participants about the quality of protections they received (or failed to receive). In retrospect, I am confused why the OHRP, IRBs, or research institutions in general do not require quality control studies to assess the efficacy of the provisions outlined in the 45 CFR 46.

LIMITATIONS

There were a few limitations of my thesis I would like to discuss. First, my entire investigation hinged on the assumption that IRBs could more effectively interpret and implement the Common Rule while reviewing research proposals involving asylum-seeking populations *if* they had an appropriate model of vulnerability. While I still believe this statement to be true, I did not explore other avenues that could have perhaps led IRBs to implement specialized provisions during their review of research involving asylum seekers.

82. Klitzman, "How IRBs View and Make Decisions About Coercion and Undue Influence," 224-229.

Furthermore, I did not thoroughly investigate how the role of a researcher might be redefined to compliment the IRB in each of the frameworks I discussed above.

Secondly, I analyzed a limited number of frameworks with little to no empirical data to support my findings. Because each framework is so complex, I figured it would be preferable to explore a few models in depth rather than all the models in brevity. I attempted to incorporate a variety of opinions by selecting two views that offered alternatives to the concept of vulnerability in addition to two models that conceptualized vulnerability in different ways (in addition to the existing paradigm of the Common Rule). Still, I recognize that there are other frameworks out there that may be superior to the ones I dissected. Because research ethics relies on complex concepts, it is difficult to find empirical data to support any claims I have made. Ideally, this thesis could be used as a starting point for future research that could reinforce my conclusions with empirical evidence.

Finally, I am not an expert in research ethics nor asylum-seeking populations. While I did consult professionals from both fields during the construction of my thesis, I came up with some of the proposed safeguards on my own. It is quite possible that someone more seasoned in either field would have identified different vulnerabilities experienced by asylum seekers and proposed different safeguards using the same frameworks that I did. The vulnerabilities and safeguards I identified were merely meant to show the logical flow that stemmed from each model.

CONCLUSION

In my thesis I aimed to demonstrate how IRBs could improve their interpretation of the Common Rule when reviewing research involving asylum-seeking populations. More specifically, I assessed the pitfalls of the Common Rule and the way it framed vulnerable populations. I also compared four different frameworks and their ability to 1) help IRBs recognize vulnerabilities relevant to asylum seeking research participants and 2) help IRBs propose specialized safeguards for asylum seekers involved in research. My analysis brought me to the conclusion that of the frameworks that were analyzed, Luna's layered approach would best aid the IRB in interpreting the provisions outlined in the Common Rule and implementing them during the review of research involving asylum seekers.

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