A Multi-Case Study of Understanding Community-Level Ethics at Community-Engaged Research Universities

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Dedication

This dissertation is dedicated to my community. Old and new, near and far, all of you have taught and inspired me along the way. I am not me without you, so I dedicate this work to “us”.

Abstract

Although the Belmont Report and associated federal regulations were written to protect individual research participants from undue risk and harm, Community-Based Participatory Research teams are concerned about insufficient protection of ethical concerns on a community level. This multi-case study examines the process institutional actors at two community-engaged universities with very high research activity use to understand and respond to community-level ethics. It also examines specific changes that are made to IRB process as a result of this understanding.

This study utilizes a conceptual framework based on sensemaking theory to explore these concerns. The key themes that emerged from this study include how environmental cues are a catalyst for IRB sensemaking, how sensemaking forums promote IRB reforms, the ways leaders are gatekeepers or facilitators of sensemaking, the critical role of CBPR experts, and the extent of community-based protections offered through IRB Offices. The final theme is that CPBR ethics ultimately remains in the hands of faculty and staff. These key understandings provide a basis for new insights for theory, practice, and research in an area that has previously received little attention in the field of higher education research.

Table of Contents

List of Tables

List of Figures

Chapter 1: Introduction

Background of the Study

Re-Imagining the Third Mission of Higher Education

American universities have evolved in the ways that they think about engaging communities in addressing societal problems. In their article, "A History of Change in the Third Mission of Higher Education: The Evolution of One-Way Service to Interactive Engagement," Roper and Hirth (2005) note that the biggest shift in the way that public higher education relates to communities was marked by a re-imagining of the "third mission" (i.e., public service/outreach) of institutions from expert-driven outreach to reciprocal engagement and partnership with community members. This change had several distinct stages, defined in large part by the evolving views of the purpose of knowledge-sharing and knowledge production in the academy.

Even before the terms public service, outreach, and extension made their way into the higher education lexicon, early American colleges included their own version of a public purpose (Dyer, 1999; Furco, 2010). Although the public purpose of the colonial colleges was quite narrow, initial institutional missions rested on college faculty sharing their expertise to prepare a "learned clergy that could lead the colonies' Puritan congregations" (Furco, 2010, p. 375) which was then seen as a public good. Additionally, college education was directly tied to social concerns of the Protestant settlers related to ensuring future leaders were educated with an emphasis on spiritual formation (Weerts, 2017). Although access to higher education was limited to clergy and wealthy white males, institutions were responding to a larger public purpose to lead a largely uneducated society (Roper & Hirth, 2005).

In the 1800's higher education changed dramatically, and rather than serving as education for religious leaders and the elite in society, it became an endeavor of practical arts aimed at the masses (Roper & Hirth, 2005). The Morrill Act of 1862 created public land-grant institutions which were focused on bringing about economic development and expanded educational access (Roper & Hirth, 2005; Weerts, 2017). Particularly for research universities, the public value of higher education was shifting from "spiritual formation and moral development…to knowledge creation, applied learning, economic development, and democratic engagement" (Weerts, 2017, p. 186). In general, these institutions were created to support agricultural and technological challenges facing America at the time which brought the idea of public service and outreach into the identity of higher education (Roper & Hirth, 2005).

The role of public service and outreach further expanded for land-grant institutions with the Hatch Act of 1887 and the Smith-Lever Act of 1914 (Fitzgerald et al., 2012; Roper & Hirth, 2005). The Hatch Act created experiment stations where research was conducted to bring practical information to farmers with the aim of increasing their production and efficiency and the Smith-Lever Act gave permanent funding to land-grants for cooperative extension which was a system used to disseminate research to the public (Roper & Hirth, 2005). These acts, together with the Morrill Act, solidified the role of universities in sharing knowledge with the broader public to build a stronger democracy (Fitzgerald et al., 2012).

As the needs of a growing society became more complex, the importance of applied knowledge waned in favor of specialized disciplinary discovery (Fitzgerald et al., 2012). The military-industrial complex that appeared in post-WWII America brought on

a tight-knit relationship between the federal government and research universities that was focused on developing new technology and maintaining world power (Fitzgerald et al., 2012). In addition, the creation of the National Science Foundation in 1950 made peer review more prominent and intensified the ever-growing disciplinary focus introduced by the German model of graduate education (Fitzgerald, et al., 2012; Roper & Hirth, 2005). The land-grant tradition of utilizing research as outreach to society was largely replaced with a focus on scientific inquiry and disciplinary advancement and away from issues of public concern (Fitzgerald et al., 2012; Roper & Hirth, 2005; Weerts, 2017). The growing insularity of academic life worked to diminish the public purpose of higher education.

As the decades wore on in the latter half of the 20th century, social unrest and economic turmoil led to a lack of trust in higher education and universities were often viewed more as the instigator of rather than the solution to issues of societal concern (Roper & Hirth, 2005). Universities were increasingly criticized for their exceedingly narrow definition of research and lack of connection to community (Strand et al., 2003). Scott Peters (2007) describes a tragic counter narrative to the story of the land-grant where the "democratization" of knowledge privileged the priorities of urban industry over the interests of farmers and rural communities. Peters (2007) notes "Rather than a success story of steady progress, agricultural modernization in the United States and elsewhere can be viewed as a tragic story of technocratic colonization and environmental destruction" (p. 10). Community leaders also grew skeptical of universities and felt they had lost touch with their foundational ideals (Weerts, 2017) and concerns from historically marginalized groups about growing research abuses mounted. A history of ignoring community authority in addition to unacknowledged cultural nuances often led

to research that lacked the context necessary to offer true community benefit (Lucero et al., 2018).

In the 1990's, several reports were released that questioned American higher education's commitment to the public good, stating that institutions were no longer meeting their civic purposes or actively solving issues of value to society (Furco, 2010). In response, many scholars committed themselves to re-defining the public purpose of higher education (Kellogg Commission, 1999). These growing concerns were impetus for a contemporary approach to serving the public good, one focused on conceding that not all knowledge exists within the four walls of academic institutions (Fitzgerald et al., 2012). Ernest Boyer, a prominent scholar at the forefront of the movement, offered a new frame for thinking about the third mission of higher education that was focused on engagement with community.

In his seminal work *Scholarship Reconsidered: Priorities of the Professoriate*, Boyer (1990) described his dissatisfaction with the narrow definition of research and its lack of integration with the other roles of a faculty member (i.e., teaching and public service/outreach). In specific, he was concerned about a focus on the scholarship of discovery rather than other types of scholarship – the scholarship of integration, of application, and of teaching. Boyer (1990) states, "Surely scholarship means engaging in original research. But the work of the scholar also means stepping back from one's own investigation, looking for connections, building bridges between theory and practice, and communicating one's knowledge effectively" (p. 16) and later he asks, "How can knowledge be responsibly applied to consequential problems?" (p. 21). In an article published posthumously he writes of what he then-called the scholarship of engagement.

He calls for academics to communicate with individuals and groups beyond campus to become a "partner in the search for answers to our most pressing social, civic, economic, and moral problems" (Boyer, 1996, p. 15). His was a vision for a two-way, reciprocal model for the creation of new knowledge.

Today, engaged scholars live out this contemporary vision of the third mission of higher education by connecting their academic work to social issues that are also seen as problems by those outside the four walls of the academy. Importantly, the work of an engaged scholar shifts community members from the position of knowledge consumers to knowledge producers. Engaged scholarship involves generating new knowledge through the combining of academic knowledge and community-based knowledge, eliminating a hierarchy and a one-way flow of information outward from the college or university (Saltmarsh, 2017). Rather than doing work "to" or "for" the community, such as in the initial outreach model of public service, engaged scholarship focuses on doing work "with" community members.

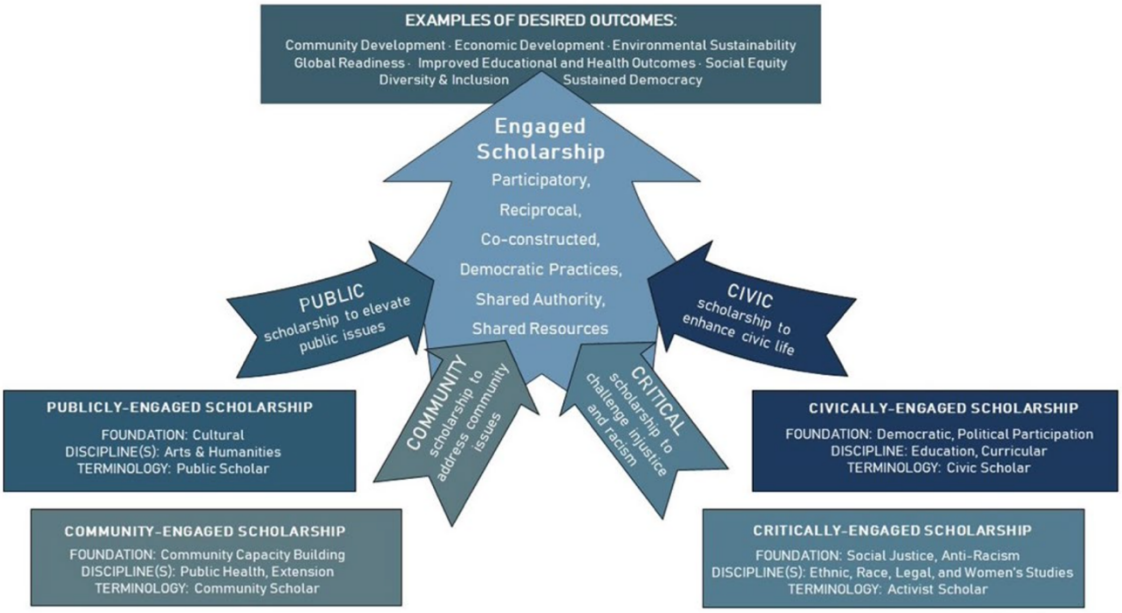
Community-Engaged Scholarship

Many types of engaged scholarship have developed in the academy since Boyer's initial call to action. Engaged practices have manifested in slightly different variations, often depending on the academic discipline. In their recent paper aimed at aiding coherence in the field of engaged scholarship, Blanchard and Furco (2021) define four frames of engaged scholarship that have developed over time: civically-engaged (focuses on advancing the democratic purpose of higher education), community-engaged (builds community capacity and situates specific community needs), publicly-engaged (emphasizes broad social issues and grand challenges), and critically-engaged scholarship

(scholarship that promotes structural change). Figure 1 outlines the differing influences and goals of each frame, but also outlines characteristics that are shared between all four frames.

Figure 1

Four Frames of Engaged Scholarship



From *Faculty Engaged Scholarship: Setting Standards and Building Conceptual Clarity* (p. 34), by L. Blanchard and A. Furco, 2021, Academy of Community Engagement Scholarship (https://doi.org/10.17615/0xj1-c495). Copyright 2021 by the Academy of Community Engagement Scholarship. Reprinted with permission.

While each frame typically utilizes a partnership approach between universities and communities and emphasizes reciprocity, community-engaged scholarship (CES) is a frame increasingly used to build capacity within communities. In many ways, the CES frame also most represents attempts by institutions of higher education to rectify past harms caused between universities and their local communities, which is why it is the central frame utilized for this study.

Clarifying the term "community" is an important part of understanding the CES frame. Some individuals define community by describing it as a physical place. Other communities may define themselves by a shared concern (i.e., a health issue such as heart disease) or shared characteristics (i.e., race, culture, or occupation) rather than geographic location (Hacker, 2013). According to Labonte (2012):

> Community has all these elements— identity, geography, issue, even institutional relations— but it is also more. *Community* derives from the Latin *communitas*, meaning "common or shared," and the *ty* suffix, meaning "to have the quality of." Sharing is not some demographic datum; it is the dynamic act of people being together. Community is, in effect, organization. (p. 97)

With all of this in mind in the context of CES, it is important for members of the research team to come together to decide what is meant by community (Blanchard & Furco, 2021; Hacker, 2013; MacQueen et al., 2001). In this way, and for the purposes of this study, the definition of community must be contextualized by members of the group.

The following definitions add conceptual clarity for the terms "community engagement" and "community-engaged scholarship":

> Community engagement is the application of institutional resources to address and solve challenges facing communities through collaboration with these communities. Scholarship is teaching, discovery, integration, application, and engagement that has clear goals, adequate preparation, appropriate methods, significant results, effective presentation, and reflective critique that is rigorous and peer reviewed. Community engaged scholarship is scholarship that involves the scholar in a mutually beneficial partnership with the community.

(Commission on Community-Engaged Scholarship in the Health Professions, 2005, p. 12, as cited in Blanchard & Furco, 2021)

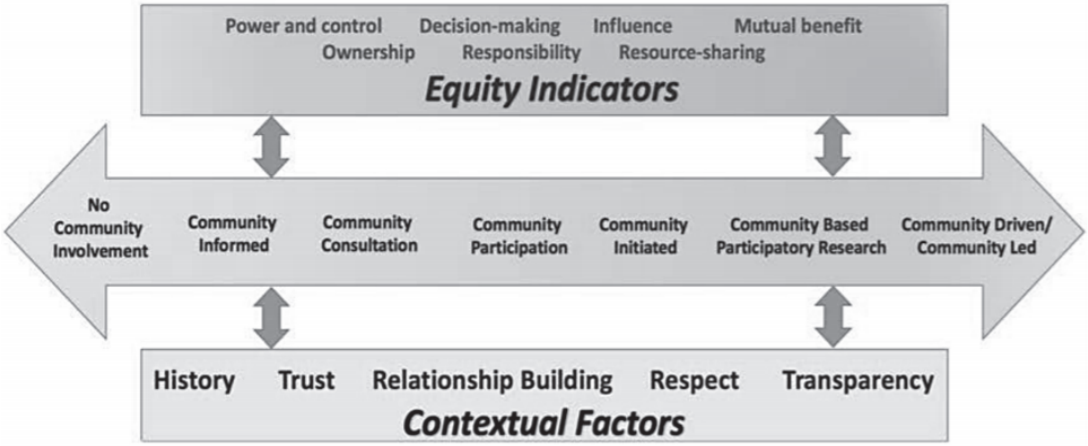
Community-Engaged Research

Within the frame of community-engaged scholarship, community-engaged research (CER) is an overarching term for a family of related action-oriented and participatory approaches to research. CER is the process of researchers and community members working collaboratively to create and disseminate knowledge about issues that impact the community's well-being (Clinical and Translational Science Awards Consortium Community Engagement Key Function Committee Task Force on the Principles of Community Engagement, 2011). Names for these research approaches are quite varied (e.g., action research, participatory research, participatory action research, community-based research, action inquiry, mutual inquiry, feminist participatory research, street and citizen science, tribal participatory research, reflexive practice) and have slightly different connotations, but similar overall principles.

According to Key et al. (2019), CER tends to fall along a continuum (see Figure 1). This continuum aligns with the historical shifts of the third mission of higher education where *less* interaction with community (i.e., no community involvement, community informed, community consultation) is representative of the expert-driven and more outreach oriented models of interaction with community while *more* interaction with community (i.e., community participation, community-initiated, community driven/community led) is representative of contemporary understandings of the scholarship of engagement and transformative, two-way partnerships.

Figure 2

Continuum of Community Engagement in Research



From "The Continuum of Community Engagement in Research: A Roadmap for Understanding and Assessing Progress," by K. D. Key, D. Furr-Holden, E. Y. Lewis, R. Cunningham, M. A. Zimmerman, V. Johnson-Lawrence, and S. Selig, 2019, *Progress in Community Health Partnerships: Research, Education, and Action*, *13*(4), p. 430 (https://doi.org/10.1353/cpr.2019.0064). Copyright 2019 by Johns Hopkins University Press. Reprinted with permission of Johns Hopkins University Press.

According to Key and colleagues (2019), there is no inherently right or wrong place for a project to be situated along the continuum. However, the article summarizes that, if desired by all partnership members and enough resources are available, actionable leverage points based on context and equity can facilitate the deepening of partnerships over time, thus moving them along the continuum (Key et al., 2019). Contextual factors that can impact this shift include partnership history, trust, respect, and transparency. As relationships are built, and as trust and transparency develop, participatory practices become more attainable. Additionally, during relationship-building, equity factors (e.g., power and control, decision-making, influence, mutual benefit, ownership, responsibility, and resource-sharing) guide the process so the partnership grows to hold space for respecting community voices (Key et al., 2019).

CER continuums such as the one presented here have developed from two distinct intellectual traditions. One tradition is action research, which is rooted in Kurt Lewin's (1946) understanding of involving individuals who are affected by a problem in the solution through a cyclical process of inquiry, action, and evaluation. Action research often refers to a narrower and more conventional approach to community-engaged research where there is some participation, but not full sharing of power and leadership throughout the research process nor as full a commitment to broader social change (Coghlan, 2004). In Figure 2, action research is nearer to the left side of the continuum, where community is informed about research or consulted about some elements of the research process, but not involved in all aspects such as research design and implementation or decisions about data interpretation and dissemination.

In contrast, participatory research, which emerged in countries such as Asia, Africa, and Latin America and was popularized by Paulo Freire in the 1970's, is specifically focused on reducing power structures and increasing freedom from the historically colonizing nature of research (Freire, 1982). Rather than simply a focus on episodic involvement from community members, its intention is to give full voice to participants throughout the entire research process (particularly to those that have been historically marginalized) and also to impact structural transformation (including within higher education) by combining social investigation, education, and action (Maguire, 2006). In Figure 2, Freire's vision for emancipatory community knowledge production is

represented by the far right on the continuum, where research is completely initiated and led by community and where equity indicators and contextual factors are highest.

Community-Based Participatory Research

Growing in popularity since the late 1990's - early 2000's, community-based participatory research (CBPR) is the most well-known CER approach (Balls-Berry & Acosta-Pérez, 2017; Ortiz et al., 2020). Wallerstein and Duran (2006) describe it as an alternative orientation to research, which focuses on relationship building between faculty and community members and incorporates community theories, knowledge, and practices into research. It is a collective and reflective approach to research that recognizes the true understanding of a given phenomenon is enhanced by community members or organizational representatives' ability to navigate and interpret social and cultural dynamics of the community (Israel et al., 1998).

At times, it can be difficult to decipher what uniquely identifies the different CER approaches, however, two fundamental ideas distinguish CBPR. The first is that CBPR was developed specifically as an ethical response to the history of exploitation of minority and low-income groups in an attempt to re-build trust between communities and universities in the research process (Blumenthal, 2011). Second, CBPR moves beyond the idea of community-placed or community-based research to focus on community empowerment, where the goal is to have the community involved in the research process to the greatest extent possible. The overarching goal is to balance power and create social change (Blumenthal, 2011). In these ways, CBPR is distinctly representative of the two-way, reciprocal engagement that seeks to shift how universities have historically understood and related both to their research mission and to communities.

CBPR is often misunderstood as a method or a methodology. Instead, it is an approach that can be used with any quantitative or qualitative research process (Israel et al., 2013). Barbara Israel and colleagues (1998) first developed a set of CBPR principles in 1998 to assist researchers in the field of public health to think carefully about their partnership process. An updated list from 2018 includes the following best practices of CBPR:

- recognizes community as a unit of identity,
- builds on strengths and resources within the community,
- facilitates collaborative, equitable partnership in all research phases and involves an empowering and power-sharing process that attends to social inequalities,
- promotes co-learning and capacity building among all partners,
- integrates and achieves a balance between research and action for the mutual benefit of all partners,
- emphasizes public health problems of local relevance and ecological perspectives that attend to multiple determinants of health and disease,
- involves systems development through a cyclical and iterative process,
- disseminates findings and knowledge gained to all partners and involves all partners in the dissemination process,
- requires a long-term process and commitment to sustainability, and
- addresses issues of race, ethnicity, racism, and social class and embraces "cultural humility" (Israel et al., 2018).

While this set of principles is widely used, it is often adapted to meet the specific

needs of the individual discipline or partnership. For example, other sets of principles with similar underlying values have been crafted for use with Native American tribes, health care for LGBTQ+ people, and international collaborations (Wallerstein & Duran, 2018). Additionally, Israel et al. (2018) acknowledge that each partnership must decide for themselves what each of the principles mean in their specific project. In this way, while the overarching principles of CBPR are similar, their application varies greatly.

CBPR has many potential benefits when these principles are followed. As an example, through the analysis of a CBPR research project where the aim was to improve the lives of HIV-positive youth, Flicker (2008) found that there were benefits to both the research process and to the stakeholders involved in the research. The research process itself was improved as there were better questions, recruitment, data collection, analysis, dissemination, and action because of the CBPR partnership (Flicker, 2008). In addition, all stakeholders in the process felt as though they benefitted from the CBPR relationship. The youth felt included, productive, and valued; academics noted that they benefitted from serving as mentors in the process, but also learned how to handle the sensitive topic in a more respectful manner; and community-based service providers felt empowered to advocate for the youth they serve through the ability to integrate knowledge into new service provision practices (Flicker, 2008).

At the same time, CBPR is not without limitations. In the same study, Flicker (2008) found that collaborators were able to identify several costs to their engagement in the project. They were frustrated by the added workload, concerned about a lack of sustainable funding, unclear about the roles related to decision-making, torn about whether the risks involved were worth the benefits, and troubled by a general sense of

lack of control (Flicker, 2008). Other researchers have identified critiques of CBPR such as the tensions between academic rigor and community involvement (Buchanan et al., 2007), concerns with scaling up CBPR initiatives and outcomes from a local to a national level (Wallerstein & Duran, 2018), and the undertheorizing of power in partnerships which could potentially lead to the marginalization of communities, even when using a process meant to redistribute power (Golob & Giles, 2013).

To many, these limitations – especially those outlined by Flicker (2008) – are indicators of ethical concerns at the community level in CBPR (Buchanan et al., 2007; Buchanan, 2019; Mikesell et al., 2013; Wilson et al., 2018). Universities that espouse a dedication to contemporary models of community engagement are increasingly paying attention to these concerns (Flicker et al., 2018) with special attention for eliminating any harm inflicted on partnering communities.

One structure in higher education that intends to ensure ethical conduct with research involving humans are Institutional Review Boards (IRBs). IRBs are best known for making ethical decisions based on the Belmont principles, for weighing research proposals to determine whether risks to human subjects are reasonable, and whether subjects are being provided with adequate opportunity to give their informed consent (Babb, 2020). However, CBPR researchers are increasingly frustrated with the IRB processes' inability to effectively review CBPR. This is because the principles of best practice for CBPR are often not well-aligned with standard ethical review protocol (Cross et al., 2015; Flicker et al., 2007; Malone et al., 2006; Ross et al., 2010; Shore, 2007). The result is that researchers using CBPR may be hindered in their scholarly pursuits and unable to justify their protocols within existing ethical review practices. In such cases,

community perspectives are often left unaddressed by review boards or protocols are delayed or rejected entirely. In order to contextualize the relationship between CBPR and ethical review, which is driven most prominently through the field of public health, it is first important to understand the history behind institutional ethics review for research involving humans.

A Brief History of the Ethical Review of Research Involving Humans

In the 1960s and early 1970s, there was public outcry in the U.S. over exploitative and abusive research projects that involved vulnerable research subjects. Some of the most well-known research abuse scandals include the Willowbrook State School Hepatitis Study, the Jewish Chronic Disease Hospital cancer research, and the decades-long and well-known Tuskegee Syphilis Study (Mandal et al., 2011; Mastroianni & Kahn, 2001). In each of these studies, participants were not protected in the ways non-vulnerable groups were protected (i.e., lack of informed consent and research transparency) and research subjects were irreversibly harmed by their inclusion in the studies. These studies, and others, damaged the overall reputation of scientific research in these participant communities, which ultimately pushed Congress to pass the National Research Act of 1974. This Act created the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research which released a report published in 1979, titled the Belmont Report, that for the first time, outlined standard ethical principles for research involving human participants on a federal level.

The three overarching principles of the Belmont Report are respect for persons, beneficence, and justice. These principles are respectively applied in research ethics practice as the assurances related to obtaining informed consent, completion of risk and

benefit assessments, and ensuring the equitable selection of participants (Emanuel et al., 2011). The principal goals of the Belmont Report are to minimize harm, balance risks and benefits, and ensure research subjects participate voluntarily. This report is still the basis for ethics involving human subjects to this day.

The Belmont Report is also the document upon which the federal regulations and, as such, legal protection for human subjects' research is based. These regulations established that any federally funded research with humans be reviewed by committees known as (previously mentioned) IRBs, which officially formalized the requirement of ethical review on university campuses seeking federal funding. When initially created in the mid 1970's, these boards were made up of amateur reviewers from university faculty. By the 1990's, however, increased nuances in the federal regulations led to IRBs developing a process to professionalize a new group of specialized university administrators who could streamline the review process. These professional staff members did not replace faculty members on IRB boards, but instead had the explicit role of managing the ethical review process and ensuring institutional compliance with federal guidelines and regulations (Babb, 2020).

The federal guidelines specifically outline the rules, policies, and procedures that IRBs must follow in the ethical review of human subjects' research. They include direction such as how to prepare and maintain adequate documentation of IRB activities, guidance for who should make up the membership of an IRB, and, importantly, the specific criteria that are required for IRB approval of research (Babb, 2020). As mentioned previously, a core purpose of the Belmont Report is to ensure that all research participants are protected from harm and that potential risks are reduced whenever

possible. This is also a goal of the federal regulations. In fact, there is a specific call in the regulations for members of IRBs to ensure that research protocols include extra protections when participants are considered vulnerable in order to offer approval to proceed.

Still, controversial ethical misconduct with research in marginalized communities from the 1990's highlights the exploitation that endured in the United States despite the existence of ethical guidelines, federal policy, and review boards that uphold them. For example, the Kennedy Krieger Lead Paint Study, which was conducted in a primarily African American, low-income neighborhood in Baltimore, led to the long-term impairment of several children due to lead paint exposure and raised important questions about the relationship between public health policy and research (Buchanan & Miller, 2006). In another case, the Havasupai Indian Tribe Genetic Research proposed studying genetic links to prevalence of type 2 diabetes. However, without consent, researchers also conducted studies with samples provided by tribe members for additional research on schizophrenia, ethnic migration, and population inbreeding all of which were not approved in the original research protocol (Garrison, 2013). These cases had serious implications for the importance of the ethics related to informed consent and for ensuring that research participants fully understand the intent of research prior to beginning a study.

During this same timeframe of the 1990's, CBPR was popularizing, which also closely aligned with the emergence of Ernest Boyer's reimagined ideas surrounding engaged scholarship in the academy. CBPR was particularly popular in the fields of environmental and public health where continued health disparities for minority

communities were obvious and prominent. In 1987, one of the first community-university CBPR projects was initiated by ministers in East St. Louis who approached leaders from the University of Illinois School of Architecture's East St. Louis Revitalization Project to research the ways that the places communities of color lived had become a "dumping ground" (p. 24) for waste and pollution in the United States (Scammell, 2004).

The era of the Clinton administration put CBPR on a national stage when in 1995 the National Institute of Environmental Health Sciences became the first entity within the National Institutes of Health to undertake a CBPR project (Green, 2003). In 1998, when President Clinton issued a long-overdue Federal apology for the ethical exploitation of the Tuskegee Syphilis Study, along with it came a request from his administration for the Department of Health and Human Services to identify strategies for increasing the participation of minority communities in research, and to imagine new ways to build trust between communities and researchers. The response was a report titled "Building Community Partnership in Research: Recommendations and Strategies" that reflected on the resulting harms of research conducted without consideration of the human context and without consultation with community. The report stated, "Individuals who participate in such research are directly affected in a variety of ways; however,…the individuals' entire group or "community" is also indirectly affected…Therefore, ethics must be addressed at the community level as well as the individual level" (Centers for Disease Control and Prevention et al., 1998, pg.1). The report goes on to call for additional accountability and oversight to ensure that community participatory research is performed in ways that protect individuals *as well as* communities from further abuse but says little about how to ensure that community-level protection.

Problem Statement/Gap in the Literature

This report was significant in that it declared that shared decision-making with community should be a best practice of ethical community-based research. Yet, a key issue that remains in the higher education context is the degree to which community-level protections are included in IRB protection protocols. Past research suggests that communities remain vulnerable in research projects (including in CBPR) since neither the Belmont Report nor the federal regulations were written to fully incorporate community-level protections (Gilbert, 2006; Key, 2017; Shore, 2007). Rather, the documents are written to protect individual research participants from risk of harm. Because of this, researchers in general, but more prominently CBPR researchers, are increasingly turning their attention to whether the Belmont Report and federal regulations should offer protection from harm on a community-level. Several scholars are concerned with a lack of protection leading from the incomplete ethical analysis of community-oriented research protocols, (Bastida et al., 2010; Buchanan, 2019; Green, 2004; Minkler, 2004) including concerns about the capacity of IRBs to appropriately review CBPR (Flicker et al., 2007; Malone et al., 2006) as IRB members tend to be most familiar with traditional forms of research (Tamariz et al., 2015).

While there is a lack of scholarly literature in the field of higher education administration that addresses the relationship between CBPR and appropriate ethical review by IRBs, much has been written on the topic by CBPR researchers in the fields of Public Health and Biomedicine. There has been substantial and continued growth in the utilization of CBPR in these disciplines (De las Nueces et al., 2012; Stacciarini et al., 2011; Vaughn et al., 2013). In fact, CBPR has been identified as a promising practice for

the reduction in health disparities (Wallerstein & Duran, 2006). Higher education professionals concerned with ensuring community-university relationships facilitate long-lasting change and equitable partnerships would benefit from an in-depth understanding of the ways that health researchers approach and identify these concerns. University leaders would also benefit from understanding the challenges and opportunities associated with reviewing community-level concerns ethically to identify mechanisms for change to advance these protections. Currently, this is an area where there is a gap in literature requiring further investigation (Shore et al., 2011; Wilson et al., 2018).

Study Purpose and Research Questions

As a practitioner/scholar in the field of community-engagement, I am committed to improving the ways that institutions of higher education build and maintain authentic relationships with their community partners. Guided by the scholarship introduced in previous sections of this paper, this study aims to generate new understandings about the ethical review of CBPR in the higher education context. A primary goal of this study is to assist institutional decision makers in learning more about current processes and potential future directions for adapting IRB processes to CBPR. This study also seeks to understand when and how institutions have accommodated for community-level concerns in CBPR in the IRB review process as there is at present no universal guidance for how to do so. In general, little is known about the "black box" of decision-making as it relates to CBPR and the IRB process. Aligned with these purposes, this study poses the following research questions:

1. How do Institutional Research Boards at community-engaged research institutions make sense of the ethics of CBPR?

a. What are the environmental cues and collective meaning-making processes used to understand community-level ethics?

b. Who else is involved in this process?

2. In what ways and to what extent are community-level ethical concerns of CBPR considered in reforms to IRB processes?

Significance of Study

Addressing these research questions is important as it contributes to our understanding of institutionalizing CBPR at research universities in two ways. First, it extends past literature by applying theoretical frameworks to understand the processes that universities use to make sense of the ethics of CBPR and how they adapt or modify institutional policies to accommodate the research practice. Currently, ethics related to CBPR practice must be retrofitted into traditional models of research ethics review. This study will offer guidance on how to understand this widely unknown process.

Second, this study will add to the literature in the domain of ethical review of CBPR which lacks conversation about this important topic from a macro/institutional level (Shore et al., 2011). While higher education researchers discuss ethical issues related to CBPR from a practice perspective, there are no known studies in the field that examine institutional-level considerations related to addressing the review process itself. This study will add important context to and extend the ongoing conversations about the best practices related to the ethics of CBPR from a higher education administration perspective.

As the use of CBPR continues to grow across the United States, national movements led by CBPR researchers (e.g., Dr. Nancy Shore along with a collaborative

initiated through Community-Campus Partnerships for Health) have included calls to update the federal regulations and the Belmont Report to add specific protections for community-level concerns. As such, the need to better understand the nuanced process and best practices related to IRB review of CBPR research will only increase. In the next chapter, I provide a review of literature that covers current understandings of the ethical issues related to the review of CBPR and what is known about IRB member capacity to effectively review CBPR projects.

Chapter Two: Literature Review

While discussions of challenges related to partnership and reciprocity are commonplace in higher education literature, discussions regarding the specific challenges of CBPR as it relates to the ethical review process are less common (see Brydon-Miller, 2008; Brydon-Miller et al., 2006; Brydon-Miller & Greenwood, 2006 as exceptions). Moreover, the literature in education relies heavily on individual commentary and opinion rather than on systematic research on the subject. As such, this chapter presents two bodies of research literature, most commonly in the fields of medicine and public health, that illuminate specific issues related to the ethical review of CBPR. Through this review, I seek to create a bridge between the issues presented here and concerns related to the institutionalization of CBPR practices in higher education.

The first body represents work completed by academic researchers, often along with community researchers, to better understand the specific ethical concerns and conundrums that are persistent in CBPR and are either left unaddressed by IRB boards or, alternatively, that cause delays in review or rejections of their research protocols entirely. To assist in organizing this body of research, it is assembled by using the ethical framework provided by the three Belmont Report principles.

The second body of literature summarizes what is known about the ethical review of CBPR from the perspectives of IRB members. Since this literature is so small, each article is summarized individually as it applies to the key research questions posed in Chapter 1.

Through the review of both bodies of literature, I will illustrate the significant and persistent concerns with the ways in which ethical review of CBPR currently occurs, and

gaps in the literature regarding the perspectives of higher education professionals who complete ethics reviews.

Literature Corresponding with Belmont Principles

Mentioned previously, the three principles outlined in the Belmont Report are respect for persons (informed consent), beneficence (risk/benefit assessments), and justice (participant selection) (Emanuel et al., 2011). One concern with this framework as it relates to CBPR has already been raised, which is the fact that these principles are seen through and applied in a way that protect individual participants rather than communities. Another concern is that the Belmont Report principles were written from a biomedical framework which privileges positivistic inquiry. Positivism assumes that a phenomenon may be removed from its context for the purposes of research, while CBPR is rooted in an ontology based in a social, participative reality and an epistemology of experiential knowing (Holkup et al., 2004). This means that the Belmont Report was not written to incorporate and consider the complexities of participatory research. Still, the Belmont Report is used here as a framework to identify points of divergence which is a strategy utilized by several previous scholars (e.g., Castro-Reyes et al., 2017; Mikesell et al., 2013; Shore, 2006).

The literature review that follows explores how CBPR researchers distinctly conceptualize the Belmont principles through a community-oriented lens. Table 1depicts a breakdown of the principles and the corresponding ethical concerns outlined in the first body of literature presented here.

Table 1

Ethical Issues in CBPR Categorized by Belmont Report Principles

Community Autonomy	
	Respecting Cultural Norms & Values
	Community Informed Consent
	Who Speaks for Community
	Community Advisory Boards
	Peer Research Assistants
	Voluntariness
	Community Involved in All Stages of Research
Community Beneficence	
	Risks to Individuals in Communities: Community Researchers
	From Subject to Co-Researchers
	Privacy and Confidentiality
	Emotional Burden
	Fear of Exposure
	Harm to Communities
	Avoidance of Paternalism
	Stigmatization
	Lack of Sustainability
Community Justice	
	Ensuring Benefit
	Capacity Building
	• Research Training for Community Researchers
	• Research that Elicits Community Challenges
	Avoidance of Gatekeeping
	Insider/Outsider Dilemma
	Making Power Imbalance Explicit
	Time and Compensation
	Trust and Relationship Building

Community Autonomy

Respect for persons is the ethical guideline where the autonomy of individual research participants is acknowledged and those with "diminished autonomy" are given additional protections (National Commission for the Protection of Human Subjects of

Biomedical and Behavioral Research [National Commission], 1979). It manifests through informed consent procedures and is often conceived through a Western lens (Dein & Bhui, 2005).

In CBPR, seeking community consent and protecting community autonomy are integral to research participation (Emanuel et al., 2004). This is especially important for culturally appropriate consent (Baydala et al., 2013) which typically involves research approval from community leaders prior to the start of a research project and as an addition to individual consent. However, when consent is sought in this way, it can sometimes cause additional ethical considerations (Deeds et al., 2008) by introducing concerns regarding voluntariness and true reciprocity (Banks et al., 2013; Bromley et al., 2015). When IRBs are not required to look for these ethical issues, they have the potential to put communities at risk in various ways.

Respecting Cultural Norms and Values

Respecting different cultural values plays a large role in navigating the review of CBPR and is seen as a key component of recognizing communities as autonomous units (Glass & Kaufert, 2007). CBPR often involves partnerships with low-income communities that are commonly communities of color, and university researchers tend not to share the racial, ethnic, or cultural background of research partners which increases potential for misunderstanding (Minkler, 2004). This can lead to oversight of important cultural practices even by the most well-intentioned researchers.

Past research has revealed the dilemmas associated with managing cultural norms and values. For example, in a retrospective mixed methods case study analysis of their CBPR project on HPV/HIV interventions in two Pacific Islander communities, DiStefano

with academic and community colleagues (2013) identified navigating cultural values as one of the most challenging ethical issues for their team. As traditional forms of Christianity played a large role in both Pacific Islander cultures in the study, it was important for the research team to construct culturally appropriate data collection methods that would also respect the communities' reticence to discuss sex and sexuality across gender and generations (DiStefano et al., 2013), which was important for respecting community autonomy.

A study about Aboriginal communities in Canada conducted by Glass and Kaufert (2007) also illustrates ways that standard ethics review can come into conflict with the ethics review practices. Their research highlighted not only the cultural differences that present challenges in navigating research implementation, but also the ways that cultural values inform views of the very nature of science. For Aboriginal scholars, local knowledge and culture are interwoven into research, while most research ethics committees have a view of science that is "objective…and value free" (p. 30) which can result in conflict during the review process (Glass & Kaufert, 2007). As an example, Poff (2006) highlights the importance of storytelling in research protocols in Aboriginal communities, even when standard ethical review procedures are not structured to accommodate or value storytelling as research. Only when cultural values are known, respected, and utilized in research implementation and review, partnerships have the potential to give voice to community-level concerns (Bastida et al., 2010).

Community Informed Consent

Informed consent is a mechanism that attempts to ensure that an individual fully understands the research protocol and their rights and responsibilities as a research

subject. In participatory research, however, the community is seen as an autonomous unit where the rights of protection and ability to choose to participate are first given to the community or group leadership who are partnering on the project (Quigley, 2006). This is an overall issue of ethical concern for researchers because standard ethical review does not address community autonomy by ensuring community consent in any way (Flicker et al., 2007; Glass & Kaufert, 2007; Holkup, et al., 2009) and often results in communities forgoing their cultural values and norms in order to engage in the research process (Castellano, 2004).

In order to explore this further, a team of academic and community researchers in Canada set out to describe lessons learned from implementing culturally appropriate informed consent procedures. The study aimed to implement a substance abuse prevention program for youth in the Alexis Nakota Sioux Nation (Baydala et al., 2013). Most significantly, Alexis elders were concerned with the risks associated with signing documents due to historical harms, and instead, recommended replacing written consent with a formal oral consent procedure that aligned with and respected community traditions (Baydala et al., 2013). These attempts to protect tribal community autonomy and respect local ways of knowing in order to work toward decolonization are noted elsewhere in the literature (Glass & Kaufert, 2007; Harding et al., 2012; Holkup et al., 2004).

Scholars note that it is important to keep in mind that Indigenous groups operate with different sets of cultural norms and protocol (Baydala et al., 2013). These complexities were underscored through Flicker and Worthington's (2012) study of the perspectives of 24 research ethics stakeholders (i.e., individuals with specific knowledge

of university ethics board procedures). Data revealed that leadership structures vary greatly among Aboriginal communities. Some Aboriginal communities have formalized leadership and formalized research ethics boards that require community consent, while others have formal leadership but no ethical review process. Still others have neither formal leadership nor a review process. This often raises the question, "Who speaks for community?" (p. 21) particularly in urban contexts when formal leadership is less common (Flicker & Worthington, 2012). This creates a need to establish project specific community representation (discussed in more detail below) in order to ensure that culturally and community-specific needs for community consent are still met (Banks et al., 2013; DePalma, 2010).

Additionally, while research ethics boards tend to be most familiar with the concept of community informed consent as it relates to Indigenous communities, Flicker and Worthington's (2012) investigation resulted in the caution "not to lower expectations for non-Aboriginal groups" (p. 22) in the ethical review process. In other words, if community consent can be applied to the ethical review of CBPR in the context of Indigenous groups, there is no reason to believe it could not be implemented for marginalized communities in general.

Who Speaks for Community

Community Advisory Boards. Building on the idea of ways that community consent can be achieved, when CBPR projects are initiated in communities without sovereign status or long-standing and well-respected communal leadership, Community Advisory Boards (CABs) are often considered a strategy to establish community autonomy. CABs afford the opportunity to discuss research protocol and create overall

strategies that are respectful to the community (Israel et al., 1998; Newman et al., 2011; Quinn, 2004). Story et al. (2010) found that CABs are key in maintaining ethical partnerships as they allow for communities to determine whether or not the project fits their goals and needs as well as gives them a voice in project approval; thus, CAB oversight "ensures...community autonomy" (p. 119). At times, community oversight can be viewed by IRBs as a conflict of interest since standard procedures are typically concerned only with the protection of individual autonomy (Chenhall et al., 2011). This creates barriers for research teams in developing ethical CBPR projects. As CBPR increases in popularity, it is important for IRBs to understand the role CABs play in ethical CBPR so they can evaluate if advisory team membership is sufficient (Glass & Kaufert, 2007).

Peer Research Assistants. The question "who speaks for the community" in ethical CBPR practice is also addressed through the utilization of Peer Research Assistants (PRAs). Similar to CABs, PRAs are typically utilized as a way to gain entry into communities that are difficult to access and also to inform university researchers on appropriate study design (Bean & Silva, 2010; Greene et al., 2009). PRAs are recruited for their ability to increase participation and trust in research when communities are likely to be skeptical of university researchers (Warr et al., 2011). In a study of a program for racially marginalized women living with HIV, Logie and colleagues (2012) found that PRAs were able to use personal connections to engage participants in the research who otherwise would have been excluded from the investigation. As a result, PRAs were able to connect participants with additional local social services to support their overall health.

However, as beneficial as PRAs are to research processes that engage marginalized communities, PRA participation remains difficult for IRBs to assess. In a thematic analysis of the IRB review in eight CBPR projects that utilized peer support for health interventions, Simmons et al. (2015) found that review boards had concerns about the impact of peer support on the participant's care (e.g., continuing to ensure a high standard of care and avoiding breeches in patient confidentiality) as well as concerns about the overall well-being of the peer support person (e.g., limiting emotional toll on PRAs, recruiting appropriate PRAs). These uncertainties in the review process left research teams with delayed schedules, and at times, impacted their relationships with community partners (Simmons et al., 2015) thus jeopardizing researcher ability to work with communities.

Voluntariness. While CABs and PRAs are seen as a way to support the informed consent process on the community level and increase respect for community autonomy (Israel et al., 1998), some researchers express concern that the "free" portion of "free and informed consent" (National Commission, 1979) has the potential for compromise when communities offer consent to participate in research on behalf of individuals, or when the relationship between community researchers and community members raise questions about coercion to the forefront (Anderson, 2010). For example, in a study that employed a cluster randomized control trial to evaluate the impact of peer educators on health outcomes in the military veteran community, community and academic researchers investigated potential ethical concerns associated with voluntariness in their project (Whittle et al., 2010). Their research found that participants in the study sometimes placed a greater value on benefit to the group (i.e., military veterans as a whole) over

individual rights, which blurs the line of whether an individual is offering their own express informed consent (Whittle et al., 2010). This privileging of group benefit over individual benefit complicates the ethical review of CBPR projects. In reviewing CBPR protocol, context-specific decisions must be made related to respecting community autonomy and the protection of community values and how that context influences consent offered by individuals.

Community Involved in All Stages of Research

Another way that researchers attempt to address issues related to respecting community autonomy that is aimed at increasing reciprocity but also complicates ethical review, is the inclusion of community in all stages of research (Blumenthal, 2005). Increasingly, CBPR researchers believe that this deep engagement from community members in the entire research process, rather than serving in a peripheral advisory capacity, increases research validity (DiStefano et al., 2013; Minkler, 2005; Mohammed et al., 2012). In one research study that aimed to improve cardiovascular health in an Indigenous community in the Pacific Northwest of the United States, researchers described how the co-development of interview protocol addressed ethical concerns of the collaborative research team (Mohammed et al., 2012). Co-constructing questions led to reflections on the part of community members regarding how institutionalization had impacted their thought processes, and academic researchers noted how the conversations broadened their understanding of the intersections of social determinants of health as well as the health issues that were most important to Indigenous members of the group (Mohammed et al., 2012).

Beyond design and implementation, presenting data that is accessible to community, (Anderson, 2013; Bastida et al., 2010; DiStefano et al., 2013) allowing for the joint interpretation of data, (Blumenthal, 2005; Bromley et al., 2015; Davison et al., 2013; DiStefano et al., 2013; Minkler, 2004) deciding collectively how to disseminate and take action on data, (Banks et al., 2013; Glass & Kaufert, 2007; Minkler, 2004) and surfacing questions related to data ownership (Banks et al., 2013; Bromley et al., 2015; Glass & Kaufert, 2007; Holkup et al., 2004) are all discussed in the literature as concerns of CBPR research teams. Oftentimes, researchers and community partners establish detailed protocol for these processes and procedures through formalized Memorandums of Agreement (Glass & Kaufert, 2007; Harding et al., 2012; Mohammed et al., 2012) or through community values statements (Blumenthal, 2005) prior to beginning a project.

However, many IRBs view this level of engagement as a conflict of interest (Chenhall et al., 2011). For example, in their investigation of the experiences of 14 different CBPR partnerships, Brown and colleagues (2010) found that IRBs were generally unfamiliar with CBPR practices, and also refrained from enacting flexibility offered in ethical guidelines that would support them. When IRBs reviewed CBPR projects that incorporated full partnership in the research process, they often expressed concerns related to confidentiality. Yet, the federal regulations themselves only require IRBs to consider confidentiality “when appropriate” (Brown et al., 2010, p. 9). This study by Brown et al. (2010) exemplifies that while flexibility in implementation of federal regulations is possible, it is often underutilized. Additional understanding of how and when IRB members feel empowered to employ this flexibility could better prepare CBPR

teams in the ethical review process, in their development of research design, and could have the added effect of educating IRBs about best practices in CBPR.

Community Beneficence

Beneficence is the ethical principle that asks researchers to consider risks and benefits of participation in research and to "do no harm" to individual participants (National Commission, 1979). In one investigation of the extent to which IRBs prioritize each of the ethical guidelines laid out in the Belmont Report, researchers found that informed consent was discussed 98% of the time while risks and benefits to participants entered into the discussion only 57% of the time. Additionally, 60% of the reviewed protocols excluded at least one category of subjects without giving adequate explanation were not subject to further review (Lidz et al., 2012). This means that the major elements of IRB ethical review are discussed and reviewed inconsistently, and informed consent procedures are considered at drastically higher rates than discussions regarding risks and harms to participants or equity of subject selection. While this is alarming to consider in the context of research involving individual participants, it is also important to consider how this impacts research involving communities (Friesen et al., 2017).

Related to this concern, Ross et al. (2010) developed a framework to outline the types of risks and harms associated with CBPR. They assert that community-level risks associated with well-being and agency in CBPR can be related to an individual's status as a member of their group (especially when this group member is a co-researcher) and also at the community or group level (Ross et al., 2010). For example, a community researcher may be viewed differently by their community when the research is completed (Mistry et al., 2015) or experience turmoil from the difficulties of maintaining

professional boundaries while in their role as a researcher (Logie et al., 2012). In addition, community-level harms include considerations such as "stigmatization, lost opportunity costs, loss of potential benefits of research participation, and potential for the misuse of limited community resources" (Buchanan, 2019, p. 345).

Risks to Individuals in Communities: Community Researchers

From Subject to Co-Researcher. The idea of protecting an individual as a member of their community is novel since IRB processes have historically separated the individual from community when assessing research ethics. A helpful concept to consider this relationship is that of relational autonomy. Relational autonomy is a portion of the relational public health ethics framework, and it seeks to respect an individual's authority to make autonomous decisions while at the same time contextualizing those choices in light of the "social, political, and economic forces" that frame individual decisions (Davison et al., 2013, p. 57).

In CBPR, concerns with relational autonomy are most often present when community members serve multiple roles in research projects. For example, Bromley et al. (2015) conducted 29 semi-structured interviews with academic and community researchers working on 10 different CBPR projects for the purpose of revealing ethical priorities and challenges present in their experience as participatory researchers, or coresearchers. They found that issues related to the co-researcher role created the most ethical challenges in and of itself as unlike research subjects, co-researchers have multi-faceted roles and "provide data but also advise, share expertise, advocate the study, or analyze data" (p. 906) and as the concept of relational autonomy suggests, "the participant is an individual and a collective actor" (Bromley et al., 2015, p.

907). The study identifies the need for researchers and IRB members to recognize the unique ways that the participant role has the potential to cause harm and to identify specific ways to mitigate those harms and create benefit for participants (Bromley et al., 2015). Some of these concerns are highlighted below.

Privacy and Confidentiality. As noted in the previous section outlining community autonomy, the research conducted by Brown et al. (2010) suggests that issues related to privacy and confidentiality are often a large stumbling block related to IRB approval of CBPR projects. While it is important to remind IRBs of the flexibility offered in the federal regulations related to these issues (Brown et al., 2010), it is also important to note some of the specific challenges related to incorporating community members in research so that a balance can be struck between inclusion and protection. Even CBPR researchers note the difficulty surrounding ensuring anonymity and confidentiality in participatory research.

In a scoping study of literature written about CBPR, Banks et al. (2013) note that anonymity and confidentiality are a few of the main ethical concerns in enacting participatory projects and that the identities of participants in the research may at times be challenging to protect. Depending on the context of the specific community, some people may wish to be identified as participants and some may not (Banks et al., 2013; Glass & Kaufert, 2007) which creates ethical dilemmas for researchers who conduct projects that require anonymity. This has implications when conducting systematic inquiry, as ensuring anonymity is often considered an important strategy to elicit research responses that are trustworthy. Other scholars add to this conversation by noting CBPR participants are often given access to information that is typically accessible only to academic

researchers (Holkup et al., 2004), which IRBs often consider a breech in confidentiality requirements.

Still others point out, importantly, that the very nature of CBPR contradicts standard protocol of ethical research practice. For example, in their study of unauthorized migrants, Brabeck et al. (2015) pointed out that when the choice to keep information confidential rests in the hands of IRBs and not communities themselves, it undermines the core values of CBPR. While privacy and confidentiality are further complicated by the nature of CBPR, it is important that IRBs do not outright reject participatory research over these concerns.

Emotional Burden. Participatory research also creates unique concerns related to the emotional burden of research that is common in CBPR, particularly for those involved as community researchers (Mistry et al., 2015). In one study that sought to compare the ethical concerns of both academic and community research partners through focus groups, both groups noted that there is an emotional toll on community researchers as it relates to participant recruitment (Anderson, 2013). Specifically, community researchers noted that it was challenging to deny members of their community the opportunity to participate (Anderson, 2013). At times this is due to a lack of clarity in eligibility requirements, but here the concern is specifically related to the community-researcher's role in denying access to financial support as a benefit of study eligibility.

To add to this, in their case study analysis of the ethics of utilizing PRAs in developing appropriate interventions for people living with HIV/AIDS, Greene (2013) describes these concerns as emotional labor, and cautions both researchers and IRBs to consider the long and short term impact of these interactions in ethical review. For one of

Greene's (2013) participants, reading interview transcripts was similar to "reading a thousand pages of tears" (p. 146), and this type of task has the risk of negatively impacting a community researcher's mental health in different ways than it might impact an academic researcher. It is important to note that while the emotional risks for research subjects are taken into account by IRBs, the risks and emotional harms for PRAs are not (Greene, 2013).

Fear of Exposure. Closely related to the idea of emotional labor are the fears for community researchers related to exposing specific issues in a community, or even exposing certain people in a community based on their identities. For example, Davison et al.'s (2013) study of field notes and progress reports submitted during an HIV/AIDS intervention study revealed several ethical challenges for nurses. Specifically, the nurses in the study were community researchers looking to improve intervention approaches through the CBPR project and were also responsible for implementing the planned interventions. Serving in these dual roles, several nurses feared resentment from colleagues related to the study's findings that there were problems with current practices in their medical facility related to quality of care (Davison et al., 2013). To the nurse-researchers, even though they had signed on as community researchers, they were afraid that their role in "exposing" poor quality of care might impact the way that their employees or colleagues viewed them in the work environment.

Similar fears of exposure are related to revealing one's own identity when participating in research. DePalma (2010) examined these fears in a participatory research project involving LGBT teachers. In this self-study that investigated policies related to LGBT equality in the school, teachers served as co-investigators for the project,

however several LGBT teachers expressed concerns about whether or how to reveal their sexual identity during the process, and if it would have negative ramifications on their employment or comfort levels with colleagues moving forward (DePalma, 2010). According to Banks et al. (2013), this dual role of participant and researcher creates new layers of ethical concern for IRBs to address during review.

Harm to Communities

Another important consideration for IRBs that often goes unrecognized is that potential harms to groups are not just collections of potential harms to individuals, but also harms that occur to entire communities (Friesen et al., 2017). This body of scholarship suggests that while community autonomy must be recognized in the ethical review of CBPR, so too must community-level harms be considered.

Avoidance of Paternalism. While CBPR seeks to involve community in research as equal partners, IRBs must recognize that partnerships in name only are harmful to communities. In a collaboration between the Morehouse School of Medicine and a nearby predominantly African American and low-income community, Blumenthal (2005) found that although advisory boards are considered a best practice in CBPR, they are often on their own insufficient to protect risks associated with paternalism. Paternalism in research refers to the idea that in traditional research, academic researchers are entrusted solely with the role of protecting research participants. However, communities are often offended by the idea that academic researchers are capable of fully considering all the ways that participants should be protected in research, particularly culturally appropriate protections. Ideally, CBPR seeks to mitigate this concern through its collaborative processes, however it is still important for partnerships to fully engage in the deep

relationship building that allows for communities to have real influence in the decision-making process in order to avoid paternalistic practices.

In the Morehouse study, the community developed a Community Coalition Board that also crafted a set of values to filter all research proposed in their community, and decisions by the Board were respected by Morehouse School of Medicine (Blumenthal, 2005). In this way, the community as a whole was able to decline to participate in research studies or make alterations to research protocol if they did not find them appropriate without fear of retaliation. It was found that paternalism was avoided, and the partnership operated on the assumption that communities are self-determining and capable of identifying their own priorities (Blumenthal, 2005).

Such structures create environments where exploitation and additional harm can be avoided "thus upholding the principle of non-maleficence" (Story et al., 2010, p. 124). Avoiding paternalism in research is important, as gone unchecked it can lead to widespread feelings of mistrust in communities (Friesen et al., 2017).

Stigmatization. A recurring issue in the ethical review of CBPR are the ways research can reinforce negative stereotypes (Holkup et al., 2004). In a study that reviewed the ethical concerns raised in a set of nine participatory research projects between elite high schools and the University of Pennsylvania's Graduate School of Education, the concern of stigmatization was paramount (Kuriloff et al., 2011). In particular, researchers were concerned about the stigma of underperformance when implementing a project aimed at developing interventions to support African American boys whose grades were falling below their peers' performance.

Another study conducted by Hunt and colleagues (2014) interviewed 37 individuals (e.g., research participants, community leaders, health care workers, academic researchers) who reviewed the ethical concerns of a participatory project aimed at reducing barriers to health care for the poorest individuals in Burkina Faso. In this study, the mere naming of research participants as "indigent" became an important topic of concern to the entire team, but especially for those labeled as "indigent" themselves (Hunt et al., 2014). In Burkina Faso, the term indigent is a descriptor chosen by the government that, when translated, is potentially offensive to those who fall into the category. Here, the concern was related to whether the harm of using the government-identified term to label and identify the most impoverished individuals in a community outweighs the benefits of conducting the study. Ensuring the ethical review of research includes creating processes and procedures to take these communal harms, such as the reinforcement of negative stereotypes, seriously (Minkler, 2004).

Lack of Sustainability. There is also harm produced by CBPR projects when academic researchers abruptly leave communities upon completion of research projects. Through a systematic literature review and semi-structured interviews with both academic and community constituents, Jamshidi and colleagues (2014) found that lack of sustainability of projects was a concern for both academic and community partners. Community members specifically noted that harm that is created when interventions crafted based on research results require continued access to knowledge and resources previously provided by the university, but support is removed upon completion of research (Jamshidi et al., 2014). Others concur with this sentiment and extend it by adding that partnerships lasting beyond the end of a research project increase the chances

interventions will be fully integrated into community (Blumenthal, 2005) and help to build trust in communities when academic researchers show a commitment to more than data gathering (Anderson, 2013). While it is not within the purview of IRBs to control the length of a project partnership, awareness of the importance of a project that sees the results through to implementation could help to ensure ethical CBPR.

Community Justice

In the Belmont Report, the principle of justice is addressed both through individual and social lenses. Researchers cannot limit research to certain individuals without proper justification, nor select and exploit marginalized populations due to ease of access (National Commission, 1979). CBPR adds significantly to this understanding of justice by including community members from project inception to data dissemination and seeking to use research for social change (Shore, 2006). However laudable, these goals are challenging to realize even in collaborative partnerships due to several factors. These include perceptions that researchers benefit more than communities (Anderson, 2013; Minkler et al., 2002), the difficulty in establishing and maintaining shared power (Brabeck et al., 2015; Wallerstein, 1999), and shallow attempts to maintain trust and relationships (Banks et al., 2010). Falling short of best practices in CBPR and not institutionalizing the requirement to hold it accountable to its social justice aims creates a new set of ethical considerations for IRBs to take into consideration when reviewing research protocol.

Ensuring Benefit

Traditional approaches to risk/benefit analysis attempt to ensure that the risks of the research do not outweigh benefits for participants. Scholars note, however, that it is

an ethical responsibility of CBPR not to *balance* risks and benefits for participants, but to *seek benefits*, where building collective action and strengthening communities are fundamental to the work (Shore, 2006). Building community capacity through research training and sustained community programming as well as seeking broad community representation when planning research programs are all ways center community benefit in CBPR research.

Capacity Building. Capacity building activities are important to include in ethically sound CBPR. Still, community partners remain skeptical and often feel as though researchers stand to gain more than communities, even when partnerships are approached through a participatory lens (Chenhall et al., 2011; Minkler, 2004). Two themes regarding capacity building in research appear prominently in the literature.

Research Training for Community Researchers. A key element in fully participating in research is understanding the processes associated with standard research protocol. In the studies described previously regarding the ethical engagement of PRAs, there was clear recognition that an ethical concern was preparing non-academic researchers with enough skill to fully engage in the process (Anderson, 2013; Logie et al., 2012). Barriers to full participation included inadequate preparation for managing the dynamics of standard qualitative processes such as interviews and focus groups (Logie et al., 2012) and language used in survey protocols (to be disseminated by community volunteers) that is inaccessible to lay researchers (Anderson, 2013). Projects that consider these nuanced barriers to full participation in the research process help "overcome obstacles to community consent" and as such are a critical component to ethical CBPR (Harding et al., 2012 p. 8).

Research that Elicits Community Challenges. While it is important for CBPR to directly partner with communities to establish an appropriate research agenda, it is also necessary to anticipate the ways CBPR may unearth – external to the research – additional challenges faced by the community. The Brabeck et al. (2015) and Hunt et al. (2014) studies on the ethics of CBPR provide two interesting examples that highlight this justice-related issue. In the Hunt et al. (2014) study, community members (who participated in the ethical analysis of the CBPR project) noted concerns about the research project addressing only access to health care (focus of study) while not addressing lack of consistent access to food (issue external to research), which was just as important to their maintenance of overall health. Their need for food was not addressed, but the research "raised expectations for some that these concerns would also receive attention" (Hunt et al., 2014, p. 5).

Brabeck and colleagues (2015) raised similar questions surrounding the duty of care that researchers should consider when engaging with marginalized communities. In working with unauthorized migrants, the researchers felt that it was important to create capacity in the community through offering free legal services to participants; however, this raised additional ethical concerns with regard to participants' heightened expectations for legal issues to be resolved over the course of the research project (Brabeck et al., 2015). In both cases, the nuances of contending with how research elicits additional community challenges highlight the importance of ethical review that is "rethought in the context of collective and participatory methodologies" (Hunt et al., 2014, p. 34) and at a minimum raises questions about what, if any, supports should be offered along with planned research activities.

Avoidance of Gatekeeping. Beyond capacity building, ensuring benefit in CBPR research also includes efforts to elicit broad representation of community members when planning research, not simply choosing the individuals most connected with community leaders. In particular, reviewed studies identified ethical concerns related to justice arising from how participant selection guided by community researchers may at times be influenced by community political pressure (Story et al., 2010) or unconscious bias that could favor certain genders or ethnic groups (Hunt et al., 2014). For example, in Glass and Kaufert's (2007) analysis of the differences between Aboriginal community values and the research ethics process, the researchers found that it is important to vet community leaders, even when they are selected by formal governing bodies, to ensure their position of influence is not used as that of a "gatekeeper" (p. 33) for research participation. While building relationships with community leaders is important for CBPR researchers, developing an opportunity for participation from lay community members is also essential.

Insider-Outsider Dilemma

The insider-outsider dilemma is a topic of discussion endemic to research that utilizes qualitative methodologies and has been widely cited in the CBPR literature (Kauffman, 1994; Minkler, 2004; Wallerstein, 1999). Minkler (2004) describes that prominent issues related to these tensions for CBPR partnerships are power (particularly when white researchers partner with communities of color) and concerns related to burdens associated with time and lack of compensation.

Making Power Imbalance Explicit. Issues of power are not mitigated by virtue of establishing a research partnership. In fact, the closer the research partnership, the

greater the chances of exploitation (Banks et al., 2013). An early example of this is made explicit through a case study analysis conducted by Nina Wallerstein (1999) of a participatory research initiative with several Native American communities in New Mexico. Even though researcher involvement in the community had been longstanding, they found that failure to adequately name and address power, as well as the failure to more deeply understand the history of mistrust of university researchers, led to results that were unreliable and participants who felt as though their participation was not truly voluntary (Wallerstein, 1999). Wallerstein (1999) concluded that engaging in ongoing and explicit conversations about the covert forces related to power can help partnerships "become reciprocal and ultimately transformed" (p. 49). Building on this work over the last several decades, CBPR researchers have more recently named this as an ethical issue, where ignoring issues of power throughout the course of the research project creates circumstances that increase likelihood of harm and lack of justice for communities (Bromley et al., 2015; Hunt et al., 2014; Jamshidi et al., 2014).

Time and Compensation. Two practical concerns related to power dynamics that manifest as ethical issues are the demands on community partners' time as well as the lack of formal reward structure for community partner participation in a project (Logie et al., 2012; Minkler, 2005). Illustrating these concepts, Flicker (2008) used a critical social science lens in a case study analysis of a participatory research project and assessed the ways in which different stakeholders were impacted. Positive impacts on community capacity were identified; however, individuals from the community who participated in the project noted that the costs of participation far outweighed the opportunities related to

participation as the amount of time invested in the project became significantly burdensome (Flicker, 2008).

Adding to this, Minkler (2005) notes that there has long been an expectation that community partners will engage in research for no personal gain, financial or otherwise, beyond the benefit to the community. This is particularly true for women and mothers who are asked to participate as partners in research (Minkler, 2005; Yoshihama & Carr, 2002). While ethical CBPR requires the participation of community members, it is important to consider burdens such as these in the ethical review process in order to keep research projects just.

Trust and Relationship Building

The importance of building trust and relationships is ubiquitous in the literature that addresses ethics of CBPR (Anderson, 2013; Jamshidi et al., 2014; Mohammed et al., 2012; Story et al., 2010) and is simultaneously seen as a matter of justice (Baydala et al., 2013). In DiStefano et al.'s (2013) study on ethical approaches to CBPR, researchers described the tension between navigating academic culture and building trust with community research team members. Before sufficient time was invested in building a community advisory board for the project, university researchers moved forward with independently developing and submitting a research protocol to the university IRB. They did so because they needed timely IRB approval to meet a grant funding opportunity. However, because community leadership was not involved in the decision-making process, trust was broken between community and university researchers. This resulted in significant delays in the project and negatively impacted the future capacity of the partnership.

Safeguards in the IRB process may help to alleviate community concerns such as these. In Flicker and Worthington's (2012) study of Canadian REB perspectives on research with Aboriginal communities, one member noted, "There must be a period of time set aside specifically for relationship building...You need to do the capacity-building and build a trusting relationship with community before that research ever begins" (p. 21). This sentiment correlates with the conclusion drawn in Banks et al.'s (2013) study related to the need to focus on the ethics of care (accountability to relationships) in IRB processes rather than principle-based ethics (individual rights and responsibilities). Reframing ethics in this way might shift ethical review of CBPR and support partnerships in realizing their social justice aims.

Critiques of CBPR in Relationship to IRB Policy Revisions

The literature that outlines the shortcomings of the ethical guidelines provided by the Belmont Report and federal regulations is not without its critiques. As mentioned in Chapter 1, some researchers have called for significant updates to the federal regulations that would fundamentally alter IRB practice given these mismatches between CBPR and current regulations (Shore et al., 2007; Cross et al., 2015). Others, while acknowledging that tensions between IRB review and CBPR best practices are real, caution against changing the federal regulations as that would increase the scope of IRB review and negatively impact the opportunity to translate CBPR research into practice (Cargill et al., 2016). These researchers suggest using the flexibility within the current regulations to focus on seven areas within current requirements of IRB review where tensions exist but improvements to practice could be made. These areas include:

- determining whether collaborating sites and individuals are engaged in research,

- evaluating the competence of teams,
- identifying the appropriate expertise to review proposals,
- ensuring fairness in the selection and recruitment of participants,
- ensuring the voluntary informed consent of research participants,
- evaluating and minimizing risks, and
- managing the review of emergent research design (Cargill et al., 2016).

Additionally, they recommend leaving broader social goals of CBPR to the authority of communities partnering on the research. Those broader goals include:

- empowering communities,
- increasing real-world usefulness and relevance of the data,
- building community trust and ownership,
- creating equitable and sustainable partnerships between academic centers and communities, and
- providing local benefit to the communities that are participating in research (Cargill et al., 2016).

In this way, their overall suggestion is that of a coordinated approach between universities and communities in the ethical review of CBPR rather than solely making alterations to the IRB process.

While the suggestion for a coordinated approach seems logical, little is known about how that process might be employed between campuses and communities, which is a gap this research has potential to fill. Currently, a small body of literature addresses questions about IRB capacity to effectively review community-level concerns related to CBPR. What is known about this topic is described in the next section.

Scholarship on IRB Capacity to Review Community-Level Concerns of CBPR

A second body of literature describes what is known about the relationship between IRB members and their capacity to review CBPR effectively. This is differentiated from the first body of research in that it focuses on IRBs as the unit of analysis. There are two distinct subsets in this body of literature.

The first is a subset of research that evaluates IRB review of CBPR by examining the forms and documents associated with the process of ethical review. The second subset is representative of a search for existing literature on the topic of this study. This small sample of articles reviews the available research that directly focuses on IRB members and their understanding of the ethical issues related to CBPR.

Capacity of IRBs to Review CBPR Through Content Analysis of Forms

Some studies have used a content analysis methodology to assess IRB and Research Ethics Committee (REC) forms to determine whether the structure in place for the committees made appropriate review of CBPR projects possible. In one study, Guta and colleagues (2010) reviewed research ethics documents (protocols and guidelines) across all institutional research ethics committees in Canada (n = 278; sample that met criteria of "likely to review CBPR" = 86) and examined whether REC forms asked about community-level concerns in their review process. Only 2% of the documents asked questions about how the community was involved in crafting the rationale for the research, and 4% asked about community involvement in formulating the research question (Guta et al., 2010). As expected, nearly all forms asked about the risks and benefits to individuals in the study, as well as required individual consent to participate forms, while only 20%-25% of the forms asked the same regarding community-level

risks, benefits, and consent (Guta et al., 2010). The results of this study suggest that even for ethics committees that are the most likely to review CBPR, their policies and practices are not appropriately geared toward the full ethical review of projects that utilize participatory practices.

A similar study completed in both Canada and the United States also gathered research ethics protocol and guideline documents, but from a convenience sample of 30 institutions (n= 27 from the US; n = 3 from Canada) with graduate schools of public health. The schools in the sample "have been some of the most receptive toward utilization of CBPR methodologies" (Flicker et al., 2007, p. 482) and had strikingly similar results to the study by Guta and colleagues (2010). None of the forms asked about input on the rationale of the research from community partners, and again, while all forms asked about consent, risks, and benefits for individuals, only 13% asked about community-level risks and benefits and none asked about community consent (Flicker et al., 2007). These studies both show that, although without speaking directly to members of IRBs or RECs, the expectations set before them in standard review protocol, at least in the United States and Canada, are often non-inclusive of community-level concerns.

Ethics of CBPR from the Perspectives of Individuals Who Review Research

The Flicker and Worthington (2012) study mentioned previously in this paper is one example of research that seeks perspectives of IRB members as it relates to participatory practices, though it is specifically directed toward the ethics involved in working with Aboriginal groups in Canada. Important findings from this study include REB acknowledgement of the unique complexities of informed consent in Aboriginal communities, that building trust and relationships with the community over a long period

of time is a necessary component of working with Aboriginal groups, and that Aboriginal research in and of itself is a unique type of research in which to engage (Flicker & Worthington, 2012). Although this is a Canadian research study, it is valuable in that it showcases the ways that REB members are beginning to notice and respond to the ways that incorporating communities and community members as partners in research impacts the overall ethical review process.

Another study by Solomon and Piechowski (2011) is also closely related to the topic of this study, as it addresses the mismatch between CBPR principles and the requirements of ethical review put in place by federal regulations that IRB members must follow. The researchers interviewed IRB managers and administrators as well as the Vice President of the Office of Research from a university in the United States and intended to learn more about the challenges that IRBs face in approving CBPR research. Specifically, they were trying to understand, "Why does [review of CBPR] take so long?" (Solomon & Piechowski, 2011, p. 24). After consultation with their participants, researchers learned of the administrative burdens that review of CBPR creates (i.e., multiple IRBs at one institution review CBPR projects as well as the burden of becoming the IRB of record for a community partner) as well as that of ensuring that community partners involved in the project are adequately trained in research ethics protocol and standards (Solomon & Piechowski, 2011). The Solomon and Piechowski (2011) study investigates the ways IRBs struggle to review CBPR projects in a timely manner and has implications for adjusting training for IRB members, researchers, and community partners alike. However, it still does not help reveal the ways that IRB members understand CBPR and

how that understanding impacts the decisions they make related to holding the methodology, and those who use it, accountable to appropriate ethical standards.

Among all the literature reviewed, the one study that centers this concern included 24 interviews at seven Canadian institutions with REB members, staff, and additional key informants with specialized experience or knowledge of CBPR and the ethical review of research (i.e., REB stakeholders) (Guta et al., 2012). Through their research, Guta and colleagues (2012) found that REB stakeholders showed an unexpected level of understanding of CBPR principles and flexibility in the ways that they thought about and reviewed protocol. This included a nuanced understanding of the impact of inauthentic CBPR relationships and the overburdening of community, as well as a concern for the potential complications of peer participatory research on an individual's relationships with other members of their community (Guta et al., 2012).

Interviews with REB stakeholders led researchers to develop a set of best practices for REBs to consider in their review of CBPR and include (1) recruiting reviewers with CBPR experience for REBs, (2) flexibility in protocol when there is little impact on material risk to participants, (3) encouraging REBs to base questions to researchers during the review process that are grounded in the proposed methodology and avoid defensive or discouraging language and finally, (4) offering the option to researchers for a pre-review or initial meeting in order to discuss potential ethics pitfalls (Guta et al., 2012).

While the results of the Guta et al. (2012) study are particularly relevant to the present study, there are limitations to the study to consider in developing future research. Notably, the authors point out that the results may be skewed given those recruited for the

study may have a higher comfort level with, and thus a more positive view and tolerance of, CBPR protocols (Guta et al., 2012). Future studies might consider intentionally including the voices of IRB/REC members who maintain that CBPR protocol should be reviewed within the standard research ethics framework. In this way, a more holistic picture can be garnered for decision-making about how to move forward with CBPR review.

All in all, studies that examine the relationship between IRB perspectives on their own understanding of or capacity to review CBPR is limited, particularly in the United States. Completing a study similar to the one carried out by Guta and colleagues (2012) in the United States would not only provide more relevant information to institutions in this country but it would also bring up to date the information gathered in theirs.

Conclusion

Considering changes to IRB review of CBPR is important as higher education moves toward the goal of creating spaces where transformational education and partnerships are possible. For public research universities, CBPR is an increasingly popular approach to knowledge production that confronts the status quo and attempts to de-center institutions as exclusive knowledge holders. However, CBPR becomes challenging for researchers to implement and risks harming communities when processes such as ethical review do not consider community-level protections (Castro-Reyes et al., 2017; Deeds et al., 2008; Flicker et al., 2007; Shore et al., 2011). This complexity often results in delays in approval or the inability to create research protocol that is fully participatory, thus disincentivizing researchers to utilize CBPR (Flicker et al., 2007; Malone et al., 2006; Tamariz et al., 2015).

The ethical principles of respect for persons, beneficence, and justice outlined in the Belmont Report inform federal guidelines regarding the review of research with human subjects. These principles offer a framework for highlighting what is known about the ways that research with communities creates unique ethical considerations outside the bounds of what is typically considered in traditional research protocol review. The concerns stemming from this misalignment in priorities has led many CBPR researchers to identify challenges that surface during the ethical review process (e.g., Brown et al., 2010; Malone et al., 2006; Shore, 2007) and develop new ethical priorities for CBPR as a research practice (e.g., Davison et al., 2013; DiStefano et al., 2013; Hunt at al., 2014; Logie et al., 2012; Mistry et al., 2015; Simmons et al., 2015).

The second set of literature summarized what is known about the capacity of IRB members to effectively review CBPR protocol. Importantly, only two studies in this reviewed literature discuss the ethical concerns related to CBPR with IRB members directly (e.g., Guta et al., 2012; Solomon & Piechowski, 2011), which indicates a need for further study in this area.

Many researchers have argued that filling this gap in the literature is a key element in further discovering the ways IRB members interpret the relationship between federal regulations and CBPR practice (Anderson, 2013; Brown et al., 2010; Mikesell et al., 2013; Wilson et al., 2018). Understanding the ways that IRBs make sense of the challenges associated with reviewing CBPR would further allow institutions of higher education to identify what structural changes can be made to support and advance the incorporation of communities in the knowledge production process.

Chapter Three: Research Methods

The purpose of this study is to generate new understandings about the ethical review of CBPR in the higher education context and to assist institutional decision makers in adapting IRB processes to the community-level concerns unique to CBPR. In Chapter 2, I presented a backdrop of the types of questions that are being asked in the literature regarding challenges in the ethical review of CBPR. The following chapter introduces a way of understanding how institutions address these challenges and what influences the ways that institutions understand the need for change. Specifically, it outlines the theoretical framework that guides the research design, data collection procedures, and interpretation for this study. This study poses the following research questions:

1. How do Institutional Research Boards at community-engaged research institutions make sense of the ethics of CBPR?
    a. What are the environmental cues and collective meaning-making processes used to understand community-level ethics?
    b. Who else is involved in this process?
2. In what ways and to what extent are community-level ethical concerns of CBPR considered in reforms to IRB processes?

Theoretical Framework

Altering the ways that IRBs review CBPR requires not only adjusting current processes and procedures; it also requires individuals at the institution to shift their mindsets to fully address the nuances present in successfully reviewing CBPR. Changes such as these are often referred to as second-order or deep changes where organizations

must challenge current assumptions about a phenomenon (Kezar, 2018). In a study of 28 colleges all undergoing transformational change to their teaching and learning processes, Eckel and Kezar (2003) found that in higher education contexts, these deep changes are best facilitated by undergoing a meaning construction process which is often referred to as organizational sensemaking. Anchored in this literature, this study utilized a sensemaking framework to understand the institutional change process related to the ethical review of CBPR at public universities.

Sensemaking Defined

This study utilizes Maitlis and Christianson's (2014) definition of sensemaking which is described as an ongoing and social process where people work to understand novel or unexpected events through interpreting cues in their environment and acting upon them to create a new, more ordered account of the situation. This process allows them to "make sense" of and continue to act in their new environment. In his well-known work *Sensemaking in Organizations*, Weick (1995) was among the first researchers to theorize how sensemaking is used to explain organizational events. To him, sensemaking involves a process of placing environmental cues within a framework, working to interpret and construct meaning around them, and then acting on this information to bring certainty to a situation (Weick, 1995). Weick (1995) describes sensemaking as different from other explanatory processes utilizing the following seven characteristics:

1. Sensemaking is grounded in the identity and identity construction of both the individual and the organization.
2. Sensemaking is retrospective whereby organizations and organizational actors create meaning by utilizing past experience as a guide.

3. Sensemaking is social and involves actors both in and outside of the organization. This results in a joint understanding of the particular issue that an organization faces.

4. Sensemaking involves enactment, where actors respond to their environments by taking spoken or written action that further assists in making sense of their environments.

5. Sensemaking is ongoing and is a part of a gradual process of change over time.

6. Sensemaking involves extracting cues from the environment which serve as points of reference to assist in interpreting an event.

7. Sensemaking is guided by plausibility rather than by accuracy which allows organizational actors to take action and move forward even in the face of incomplete information or multiple understandings of an event or issue.

Weick's (1995) theory allows researchers to recognize how organizations and individual actors respond to uncertain environments and reconstruct them into something more sensible and elucidates several strategies that are incorporated in this change process. The following sections offer more detail related to how sensemaking occurs in an organizational context.

How Sensemaking Happens

While Weick's (1995) early work offers a framework to understand sensemaking theory and its components, other researchers provide greater detail about the sensemaking process itself. In a recent synthesis of research that identifies how sensemaking is accomplished, Maitlis and Christianson (2014) identify three main "sensemaking moves" (p. 59) by asking the following three questions: How do events become cues for

sensemaking? How is intersubjective meaning constructed? What is the role of action in sensemaking?

How Events Become Cues for Sensemaking. In sensemaking, noticed discrepancies between expectations and reality where meanings are unclear and the outcomes are uncertain are called environmental cues (Maitlis & Christianson, 2014). These cues initiate or become "triggers" (p. 70) for sensemaking through the following contexts: environmental jolts (e.g., technological advances or governmental policy changes) or organizational crisis (e.g., building collapse), threats to organizational identity (e.g., release of new rankings in higher education or when organizational identity is ambiguous or uncertain), and planned organizational change initiatives (e.g., arrival of a new President or CEO or major restructuring initiatives) (Maitlis & Christianson, 2014). When one of the preceding scenarios occur, sensemaking is triggered to reduce incongruence in a previously well-understood process or reality.

Applied to higher education, external environmental cues have historically played a role in triggering the new ideas about what it meant to become an "engaged university." Specifically, shifting political winds and declining state support for higher education during the 1980s contributed to the creation of forums to rethink the public purposes of higher education (Saltmarsh et al., 2014). In the specific context of CBPR, moves made by the Clinton administration in the 1990's and even recent calls-to-action by politicians for higher education to be of more "value" to society are examples of external environmental cues that change the ways faculty and institutions conceptualize partnering with communities. Internally, the requirements of a large government grant, such as the

Clinical and Translational Science Award, may trigger sensemaking due to forced change in institutional process and procedure.

How Collective Meaning is Constructed. In this study, sensemaking is seen as constructivist, which means it can be considered through the interactions between individuals and groups, spoken and written word, and the actions of individual organizational actors (Maitlis & Christianson, 2014; Weick, 1995). Collaborative sensemaking allows for the construction of what Weick (1995) called plausible knowledge which facilitates the change process in groups. Maitlis and Christianson (2014) refer to this process the construction of intersubjective meaning which is a "mutually-constituted process, as members jointly engage with an issue and build their understanding of it together" (p. 78).

These collaborative efforts are often facilitated through the exchange of ideas between leaders and group members in a process that involves both sensemaking as well as sensegiving (Gioia & Chittipeddi, 1991). Sensegiving is defined by Gioia and Chittipeddi as "the process of attempting to influence the sensemaking and meaning construction of others toward a preferred redefinition of organizational reality" (1991, p. 442). They also identified a four-stage process – envisioning (sensemaking by leader), signaling (sensegiving by leader), revisioning (sensemaking by stakeholders), and energizing (sensegiving by stakeholders) – that characterizes the beginning stages of strategic change (Gioia & Chittipeddi, 1991).

Building on the influence of sensegiving in the sensemaking process, Maitlis (2005) conducted a longitudinal study that further explored the social process of sensemaking. Maitlis (2005) found that there are four forms of organizational

sensemaking that unfold depending on the extent to which leaders and stakeholders engage in sensegiving. The four forms are guided (i.e., leaders and stakeholders actively engaged in process), fragmented (i.e., stakeholders raise issues but leaders do not respond), restricted (i.e., leaders communicate broad vision which stakeholders accept without offering alternate interpretations) and minimal (i.e., leaders and stakeholders wait for the other group to interpret an issue) (Maitlis, 2005). This research helps to explain how the sensemaking and sensegiving process can lead to different outcomes in understanding a given issue or event.

In addition to the ways that individuals within organizations interact, collective meaning is also constructed through spoken and written word of organizational actors. Sensemaking is constructed through the stories people share about their experiences which in turn creates a new collective reality that facilitates action (Weick, 1995). In addition to the importance of creating a shared narrative in sensemaking, Maitlis and Christianson (2014) found that the use of metaphor to connect cues to new frames of understanding as well as the use of various discursive practices are strategies used to build collective meaning in the sensemaking process.

Applied to the present study, Kezar and Eckel (2002) and Kezar (2013) provide insights into how collective meaning is constructed in the field of higher education. The literature outlines both a top-down approach as well as a bottom-up approach. In their study on how transformational change happened on college campuses, Kezar and Eckel (2002) outlined that the process of sensemaking and sensegiving unfolded through five core strategies initiated by institutional leadership: senior administrative support (i.e., provision of support through value statements, resources, or new administrative

structures), collaborative leadership (i.e., individuals throughout campus are involved in the change initiative from conception to implementation), robust design (i.e., leaders create a vision for the future that is clear and understandable), staff development (i.e., programmatic efforts for learning certain skills or knowledge), and visible action (i.e., steps in the change process are noticeable, promoted, and continuing) (Kezar & Eckel, 2002). These strategies were impactful because of their ability to help individuals conceptualize a new identity of the organization, to help them feel like their input mattered, and to be a part of the institutional and administrative goals – all of which constitute sensemaking (Kezar & Eckel, 2002).

While this study illuminated several key aspects of sensemaking on college campuses, it only focused on the ways in which leadership impacts the sensemaking process from the top down during the initial phases of change (Kezar, 2013). Since deep, transformational change in higher education requires buy in from high-level administrators, but also sustained buy-in from leaders on the ground, Kezar (2013) completed a study to learn more about how sensemaking happens from the bottom up, as well as whether it continues to happen beyond initial stages of change.

In this follow-up study, data was collected from teams of faculty and low-level administrators that were engaged in transforming institutional views and processes surrounding interdisciplinary learning. Kezar (2013) found that sensemaking continued beyond the mobilization phase into implementation and institutionalization phases of change. It included alternating sensemaking and sensegiving mechanisms similar to Gioia & Chittipeddi's (1991) four stages at both the departmental and campus-wide level in order to garner understanding and support for the initiative. However, rather than

happening in a linear fashion, the stages were often overlapped or happening simultaneously (Kezar, 2013). Institutions that made the most change over time demonstrated three attributes: depth of process, breadth of engagement across departments and campus-wide, and connections to strategies and barriers (Kezar, 2013). Importantly, Kezar (2013) noted that in bottom-up change, sensemaking happened in similar ways to Gioia and Chitipeddi's (1991) model (envisioning and revisioning), but sensegiving often included persuasion and overcoming barriers rather than the signaling and energizing present in top-down sensemaking. This study showed that sensemaking in the higher education context is a process over time that requires moving through a series of steps at both the department and campus level. In addition, that sensemaking develops through different strategies depending on whether change is initiated from the top-down or bottom-up.

The Role of Action in Sensemaking. To Weick (1995), sensemaking requires action. Important in the process of sensemaking is the idea that the actions people take to make sense of a situation enact the environment they would like to understand. This attribute of enactment is the driving force behind meaning making and is what makes sensemaking distinct from interpretation (Maitlis & Christianson, 2014). Additionally, actions can be used to test previous understandings derived through sensemaking and in this way action and sensemaking are linked together where "action serves as fodder for new sensemaking, while simultaneously providing feedback about the sense that has already been made (Maitlis & Christianson, 2014, p. 84).

In the field of higher education, the move from meaning construction to action is expressed through use of several vehicles (Weick (1995) called them "mechanisms") that

allowed individual actors to make meaning regarding the new activities of the institution (Kezar & Eckel, 2002). These sensemaking activities were what made Kezar and Eckel's core strategies effective in transformational change. There is not a fixed set of specific vehicles that are used, however, in her book *How Colleges Change,* Kezar (2018) identified several strategies used in the context of higher education:

- developing cross-departmental teams or working groups,
- drawing on and discussing external ideas,
- sponsoring faculty and staff development opportunities,
- preparing and giving public presentations,
- creating documents and concept papers.

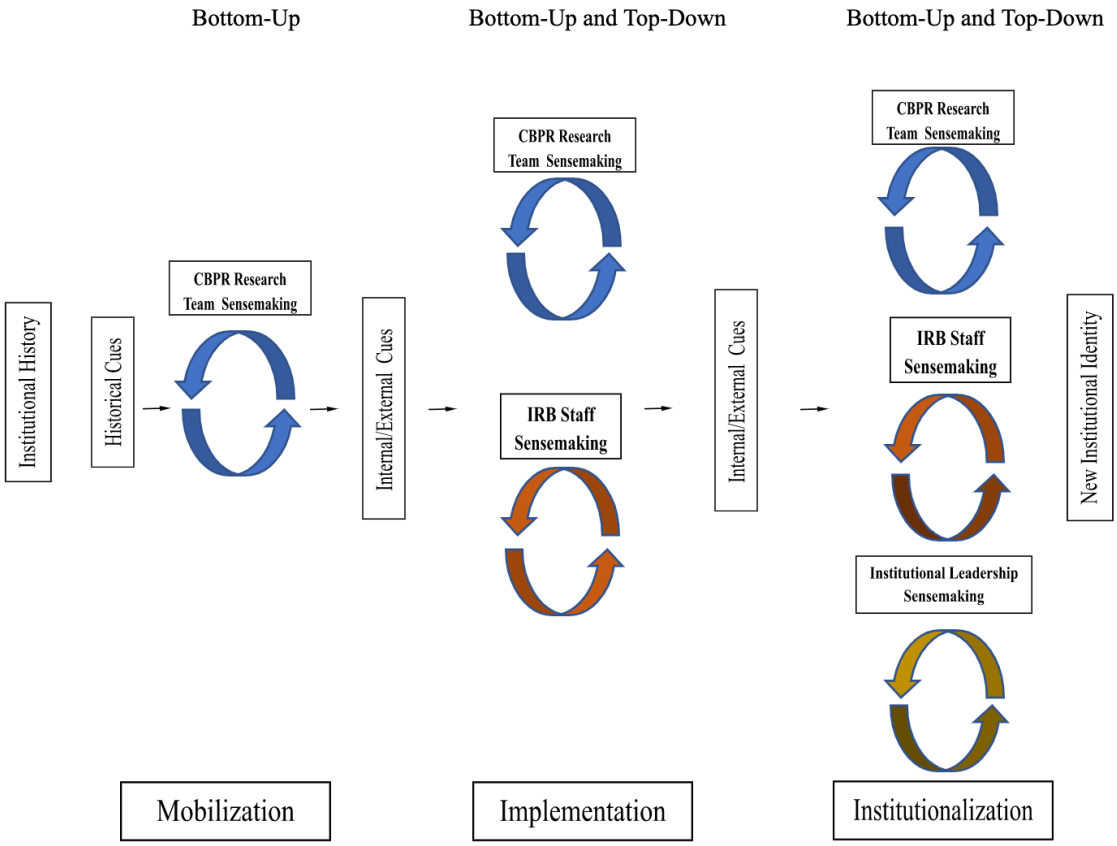
Related to community engagement and CBPR, this may include the creation of a task force that considers the role of engagement in a university-wide strategic plan or in developing trainings that have been developed internally or externally on ethical issues related to CBPR.

Conceptual Framework

The conceptual framework below emanates from the literature review presented in Chapter 2 as well as the theoretical framework presented in the previous section of this chapter. This framework provides a mechanism to conceptualize how community-engaged research universities adopt and incorporate CPBR within research planning processes. Figure 3 depicts how sensemaking may inform the adoption and incorporation of CBPR within these processes.

Figure 3

Conceptual Framework for Sensemaking of Community-Level Ethics of CBPR



There are three key assumptions posited by the framework. First, as Weick (1995) pointed out, this framework assumes that sensemaking occurs over time and has no absolute start or end points. It is ongoing and includes constant new interpretations of an issue based on internal and external environmental cues and the enacted environment created by individuals within an organization. Practically, this process typically results in the accumulation of individuals that are involved in the sensemaking process. The conceptual framework presented here represents this by using Kezar's (2013) stages of mobilization, implementation, and institutionalization. The circular arrows are used to

depict the ongoing sensemaking process, where sensemaking is represented by the arrow pointing upward and sensegiving is represented by the arrow pointing downward.

It is the assumption of this model that in the mobilization phase, cycles of sensemaking are initiated by CBPR research teams which likely includes concerns about the ethics of CBPR being raised by CBPR researchers with IRB staff members during the protocol review process. This enacted environment triggers sensemaking within the IRB. In addition to these internal cues, external cues could play a role in moving toward the implementation phase. One example of an external cue that could initiate sensemaking for IRBs might be increased resistance from community to participate in research studies. Another external cue might be reports produced by national organizations such as Campus-Community Partnerships for Health that offer suggestions for increased alignment between IRB review and CBPR (Castro-Reyes et al., 2017).

In the implementation phase, sensemaking occurs both at the CBPR research partnership level as well as among IRB staff. It is assumed that the internal enactment of the sensemaking process in the implementation phase creates cues (e.g., requests to clarify or alter institutional policy) that could initiate administrative leadership sensemaking. In addition to internal cues, external cues could trigger sensemaking at the institutional leadership level. For example, a publicized failure regarding the way an institution interacts with their community in a research partnership might require institutional response and garner leadership attention.

In the institutionalization phase, sensemaking occurs within CBPR Research teams, the IRB staff, and institutional leadership simultaneously. It is assumed that at this

stage the process will exhibit characteristics of “guided” sensemaking (i.e., leaders and stakeholders are actively engaged in the sensemaking process) (Maitlis, 2005).

Second, based on the review of the literature, it is likely that sensemaking of the community-level ethics begins as a bottom-up initiative rather than a top-down initiative. Almost all reviewed articles indicate that ethical concerns related to CBPR were first identified by CBPR research teams. An example of an internal cue identified in the literature was concerns raised by community partners during conversation or reflection on the research process. External cues included confusion about their rejected or delayed CBPR research protocol in the IRB review process. These cues triggered sensemaking of community-level ethics and a desire to take action. Given this, the framework also assumes that cycles of sensemaking and sensegiving include the use of mechanisms to garner attention of a broader audience of individuals. According to Kezar (2013), a bottom-up approach to sensemaking will include sensegiving mechanisms that are focused on persuasion and overcoming barriers to initiate change.

Once a campus reaches the implementation phase, both bottom-up and top-down sensemaking occurs as mid-level leadership is engaged in and responding to concerns related to community-level ethics. The same is true during institutionalization which includes sensemaking of mid-level as well as institutional leadership.

Finally, Weick (1995) theorizes that institutional identity and the construction of institutional identity are core tenants of sensemaking. This literature suggests that institutions that are deeply committed to community engagement may be especially attuned to ethical issues in CBPR. In such cases, there may be a noticeable change in institutional identity and understanding once campus-wide engagement with sensemaking

of community protection occurs. According to Kezar (2013), indicators of change in institutional identity and understanding are depth of process, breadth of engagement across administrative units and campus-wide, and connections to strategies and barriers. This model proposes that by considering institutional history and understanding the enacted institutional context, it is possible to identify an institutions' location in the sensemaking phases.

Research Design

In order to answer the proposed research questions, I utilized a qualitative design which is an approach that allows for exploring and understanding the meaning people or groups of people give to a particular phenomenon (Creswell & Creswell, 2018). In qualitative research, because the key concern is related to insider perspectives, it is considered an emic approach (Merriam & Tisdell, 2016). In qualitative approaches, the researcher utilizes these perspectives and interprets them based on the specific context. This interpretive approach allows the researcher to carefully consider the complexities of any given phenomenon (Creswell & Creswell, 2018).

Case study is a qualitative methodology useful for answering my research questions as it is suitable when a researcher desires to study what happens in a system of people rather than gathering understanding about the experiences of one individual (Plano Clark & Creswell, 2015). I relied on methodologists Merriam (1998, 2009) and Stake (1995, 2005) to guide my understanding of the case study design. Merriam (1998) refers to this system of people in a case study as a bounded system. Public research universities are bounded since they can be distinguished by a particular physical space and specific, identifiable groups of people. Case study research is a valuable approach

when a “rich and holistic” understanding of the phenomenon of interest is desired (Merriam, 2009, p. 51). Given the absence in the literature of a comprehensive view of how public universities make sense of CBPR in the IRB process, this research project benefitted from the depth of analysis provided by the case study method.

Specifically, I conducted a multi-case study to understand how two community-engaged public research universities came to alter their IRB processes. The multi-case study design was appropriate for this study because no two institutions of higher education are alike. Choosing just one institution would not lead to the opportunity to discover the nuances in each setting and the contexts that play a role in those similarities and differences. To Stake (2005), this comparing and contrasting of multiple cases allows for the ability to gain deeper knowledge, as the goal of the multi case study is less to understand an individual case and more to understand the overall phenomenon. This method allowed for an investigation of a range of opportunities and barriers for institutional change in the IRB process and required evaluating multiple sites. For example, this allowed for an exploration of structures and people that are in place to implement changes to the IRB process. Furthermore, it allowed for examination of institutional differences in addressing community-level concerns based on unique institutional histories.

Case Selection

The research questions in this study focus on understanding the ways that institutions of higher education in the United States have come to make sense of the ethical review of CBPR. To identify appropriate institutional contexts to study my questions, I plan to focus on community-engaged public universities that are classified

through the Carnegie Classification as doctoral universities with very high research activity. These universities are located in the United States and house medical schools and schools of public health. There are three reasons for choosing these as initial guidelines for case selection. First, institutions with very high research activity are the most likely to have robust IRBs, which increases the likelihood they have addressed issues related to CBPR. Second, research in this area is most often written by researchers and their community partners in the fields of medicine and public health. For this reason, choosing institutions that house the medical school and schools of public health have likely thought in a more nuanced way regarding the implications of ethical review of CBPR, making them better choices for my study.

Third, I focus on universities that have received the Carnegie Classification for Community Engagement (see Carnegie Classification of Institutions of Higher Education, n.d.). These institutions are working toward community engagement as an institutional priority, and not simply as a priority of the medical school. The classification is an elective designation in which institutions participate voluntarily. Receiving the designation takes much effort by institutions and requires data collection and documentation of significant commitment to community engagement. Rather than an award, it is a process of self-study similar to an accreditation. Currently, 359 campuses are classified (Carnegie Classification of Institutions of Higher Education, n.d.).

To further narrow my group of potential institutions, I considered universities that were awarded the Spencer Foreman Award for Outstanding Community Engagement. This award denotes exceptional commitment to community-engaged practices in the area

of health, a common context where CBPR is conducted. It is given each year to a medical school or teaching hospital and their community partners that:

> Engage in bidirectional collaboration and shared leadership in service of advancing the health and vitality of the community, its residents, and the academic institution. This commitment should be demonstrated through the development, implementation, evaluation, and sustainment of exceptional educational, clinical, and research programs that go well beyond the traditional service role of academic medicine and rely on the local community's wisdom and expertise to address community health needs (American Association of Medical Colleges, n.d.).

The award has been given 24 times since 1998, and of the 24 recipients, four were teaching hospitals and 20 were institutions of higher education. Of this list of 20, nine were public, comprehensive research-intensive universities eligible for inclusion in the study.

After examining the eligible Spencer Forman Awardees and those institutions that are currently classified with the Carnegie Community Engagement designation, six institutions fit the selection criteria. To further narrow this list of institutions, I consulted with field experts from the non-profit Community-Campus Partnerships for Health and researchers with IRB expertise to identify which institutions have shown a commitment to the ethical review of CBPR. This strategy is consistent with past studies that have relied on expert panels to make decisions about case study sampling (see Weerts & Sandmann, 2008).

From this subset, I selected two cases that have demonstrated commitment to the ethical review of CBPR. In this way, I chose institutions that have high quality information regarding the phenomenon at hand "from which the most can be learned" (Merriam, 1998, p. 61). As such, this method of selection was purposive, rather than a random selection of institutions from the larger subset.

Selection of Green University and Valley University

Based on this process, I chose two institutions with the pseudonyms Green University and Valley University. Green University is a public, not-for-profit, comprehensive research university classified it as having "very high research activity" (Carnegie Foundation for the Advancement of Teaching, n.d.). It is ranked among the top 50 universities in the National Universities category in the *U.S. News & World Report* rankings (n.d.). Green University invests in campus wide support for the growth and development of faculty, staff, and students (undergraduate and graduate) in the areas of community, civic, and public engagement. It has a long tradition of and reputation for its deep connection to life outside the classroom and research labs. As a university it is well-known for its commitment to the public good, particularly related to its status as a land-grant institution.

Valley University is a public, not-for-profit, comprehensive research university classified as having "very high research activity" (Carnegie Foundation for the Advancement of Teaching, n.d.). According to U.S. News & World Report, it is ranked among the top 200 universities in the National Universities category (n.d.). As a Minority-Serving Institution, Valley is deeply committed to the diverse constituents that make up its student, staff, and faculty bodies. Those committed to community

engagement efforts on campus have long understood and incorporated community expertise and community voice into their work. Additionally, field experts indicated that Valley is an institution known for having a group of nationally-recognized CBPR faculty members. More detailed case descriptions are included in Chapter 4.

Data Collection

The primary data collected were from semi-structured interviews. Interviews were useful because it was not possible to directly observe participants which also allowed for eliciting information about past events (Creswell & Creswell, 2018). Semi-structured interviews allowed for flexibility to include structured and unstructured questions in the interview protocol. Specifically, interviews were responsive to emerging ideas shared by the interviewee (Merriam & Tisdell, 2016). Semi-structured interviews allowed me to adjust questions based on the specific contextual knowledge of each participant.

In addition to main questions, the interview protocol (see Appendix A) included prompts and follow up questions to ensure nuance and depth in responses. Open-ended interview questions were written to elicit stories and information to answer the research questions identified in Chapter 1 in relationship to the theoretical and conceptual frameworks presented in this chapter.

Each interview began with an introduction of myself, the study, and the study purpose. Once participants had all questions answered, they were asked for verbal consent to record and continue with the interview process. The recorded interview began by sharing the definition of CBPR used for the study as well as an outline of the community-level ethical concerns identified through the literature review presented in Chapter 2. Participants were then given the opportunity to ask any clarifying questions

before moving on to the content-based portion of the protocol. This section was used to gauge the participant's current level of understanding related to community-level ethics.

First, participants were asked to describe their understanding of any changes made at the IRB-level related to community level ethics. Second, participants were asked to describe their experience with or understanding of the institutional historical context related to sensemaking of community-level ethics. Then, participants were asked to describe the current institutional state of being as it relates to understanding of and response to community-level ethics. In each of these first three sections, follow up questions were utilized after the participants' initial response to elicit specific information connected to the sensemaking framework. Examples include prompting to learn more about bottom-up and top-down efforts, internal/external environmental cues, and which mechanisms were utilized for change. The final part of the interview sought to unearth information regarding institutional context that brought about changes related to the ethical review of CBPR. Together, these questions sought to elicit information about whether the sensemaking processes at the institutions led to identifiable changes that address specific ethical challenges presented in the literature.

Interview participants were identified using a purposeful sampling strategy, which is used in qualitative research to select individuals who are best suited for the study because they have experienced the phenomenon of interest (Plano Clark & Creswell, 2015). At each case study site, I identified and contacted administrators responsible for the oversight of research ethics including Vice Presidents for Research, Directors of the Human Research Protection Program, and Directors of the IRB. I also identified and contacted faculty members whose online profiles or national reputations indicated they

were highly involved with CBPR research. Through snowball sampling, I identified specific IRB members or managers/directors with experience reviewing CBPR protocols, as well as community partners and additional faculty members who have engaged meaningfully with the university on issues related to the ethical review of CBPR (Plano Clark & Creswell, 2015).

For each case, I interviewed participants until saturation was reached among informants. Data saturation refers to the point in research where "data no longer sparks new insights or reveals new properties" (Creswell & Creswell, 2018, p. 186). Informants are considered individuals who have specific knowledge of a particular issue. I focused on interviewing individuals with first-hand experience of the intersections of CBPR and the IRB since this study is the first of its kind. Future studies might include additional participants with peripheral knowledge to add more detail to key understandings found in this study.

For this study, data saturation was reached when no new informants were identified for interviews and when statements were repeated by multiple participants. This resulted in nine participants from Green and eight participants from Valley. One individual from each institution was interviewed twice as a means of verifying and gathering additional data. Interview participants and their role at each institution can be found in Table 2.

Table 2

Interview Participants and Role at Institution

Institution	Pseudonym	Role
Green	Ashley	Current IRB Staff
Green	Kathleen	Previous IRB Director
Green	Anne	Previous IRB Director
Green	Amy	Research Support Staff/Former IRB Staff
Green	Lou	CBPR Faculty
Green	Naomi	CBPR Faculty
Green	Eve	CBPR Research Administrator
Green	Emelia	Community Partner
Green	Ray	Community Partner
Valley	Grace	Research Integrity and Compliance Administrator (Main)
Valley	Tom	Research Ethics Administrator (Main)/Formerly on IRB (HSC)
Valley	Carol	Current IRB Manager (Main)/Former IRB Staff (HSC)
Valley	Mary	CBPR Faculty/CBPR Center Director (HSC)
Valley	Susan	CBPR Faculty (HSC)
Valley	Ericka	CBPR Faculty (Main)
Valley	Diana	Research Support Staff (HSC)
Valley	Sam	Research Support Staff (HSC)

Interviews were completed via Zoom between February and June 2022. During the interview, additional data was requested from the interviewees (e.g., policies, meeting minutes, annual reports, handbooks, training materials, meeting notes, digital recordings) if it pertained to the processes and progress related to adapting ethical review to CBPR. These materials, along with publicly available documents and data (e.g., websites, press releases, etc.), were analyzed in addition to the data gathered from interviews. This use of document analysis provided a means for triangulation to achieve increased data reliability (Creswell & Creswell, 2018).

At the conclusion of each interview, I drafted initial thoughts and questions into a memo and made notes regarding ideas for additional questions or additional contacts for future interviews. The recordings were also saved and stored securely.

Data Analysis

In this study, I relied on the constructivist research paradigm to analyze the data. In this research paradigm, the goal is to utilize the views of the participants being studied as much as possible to understand the meaning they have constructed both socially and historically on a given phenomenon so that it is useful as a basis for future studies (Creswell & Creswell, 2018).

Data analysis began at the same time as data collection with the use of memoing throughout the interviewing process (Creswell & Creswell, 2018) and continued until the completion of interviews. All interviews were transcribed into Microsoft Word documents and uploaded into Dedoose. Analysis followed Creswell and Creswell's (2018) data analysis process which consists of organizing and preparing the data for analysis, reading the data, coding the data, generating descriptions and themes (including interconnected themes), and representing the description and themes (including interpreting their meanings) (p. 193-195).

Categories from the conceptual framework, research questions, and interview protocol (see Appendix A) were used to initially organize (i.e., code) the data. From there, I transcribed interviews as they were completed and scanned through documents as I received them. I then re-read interviews and document texts one case at a time, memoing and noting where there were emerging ideas and patterns. New codes were created to represent these ideas either in vivo or with concepts from scholarly literature. When the coding process for one case was complete, I narrowed the list of codes and reduce them to a set of themes. This process was then completed for the second case. Through coding, recoding, and creating themes for each case, I was able to identify

relationships between categories of data within cases and also between cases. I then identified patterns and discrepancies between the cases which are discussed through the lens of the conceptual framework.

Data Reliability and Validity

The process of establishing the reliability and validity is important in qualitative research because it is a means of checking for the accuracy and credibility of the study findings (Creswell & Creswell, 2018). In qualitative studies, establishing reliability and validity does not equate to generalizability, as is the case in quantitative research; however, it does allow for future research to build on the findings. For this study, I followed the guidance of Creswell and Creswell (2018) in using multiple validity and reliability procedures. The list below are several employed strategies:

- triangulation of data using multiple data sources,
- data collection until saturation (e.g., themes repeated across key informants),
- use a rich, thick, description to describe the findings,
- discussing conceptual interpretations with an external researcher,
- read transcripts to ensure they do not contain transcription mistakes,
- staying close to the verbatim transcripts,
- use memos during the coding process to establish their definitions, and
- ensure there is not a drift in the application of codes.

Consent and Confidentiality

Appendices A-C include the documents submitted to the University of Minnesota Institutional Review Board for review and approval. This process was completed before

data collection began. The protocol was determined to be not human research (See Appendix E). As such, obtaining informed consent or promising confidentiality to participants was not required. However, as a means to encourage honest responses from participants and to assist in encouraging confidence in the process and purpose of my interviews, I still followed my intended verbal consent process (Appendix C). Appendix D includes the information sheet shared with each participant prior to the interview.

All data were kept confidential and identifying information was excluded from the final version of this dissertation. Additionally, data from this study will be destroyed or deleted within one year of final approval of this dissertation. To further ensure the confidentiality and privacy of each participant, I utilized the following procedures:

- promptly transcribed interview data using pseudonyms to de-identify each participant (including role at institution, institution name, as well as references to their or other institutions' programs or initiatives),
- stored a document with real and anonymous identifiers in a separate, password protected drive, and
- stored audio recordings as well as other digital documents on a secure server.

Limitations

There are a few limitations when completing this type of qualitative research project and when applying the results of the study. First, this study included only a small number of perspectives at each institution. While it is true that I pursued interviews with individuals that oversee large functional areas in the institution as well as individuals who work "on the ground" on a day-to-day basis, the study is limited to the experiences and perspectives of these participants. In some cases, individuals who were key to change

process at either institution were not available for interviews which left potential holes in telling the overall institutional story and describing the sensemaking process.

A second limitation is that protection of participant confidentiality at Green and Valley sometimes meant that I used more general descriptions in the cases rather than providing detailed characteristics of participants and institutions. Confidentiality likely allowed for increased transparency from the participants, but it also limited my ability to discuss certain details and context in the findings. A study conducted without the promise of confidentiality may have allowed for the inclusion of greater depth and detail in the case studies.

Chapter 4: Case Results

According to Merriam (2009), case study research involves "an in-depth description and analysis of a bounded system" (p. 40). Multi case study involves comparing and contrasting cases in order to draw out themes from the data utilizing research questions and theoretical framework as a guide. Based on best practices of multi case study methodology (see Stake, 2005), I first present extensive narratives of the two cases' efforts to accommodate community level ethics. In Chapter 5 I will compare these cases by applying sensemaking theory which will allow me to draw out understandings from my research questions (Stake, 2005). Utilizing the constructivist approach characteristic of both the sensemaking framework as well as the multi case study methodology, the case narratives include extensive use of the interviewees' words so that analysis and meaning can "rely as much as possible on the participants' views of the situation being studied" (Creswell & Creswell, 2018, p. 8). Each university is placed within its unique set of historical and economic contexts as those factors guide participants' understanding of the phenomenon as well as interpretation of the data.

Green University

Background

Green University is a public, not-for-profit, comprehensive research university classified it as having "very high research activity" (Carnegie Foundation for the Advancement of Teaching, n.d.). Its flagship campus is located in an urban area in a mid-sized city in the United States. All further references to Green University are referencing this flagship campus. It is ranked among the top 50 universities in the National Universities category in the *U.S. News & World Report* rankings (n.d.).

Green University is also ranked as a top institution on *Washington Monthly's* National Universities list. Since 2005, *Washington Monthly* has served as a ranking system that measures the degree to which 4-year degree-granting institutions "contribute to the public good" based on the measures of social mobility, research, and promoting public service rather than the *U.S. News & World Report's* measures that are more indicative of "wealth, exclusivity, and prestige" (Washington Monthly, n.d.). In order to be ranked on this list, colleges and universities have to meet four criteria: at least 20 percent of their students must be Pell-eligible, a graduation rate of at least 50 percent, a graduation rate that meets or exceeds what would be expected of the school given the number of admitted low-income students, and they must have a loan default rate of 10 percent or less. According to the magazine, "The Monthly's rankings are crafted to push institutions of higher learning to be engines of upward mobility, scientific progress, and democratic participation" (Washington Monthly, n.d.). Due to its overall reputation for highly ranked academic departments, internationally renowned research programs, and commitment to serving the public good, Green University is a highly regarded national university and has high demand for both its undergraduate and graduate programs.

In addition to its position in the rankings, as a public land-grant university, a central tenant of the Green University mission is its devotion to the pursuit of the public good. It has a long tradition of being deeply connected to the importance of life outside the classroom and research labs, ensuring that academic life across the board incorporates an understanding of the greater impact of the work of the university. Although all public institutions claim a certain devotion to the public good, Green University's commitment can be evaluated by metrics such as the number of students who volunteer, number of

students who register and engage in elections, number of undergraduate and graduate students entering into public service careers each year, and amount of research dollars committed to projects with public impact.

In addition to these measures, Green University invests in campus-wide support for the growth and development of faculty, staff, and students (undergraduate and graduate alike) in the areas of community, civic, and public engagement. According to one participant, historical funding choices made by the state have positively influenced the institutional capacity to invest in community-engaged practices (Eve). Another interviewee claimed Green University's status as a land-grant is a hallmark of the institution and rivaled by no other. According to this participant, the people completing community development work through Green's extension services are "off the charts amazing, in their ethical standards as well as their practice" (Lou).

Historical Structure of the IRB at Green University

The IRB at Green University has undergone several structural changes over the past 30 years. Several participants had a long enough memory of the institution to recall that more than two decades ago, IRBs were set up through colleges or schools:

> Before 2000 it used to be that whatever school or college you were in, or whatever program you worked with, you would go to [that] IRB regardless of what kind of research you were doing, and that led to some interesting interpretations of research. (Kathleen)

This meant that if researchers were conducting studies using methods outside the norms in their discipline, the reviewers often didn't have enough knowledge to appropriately review protocol. Because of this, around the year 2000, the IRB was reorganized into two separate offices where the goal was, "to route people to the appropriate committee that has the expertise to review" (Kathleen). However, this

arrangement presented a different type of confusion for researchers about where to send their protocol:

> The health sciences IRB and the minimal risk IRB actually are within one office…and [the Social and Behavioral Science IRB] has a [different] reporting structure…We are unusual amongst many academic centers, in that we do not have a central office that oversees IRB…So one of the things that may be a challenge for researchers is, "well, which IRB do I submit my application to?" (Kathleen)

Internal Pressure on IRB

Over time, several campus constituents put pressure on the IRB to reduce this lack of clarity. For faculty, their frustration with the process stemmed most prominently from the amount of overall time it took to review their research protocols. One previous IRB staff member pointed out the way this pressure impacts staff reviewers:

> I just can't emphasize enough how much pressure is on the IRB, and I think it's not just [Green], it's universal to, to reduce burden, and there's a lot of anger when things get hung up. Generally people who work at IRBs really do want to make things work…But sometimes it's not a completely clear path. And there's a lot of gray area, but [IRB staff] do have that idea of like, "Hey, we're on the same team", but faculty don't necessarily feel like that. They think it's just, you know, this IRB is just trying to slow me down. (Amy)

Another IRB staff member described how the time it takes to review protocol is sometimes out of their control because of the need to seek approvals from others on campus and to collaborate with other offices to gain final approval:

> As an IRB, yes, we're the ones approving it. But you can imagine all the other things we have to consider…like campus policies…like our guidance. If it's cancer research, they have to go to the cancer center review committee…or if it's VA Research, Veterans Affairs has their own research and development committee that sometimes requires additional modifications on top of what we just conditionally approved. So it's super complicated. (Ashley)

In addition to the frustrations IRBs feel from faculty, expectations from campus leadership at Green also plays a role in pressures on IRB review. One participant

described how the institutions' central identity as a nationally and internationally recognized research institution shows up in expectations for the IRB to ensure high quality research review. The importance of their status and research rankings leads institutional leadership to keep a close eye on the research operation:

> We obviously have a really strong research program here…We're one of the top six or top eight research institutions…the Chancellor holds us accountable…and has had things to say about human subjects research. When we dip [in rankings]...[the Chancellor] has stuff to say about it. (Ashley)

External Influences on IRB Operations

In addition to internal pressure, several participants described external influences on IRB operations. One of the most obvious influences are the federal policies and agencies that guide and mandate the review of human subjects research. One participant noted, "We just have to follow the rules…" (Ashley) and another offered historical context on IRB response to federal agencies that control research review regulations:

> We've been running scared for a long time because the federal agencies, especially in the mid 90s, were shutting down institutions because they felt IRBs were not making the right determinations, or not being as thorough as possible. (Kathleen)

This sense of fear and the expectation of high standards of quality research review was not unique to Green University. In response to a need for assurance of quality review, in the early 2000's, the Association for the Accreditation of Human Research Protection Programs (AAHRPP) was founded. Within five years of AAHRPP's founding, Green University submitted their first application for accreditation as a way to offer assurance to those on and off campus that they were holding themselves to the highest standard possible. According to one IRB staff member, AAHRPP accreditation is "the gold seal of excellence for Human Subject's Research Protections…it means a lot to the

public" (Ashley) and Green has retained their accreditation status with AAHRPP since their first application.

IRB Compliance Role

These multiple pressures on the IRB for timely, quality, and accurate review determinations lead the IRB at Green to see themselves in a compliance role at the institution, while remaining cognizant of their role in ensuring the very real concern of protecting research subjects. One IRB staff member described it this way:

> If you talk to some faculty, they would think it's a lot of bureaucracy. But…we are a compliance institution,...like who likes the IRS, right?…we're just going off of regulations, we're trying our best to hold ourselves to a high standard and protect human subjects. There's just a lot of layers we have to take into consideration. (Ashley)

Additional Frustrations for CBPR Research Teams

At Green, CBPR researchers were no less frustrated than other researchers with the burden of the IRB process. In fact, lack of understanding of CBPR protocols led to even more disruptions in the review process. The separated structure of the IRB was particularly confusing for CBPR researchers, especially when research teams included cross-departmental collaboration:

> CBPR researchers were stuck in this no man's land of like, "I'm a faculty in the health sciences, I'm talking to patients and families, but the health sciences IRB doesn't seem to recognize much about this kind of work or the approach, they don't have experts on hand, they're kind of a little lost. And then you've got folks on the behavioral, social sciences [side] who want to do work in conjunction with health science professionals, and in health sciences settings, like long term care, primary care, and they're struggling. They were operating in two distinct entities. (Eve)

One of the most frequently misunderstood parts of CBPR research was how to handle community partners who also served as co-researchers in the process:

> So my experience was, in those early days [20-30 years ago], a lot of tradition and usual practice coming from an institution with a long history of basic science, some clinical sciences. But we were at the front of some of the larger community engaged projects, whether they were CBPR, or some variation…So any researchers doing community engaged work had this additional hurdle of like, neither of these [IRBs] recognized community partners. In the IRB world, it's like, they're subjects. They're not part of the collaborative team…IRBs were and continue to really struggle with the distinction. You had to find the IRB members who were curious, willing to talk a little bit about what you were trying to get to and then almost come in from the back end for a very long time. (Eve)

Misunderstanding CBPR research in this way often led to inaccurately determining the protocols as human subjects' research rather than being considered exempt from further IRB review. A major benefit of a study being deemed exempt from IRB board review is that it is often reviewed and approved more quickly and thus, researchers can move forward with their study without the full IRB meeting to review the protocol. Often CBPR protocols were sent to full board review even for studies that presented minimal risk to participants. A participant with experience supporting CBPR faculty preparing IRB protocol shared:

> There was a lot of discomfort with exemptions for a long time. It was like you had IRB's mistakenly trying to make it human subjects research, instead of looking at the regulations. It was very rare to have exemptions. They were hard fought. (Eve)

Overall a lack of understanding CBPR protocol led to increased review time and burden for CBPR researchers at an institution with an already highly scrutinized IRB process.

Unintentional Impacts on CBPR Review

Pre-Review Process. For many researchers, including CBPR researchers, concerns abounded regarding the ability of Green's IRBs to effectively review their research protocol. Acknowledging that IRB members do not always have the expertise to

effectively review all research protocols, Green University implemented a pre-review process. This process decreased the average time for reviews and increased the IRBs ability to understand the nuances of many research protocol:

> The way we do it now is faster…the pre review would mean that it goes to a staff person who's very knowledgeable, and that staff person is going to go with a fine tooth comb through the application…to spot regulatory or ethical issues that might be deal breakers for the IRB, and try to address them…it's unfortunate, but it's true that you kind of need to know how to present your research the IRB… staff reviewers can help with that to some extent and say, I don't get your research, can you explain this in a different way because if a staff reviewer doesn't get it, the IRB is not going to get it. (Kathleen)

This positively impacted CBPR researchers since staff reviewers with more expertise in the areas of qualitative research and community-engaged practices were often routed these protocols. One study participant was one of the individuals who received CBPR protocol while she worked at the Health Sciences IRB. She reiterated the need for additional expertise when reviewing CBPR:

> A lot of projects would get funneled to me because…I was much more interested in the qualitative side of things and an interpretivist paradigm and had worked in the human services sector on the ground. That was just more of my world and I felt comfortable there. There was obviously a need for someone with a background more like mine, because I was able to understand the write ups a little bit more…Sometimes other reviewers might look at something and say like, this isn't even research, what are they doing?…I think that staff level review really provides kind of an important translational element to explain cross talk between a board of primarily physicians and a research team that wants to do something very different. (Amy)

A previous IRB Director also emphasized this need to “translate” CBPR protocols, especially in the 2000’s due to the newness of the approach:

> One of the realizations we've had is that a lot of the community-based research is just growing, which is an exciting, wonderful thing. But one of the things that is difficult for community-based researchers is either this might be some of the first times doing IRB reviews, or they might be doing something slightly different than before and…they need kind of a translator. (Kathleen)

This participant expressed a desire to "formalize" (Kathleen) this role on staff and create a community-based research liaison position, but to date, this has not been accomplished. The staff reviewer who was routed CBPR proposals noted that their position was still "more about individual level risk and harm…and the regulatory framework" (Amy) than it was about community-level ethical concerns. Today, there are staff reviewers who have slightly more experience than others with CBPR, but there is still not a formalized position.

Changes to Exemptions. More recently, a revision to the federal regulations created a major shift in the way CBPR protocols are reviewed at Green. In 2017, the Office of Human Research Protections stated that the revisions ensured "that the oversight system does not add inappropriate administrative burdens, particularly to low-risk research. It also allows more flexibility in keeping with today's dynamic research environment" (Office for Human Research Protections, n.d.) A key change to the regulations was a broadening of the types of research that qualify for exemption. A current IRB staff member described this impact of this change on CBPR researchers:

> The Common Rule, you know, the human subjects regulations, has changed since 2019. We are [now] exempting a lot of community based research because a lot of community based research that we see are just surveys and interviews, focus groups, perhaps that fall under those [new] exemption categories…prior to the revised Common Rule, when we weren't exempting as much, it was an extra layer of burden for the researcher, but these added flexibilities with the exemptions now sort of right, take that burden off of the study team, and we can move applications through and approve them a lot faster. (Ashley)

A past IRB staff member reflected on the flexibility of the new exemption regulations:

> The exemption categories are so methods oriented, that if the method fits, almost you can make it fit into one of the exemption categories. Like if you receive a study that, you know, regardless of who they involve, and how much community

> involvement there is, if the actual data collection is really more, you know, just interviews, then that meets an exemption category. So that was sort of the main driver of things. (Amy)

Implementing an internal pre-review process and responding to the external changes in new flexibilities for exempting research were two changes that unintentionally had positive implications for the speed and quality of CBPR protocol at Green University.

Protecting Community-Level Ethical Concerns

As research on the community-engaged research spectrum began to increase, IRB staff and IRB members were confronted with new challenges and considerations unique to CBPR research. Since that time, prominent concerns at the Green IRB have been obtaining site permissions from the community as well as ensuring that non-academic researchers are trained in the ethics of research. In the beginning, just like the addition of pre-review and the impact of federal exemption categories, addressing these concerns was motivated by attention to ensuring high quality data collection and staying in compliance with federal regulations. Over time, and with influence from individuals engaged in planning CBPR research designs, the IRB began to seek more community-centered approaches to these ethical concerns.

Site Permissions that Address Community-Informed Consent. At Green University, a long-standing requirement for any researcher submitting community-engaged protocol is to receive approval from their off-campus research site to conduct research. This indicates to the IRB that community sites are aware that the research is happening and approve of the particular form and function of the research taking place at their site. One participant indicated that the origin of this requirement had to do with

ensuring there was buy-in for researchers in clinical settings with concerns for ensuring the collection of high quality and ethical data:

> So it was almost more from a managerial perspective of making sure it's okay to, you know, kind of disrupt clinic flow…that there actually is support there. But also just, to sort of build confidence that the research can be done, right. Because if you don't have that kind of buy-in from a site, then it could affect how the study goes, which in turn has implications for the risk benefit of the people involved with it. If it's going to be a bad study with bad data, then why even do it? (Amy)

In addition to site permission requirements for hospital settings, another IRB member articulated an understanding of community autonomy in community-based groups, even when those groups have their own formal approval processes. In these settings, community-autonomy is a bit more nuanced, and requires more than a simple agreement to participate. The important role of communities in protecting themselves from community-level ethical concerns or "group-effects" was acknowledged:

> It's critical for a lot of research, and especially in community-based groups [where] there are group effects…rely on some sort of review of local context. So for example, for Native American research, even if it weren't required, we would want review by a local ethics group or their equivalent of an Institutional Review Board, because we would be hoping that those issues will be addressed, And what we're looking for is not just regulatory evidence that they did their duty, [to confirm], "Yes, we are allowing this research to go forward in our community", we [also] want the community to tell us what they think should or should not go into these projects. (Kathleen)

IRB staff members also explained that the site permission requirement is intended to ensure that smaller community organizations without formal approval processes or structures have a chance to present community-level consent. One IRB staff participant explained it this way:

> The first question [I ask CBPR researchers] is, "Is there an IRB or an ethics committee or some sort of an approval process at the institution that you're working with?" And very often it's a community based organization that doesn't have one but,…at minimum we want a letter of support…And that letter should clearly indicate that they understand exactly what's going to take place at their

> site. Not just three sentences that says, you know, I understand you're going to conduct research here. (Anne)

In these cases, IRB staff did not indicate requiring a process for deciphering who in the community is the most qualified to offer site permission statements. That responsibility is still left up to the research teams to decide. Regardless, the blanket requirement for site permission that protects community autonomy, particularly at a school with a large and complex research ecosystem, is quite rare. A previous IRB staff member noted that any type of site permission requirement "definitely falls outside of the [federal] regs" and is "definitely…a local requirement" (Amy). Ensuring that the community has a voice in the overall permission for research to occur indicates that, at least in a small way, Green's IRB recognizes a community-level ethical concern of CBPR.

Human Subjects Training for Co-Researchers. In addition to community-engaged research initiating the need for site permission requirements, at Green, it also revealed a need to carefully decide if non-academic partners are engaged in research activities. Being "engaged in research" includes anyone who is, "essentially, talking to people in a protocol prescribed way" (Kathleen). This is important to IRBs, because federal guidance requires several additional steps, including "that the person engaged in research needs to take human subject protection training" (Kathleen). Because this denotation puts extra burden on study teams, this IRB staff member noted that, "making the call about whether someone is engaged in human subjects' research or not is one of the hardest questions we have" (Kathleen).

For many years, IRB staff at Green's IRB have recognized the challenges this presents to community members because the training is "internet-based, it's complicated,

it's highfalutin" (Kathleen). Another IRB staff member acknowledged these concerns, while also reiterating the importance of ensuring that all researchers have appropriate human subjects' training:

> The training issue is a huge issue. We're very aware of it. And we're always trying to work on it. And yet, I will say that I do not want anyone that is truly engaged, that does not have some kind of training. I mean, there's sensitive data, there's data security. This is a research project, not just something I'm volunteering for out of the good of my heart. So I think there are certain elements of the training that no matter what your educational level, no matter what your background, have to be there. (Anne)

On one hand, it is good that the IRB is ensuring that community-partners are trained in research policies and procedures as it addresses ethical concerns related to community beneficence by ensuring communities benefit in some way (e.g., training) through partnering in the research process. On the other hand, for quite some time, the requirements from the IRB to take CITI training through the same mechanisms as university staff and faculty added extra burden to CBPR partnerships. Several participants gave specific examples of these additional burdens. A CBPR faculty mentioned challenges related to access to the training:

> My research specialist, who is also from the community, came to me and said, I don't think this is gonna work. I was thinking at that point, you know, we're gonna find, like the library, and then we're going to set up computers, and we're going to be there to assist them with any questions they had. We did that for the first proof of concept study and it was a total disaster. It didn't work out. It was too hard. (Naomi)

Another CBPR faculty member shared concerns about training older adults with limited computer skills. They explained, "We had one guy who was like, he was like 85 years old, he hadn't taken a multiple-choice test in six decades" (Lou). Additionally, a community partner noted that the training was too complicated for English language learners:

> In the past, our staff would sign up on the website and try to do the classes in English [but] the wording was too complicated and didn't apply to some [community researchers]. So they weren't passing it…and it delayed the start of the project, So that was a frustration that bubbled out. (Ray)

In light of these concerns, IRB staff allowed research teams to develop and initiate their own trainings to deliver to their community co-researchers as long as it was approved by the IRB first. However, IRB staff admitted that this also put "extra burden on the research teams" (Kathleen). Another way that the IRB tried to help alleviate this burden was clarifying with research teams if and when community partners are truly co-researchers:

> We are often trying to work with research teams to figure out how the collaborators are not engaged in human subjects research. Not because we want to cheat on protecting human subjects. But we would like to avoid some of the complications that arise. (Kathleen)

However, this was not an option for study teams interested in co-delivering interventions with community partners. To CBPR study teams working with community researchers, the flexibility to provide accessible training didn't become straightforward until recently. One participant described how the IRB decision in Spring 2022 to approve a CITI training specifically designed for community partners relieved much of this burden from research partnerships:

> Now more recently, it's quite different. I just successfully got our campus to formally adopt and make visible their adoption of [another institution's community partner CITI training]. You know, we are so late in the game of doing that formal embrace. It doesn't say that there aren't people here doing sophisticated work in that arena. But like we're so slow in the infrastructure to really make it easy for people who come onto campus to find that stuff. And that's just an IRB saying, we've reviewed the certification, it appears to meet the standards of CITI [training]. (Eve)

The openness and flexibility of Green's IRB shows their willingness to problem solve an issue that made the IRB process unnecessarily burdensome for CBPR study

teams. However, it took advocates outside the IRB to initiate change and understanding that truly simplified the research training process for community partners.

Limits on IRB Purview

At Green University, IRB members articulated at least some responsibility for two issues indicated as community-level ethical concerns of CBPR: that some sort of community consent should be obtained for research that happens both in and with community, and that community members engaged in research also need to be adequately trained to participate in research that involves humans. At the same time, the data showed that members of Green University's IRB staff have, over time, articulated that there are limits to IRB review in considering and managing the community-level ethical considerations specific to CBPR protocols.

IRB members articulated two ways that the federal regulations put limits on their ability to consider risks and harm to communities (community beneficence). One IRB staff member explained that IRBs are explicitly advised by the federal Office for Human Research Protections (OHRP) *not* to consider the long term, community-level effects of research:

> The regulations have IRB look at the risks of subjects, but very specifically say, I'm going to quote, "The IRB should *not* consider possible long-range effects of applying knowledge gained in the research, for example, the possible effects of the research on public policy, as among those research risks that fall within the purview of this responsibility". Looking at the IRB guidebook that the OHRP puts out, it says, you know, research might have adverse consequences for communities, but it's really not the IRBs responsibility. And that sounds like an ironic statement, because it's the very Western idea of, we're protecting an individual, never mind the group. (Kathleen)

Another IRB staff member expanded on the ways they are limited in considering community beneficence and guaranteeing that the community at large will gain

something from certain individuals participating in a research project. This IRB member explained that definitionally speaking, especially in minimal risk research which CBPR tends to be, direct benefits cannot be guaranteed even to the individual, let alone the community:

> That's like the number one thing that we have to weigh is the risk benefit ratio. Now, I will say though, in minimal risk research, there isn't much risk benefit ratio. Typically a direct benefit can't be guaranteed, it's not a tangible benefit. This isn't like a drug or device trial, where you can actually see a direct benefit...There's still risk in minimal risk research that we take into consideration when we're reviewing any sort of research, even if that's a community based research project, [but] in minimal risk research, the risk benefit ratio is not something we have to worry about. (Ashley)

This participant went on to say that staff reviewers are still concerned about small risks that come into play but specified that due to the nature of the regulations, they have no mechanism to require researchers engaging in minimal risk research to ensure that there is a benefit for individuals or communities partnering in research projects.

Beyond limitations from the federal government that restrict IRB influence on any given research project, IRB staff participants also described the ways that institutional policy as well as research teams ultimately have more responsibility to protect the ethical concerns of CBPR. One IRB staff member conceded, “IRBs are only part of the protection of human subjects. In some ways, I wonder how important our role is some days” (Kathleen).

One example of the influence and control of institutional policy was given related to community autonomy and the dissemination and ownership of data. The previous IRB Director reiterated that although IRB members might be aware of and even feel obligated to address these as important ethical issues, they are outside of their sphere of influence and decision-making:

> Some of the [ethical] questions we had to think about [were], "What do IRBs do about dissemination of results?" "Who owns the results?" Not IRB purview. It's an institutional purview issue. And what does this institution think about that? And quite frankly, there aren't statements out there. But this is also another reason why, if IRBs are not supposed to be thinking about these issues, (doesn't mean that we don't, to some extent) who does? There have to be mechanisms beyond the IRB. (Kathleen)

Beyond institutional policy mechanisms that can help to clarify the university's stance on protection of community-level ethical concerns, the important role that research teams play in these protections was emphasized:

> It's really the researchers that are the ones that are protecting human subjects. And if researchers don't know what they're doing, or what the important tenets of the protection are, then that's where we run into trouble. And it's really absolutely critical that research teams have the infrastructure in the training and oversight of their personnel. (Kathleen)

In addition to institutional leadership and research teams, this IRB member also called upon resources available at the state level as a way to craft an overall solution to concerns regarding community-level protection:

> It's one of those things that's beyond the IRB [and] I think the university and others have an obligation to try to build this capacity, because we have quite an amazing set of resources in the state…and a lot of dedicated people. But we just need to make research better and better monitored, and better educated people about it. (Kathleen)

These calls to action came not without a reminder of the IRBs willingness to participate in problem solving:

> The IRBs would be happy to be part of the discussion, but we are not going to be the ones leading that discussion. Not because we don't care, but [because] we've got a bit of [other] stuff to deal with. (Kathleen)

Considering this strong stance from the IRB, it is unsurprising that some individuals at Green University find that "the IRBs don't actually offer much in the way of ethical, practical advice" (Eve) for addressing ethics related to CBPR. A staff member

at Green who supports CBPR researchers described a perceived understanding of the IRB's narrow scope of influence:

> My sense is that there's still a lot of traditional flavor of "We're here to look at what you give us [and] do an interpretation by the regs". I do think they've made a lot of strides …there have been improvements, but it's not stuff I'm recognizing happening in day to day practice. I think there's a lot of things that derail practice into ethic areas that the IRB is never going to be a part of or even know about…I feel like the IRB review is sort of like "it starts here and it ends here". And whatever is going on over on these other sides…Why would they feel obligated to be concerned with that? (Eve)

One faculty member described how a perceived lack of care regarding their participatory methodologies led them to de-emphasize those portions of their research in the IRB proposal:

> Our IRB doesn't care if you're working with an organization. All they care about is that you follow all the rules for research. I don't even tell them I'm doing community-based research. Just, here's the research project. We're going to interview these people. And here's how we're going to store the data and here's how we're going to recruit them. And here's the informed consent and just like any other research project because they don't care about the participatory part. (Lou)

Ultimately, however, participants admit that in the face of narrow IRB review, one agreeable solution would be to add transparency and clarity to their process and responsibilities:

> I'm not even sure I know what the [IRBs] obligation is…But if your examination is only what's provided to you, and doesn't accommodate a review group that is very diverse or knowledgeable about CBPR, I just wonder how valuable is it? Or is it more of a liability mitigator? Right, like that's what they are, but then let's recognize it and be transparent about what they're not doing and not blame them [for] their scope, and [ensure] that somebody picks up from here to make sure things are tended to. (Eve)

To reiterate the sentiment of a past Green IRB Director, "If IRBs aren't supposed to be thinking about these issues…who does?" (Kathleen). From the IRB's perspective, there is a role for IRB to play in protecting community ethics, but federal regulations and

policy, use of state funding, institutional leadership, and research teams all have responsibilities for protecting them, as well.

Influences from Outside the IRB

Over the last 10-15 years, participants shared several ways that entities outside of the IRB have shown support for research involving communities. Although it isn't specific to ethical issues, this support signals to members of the Green community that community-engagement is an important part of the ethos and worthy of investment by the institution. One example is protected state funding for community-engaged work. A participant described this arrangement,

> When [a prominent insurance company] went from a public to a private insurance standing, our state demanded that some of its profits be turned over to public health work [and] our insurance commissioner oversaw the distribution of those profits into two endowments, one at each of our medical schools. And because they've been so well protected…we've been able to maintain that endowment and those monies shore up a lot of community engaged work, that wouldn't be happening at the pace that it happens [at Green] without those endowments. (Eve)

Another is money set aside by the Chancellor's office with aims to develop meaningful relationships in and with community:

> Institutionally, campus has invested in standing up spaces in community meant to support community campus partnerships, not exclusive to research but inclusive of research…and that is coming from Central Campus Chancellor's office, not an investment made by a particular research team or research center. (Eve)

One participant acknowledged the role that national conversations, including priorities initiated by federal agencies, have played in initiating discussions about community-engaged research:

> So just like right now, coming off of COVID and George Floyd, you have an incredible spotlight on all things DEI and health equity…there are drivers [related to community-engaged research] that did the same. So some of it was where NIH was putting its dollars. Some of it was people sick and tired of being sick and tired of research that wasn't affecting disparities…there were drivers fiscally

> there's drivers, clinical trials, there's drivers with industry and the ebb and flow of that, …there are lots of things…these things tend to come in cycles…So there's different people who come in and out that sort of have their agendas and their interests and you learn to appreciate the long view. (Eve)

Several participants acknowledged that the nexus of state and national conversations with mid-level leadership ready to prioritize community-engaged work led to the development of several departments and centers around campus that support high quality community-engaged practices through faculty leadership, coursework, training programs, or community-advisory boards. The director of one of these centers sees her role on campus closely aligning with the protection of multiple intersections of the ethics of CBPR:

> I think my experience is rather specific that way…20 years ago, because a leader in the Dean's area, so a faculty with seniority, secured the first NIH grant from the Minority Health/Health Disparities Institute. And I came over as her first administrative person…and I think, because my arrival coincided with the schools having to address minority health, health disparities, it made a lot of these things - CBPR, community engaged work, ethics, status, race, racism, it put those things right at the ready. So I wasn't necessarily having to make that fight or make that argument. It's like, "You guys already landed a grant. And this is what it says has to happen". So there was a little bit of momentum that way. (Eve)

Part of the influence and success this Director has had in developing conversations and making change regarding the ethics of CBPR rests on this momentum and institutional readiness to address issues related to health equity. There are at least two other factors that also play an important role in her advocacy efforts. First is her long-term commitment to the field which includes 30 years of dedication to Green University. While her time at Green has included work in multiple departments, she has always been involved with community-driven research. Her longevity at the institution and knowledge of CBPR best practices have positioned her to influence college and university-wide change:

> I do have an opportunity to set policy and practice on our end of campus but also at the campus level…I'm pushing with others here at [Green University] to really reinforce [for] future investigators sort of being tasked with, "Have you thought about this?" (Eve)

Another reason for her success rests on her collaborative approach to leadership. According to this administrator, building a network of relationships in and outside of the institution is critical to success in a decentralized environment:

> In order to perform effectively in a place like this, you've got to create a network of professionals. So it's me connecting with the other administrators of departments of centers and institutes…finding those common strategic values and objectives and just being able to say…Do you want to go in on this together? Yeah, but you only get things done at this campus through that kind of background effort.
>
> And then over the years, mentors of mine moved into leadership roles… And now I'm like hitting with both barrels, like, let's go, here's this policy that needs adjusting. And I'm not alone, I have a lot of great colleagues…we have a lot of investment in community engagement. The challenge here is it's such a big campus, it's really hard to coordinate. And so, you know, staying informed, staying connected, while you're trying to kind of get your day to day done is where the push and pull comes. I don't have all the answers. I have a very unique set of circumstances on this campus, but it's because I'm connected to those national conversations that I can bring models from [other institutions] or grab a policy from over here. So I just very quickly give credit, you know, say, "Hey, I heard this what do you think?" And then there might be some uptake? That would be different than a single woman working, you know, in a sole silo role. (Eve)

A Hub for Collaborative Action

Today, this Director runs a Center with the explicit purpose of building relationships between faculty/staff/students within Health Science departments at Green and communities across the state to improve health equity outcomes through teaching, research, and service. Several strategies driven by this Director and the Center have increased growth and understanding of the ethics and best practices related to CBPR at

Green University. The first is related to collaborative faculty development on CBPR best practices.

Collaborating with Faculty. According to the Director of the Center, many faculty at Green, especially junior faculty members, are often not being departmentally advised on matters related to the ethical design of CBPR studies:

> I think Junior folks are sort of shown the [IRB] application and they fill it in. And maybe there's a little bit of oversight, but like, again, who's on that team, thinking about the scholarship, but also the ethics related to how you partner, how you recognize contributions? (Eve)

To fill the gap in understanding of the ethics of CBPR, the Center provides support for faculty and research teams interested in learning more about designing CBPR projects. A form on the Center's website confirms that individual consultations focus on getting to know the faculty, learning their motivations, and understanding the characteristics of and outcomes related to their research project. In this way, Center staff are modeling the collaborative way they hope faculty would build relationships with community:

> My approach is very much: So who are you? What are you doing?…I do a lot of background work before I talk to people, just like I would do going into any setting I wasn't familiar with. I would be really seeking to grow my network. And also do some checking about like, who knows this person? Where do they come from? What might they bring from experiences in the past. (Eve)

A main goal of these conversations is to set the expectation to think through the entire research project plan, and how they might incorporate community in all aspects of the project:

> [In consultations] we go all the way through to talking with investigators about publication, or even before that when you get to data analysis, or the partners part of interpretation. What do you mean? Well, what I mean is when you run your numbers and come up with your findings, there's another stage of interpretation. (Eve)

While the director admitted that she'd love to say all of the faculty they speak with are ready for this "ideal state called CBPR" (Eve) more often the faculty she meets with are just beginning their journey on the community-engaged research spectrum and may not yet have community partners in mind or even any idea of how to go about building an ethical partnership. In these instances, the opportunity for sensemaking of the ethics of CBPR comes through meeting faculty where they are at in the process:

> We are getting investigators and scholars, students, scholars, and faculty at every stage, some of them need rescuing, they've started something and realize they didn't set up their budget to compensate, or they don't have people on their team to do certain skills, they just didn't have the necessary context around them when they framed things to be kind of planning ahead for that. So we do a lot in our center of technical assistance. (Eve)

One specific example of technical assistance that supports faculty in sensemaking of CBPR ethics is that the office provides agreements that faculty can adapt to start conversations and open the door for trust and relationship development with community partners:

> Our center uses an agreement that you can…attach an addendum to make sure everybody's abiding by the same rules and covering the same practices and principles…it's got all the required elements. And even if you're not passing money back and forth, you should be having conversations with your partners on all these topics: data sharing, dissemination… (Eve)

Another support the Center offers is pairing new CBPR faculty with experienced faculty mentors in order to provide guidance that may be lacking from their own departments. One faculty participant, who now collaborates with the Center to deliver trainings to their colleagues, describes her experience working with a CBPR mentor:

> A program that is run through the Center…was mentors who have done this for a long time sharing their wisdom, sharing how to do this work, sharing how to do this in a way that makes sense…And so I kind of evolved also my continuum of how to actually do this in high quality ways…And I'm still continuing to learn, too. I also got to learn about like, don't do an ask during your first

> meeting…spend time to develop that trust and build that relationship before doing an ask...When I first started doing this work … there were ethical concerns that, to be honest, I didn't even know how to address…And now I know what to do and how do I involve the community in…my work. (Naomi)

Collaborating with Community. In an ideal scenario, once staff from the Center have an opportunity to get to know faculty and their priorities, they introduce faculty to community partners utilizing their Research Ambassador Program. According to the Director, the main function of this program, "is to be this platform of matchmaking…finding things that the community prioritizes that they would like to partner around or get from campus" (Eve). Several key features highlight how these partnerships with Research Ambassadors (RAs) address issues related to community justice, community beneficence, and community autonomy.

Research Ambassadors and Community Justice. The Director explained the origins of this idea and what makes it truly unique. Not only does the university pay individuals designated as community knowledge holders to advise faculty and research teams on developing projects, but the community staff members also get to work in and with community and community agencies rather than being situated on the university campus. According to the Director, the idea came from a faculty working with Indigenous populations:

> The origin [of the Research Ambassador Program] was from one faculty who did a lot of work with tribal partners. She was very CBPR oriented. She was explaining some of the challenges of working at a distance from some of our tribal partners and explained the incredible value of having ambassadors on site in community. And she was one of the first people who began employing people in community [to assist with research], not sort of deploying people up from campus to community.
>
> And the tribal community and sovereign nations were like, you can employ our person through us, not through you. Which was [destabilizing] for us, right? Because we were thinking in a very inequitable way, and a very white

> supremacist way. "You'll want to be a [Green] employee. What an honor for you." And they were like, "yeah, no…but we'll take your money, you can invest in the concept, we agree with the concept." So it was very, it was like, so wonderful. And this would have been like 10-12 years ago. (Eve)

Building on this faculty's responsiveness to community preferences, and with support to spend university dollars to employ community members off campus, the Director replicated this structure in several other communities in the state. The Director acknowledged that this type of arrangement is atypical for an institution like Green, "that's really high-risk business for a university to give up control of the employee. But…it's the basis and foundation of CBPR and good principles around equity" (Eve).

Research Ambassadors and Community Beneficence. In addition to valuing community knowledge by offering full financial compensation, one of the community partner RAs described a core motivation to build an RA program in their community was consideration for community beneficence and the ability to build sustainable research partnerships:

> [Our organization] was growing like crazy, and the university [was] reaching out to us. But [faculty] come in, they do their research, they publish, and they go away, and we're left with nothing but a paper. So how do we sustain? So the conversation started from [the Director] well, why don't we help you build that structure inside where you will have an expert who's trained in research to be that voice, that connector, so you don't have to start over each time. And they can be at the table with the research team when developing the project, etc, etc. So it was based out of frustration and opportunity, I guess. (Ray)

Sustained partnerships also allow for reciprocal training opportunities, which is also a matter of beneficence. Through the RA partnerships, community partners are invited to: "educate researchers…so when they approach us for a research study, they already know a little bit about [best practices of CBPR]...because that's something that usually researchers don't get exposed to" (Emelia). Importantly, this training structure at

Green is set up not only to center community members as knowledge-holders, but also allows community partners to access and benefit from resources traditionally only accessible to individuals on campus. One community RA described this teaching and learning as "bi-directional learning" (Ray). According to this RA:

> This is where [Green University] has been very good. [They] invite us to the table when there are seminars, when there are workshops. We get to participate for free because we help them…or for a discount…and then I bring other community partners to also be a part of that…train us too, let us take advantage of things like that. (Ray)

Research Ambassadors and Community Autonomy. With a partnership foundation built on respect and sustainability, the Center leans on RAs to serve as community liaisons and gatekeepers who are emboldened to protect the community and assist in building research partnerships that truly incorporate community voice. One community RA described the program this way:

> [The Research Ambassador Program] was developed to create that genuine, that connection between the institution and the community in a respectful manner. Because having a Research Ambassador embedded in the community, it's something not so common, right? And it helps to kind of address ethical issues and to make sure that the community voice…knowledge…and background that Research Ambassadors have is present in every step. And [the partnership] definitely addresses specific ethical issues because we're kind of like the security guard of the research. Everything goes through us and we can collaborate with the researcher to make sure that the community is protected. (Emelia)

RAs who participated in the study named several ways that their role increases community autonomy by allowing them to build relationship with faculty and influence study design and implementation. Of central importance in this process is respecting cultural norms in their particular communities. One RA explained the difference between high and low context cultures and how the differences between the two influence research practice:

> Most research, it tends to come from the Anglo European perspective, from highly educated people who talk and interact in a different way than some of the cultures and communities that are being studied…Latinos, Asians, American Indians, African Americans, we're very high context communicators,...we put a lot of value on how something is being said, or this relationship that we have with you. I want to spend time getting to know you. Before we open up…move into business…the relationship is key.
>
> High context culture, like they tend to be more business, let's get to the point, make sure we get our money, I got my agenda to get through, right, I want to get to all my informed consent points to talk to you about so you can sign the form…tend to kind of see that the speaker might have a more educated or more informed… "we're more advanced or sophisticated. So we expect you to kind of respect the title" and focus more on getting the test done on time and move on…and that's okay there's no right or wrong… research has to be structured, it's got a format, there's IRB protocol, consent forms… (Ray)

And while RAs acknowledged that many faculty members have "come a long way" in understanding these cultural nuances, others' lack of cultural context, understanding, and respect creates ethical issues for the community partners. In these instances:

> Culture sometimes can slip past each other where somebody might get offended or misunderstand what the response was…So the research team has to understand that they have a different context on how their culture is and the science culture is, and it's not going to always jive with the community culture they're working with. (Ray)

One community RA explained a scenario where a lack of cultural context in developing data gathering strategies led to confusion and frustration from community members. When community study participants expressed a desire to have more of their family members involved with a study intervention, rather than re-designing the intervention to include these family members and re-submitting to the IRB, the research team simply let them participate. Unsurprisingly, this raised red flags for the IRB and as such, the next iteration of the intervention was even more restrictive, which led to skepticism from community members:

> When a research team approaches us,…they have to understand their role is they can only provide the intervention to the subject, right? Which is fine if it's clinical one on one type of thing. But a lot of community work you are here in the community, you've been in groups are family members. So that's why we got into trouble. [The research team] was allowing family members to sit in on the conversation or inviting them to the workshop…But they weren't enrolled. And of course, we get the pushback… "[We] come to a group and only the participant gets the incentive, but the other people don't? Hey, how come we don't get a gift card?"…So we start giving [gift cards] to everybody and let them sit in [on study interventions] and we got dinged. The IRB said you can't do that…
>
> [The next year community members say] "how come last year, all my kids were going to the [study] and only this kid can this time…you're not being fair", things like that. So when the research team is putting the project together, be sure to train and help that person understand…for this group, you can do that…the term fidelity means nothing to us, explain why better, and then be able to coach or give the researcher scripts on how to answer the situations that come up. (Ray)

In addition to the ways that cultural context impacts data gathering, another RA participants explained how researchers need to consider the importance of incorporating community voice in data analysis. Doing so is one way of ensuring that collected data is accurate and representative of community experiences:

> The ownership of what you discovered through research should be also accessible for the community…obviously not the raw data, but what it's gained from the research, usually those final thoughts or those final lessons learned from the research, I feel that…meeting with the community, having kind of just a deep conversation about what was learned through the research. I know that usually we include the community at the beginning of the project, like, oh, let's talk about how we should do this. And let's talk about, you know, what will benefit us what will benefit the community, and that's great.
>
> It's also important to kind of have the same meeting at the end and try to look at what happened and look at what we learn and what we can use in the future…that will not only benefit the community, but also can benefit the institution, right, because this could lead to more research. This could lead to another perspective…And it's always good for the researcher to have that perspective when they are trying to understand the data. (Emelia)

Changing Institutional Practice

Overall, participants agreed that the collaborative efforts of the Center have helped tremendously in facilitating ethical CBPR, however, several participants also pointed out ways that institutional policies and practice hinder progress toward protecting community interests. One faculty member explained the overwhelming challenge to implement a simple community celebration to disseminate research results to her community partners:

> So I think to some extent that the institution tries to support it. The barrier is sometimes there's just so much bureaucracy. I'll give you a good example, taking the results back to the community. A couple of years ago, I wanted to run a dissemination event…And then when it came to pay for it, we got some pushback, that well, you cannot use the money because it doesn't have a business purpose….And shockingly, I was told that we needed to craft a business purpose for the event. And so we went through all this paperwork that shouldn't be there, just because we wanted to take our results back to the community?
>
> Any other researcher would be like, Okay, that's it, I'm done. I can explain to the partners, I can explain to the participants, and…I'm just going to publish the paper and send it to them to read.
>
> Well, we didn't do that, we found a way to make it work. And so we had to change our invitation letter to the partners…it was so institutional, it was about policies, it was about the way money could be spent, or the way we could call what we wanted to do that was benefiting the community and the university didn't get it. Because it wasn't cut and dry.
>
> And I'm like, it doesn't work like that with community members…so unfortunately, we had to sort of dance to their tune and try to call it a name that was very academic, which is not what I wanted to do. I would have wanted to call it a celebratory dinner or you know, something that is informal and speaks to community language. (Naomi)

According to the Director, these types of roadblocks aren’t uncommon, and after a certain amount of time, navigating these institutional barriers began exhausting her and her team:

> We're spending time on work arounds instead of focusing energy in other places. That begins to be a pull from for me and my team and my colleagues away from things we want to be doing to correcting. You do enough of that and you're like, Okay, this is like that old proverb of, should we go upriver and see what's going to modify practice? (Eve)

For the Director, going "upriver" (Eve) included addressing specific ethical issues within the IRB that she encountered as frequent roadblocks for research teams. For example, she was the staff member that pushed the IRB to "make visible their adoption of [community-friendly research ethics training]" (Eve). But as time has gone on, she sees IRBs as less of a central focus for ensuring ethical practice of CBPR and turns now toward institutional-level responsibilities:

> Some of it is standing up and correcting some of these operational infrastructure, transactional pieces. So in some ways, like 10 years ago, I would have been like IRBs are absolutely pivotal. They are. To the conduct of research, the protection of human subjects. Absolutely. But a lot of work in the last five to 10 years has also involved this rapid infrastructure development in recognition of - we don't have our systems designed - IRB aside - to support practitioners, to support researchers, to support methods… (Eve)

From her 30 years of experience on Green's campus, she believes that administrative policies have not kept up with new forms of research that get in the way of good practice:

> It's the administrative areas that are segmented away from research and yet have huge impacts on the ability to do good CBPR because of delays, transactional problems, eligibility for doing work with the campus [such as] liability insurance of a certain amount… (Eve)

As mentioned previously by a Green faculty member, the transactional nature of fiscal policies are some of the most common policies that "disrupt or distort CBPR" (Eve). Examples of these disruptions include:

> Trying to pay partners for their time, trying to employ knowledge holders…you may want to utilize a community-based space, restaurant, or caterer in an effort to

> create partnership with an equity lens and we are not designed to do any of that. (Eve)

One important way that the Director helps others on campus make sense of the ethics of CBPR is by drawing on ideas from outside the institution. According to her, there's "quite a movement afoot nationally" (Eve) to define and describe how fiscal practices can have "huge impacts on the ability to good CBPR." Her involvement in national conversations made her aware of a research paper by Carter-Edwards et al. (2021) on fiscal readiness for community-engaged work and of models for effective administrative practice and policy from other universities. According to this administrator, she and others from the institution are "very much in conversation nationally in making recommendations up to the NIH around some of these issues" (Eve). In this way, she is influencing practice at a national level while also gaining new knowledge about ethical intersections of CBPR and administrative practice that she seeks to implement at Green.

Outside of the IRB, many offices across campus work to support faculty in improving their CBPR practice, including attention to ethical issues that go beyond what the IRB has determined as their purview. In The Center in particular, the Director has made huge strides in supporting ethical CBPR by expanding the Research Ambassador Program, supporting faculty in designing ethical research protocol, and serving as an advocate on and off campus for sound ethical CBPR practice.

Conclusion

Many actors on and off Green's campus have made considerable contributions to practice surrounding the ethics of CBPR. It is evident from the findings that participants believe there is room for improvement of institutional policy regarding the ethical

practice of CBPR. However, many participants have reservations on whether leadership at Green will prioritize community-level ethics. One participant acknowledged that while leadership would likely be receptive to new ideas, demands on resources could ultimately hinder more transformational change:

> It would be interesting to see where [a request for a community-advisory board for research] would land now, because on the one hand, I think, you know, sort of higher-level leadership would understand the importance of that, and what it could add, and all of that, but there's still a lot of competing pressure. (Amy)

In addition, division among participants remains with regard to the IRBs role in providing ethical guidance for CBPR protocol. As is obvious from the findings, IRB staff were clear in the boundaries with regard to review of community-level ethics. However, others see potential for more CBPR expertise during IRB review. One community partner described a desire to have IRB staff with more expertise:

> Or a form of structure, where they always will add staff or representatives that come from [a community] background almost as a requirement. So…the IRBs have that outside thinking, they'll bring those questions to light and challenge the researchers…To build the internal structure either in house with somebody [with] CBPR background, and hopefully representing, hopefully get some structure for community reps from communities of color to be there. (Ray)

A faculty member described a similar sentiment:

> I think it's hard for the IRB which has a bunch of scientists and researchers who are from biomedical research and social science research - all over the place, come together and think about these issues. And this is where a community level person or community membership comes into place to think about the community norm that community harm, going beyond that individual level harm, because that is what as a PhD - that's how you're trained. And so the composition of the IRB, it's not just putting one person, it's the diversity of the experiences in terms of the community, and also the numbers, because I think quantity matters as well. (Naomi)

While respondents may have concerns about institutional leadership and disagree about the level of responsibility each entity might have for protecting community-level

ethics, one thing is clear. Participants in the study believe that ideally, protecting community-level ethics "is a shared responsibility" (Amy) even if difficult at a large place like Green. Another participant described the same sentiment in this way, and acknowledged the importance of collaborative action:

> I can only see it getting better if it's a shared value the whole way through. Finding those common strategic values and objectives…you know, we have a lot of investment in community engagement. The challenge here is it's such a big campus, it's really hard to coordinate. And so…staying informed, staying connected, that's different than working…in a sole silo role. (Eve)

Valley University

Background

The second case is for Valley University. It is classified as a public, not-for-profit, comprehensive research university with "very high research activity" (Carnegie Foundation for the Advancement of Teaching, n.d.). Its flagship campus is located in an urban area in a large city in the United States. While Valley University is a multi-campus system with regional campuses across the state, this study will focus on the flagship institution. According to *U.S. News & World Report*, it is ranked among the top 200 universities in the National Universities category (n.d.).

In addition to its position in these rankings, as a Minority-Serving Institution, a central tenant of the Valley University mission is its devotion to serving students from the region. Valley also prides itself in supporting first-generation students and has a first-year promise to cover tuition and student fees for state residents with the most financial need. Finally, Valley is considered a "Gold" level Military-Friendly institution. This means that it is recognized as a civilian organization that is respected for its efforts to recruit and support Veterans (Military Friendly, n.d.). As an example, Valley was acknowledged for

its Evening and Weekend Programs which allow for thousands of non-traditional working students to earn their degrees. One participant related these core institutional characteristics to the way those on campus define the term "community":

> Everybody talks about being diverse, but we're a very minority-serving institution, our primary constituency is a minority constituency, not just racial but in every way you can think of… we have so many first-generation graduates so even our students are our community, you know what I mean? (Grace)

Valley University has earned these accolades with limited financial resources. A common theme among participants was related to a lack of state financial support and references to being one of the "poorer states that really is struggling financially" (Grace). One participant acknowledged that this attracts external funding to the institution from organizations and foundations that prefer to support states with large financial needs. Even with this influx of external funding, and a permanent fund at the state level that could be invested for growth, another participant summarized what many expressed by stating, "We call ourselves, we feel like a poor state [and] people experience us as a poor state" (Mary). Still, regardless of this financial position, one participant was careful to offer a caveat to this general sentiment:

> And also we are one of the biggest economic engines for this state. So as a result, a lot of attention is paid to how we engage, you know, sort of marginalized communities and I'm not talking about just marginalized in terms of minority status, and you know, underprivileged and underrepresented but also geographically marginalized. So…[Valley] is really maybe playing a bigger role in our state than other flagship schools do in more developed states. (Grace)

Structure of Valley IRB

An important feature of Valley is the way that staff, faculty, and students experience a distinction between the Main campus and the Health Sciences campus. While the campuses are physically adjacent to one other, are under the leadership of the

same president, and together make up the flagship campus, participants described feeling like the two were separate institutions, "especially with different DUNS numbers…we can even compete against each other [for funding]" (Mary). According to Board of Regents meeting minutes, the structural division between the two campuses was solidified in the early 1990's. Due to increased pressure to prioritize health delivery, health science, and health from the Board of Regents, and with a belief that health care was the major public policy issue of the time, the president recommended to the board that a Health Sciences Center be created. This recommendation included the hiring of a Vice President for Health Sciences and eventually led to a research administration that was separate from Main campus.

Another part of what makes the campus feel separated to researchers is the fact that there are two distinct IRBs. One is on the Main campus and also serves branch campuses, and the other is in the Health Sciences Center. These IRBs operate independently from one another as they have different physical locations as well as separate reporting lines. One participant who has served as a member of both IRBs described the types of protocols each campus receives and the structure of each:

> The Health Sciences [IRB] has three committees, and they're all biomedical obviously, having to do with medical devices and drug trials and clinical trials. All the Social Behavioral and Educational studies are on our Main campus. Main campus has one standing committee, and they have a couple of expedited review committees. So, the Health Sciences doesn't do anything with or they shouldn't do anything with SB sorts of studies. (Tom)

How IRB Structure Impacts CBPR

This division in the IRB structure can be difficult for CBPR research teams to navigate. For example, one researcher described confusion when her faculty appointment

moved to Main campus, but she was doing cross-disciplinary CBPR work through a center located in the Health Sciences:

> I have a lot of experience with both IRBs because I used to be in the Health Sciences Center, I used to be faculty in the School of Medicine. And so all my studies were running through that IRB, but then when I moved to Main campus in 2013, at first I wasn't sure which IRB to run it through, because the [center] is through Health Sciences Center, but I'm not on Health Sciences campus. And so then the PIs of the center clarified this and they said to run our research project through Main campus IRB, and my other studies are now running through Main Campus IRB, but I have had many studies in the past running through the Health Sciences Center. (Ericka)

Another CBPR researcher from the Health Sciences campus described frustrations with requirements to take multiple versions of the same types of trainings on each campus:

> Many of us work across campus. So I know that when we get real frust…, there's been a recent interest in moving some IRB protocols together and adopting each other's CITI training. I mean, I have had to do the CITI training on Main campus and CITI training on HSC campus with a few different kinds of modules. I have to do COI training on Main campus and COI training on HSC because I do work with researchers on Main campus, so I have to follow that protocol. (Mary)

This researcher goes on to describe her efforts to ease these concerns for CBPR researchers through imploring that leadership pay attention to the issue, which has resulted in some recognition of faculty frustrations, albeit minimal:

> I've challenged our research VP many times on this, and they claim they're trying to finally make it so that if I do [the training] at Health Sciences, they will just accept it on Main campus, but it's not done yet. It's happening more I would say in the last year or two, with our new management of IRB [they have] been more receptive. You know, it all revolves on our part of what [the] VP for research allows on HSC. There's a new VP for research on Main campus side.
>
> …In June [2022] our [center], which has faculty and community partners from all sides of campus, is hosting for the first time where the Offices of Research are going to come together and hear about the [center] and its accomplishments and strategies. That's never been done. And we're dealing with IRB on both sides of campus with this single center established on the Health Sciences side. So I think there's an attempt to bring some things together. And of course, there's definite

> funding priorities and different support for faculty on both sides of campus. (Mary)

Beyond the extra time required in deciphering how to navigate the two separate IRBs and their separate training requirements, researchers and IRB staff noted a difference in the ease of submitting CBPR protocols at each IRB. One CBPR researcher noted, “[At] the main campus IRB, I've had pretty good experiences with them, and it hasn't been too difficult.” (Ericka) One reason for this might be because the Main campus IRB has only recently begun formalizing its policies and processes. The current Director of the Main campus IRB, who was previously on staff at the Health Sciences IRB, described her role in developing the program:

> When I came onto the Main campus a little over six years ago, I kind of had to build the program. There wasn't much going on and there wasn't a well-functioning IRB. They had no guidance, no good policies. I was really building the program from the ground up. (Carol)

The Director also noted that in her experience, the Main campus IRB has fewer studies than the Health Science IRB, and a smaller percentage of them are CBPR:

> You know, we have 450 active studies. So we're not a huge group. We have, I'd say, a little bit less of the [CBPR] research because we're not necessarily as health focused as the Health Science Center. But we do have a few big programs that are federally funded but it's a very small piece of our portfolio. (Carol)

This lower volume of CBPR studies impacts the way the Director addresses their review:

> I'd say, over the course of the six years, we've had members who've had some experience with community based participatory research [but] because we don't have a ton of this coming through, we don't have someone specifically identified as an expert in that area, and I feel if we needed that, I could definitely reach out to someone. I'm very big on the use of consultants when we need them. If I come across a study where I'm like, this doesn't seem to make sense, we will seek outside help on that. (Carol)

With newly forming policies and procedures and a low volume of CBPR studies to review, the Director of the Main campus IRB relies on a model of approachability and relationship-building in hopes that new or veteran CBPR researchers will discuss potential issues in the approval process. Although it is time intensive, she believes it significantly improves the IRB process for researchers:

> I'm a people person, too. I find people react better to the IRB if you get to know them and kind of understand where they're coming from and what research they're doing. It's forming a collaboration if you will, with the investigator, so you trust each other. So our office does a lot of consulting. It's a big part of our efforts. We encourage researchers, both faculty and student researchers, to consult with us prior to submitting their projects. It's very time consuming, but we find that that helps our staff to understand the research better…they give us an overview and then we can kind of fill in the holes, as opposed to it being very prescriptive. We try to give them guidance based on their type of research.
>
> I think I'm more open to that than a lot of other IRBs. One, because we have a small portfolio and we can manage, and we definitely have a group of researchers that are high submitters that we can form relationship with. And they feel understood by us which I think just makes it so much easier. (Carol)

To her, this is a different approach than the one she saw while on staff at Valley's Health Science IRB.

> Eleven years ago, I left the Health Science Center. The way they run the IRB is quite different. They are very strict, much more than they were when I was there. I'm a different person than when I started in the compliance field. When you start out in this world, it's very black and white, especially because I started the Health Science Center, and we're looking at protocols from pharma companies, I mean, it's really intense. You're very much focused on consistency, where on this side, you really have to understand what they're doing. And, in a way, develop an appreciation for the type of research that's done. That being said, you have to draw the line when you have to draw the line. (Carol)

For CBPR researchers, this stricter approach on the Health Science campus often leads to additional burden in their review. One CBPR researcher described her frustrations when the IRB took issue with how her research team gathered informed consent documents for the study:

> In my last big CBPR study that was under the Health Sciences IRB, we got audited, and I thought it was a ridiculous thing. We were working with people in all these languages. We would go to people's houses to do the interviews, right? Like we weren't, it's not like a lot of medical studies where people come into your lab. So, we just had people sign two consent forms. They would keep one copy and we would keep one copy. And we got into this whole thing with [the IRB], where they're like, how do we know that you really had them sign it? Because we didn't photocopy [the consent forms]. I was like, well, we don't have a photocopier to bring with us. And, I don't know, there were a lot of random things in that audit. (Ericka)

Although the Health Sciences IRB is known for their stricter approach to initial and continuing review, CBPR researchers also noted that the team is not uncompromising. One researcher mentioned that especially in recent years, "the current manager of the [Health Sciences] IRB has been very open." (Mary) Another CBPR researcher explained that although it requires advocacy, the IRB typically takes time to work through sensitive issues:

> I find that if we're not in agreement, like if…there's a discrepancy. I have a meeting with them. And they usually, they always understand.
> For [example], we came to realize that a barrier to getting youth enrolled was getting parental consent to participate in the study, because some youth didn't want their parents or caregivers to know that they will get behavioral health services. And in [our state], the age of consent for behavioral health service is 14, but to participate in research, it's 18, and so I asked to get a waiver of consent, saying that it would be more harmful to the youth for the parents to know, especially the ones in homes with domestic violence, and so it will be more harmful for them to get consent than not.
>
> And at first, they said no, or they wanted more information. And then I met with them. And they said, Okay, we'll give you the waiver as long as the parents could ultimately get the data if they wanted to. And I said there's no way the parents should get the data, because it would be terrible if parents found out that they were participating in this. So they say, oh, okay, now I understand that. And so they do. They do take time. (Susan)

Each in their own ways, the IRBs at Valley are open to hearing from CBPR faculty regarding the specific ways that they would like to build community protection

into their protocol. However, there were no specific discussions with participants regarding the ways either IRB has self-initiated community-level protections.

Faculty and Staff Influence on Community-Level Ethics

Bringing Awareness of CBPR to Campus as a Whole. There were several discussions with participants about the ways that faculty and staff advocacy on campus has impacted IRB members' understanding of CBPR. One particularly prominent CBPR researcher, situated on the Health Sciences side of campus, has had both direct and indirect influence on both IRBs. Nearly all participants described without prompting how this faculty member influenced either their personal understanding of CBPR or the institutions' familiarity with the practice. Several participants indicated they had taken her CBPR training course to become more grounded in best practices. One research coordinator that facilitates CBPR partnerships described this faculty member's influence on institutional understanding of CBPR:

> I think the reason why [people can distinguish community engaged research from CBPR] is because [this faculty member] brought CBPR to Valley. I credit her for laying that groundwork. And because it's [her] realm at [Valley], I think we associate CBPR, like, this is [her] domain. We try not to use that term lightly, CBPR, because it's so specific. We think of [our research] more as community-engaged research...Even though, [our research] definitely is that [CBPR] model, it's just we don't use that word. And also, because it's [the faculty expert's area], we get told from the top down, be very careful when you use those four letters, CBPR. Even though so much of [our research] is like ingrained in [CBPR principles], we still have to be very careful not to say we're doing CBPR. (Diana)

This researcher acknowledged her reputation: "People know me. Yes, I'm called all the time. Any individual requests I get, I will meet with people" (Mary).

Bringing Awareness of CBPR to the IRBs. Over time, her expertise and presence on campus directly influenced the Health Sciences IRB process. When the Director of the Main campus IRB was still working at the Health Sciences IRB, this

faculty member was the one who helped the Director gain a better understanding of CBPR:

> When I worked with [the faculty expert], me and her established a bond. I feel like when I came into that job, I really tried to understand the research she was doing. Because a lot of the portfolio at the Health Science Center was not community based participatory research. It was biomedical clinical studies. She wasn't the only [CBPR researcher], but she was the biggest one, for sure, because she was the one getting all the money. A lot of money. And she seemed to be involved in every other person's CBPR project. She was just kind of, you know, that's just how she is. She's just the resource for everybody.
>
> And [the Health Science IRB] had a [speaker] come in who had worked with native groups. And [the faculty expert] knew [the speaker] through her work. She gave a whole presentation on community based research and how IRB should be looking at that. So that was really my first introduction. And it was like this whole new kind of world. (Carol)

When this IRB staff member took an interest in this faculty's work, and learned from her about the best practices of CBPR, she began giving presentations and planning trainings to extend knowledge about the intersections of the IRB and CBPR:

> So [the faculty expert] had this little niche and this was, I started there in 2003, so we're talking almost 20 years ago. She felt misunderstood by the IRB, and so I formed a relationship with her because I was new. I was like, it doesn't hurt to kind of try and understand. So we actually put together a training for our IRB…I used to go to the Masters of Public Health and do a whole presentation in their class on IRB and how to incorporate CBPR in an IRB application. So I really did do a lot of work over there on trying to lay the foundation and do training. (Carol)

In addition to class presentations for graduate students and training for IRB staff, another movement toward change was an attempt to require community engaged and CBPR researchers to take additional IRB training specific to community work. However, according to the faculty expert, the training never came to fruition:

> For a while there was a goal to create a community engagement module that every researcher would have to go through if they were claiming they were doing community engaged research. It hasn't manifested as far as…I was asked to help develop it. But then we were kind of dropped or, we didn't finish it. And it didn't

> receive the attention it needed. And so as a continued community engaged researcher, I would be one to be asked to complete it. And it doesn't exist. (Mary)

Because of her experiences with this faculty member on the Health Sciences campus, the Director of the Main campus IRB harnessed interest in the topic and guided staff on her IRB to gain more knowledge on CBPR. Very soon after her tenure as Director of the Main campus IRB began, she and her colleagues developed a best practices worksheet for CBPR researchers as well as a training for IRB members:

> So the first thing we did was develop guidance on the community based participatory research, which we published in 2016…And of course, we did a training with our members at that time on it. (Carol)

Analysis of the IRB's website confirmed that the best practices document is publicly available for current CBPR faculty to reference.

But this faculty expert is not the only influential figure on campus. One participant acknowledged that other faculty leaders also prioritize this work in influential ways:

> We also have the [Native American Center], led by another wonderful faculty person. [That faculty] she herself is native. And so they do research as well, with Indigenous communities and tribal nations. I think [these researchers] just help bring this community together and like, create mindfulness for [CBPR]. (Diana)

This participant went on to identify an observation of the historic role these faculty leaders play in sensemaking of CBPR on campus:

> Research has not always been done with different people of different backgrounds. And years and years ago, it was very dominantly like white males that were leaders in our faculties. And so just having this different dynamic of different people, different genders, different races, being in these positions of power has really, really helped. (Diana)

Bringing Change to Human Subjects Training. Increased education and awareness-raising on both IRBs related to the ethical concerns related to CBPR have not

mitigated CBPR researchers' concerns with the IRB process for their studies. Requirements to train community partners who are involved in the delivery of the research protocol is a struggle for researchers and research coordinators on both campuses. On Main campus, IRB staff recognize the need to train community partners differently, but put the onus on the faculty members to find a way to train them appropriately:

> CITI, it's a structured way to learn if you're a researcher, but if you're a community member…that training isn't helpful, necessarily. So if we have community members being trained to be on the research team, what we allow is we usually meet with the PIs and kind of talk about what that training would look like And then we would have them submit that to us as part of their IRB, we'd look at it, we'd make sure it looked appropriate. And then we'd allow them to do the training and not have them do the CITI. I think it's much better for a community member be trained directly by an investigator on the protocol, what they're supposed to do, autonomy, how to recruit appropriately, then to just sit on CITI and read about, you know, Tuskegee. (Carol)

However, a Main campus faculty member shared frustrations with this process and expectation:

> I mean, overall, I think the hard part is finding human subjects training for our community partners that's meaningful. We just have to spend a lot of time going through it with our community partners to make sure they understand it and help them you know, sometimes do it and it's not always available in every language, you know, that you would want. (Ericka)

On the Health Sciences campus, faculty and staff shared different frustrations that historically, the IRB there has not allowed for alternative training, even when developed and presented to the IRB for consideration. A research coordinator shared a situation that exemplified this concern:

> I was working with people who were in the juvenile justice system, like some of them were social workers. And because they were the ones working with the youth, we thought it best if they could be the ones to collect some of the data for us, because they're working with kids that are in crisis all the time. But that meant

> they would have to be trained [in human subjects research] and understand the research process, patient confidentiality, everything that goes into consenting.
>
> And for someone who isn't a researcher, they're not gonna want to sit for eight hours doing modules to get certified to answer a few questions on a survey. So we thought it would be really neat if the IRB process to getting your CITI certification was a little bit different, and catered more towards community members like this, where you get the gist of it, but you don't have to go into the depth and background of the Belmont Report.
>
> And we set up so many meetings, we sent like a faculty person who we thought best represented, we asked [the faculty expert] if she had any ideas, she thought this was a great idea. And it was needed. And we just could not get the IRB to budge at all.
>
> So I ended up renting out a computer lab at the library. I had to get parking passes because parking at our campus is ridiculous as well. So it was just all these little logistical things just to get these community members into our library, so that I could go through the modules with them and try to get the most important parts so that they could pass their quizzes so we could get them certified to help us collect this information. (Diana)

After many research teams shared frustrations with this issue, and with the new Health Science IRB manager showing more openness to alternative ideas, the faculty expert explained that the "one thing that our new IRB manager has helped facilitate is a condensed CITI training for community partners" (Mary) a research coordinator also explained how a physician researcher on campus was able to offer a solution that was acceptable to the IRB:

> Recently, [the physician researcher] I believe she is a kidney doctor; she was able to make a breakthrough with the IRB to make it so that getting your CITI training for community members is a lot easier… it was approved as far as I know. (Diana)

The faculty expert on CBPR was able to offer additional details on this approved training and also shared how the Health Sciences IRB has recently begun providing support for conflict of interest training with community members:

> We use the Harvard Catalyst and that's approved by NIH. But that's recent. We asked our IRB if we could do it, and they went through some flurry of activity. Our IRB also helped us provide the financial conflict of interest training to some of our community partners who didn't have good access to internet. We were able to do it by mailing things back and forth or scanning documents. So they're receptive to that. (Mary)

External Influence on IRB Process

Tribal Nations. At Valley, both IRB managers have exhibited a willingness to learn from CBPR faculty and research teams which has resulted in flexibility when it comes to human subjects training for community partners. A factor that has led to more change, however, are the requirements set forth by tribal IRBs. All participants agreed that tribal IRBs have significantly impacted the ways in which Valley's researchers, CBPR and otherwise, must interact with tribal communities. In turn, these requirements force both of the IRBs at Valley University to be aware of the processes required any time a researcher partners with or wants to study tribal nations. The faculty expert noted, "I don't think our IRB deals with community-level ethics in general, except for the requirements that a tribal IRB has placed on us" (Mary). She went on to articulate some of the specific tribal IRB requirements and how these additional protections relate to community autonomy, community beneficence and community justice:

> Involving community members from design to dissemination is a well-regarded practice in CBPR, but it's not part of our [IRBs] ethical standards per say, nor is respecting cultural norms part of our [IRBs] ethical standards…[but] tribal IRBs have led the way in this. They ask about how we are addressing cultural issues in terms of having cultural experts working with us, etc. And that's not an IRB [requirement]. I don't think that's being done too much [anywhere].
>
> Community Beneficence is not an IRB norm at all. IRB norms are individual risk benefit, and obviously individual benefit over risk in terms of that ratio. But tribal IRB's always have community beneficence…[those at Valley] have to respond to tribal IRBs because tribal IRBs require the [Valley] IRB to be shown first, then we take that to the tribal IRB for the final approval process and have to add

> additional sections in the IRB application around community beneficence. So that one is really common in a tribal structure.
>
> The Community Justice one we deal with related to what we call data justice. And that's an IRB issue, and sovereignty of tribes, again, direct our tribal research, but it's not as integrated [into our IRB]. You know, we talk about it a lot. A number of us individual faculty talk about data justice a lot. We're trying to create a data justice policy. It's not, I don't think, in our [IRB] except, again, for tribal IRBs which demand return of the data and ownership of the data. (Mary)

The Director of Main campus' IRB described how she became intimately familiar with these processes and how it influenced her IRBs' understanding of tribal protections. One of the larger tribal IRBs in the area reached out to her early after she began her new role at the Main campus IRB. Mainly, the tribal IRB wanted to increase the amount of research proposals coming through Valley and felt that educating the IRB staff would be a useful tool in accomplishing that goal. The Director remembered this process:

> Something we did, which lends itself to us becoming the IRB that we are, is, I want to say [in] 2017, [one of the tribal] IRBs reached out to us and they were trying to meet up with different IRBs in their area…kind of as an outreach thing. They came to [Valley] for a day and we hosted them, they observed our meeting, we did some trainings with them, some discussions, and then after that, that led to our IRB going to [their IRB].
>
> We had food with them. They showed us some traditional ceremonies. I think it was very enlightening. It really helped us to see a different way of thinking about things [like] data ownership. And not just the helicopter research where you're dropping in and dropping out, they really want to make sure there's some benefit to their community.
>
> They were not shy about disproving research, they would just be like, "Hell no, you're not coming in." I mean, they were hardcore. And there was a reason for that. They just came from a place where they felt they had a lot of abuses and so they swung to the right. I think they're getting a little better now. But one of the main reasons they reached out to us is because they were finding that no [students from their tribe] wanted to come and do research on the nation. And we're kind of like well you're making it kind of hard on them. So we were really, how can your IRB and our IRB work together to help facilitate better research on the Nation. So there was a whole conversation around that. [It] was a really unique thing…to have that kind of interaction between IRBs. That was early on in my tenure here, I think that went a long way for opening our eyes and really understanding what it

> means to be engaged with community, especially tribal community…And it really made you appreciate that community and respecting that. (Carol)

Formalized IRB processes essentially serve as tribal approvals to conduct research in their community. However, not all tribes have these formalized IRB processes. Given this, at the Health Science IRB a previous IRB Manager, who happened to be Native herself, was able to extend tribal approval requirements to all tribes, not just those with formal IRBs. Now, researchers who utilize the Health Sciences IRB must receive tribal resolutions prior to engaging in research with any tribal nation. One CBPR faculty member in the Health Sciences recalled:

> I can't remember how long ago, at least eight years ago, the head of the IRB was someone from the tribal community. And she really said that if you're going to do any sort of research or data collection in the [tribal] community, you need to do an IRB, and you need to get a tribal resolution…They won't let you put in an IRB with a tribe at [the Health Sciences IRB] without having a tribal resolution. (Susan)

Despite both IRBs' familiarity with tribal protections, the faculty expert pointed out that "neither [IRB] has brought these three issues (i.e., community autonomy, beneficence, and justice) to the fore except for tribes" (Mary). She went on to describe how other communities in the state would appreciate additional protections and noted the contradiction involved in not extending similar requirements to these communities:

> Those [universities] or states where there's a lot of tribal research going on will have a much better [understanding] and also where other communities have demanded [additional protections]. Our communities in [the state] would love it If [Valley] was more protective… I mean, they don't want to be treated as just subjects. But they are…You know, it's interesting, of course, in a state like ours where we have so much tribal research going on, that the same processes are not in place for anybody else. I think it's worth asking the question, because it might spur infrastructure decision makers to say, wait a minute, how come? (Mary)

IRB Claims Limits to Purview Over Community-Level Ethics

Beyond the more accessible CITI trainings for community members approved through the Health Sciences IRB, and both IRB's responsiveness to review board processes set by tribal nations, the IRBs at Valley don't consider themselves responsible for community-level ethical protections. The IRB Director on Main campus shared her perspective from her time as staff on both IRBs. To her, there are limits to IRB purview for considering community-level ethics and ultimate responsibility for these issues lies with CBPR researchers:

> We can do only so much. The investigator at the end of the day is the one executing the research and we can put all the protections in place and do everything we think is right but if they're not going to follow through properly, you know,...a lot of trust goes into the researcher themselves what they're telling us they're going to do. (Carol)

Support from Research Centers for Community-Level Ethics

Since CBPR faculty and research teams do not receive much guidance regarding community-level ethics from either IRB at Valley, CBPR faculty must look elsewhere for support. One place that faculty seek support is through a Center established by the faculty expert on CBPR. While there are many centers and departments across both campuses at Valley that support CBPR research teams, this center is explicitly dedicated to CBPR. The Center was established as a way to gather all individuals on and off campus involved in CBPR projects:

> By 2009, which is when we officially started the center, I realized it would be really good, because it was all over the place, just to kind of create a space that we could name. I have created it for my own environment to show that we have a strength of environment and teams across campus, every contract and grant I work with is with faculty teams, staff, students across campus...I'm trying to create a safe space for people to come together and do collaborative work together in CBPR…But, so I just created it, it was in my head, I just created it and created a website. (Mary)

In addition to creating a collaborative network of CBPR practitioners, the Center also offers training and consultations for anyone interested in learning more about best practices in CBPR which was confirmed through review of documents available on the Center's website. In all of her work, the faculty expert models respect for and understanding of community-level ethical concerns in the way she develops partnerships for her own research and for projects associated with the Center:

> We don't have a different set of ethical guidelines. We just operate that way. We draw from agreements that we've done with tribes and other communities**…**we only operate with a data justice and community benefit model and respect, autonomy. None of our projects don't do that. We spend a lot of time listening to community partners, we try and develop long term community relationships and we show up… a lot of people don't go out to communities. We go out. (Mary)

Limits to Influence of Research Centers that Support CBPR

Regardless of this Center's local and national reputation, Valley University has not dedicated financial or significant physical resources to the Center. Instead, this faculty member and a few others do their best to write in support for the Center into some of their own grant funding:

> It's a virtual center, it has no institutional funding, zero. I don't have enough staff to really make it live and keep it going. I don't have a social media person. We have one staff member, who is the program coordinator of the Center that a couple of us mutually fund on grants. I fund mostly students and co-faculty. I don't generally fund staff.
>
> So I'm funding it. My Center has moved…I was floating [between departments] but it didn't matter because it was beneficial. I was getting good grants by having a center. And my colleagues were getting good grants by saying they were affiliated with a center. [When] I was requested to move the Center into the college I thought that might be [beneficial financially]...so I moved the Center into the college and now no longer floated around Health Sciences…I do have space. I have about four offices. So yes, they can say they've given me - I just kind of moved in and nobody kicked me out. But we pay for all of the. So, you know, I would like it to be supported institutionally, I have requested institutional support. (Mary)

This faculty also explained that hers is not the only Center that supports CBPR and lacks institutional financial support. Most of these centers across campus rely on external funding to exist:

> There are multiple centers…we've had to find all our own [financial resources]. Like [there] is a center of excellence that's a major community engagement center that's done incredible work…funded [externally] and does not have institutional resources behind it. The [center for community engagement] on Main campus was funded [externally], the [social policy center] was funded [externally]…[our state] is poor. The [Native American Center] got legislative support, but it came from tribal leaders' demands. I don't have that. I've worked with a lot of partners across the state, but I don't have any demands saying fund [my] Center…There's no real institutional support, except through the CTSA on our side of campus. (Mary)

As will be discussed in detail in the next section, CTSA refers to the Clinical and Translational Science Award that Valley receives though the NIH. As noted by this participant, this award is supplemented through campus funds. A part of the NIH funding is earmarked for community engagement support, which is interpreted differently from institution to institution. While the faculty expert is not directly employed by the CTSA, she collaborates with many CTSA staff and researchers.

Clinical and Translational Science Support for Community-Level Ethics

Valley University's Health Sciences Center is one of more than 50 institutions that receive funding through the NIH Clinical and Translational Science Award (CTSA). The central goal of CTSA's is "to improve the translational research process to get more treatments to more patients more quickly" (National Center for Advancing Translational Sciences, n.d.-a) Part of CTSA funding is allocated to staff tasked with increasing community engagement in research. The goal of this funding is "to ensure patient involvement and community engagement throughout the research process" by

encouraging institutions to partner with community organizations to identify and understand their public health needs more effectively (National Center for Advancing Translational Sciences, n.d.-b).

Some of the services provided by the CTSA Community Engagement (CE) staff at Valley are geared toward developing community partnerships and assisting faculty who are new to community engaged research. Participants who are staff in this area understand the principles of CBPR and see it as a part of their work to move faculty along the continuum toward increasing community inclusion in research projects. In considering community-level ethical concerns, one staff member indicated their importance to the team:

> My group definitely talks about these, I hadn't thought about them in these particular categories, (i.e., community autonomy, beneficence, and justice) but I feel like each and every one of these topics has come up in the seven years I've been at [Valley]. (Diana)

This participant's role through the CTSA is to connect with Health Councils across the state and bring information about their health priorities back to the institution. Further describing her work, this participant identified the ways she approaches her position to prioritize community autonomy and beneficence. In building relationships with the Health Councils, she respects community autonomy by taking the time to understand cultural norms and build trust with community members and gatekeepers:

> The first thing I knew was important was to establish a presence [at the Health Councils]…that was my commitment to myself. The other is to learn. So with the different Health Councils because the culture can be so different, there might be more Hispanic based populations in some health councils or there might be some more racially White or Indigenous. I needed to be a fly on the wall and learn, learn, learn, learn.
>
> Respecting cultural norms, that just comes with spending time with them… Community-informed consent, that always comes up once we do a presentation.

> The Council always takes time to discuss with the researcher or whoever our guest is, so that we can get a consensus of what people are really thinking. Do they think this is a good idea? Is this a bad idea?
>
> Also, the coordinators of these councils have been really important to me, because once I establish that I'm coming, I reach out to them first, before I have any research questions or research interests, I talk to them first about it before I can even approach the bigger group…It would feel a little but more organic to say, this county over here, their mission is to help people with diabetes. (Diana)

Another decision she's made in her position is to help researchers see the importance of thinking through community benefit that extends beyond offering participant incentives. To this participant, extending the opportunity to consider community benefit invites researchers into her hard-earned relationships with community in a more respectful way:

> Whenever I meet with a researcher, before I introduce them to communities that I've been attending for so long, I always tell them, this is what I expect of you. After you do the study, if I help talk about your study to this community, one of the things they're always gonna ask me is how does this benefit us? What do we get out of it? Not just the individual level, oh, you get a $25 gift card. What more is there really from your study that's going to benefit the community? (Diana)

Beyond community benefit, she expressed a deep commitment to encouraging faculty to, at the very least, make a conscious effort to share their research results back with community members. This desire is driven from her past experiences when community members positively responded to hearing firsthand from researchers:

> I think it's really important to disseminate the findings back. I don't think we've been successful at doing that part of our research for a lot of different reasons. It takes time to do research, it takes time to do the analyses after you transcribed your data. It might be years before you publish something. Then to bring it back, who are you bringing it back to? Are you keeping track of people individually? So I get it, there's hardship that comes with disseminating results back.
>
> But the end of last year was the end of some of the first studies that I had been promoting. And we got to bring it back to these communities…they were grateful that we were bringing it back. And it led to a really great discussion about what does this mean for our community. How do we want to go to our school boards in

> our community to ask them to change things? They were just so excited. It was really well received. (Diana)

Other CE staff have less involvement with building community relationships and focus instead on wrap around services for faculty who engage in or with the community. A CE staff member described these additional services:

> We have a whole team. Their whole thing is community engagement. They're like a research team for hire. So if you're a lone researcher, you want to do research, and you want it to be community focused or based, but don't have a team, we have someone who can do the coordination for you. There's someone who can do qualitative work. We have someone who's an expert in, like, doing different types of analyses with for interviews, we are, you know, experts in focus groups. So we have someone that can help you in all of these different ways of doing your research, we can even help write your IRB. (Diana)

Limits to Influence of CTSA Community Engagement Team

Regardless of the obvious intention of the CTSA CE team to encourage researchers to incorporate CBPR best practices more fully and consider community-level ethics, multiple participants agreed that the team does not have the opportunities it should to influence community-based research projects. Participants noted at least two reasons for this. One participant noted struggles to retrofit studies that have already been designed before faculty are encouraged to seek assistance with incorporating community:

> I've been trained by a CBPR expert so I'm aware of what's all involved. Most of my projects, however, fall in the middle of the community-engaged research spectrum. I don't have control over what projects come to me, so all I can do is try to influence them. I'm rarely involved from the very beginning, it's usually after the idea has already formed, sometimes I get in before they submit the grant [but] more than half the time they already have grant funding…I wouldn't say researchers are necessarily to blame. They are usually very open to suggestions to make the project more community-engaged but are up against grant requirements that make it impossible to follow best practices of CBPR. So, many of my projects are not as community-engaged as I would like them to be, but we do our best to work around these limitations. (Sam)

A second, more pointed concern is the impact that leadership has on the community-engaged focus of the grant. The faculty expert described how the PI for the CTSA grant, who also serves as the Vice President of Research in the Health Sciences, is often focused on finding ways to generate funds through services provided by the grant. This has resulted in the CTSA CE team prioritizing fee for service work on the qualitative portions of research projects and conflating that work with meaningful community development activities:

> They charge for this…I think there's two free [consultations] and then they start charging. If you want community engagement support for doing okay, well, our [CTSA grant] conflates qualitative work and community engagement. So our community engagement staff help researchers [with] the focus groups, doing the data collection, and then creating a transcript and doing some data analysis and qualitative work. Of course, CBPR is not method specific…[Some leadership doesn't] get it. They think it's qualitative, or they've, they put them together. So if you contract their services, they will do the transcripts for you, they will do some of the analysis, they'll give you a gorgeous report.
>
> …I know of community cores [at other CTSAs] that it's not fee for service. This is [the Vice President for Research's] view, that it should be fees. And he also establishes more institutional support, because he says we're not just waiting for grant money, we're generating our own revenue. So it helps inside the institution to do that. He's a very smart man. He doesn't share my values in many ways, but he's a very smart man. And he's a very solid PI of the [CTSA grant]. He's been successful, but he doesn't do community engagement the way I would, or the way many would. (Mary)

In sum, the faculty expert remains frustrated that the center on campus with the largest institutional support for community engaged research is in her view, guided by leadership that misinterprets the purposes of community engagement funds and misses opportunities for authentic community connection.

Institutional Barriers for Faculty who Protect Community-Level Ethics

Lack of institutional support does not only impact staff and faculty in research centers that facilitate CBPR projects. Seasoned CBPR researchers also identified how

institutional practice or policies impede their ability to easily engage communities on their research teams. Centering community voice and working to ensure the sustainability of relationships and projects were of paramount importance to these researchers. One CBPR researcher from Main campus described how a conflict of interest investigation nearly thwarted her ability to engage with a non-profit she established as a way to extend and sustain the research projects that she had completed with her community partners:

> In the last few years, I helped form a nonprofit organization…And the idea is…we've really been really successful with the [research] project. We already know it works and we don't need to keep researching it in the same way. But we need full time, good paying jobs for [community] leaders who are implementing this project and doing other work that they know their communities need. And so that's why we created this organization, so that it's not about research anymore. It's about sustaining this project and other programs and efforts that are what [these community members] need. Guided and led by [community members] who know better than anybody else.
>
> I spent a lot of time for a while doing unpaid work that took a lot of time but wasn't part of my job description as a faculty member. But I was committed…this is what needed to come out of all this research partnership from all these years. Former participants and former students in the project really wanted to form this organization.
>
> …I will say that I just got investigated in a major conflict of interest investigation because of my work helping form this nonprofit. And that took hours and hours of my time and responses. [Valley] was worried that I was taking business from [them] by helping start this nonprofit even though this nonprofit isn't doing research. They're a partner in research, but their main mission is not research and education. Their main mission is direct service and advocacy. So you know that I found kind of really frustrating to be honest. (Ericka)

Another long-time CBPR researcher from the Health Sciences campus described frustrations with fairly employing and compensating community experts on her research team:

> I hire a lot of people who don't have college degrees. And so they want to know, like, it says they worked in their casino and how their salaries' going to be this and I say but they worked in their casino for 10 years where they did a youth

> leadership thing at a casino so they need a higher salary. So it's always a negotiation.
>
> Even hiring not for the tribal study, but for others, like we've had jail diversion studies. And we want to have people with lived experience. So we want to hire people who have been incarcerated. And the university will say, well, that's against our policy, when we say, well, they're going to know better what's going to work and what's not going to work. So we have to go to bat a lot. It's not set up for us. And I have one person working with me, he's been working with me for eight years now and is very bright, extremely bright, but did not go to college. I want him to be able to move up professionally, get more money. So that's kind of a barrier. It's frustrating to be able to pay what you want to pay someone and really have to fight to get increases. (Susan)

To her, the difficulty in hiring community members to participate as co-researchers makes it harder to engage in research ethically, “I don't think [community-engaged research] should be a check the box. It should be an ongoing collaboration. I think that the university has to make that commitment to ongoing collaboration” (Susan).

While these researchers have come up against institutional barriers as they’ve gone to great lengths to prioritize community voice and partnership sustainability, they still also run into barriers related to institutional process when it comes to lower-hanging fruit such as incentivizing community partners in contextually appropriate ways:

> I don't think the institution is set up thinking about CBPR. So we're always pushing boundaries, whether it's with contracts [or] participant incentives, we're always pushing boundaries. So we fight and get it that the system isn't set up for that, it's a Health Sciences Center. It's set up to do drug trials and bench science. So doing community work is really difficult. Why do we need to buy gas cards for people to get places? Or why would we need to purchase someone's internet? iPads, hotspots, you know, shouldn't that be up to them? It's like no, no, no. (Susan)

A faculty member who does research across campuses expresses the ways that inefficient processes impact timely payment of community partners from their grants due to requirements to complete multiple conflict of interest certifications:

> Yeah, and the conflict of interest, because our community partners have to complete conflict of interest training, and then conflict of interest certification and the processes are not smooth at all. And like, with definitely the Health Sciences Center [project], our community partners had to do the conflict of interest stuff for both campuses, because they had to do one for the IRB, which was on Main campus. And then for the financial part of it, they had to do conflict of interest training from [Health Sciences]. So it was a huge burden. And then it's so hard to get an account to do it if you're not a [Valley] employee, so it's just this huge, huge…it needs to be streamlined in a major, major way.
>
> Just to give you an example, the…funding ends [soon] and our community partners haven't gotten any of the money yet, because it's still being held up by conflict of interest reporting, and all these trainings that they do every year and report every year and the time goes by and it's like, ridiculous. I know the pandemic has made everyone busy and everything slowed down and all this administration stuff, but I mean, it's not logical, right? It's all like, covering people, okay, we can say we did this, but our community partners have already done this. And now they have to do these things over and over again, and no one can figure out how to send them what they need to do it. I mean, it just goes on and on. But literally, it's been 11 months and nothing. You know, that's ridiculous. (Ericka)

In an attempt to rectify ongoing institutional barriers to incorporating her partners meaningfully in research, this faculty member also described an attempt at finding a solution to by asking her Dean to consider increasing start-up funds for community-engaged researchers:

> But I mean, it's really frustrating. It takes away time from doing the intellectual work that we need to do, because we spend so so so much time dealing with all this stuff.
>
> …I've given this feedback to our Dean for Research in the College of Arts and Sciences. If we really want people to be able to do community engaged research, you know, when you bring on a new faculty member in chemistry, they might get like $300,000 startup funds, because they need to purchase equipment, right? And they do need all that equipment. But if you're gonna hire junior faculty to do community-engaged research, like in our department, you know, any junior faculty gets $15,000 startup.
>
> If we really want people to be able to do it, then we have to support them. And that means money to pay community partners, and to invest in the things that we want to do to build those relationships. Universities are, you know, these huge bureaucracies and everything we need to do from like, how we pay our

> community partners to how they do conflict of interest training, and IRB, human subjects training…it's the hugest time sucks, and none of it is set up. Nothing at our institution, honestly, is set up to actually make it possible. And it just makes it so much harder and exhausting to do this research. (Ericka)

Participants agreed that even with limited funding, the institution could be doing more to prioritize the importance of involving communities in research. The Director of Research Ethics at Valley University shared his perspective on the important role that leadership plays in solving the issues described by the CBPR faculty, and balked at the idea that lack of funding is always the central problem for prioritizing these considerations:

> Looking at the ethics and ethical review of institutions. There's a lot of variety out there. And it does depend on leadership, in my opinion. I mean, there's those that just want to check the box and move on because it's too much trouble to think about. Let me just say that Health Science Center, they certainly have money to have a deep Office of Ethics. They obviously have a medical ethics committee that advises the hospital, but they don't have anything for research. (Tom)

Faculty Desire Assurance of Ethical Standards

From the IRB. While all participants agreed that faculty have a baseline responsibility to protect community-level ethics, most participants also agreed that major barriers exist at the institutional level in order for faculty to successfully implement their plans for protection. Regardless of feeling frustrated by institutional processes, faculty still articulated a desire for more oversight of community-level ethics. To them, it is too important to leave these concerns up to individual decision-making. One faculty participant explained these sentiments by suggesting the IRB change their process internally for CBPR researchers, much like what was attempted years ago at the Health Sciences IRB:

> Some of those ethical issues have to be addressed through the partnership. But researchers probably always think they're doing the right thing, the ethical thing.

> That's the whole problem, right? The idea of IRB is to help make sure because sometimes there's things that people don't think about or they're new to this research or they have their one perspective. I think there needs to be more institutional support for community-engaged research, which would also involve thought and reflection on the ethical issues.
>
> I guess it would be the IRB that should help be responsible for that ultimately...maybe it doesn't look the way traditional IRB looks. Maybe there's some reflective, PIs need to meet periodically with other PIs or with the IRB staff member in a group to talk through, or have a way to think, reflect on particular issues that may be more meaningful than some of what happens with IRB, even though what the IRB does is important. (Ericka)

From Federal Regulation Change. The faculty expert shared a slightly different perspective on ways to ensure community-level protection. While unopposed to and familiar with initiating discussions with IRB staff to advocate for protection of community concerns, ultimately, she thinks federal regulations would more effectively change the IRB process rather than working from the ground up:

> I think it comes down from federal guidelines, and we will have [to] respond at a university level. Can I just give one example? Early on, our IRB was much more structured, much more clinical. So you had these long, long [consent forms] and I was trying to do focus groups in a tribe, and they gave me the same long consent form, a four or five page consent form. And the governor of the tribe said, you can leave now we're not doing that. And I said will you please write a letter to the IRB that you want a one page consent form. And he did, or his staff did for him. Anyway, I got a one page consent form. If I hadn't tried to do that [the research] wouldn't have happened. So I think there can be advocacy from the grassroots. But I think ultimately, it's at this highest level. (Mary)

From her perspective, it would be entirely possible for federal regulations to change specifically related to considerations of community-level risk and harm through seeking community approvals:

> I actually think community beneficence…the cultural autonomy and respect is going to be a little harder, and even data justice or Community Justice a little harder. I think federal regulation could change related to community benefit. Okay. A lot. I mean, you could take the tribes as the lead. And obviously respect and autonomy, resonate, all of the others resonate, but I don't think they have as direct a strategy…So yes absolutely, absolutely…I think it's going to be really

> important to move that, the federal, to move out of individual risk harm is really important. (Mary)

However, the Director of the IRB on Main campus is resistant to and exhausted by the idea of new federal regulations:

> First of all, the regulations aren't going to change, because they just changed and they did a poor job of it. The thought of it changing again, it's not going to happen in my career, I can guarantee that. That being said,...my perspective is I think it's hard because, the more regulations you build up, the less flexibility you have to be honest with you, as an IRB, and I'm speaking from my experience, which is limited to working with the two IRB's at [Valley University], but the way they're written, it allows you to expand your definition of vulnerable population if there is situational vulnerability in the project. (Carol)

From her perspective, the current flexibility afforded to IRBs in deciding how and when communities are vulnerable is important to maintain. Although the Director of the IRB is resistant on a practical level, other staff in the research integrity and compliance department on Main campus articulated the value of additional federal oversight, albeit with a caveat that community voice is included. According to the IRB Director's supervisor:

> Federal oversight [of community-level ethics] is a good idea in my mind, but it has to be with the input from diverse constituencies rather than just protecting the government's interest…I do think especially for community-based research, that there should be some prescription, some level of support to understand what's right or wrong, because people can get very edgy and very divided. So we need to make sure that you know, our norms of protecting everybody are sound. (Grace)

From Grant Mechanisms. While faculty and staff outside the IRB expressed how federal regulations could be changed to influence community protections, this solution feels distant to many participants. Many participants were more eager to identify a need for change when acknowledging the influence large granting organizations have on the ways faculty and research teams interact with communities. The Director of the IRB explained that the structure of some grants do not encourage the type of sustained

partnerships with community that are necessary to build relationships in a meaningful way:

> One of the concerns with participatory research is when people do the flyby, oh, I got this grant. And I'm going to do this and then I'm going to pull my resources and the university resources out of it. And then that really hurts the community. Actually, I have not seen anything like that come through our IRB [on Main campus]. It's more of a concern in the Health Sciences. It's a little more quantitative, where they're trying to administer something and prove that it's effective. (Carol)

The faculty expert, who is situated on the Health Sciences side of campus and has won large, competitive NIH funding for decades, acknowledged the important role of these granting organizations. From her perspective, there has been movement by some of these organizations to be more explicit about community ethics and she has hopes that these changes will influence federal funding mechanisms such as the National Institute of Health (NIH):

> I think NIH has had influence on this…How NIH demands, you know, their human subjects sections in grants determines everything. The NIH has focused its current equity issues on recruitment of minorities into trials. And so how do you do recruitment and retention of diverse populations into science? And whether it's precision medicine huge, you know, data collection processes going on, how do we ensure populations are being represented? There [are] still protections, but not approvals. IRB doesn't really fully address that.
>
> I mean, I think I'll just say, PCORI (Patient-Centered Outcomes Research Institute) is much nimbler and has an opportunity to make changes faster. And I'm banking on PCORI to influence NIH right now, because PCORI is going in a complete equity direction, and PCORI has the opportunity to do things like that. And then to change the way NIH will eventually do things. (Mary)

Conclusion

The data from Valley University suggests that protection of community ethics in research is most commonly addressed through faculty and their research teams. Barriers such as limited funding, differing views of community-engaged and CBPR research

among executive leaders at Valley and leaders in the field, and institutional processes that are not built to fully value community voice (including both IRBs) hinder progress toward further institutional understanding of community protection. These barriers also lead faculty to feel limited in their ability to affect change on campus and within their own partnerships. Even the faculty expert feels limited in her ability to affect change and admitted, “It’s hard to be a prophet in your own land. You know, I can be a national and international influence more than even on campus” (Mary).

While most participants do not currently believe that Valley has capacity to systematically address many of the community-level ethical concerns in CBPR, participants described how external grant-making bodies have opportunities to build in additional expectations for CBPR teams as well as institutions as a whole. One participant quipped, “So as with anything that’s controversial, you have to kind of follow the money, right?” (Tom).

Nevertheless, there are signs that Valley’s inability to make institutional change regarding community-level ethics is not a foregone conclusion. Although the Health Science IRB has historically been more difficult for CBPR researchers to navigate, participants also agreed that leadership within the Health Science IRB is changing to be open and more receptive. Additionally, the faculty expert described an upcoming project to “study these same issues” (Mary) with a group of other institutions across the country. She hopes to publish that information and bring it back to her campus leadership to continue discussions on best practices for protecting community-level ethics in research. Finally, there is excitement among participants regarding probable leadership change in an area that could significantly impact how the Health Science campus sets expectations

for research with communities. One participant described their perspective with energy and optimism:

> I'm so excited for our new faculty leader. She is a full-blown community engaged researcher and knows all the right things to do and why it's important. With her, I think we'll be able to do more true community engagement. (Sam)

Faculty and staff interviewed at Valley clearly value the continued pursuit of change related to community-level ethical concerns. A sense of exhaustion brought on by a need to constantly advocate to protect community-level ethics is not enough to deter one CBPR faculty member from doing the work: “It causes a lot of burnout and frustration. [But] all of us doing this work, we're doing it because we believe in it. We're committed to it” (Ericka).

Chapter 5: Cross-Case Analysis

Chapter 4 outlined two case studies of community-engaged research universities in the United States and the ways they have made sense of and accommodated the community-level ethical concerns of community-based participatory research (CBPR). Data from this study suggests that Green University and Valley University are motivated to understand these issues for different reasons. Even though the institutions highlighted in this study share similarities across several dimensions, the data indicate that institutional context plays a large role in which internal or external factors have the most potential for impacting long-term change.

While pathways for change may differ from institution to institution, institutional actors universally desired to push for increased understanding and accommodation of community-level ethics. This chapter presents themes across both institutions that might affect an institution's ability or will to fully address issues related to the community-level ethical concerns of CBPR. The comparisons between these institutions appear in the following areas: centrality of IRB approval, financial resources, community context, internal influence, and perceptions of progress.

Centrality of IRB Approval

A primary difference between Green and Valley is the centrality of the IRB offices at each institution. The IRB Office at Green University operates with three IRB boards under the leadership of one director. Additionally, the IRBs are housed in the same physical location which increases opportunities for collaboration. IRB staff at Green acknowledged that at times, interpretation of the federal regulations can be slightly different between each review board, but also explained the ways that they work together

to bring disparate opinions together. One IRB staff member described both the formal and informal ways this happens at Green's IRB:

> I think in those cases, we try when we recognize what the differences are, either we have some conversation, [or] there's a committee called the Human Research Protection Program Advisory Committee, which is out of the Office of Research Policy..especially if they rise to a certain level where we think we're really disparate and try to resolve it so that we can be consistent across committees, too. So I just wanted to add that there is a mechanism in place and sometimes it's just an informal conversation between the two [IRBs] saying, oh, yeah, that makes sense that you would do it that way. (Kathleen)

While participants at Green discussed how the IRB structure moved through several iterations in the past 20 years, it was clear that each change was geared toward increased information sharing with a focus on streamlining process.

At Valley, there are two IRB Offices that operate completely independently from one another as they report through separate Offices of Research and are housed in different physical locations. Until very recently, the offices rarely collaborated with one another which is seen by participants, particularly those who facilitate CBPR projects, as a detriment.

Separate offices at Valley seem to hinder IRB staff in knowledge sharing regarding CBPR review. For example, neither IRB manager has a clear understanding of the type or amount of CBPR research reviewed as a whole at the institution. In addition, although the Valley IRB manager who participated in the study is aware that CBPR researchers collaborate across campus, there was no recognition of the hardship CBPR teams face when the same trainings are required at Valley through both campuses. Each of the faculty members interviewed for the study acknowledged this as one of their largest frustrations. In contrast, no interviewee from Green indicated duplicative work when it came to human subjects' training or conflict of interest training requirements.

Financial Resources

Another key marker of difference across the two environments was levels and types of resources available to the research enterprise. Green University is a resource rich institution with high levels of research expenditures and research volume. It is also a large enterprise with more than twice the graduate students when compared to Valley University. State support for community engagement work in medical and public health research as well as a deep commitment to extension research were specifically mentioned by participants at Green and considered a large factor in the institution's ability to continually evolve their work in engaged research.

This robust environment plays a role in the size and scope of the research enterprise at Green. Practically speaking, this means that the institution employs more IRB administration and staff analysts and sees a greater variety of research protocol, likely including a higher volume of CBPR studies in both the Health Sciences and Social/Behavioral Sciences. In other words, there is greater opportunity for specialization in and familiarity with CBPR protocol at Green's IRB.

This was exemplified through a publicly available video on Green's website. This video is a recorded conversation from 2010 of a panel of three IRB staff members brought together to discuss and answer faculty questions specifically related to community-engaged research as well as the specifics of CBPR review. In it, the staff reviewer who was at the time tasked with receiving CBPR protocols at the Health Sciences IRBs signaled that CBPR was not a new topic of discussion for their board. Additionally, the IRB staff member described the importance of collaborating across groups on campus to increase understanding of CBPR's unique features:

> I think the Health Sciences IRBs, at least in the last several years, really have moved forward in our understanding of community research, and how to review that kind of protocol and how to work successfully with research teams…full blown CBPR, which you know, just at the level of paradigm, is radically different than from what standard research looks like, especially in the medical school environment. So I think addressing that, obviously takes time. It takes…collaborations with different groups across campus. And that's something our IRB is trying to do a little bit more…I see representation in the audience from groups that we work with regularly to have conversations about emerging practice in research. (Amy)

Alternatively, financial resources Valley University seemed scarce. Nearly every participant who supports CBPR research mentioned the influence a lack of resources had on their work. Several participants described the state where Valley is located as poor which results in a lack of funds for the University, community engagement or otherwise. Additionally, community engagement centers on campus, except for centers that exclusively serve Native populations, exist because external funding agencies have invested in those efforts at the institution. In at least one case, staff who are employed to further develop community engaged and CBPR research are instead utilized for general qualitative research support.

One way a smaller, less well-resourced research and community-engagement enterprise has influenced Valley's IRBs is that it was only recently that a full IRB office was established on the Main campus. While the current IRB Director there crafted a guidance document for CBPR researchers soon after she began her position in 2016, the document is only about five years old. In addition, she described that the frequency with which she sees CBPR protocol is scarce:

> I'd say we have a little bit less of the CBPR research because we're not as health focused as the Health Science Center. But we do have a few big projects that are federally funded that are definitely community engaged research. But it's a very small piece of our portfolio, I guess I would say. (Carol)

The Health Sciences IRB Director declined to participate in this study which could be interpreted to mean that they remain disengaged when given the opportunity to discuss issues related to community protection. Regardless of the reasons, the stances taken by both IRB directors indicates this is not a broadly prioritized issue for either IRB at Valley.

Overall, data revealed that the staff at the Green University IRB have a longer history of discussing the issues related to the ethics of community engaged and CBPR research. A centralized IRB that utilized a collaborative approach to information sharing as well as decades of comparatively frequent exposure to CBPR protocol seem to play a role in their deeper understanding of the specifics of the ethics of CBPR.

Community Influence on IRB Process

Communities outside both institutions have also played a role in IRB staff members' understandings of the ethics related to CBPR. Although community influence stemmed from different groups at each institution, each outside group was established enough to have their own review processes for research. Influence from these groups resulted in the addition of site permission requirements at both institutions.

At Green, the first site permissions were required through the Health Science IRB for clinical environments and driven from a logistical perspective and a desire for accurate research data:

> [Site permissions] arose because of the amount of research that was done in clinical environments. It was almost more from kind of a managerial perspective of making sure it's okay to disrupt clinic flow, that there actually is support there. But also to build confidence that the research can be done, right. Because if you don't have that kind of buy in from a site, then it could affect how the study goes …if it's going to be a bad study with bad data, then why even do it. (Amy)

Site permissions also made an appearance on the Social/Behavioral side of the IRB because one large school district required that Green faculty receive approval before proceeding with research of any kind in their buildings. One IRB staff member described it as “an external review committee…they have their own IRB of sorts” (Anne). Since research in this prominent metro school district would be blocked if these permissions were not granted, the Green IRB made it a part of their process to alert any faculty with proposals to complete research in the district of this requirement. With these influences from the clinical and educational settings as a backdrop, over time the Green IRB began extending the site permission requirement to all community-based organizations and now require letters of support for all non-exempt research that takes place in community settings. In addition, while exempted research does not require a site permission letter given the status of exempted from further IRB review, researchers are still advised to gain formal approval from their sites or community partners as a part of their research process.

At Valley University, the community influence on both IRBs was even more substantial. Nearly all participants specifically described the influence of Tribal IRBs on process and procedure for any researcher or research team that partners with or includes participants from any Tribal Nation. Essentially, researchers must follow several rules laid out by Tribal IRBs that are quite specific. The Valley faculty expert described some of the specific requirements:

> [Tribes with IRBs] demand, you can't submit a paper for publication or a conference paper or anything without tribal approval. Then they want, and [the tribal IRB] very much has the capacity to do this, but you have to turn over all your data to [them]...Tribal IRBs keep the IRBs open until every single publication and presentation is done. They have to approve everything. And then

> all of the data, focus group transcripts, all of that gets sent to the [tribal IRB]. Tribes are really serious about it. (Mary)

She went on to describe how Valley, and all its research centers and offices, have no choice but to follow and encourage these rules, or the institution will not be able to gain access to the tribes for research purposes:

> I think, you know, you have to deal with this. If [Valley] wants to support faculty or scientists to work with tribes, they have to deal with the approval processes of the tribes. [Valley] could say, oh, we're gonna pretend it doesn't exist and the tribes can say, Well, we're a sovereign nation, just get out. (Mary)

While some Tribes have their own IRBs, some only have a review committee or no formal process at all. Based on the precedent of the Tribal IRBs the Valley IRB worked with, in the mid-2010's, the Health Science IRB Manager expanded protection for tribes who do not have a full IRB process. Today, researchers must receive a tribal resolution from all tribes, regardless of their internal structure or process for reviewing IRB protocol. This essentially established a site permission requirement for research with all tribal groups.

At both institutions, communities with established review processes influenced the IRBs by requiring site permissions to complete research in their communities. In other words, these communities had the institutional power to say no to a proposed research project. The Green University IRB decided to extend site permission requirements to all non-exempt research and, as a matter of process, also encourage researchers with exempt community-based research to acquire site permissions. Notably, even though Valley's IRB described a deep familiarity with the highly specified Tribal IRB processes, several participants at Valley took time to explicitly describe how no

effort has been made to formalize additional protections for other marginalized community groups.

Internal Influence on IRB Process

In addition to influences on the IRB from communities outside the institution, internal members of the university communities have also played a role in change that considers community-level ethics. At both institutions, research teams have long advocated for change related to human subjects' protection training for community researchers on their teams. Within the past year at Green and at Valley's Health Science IRB, virtual trainings developed by other University IRBs were formally adopted for community research partners. This makes the process far less cumbersome and significantly reduces time burden on the part of academics and community members in preparing for CBPR projects.

In considering what has most influenced this ability to create change, the data suggest that characteristics of staff and faculty leaders, inclusive of IRB staff, impacted their likelihood to understand and advocate for community protection. One staff participant from Valley noted that "having this different dynamic of different people, different genders, different races, being in these positions of power has really, really helped" (Diana). At Valley specifically, changes made to the Health Sciences IRB process that positively influenced CBPR were made under the direction of women of color. A faculty member from Green described how they have seen BIPOC faculty, in particular Indigenous faculty, lead the way in creating standards for authentically engaged and participatory research:

> The other thing that's starting to happen is there is a wave of researchers who are starting to reconnect with their communities of origin…they're kind of

> everywhere now. And, and so especially Indigenous academics are starting to come up with standards. And mean, interestingly enough as the colonizing academics back off, it creates more and more space for BIPOC academics, to who, at least in my experience, are more likely to be considering these [community-level] issues the way I think about them and actually get space to do this work. (Lou)

Perceptions of Progress

While participants at both institutions were excited to share about recent progress within the IRB, CBPR research facilitators also shared discontent with limited recognition of community-level ethical concerns at their IRB and within their institutions. At Green, frustrations stemmed from feeling a lack of progress regardless of an overall institutional commitment to community engagement and relatively large resource pool to support engagement efforts. At Valley, CBPR faculty and research staff were disappointed that even with deep institutional knowledge of CBPR as well as long history with tribal IRBs, community protections have not moved beyond tribal partnerships.

These ideas were most explicitly articulated by participants identifiable as CBPR thought leaders on each campus. Each of these thought leaders have 30 years of experience working in their campus context and nearly decades of experience facilitating trainings and consultations with CBPR research teams on best practices of CBPR. Both have played advocacy roles specifically related to the IRB and institutional process and how neither fully protect community-level ethics. Both experts also engage in conversations larger than their individual institution to build best practices for CBPR and indicated that they are aware of other institutions that are “further along” than their institution as it relates to protecting community-level ethics. They supported arguments made in the literature that meaningful change related to protecting communities in research must come from more than individual faculty and research teams. In other

words, the experts agree that community-level ethical concerns are important but have not yet been meaningfully addressed by their IRBs or institutions.

Barriers to IRB Engagement in Protecting Community-Level Ethics

Even though IRB staff in both institutions are aware of the difference between and importance of individual and community-level ethics in CBPR research there seems to be little indication that IRB staff view it as their responsibility to serve as the impetus for systemic change in this area. They are most heavily influenced by the federal regulations, as described in Chapter 2, which currently do not include any guidance or requirements related to community-level ethical concerns. In fact, one IRB staff member from Green quoted a clause in the regulations that guides IRBs to keep their reviews from considering long-term community impact:

> What it makes me think of is what the limits of IRB purview and authority are, because I think you're raising an issue that is beyond IRB purview. The regulations have IRB look at the risks of subjects, but very specifically say, I'm going to quote, "The IRB should not consider possible long-range effects of applying knowledge gained in the research, for example, the possible effects of the research on public policy, as among those research risks that fall within the purview of this responsibility." Looking at the IRB guidebook that the Office for Human Research protection puts out, it says research might have adverse consequences for communities, but it's really not the IRBs responsibility. (Kathleen)

This statement specifically limits IRBs from considering issues related to community beneficence. This is interesting considering that when asked what, if anything, could change at the federal level, the expert at Valley indicated that expanding regulations to incorporate community beneficence would be the most likely to succeed because there are "direct strategies" to use to assess risks and harms to communities. According to her "to move out of individual risk/harm is really important" (Mary). While regulations are currently a barrier to IRB action on community beneficence, a change in

this clause or a federal recognition of the importance of community beneficence could alter institutional response to community risk and benefit considerations.

If, in general, it is not the role of an IRB staff member to advocate for change related to community-level protections, it was still important to community members, staff, and faculty participants that IRB staff reviewers and IRB members continue to increase knowledge about CBPR. In this way, the IRB would serve as additional support to CBPR research teams in developing protocol that considers community protection. Small scale efforts to train IRB staff were described by participants at Valley, and at one time Green had a staff reviewer that received all CBPR protocol because she had a personal interest in and experience with qualitative studies. However, participants outside the IRBs at both institutions clearly desire those within the IRB office to have a deeper knowledge of both community-engaged and CBPR research. Thus, from the perspective of CBPR research teams, a lack of knowledge from the IRB regarding community-level ethics remains a barrier to further change.

The expert at Green described how improving hiring and training practices for IRB reviewers and board members are two features within the current structure of the IRB that could positively impact ethics that are unique to CBPR:

> Because of my time in I'm, I'm invited to be a part of hiring teams for IRBs. In my experience, the tendency is to find people who are really happy being regulatory compliance reviewers. So you start with an employee group that isn't necessarily tied to any particular thinking about research even. They're just matching application to reg. And then they specialize within the IRB, oh, you're going to be more in this area versus this area, but it's not very dynamic. The IRB Director here for many decades was an anthropologist and so thank God I met her early on in my career, and could have conversations about, oh, you recognize there are other methods? You know what fieldwork is? You did science on monkeys? It was very different than the makeup of the [IRB] members.

> Even that's a place where I think there's some ethical examination, those meetings are hideous, marathon sessions, very little discussion. Again, the community voice is absent. If you were going to bring somebody in to represent community, how would they be supportive? How would any of that change, so that they could actually voice something that would bring some diverse perspective into the room? Many people serve for long periods of time, that's great for efficiency, but also just blasts any creativity or innovation, like pushes it out.
>
> Those are features of the office that in my experience watching the talent acquisition, what's valued. People who can't get with the program leave really quickly. It's a very expensive endeavor because there's a ton of training. I wonder about could those employees be exposed to some other parts of this journey to bring perspective that would help with this sort of bigger vision. (Eve)

At Valley, increasing knowledge about the importance of the ethics of CBPR on IRB staff and among IRB membership might result in expansion on protection that is currently only offered to Native populations. At Green, attention to CBPR knowledge among IRB staff might help to maintain their broader site permission requirements. This is true because a current staff member who was not around during the initial phases of site permission requirements is beginning to question whether they are worth the effort to maintain:

> When I started here at [Green] in 2012, the site permission requirements [for] community engagement were in place...And I just reached out to our legal counsel on that and she was like, I don't know where that requirement necessarily came from. But she said, because it's not a regulatory requirement. And if the institution is fine not requiring that for final approval, that's something that we could essentially remove as a requirement.
>
> So…there's no regulatory requirement, nor is it an AAHRPP [accreditation] requirement that you have to provide school or site permissions in the IRB application. That's not why we've had this requirement as an institution to get these site permission letters in there…it's not institutional policy…And that's why we might be getting away from that, these things for community-based research being in the application. Again, I don't know when we didn't have that. I just know we're now at a point where we're thinking about not requiring it.
>
> It's not like it's really adding much value to get that site permission into the file…It's not like somebody's just gonna walk into [a community organization] and start recruiting and sitting down and interviewing there. We know there has to

> be some conversation. So, what's the risk benefit here, you know? We're not gaining much by making researchers put that in the in the application and delaying final approval until we get that, the benefit isn't there. And I feel like the benefit of not requiring it certainly outweighs the benefit of requiring it. (Ashley)

Other Barriers to Understanding Community-Level Ethics

Previous literature indicated that the IRB may be a central hub for protecting community-level ethics. As such, this study focused on the ways in which IRBs are responsible for protecting community-level ethics. Results of this study also indicate that there are real limitations of IRB staff and IRB boards in considering these concerns. Additionally, experts who used to think that IRBs were "pivotal" (Eve) in protecting communities are now turning their focus toward other systems that may play a larger role in long-term change for CBPR research teams and the protection of communities. Two themes emerged in this area from participants at both institutions.

The first theme was related to the culture of academia. Most specifically, this theme centered around quick turnaround time for grants which makes the choice to sustainably incorporate community voice in research projects challenging, even when working with CBPR experts. One staff member from Valley described this pressure as the largest barrier to developing ethically sound CBPR projects:

> I think it really comes down to the structure of academia and academia's priorities, which I am seeing a shift, very slow shift, but it is shifting in the right direction. Although I think we went a little backwards during the pandemic with so many short cycle grants that came out. I'm actually on one of those grants. There were really strong community-engaged researchers on this project and they had the best intentions. But in a month, how can you possibly put together a multi-million dollar grant for only one year and include all the CBPR principles? (Sam)

A faculty member from Green also discussed grant timelines as a barrier for sustained investment in communities where she does her research:

> This is a big [barrier] and actually is a big one right now in terms of ethical concerns. You come in and run the program, the grants pay for it. And then the grant is done in a year or five years. But we want to keep the program in the community because we benefited, but we can't keep the program, because the grant is over that paid for it. That is a huge ethical concern that I've seen in some of the work I'm also doing as well, is what happens to all these amazing, innovative programs you bring into our community. How do you keep this going as sustainable? It works for us, we like it. But then you are going away because there is no more funding to keep the program going. (Naomi)

One proposed avenue for change, according to the faculty expert at Valley, are the major federal grantors. In her opinion, there is a shift beginning at a high level for how calls for funding are proposed which are more and more focused on identifying mechanisms that truly allow for community participation in research. Other participants described a desire for institutional change in this arena and called for increased institutional financial support for faculty brought on as CBPR researchers.

The second barrier to protecting communities calls for increased structural support for and understanding of CBPR. Participants frequently lamented bureaucratic policies and procedures that kept them from undertaking their CBPR research ethically Most often, frustrations were tied to paying communities for their work whether it was through grant funding, honorariums paid out by departments, or hiring policies that limit which positions within the university are accessible to community partners.

In 2021, Carter-Edwards et al. published a research paper that addressed many of these bureaucratic issues for community-engaged and CBPR research teams. The research paper has had an impact, as both campus experts shared it as an example of progress made in support of ethical CBPR. Researchers in the study interviewed community partners, academic researchers, and research administrators who work on research projects in several Clinical and Translational Science Centers across the country.

In the interviews they discussed the fiscal and administrative barriers and facilitators to conducting community-engaged research. The work by Carter-Edwards et al. (2020) only offers recommendations for "fiscal readiness" for research teams themselves, rather than outlining organizational changes to be implemented by research centers or larger institutional structures.

Regardless of the focus on best practices for research teams, this article did identify the need for changes to institutional fiscal processes, specifically calling out the importance of doing so for building trust within communities:

> Our findings complement recent national findings that financial management in the pre-award (e.g., budgets, budget justifications) and post-award (e.g., subcontract and subaward monitoring) periods are investigator-identified high priority areas in vital need of change within academic institutions. Not only must fiscal processes within academic institutions be improved, but they must also be recognized as key factors in the building and maintenance of partnerships and trust within community-engaged research. (Carter-Edwards et al., 2020)

These types of nuanced process changes are often only possible with executive leadership that recognizes and prioritizes specific challenges and intentionally seeks to address them. While individuals at both Valley and Green have attempted and made various inroads related to prioritizing community-level ethical concerns from mid-level leadership positions, participants at both institutions agree that neither currently have high-level leadership that are prioritizing these issues.

Conclusion

In comparing and contrasting both cases, it seems that some barriers to making sense of and accommodating for community-level ethical concerns apply universally. The limits to IRB review via federal regulations, an academic culture driven by time-sensitive grant mechanisms, and bureaucratic administrative structures would likely apply to any research-intensive institution interested in protecting community-level ethics. The differences between these cases appear largely tied to institutional context and overall support gained through committed finances or advantage gained through prestige.

In the next chapter, I will align the findings discussed in chapters four and five to the conceptual framework guiding this study. By analyzing these findings at a conceptual level, I will be able to interpret how existing organizational sensemaking theories apply to the consideration and accommodation of community-level ethical concerns in the two cases selected for this study.

Chapter 6: Summary and Discussion

Although many studies describe the importance of community-level ethical concerns in community based participatory research (CBPR), there are only a few studies that investigate how Institutional Research Board (IRB) staff understand their role in community protection. The research questions in this study include:

1. How do Institutional Research Boards at community-engaged research institutions make sense of the ethics of CBPR?
    a. What are the environmental cues and collective meaning-making processes used to understand community-level ethics?
    b. Who else is involved in this process?
2. In what ways and to what extent are community-level ethical concerns of CBPR considered in reforms to IRB processes?

Two case studies were written using participant interviews and document analysis to answer these questions. A cross-case analysis compared common themes that were relevant to both institutions. This chapter includes key themes from the study as well as updates to the conceptual framework. It also discusses how the study results inform implications for practice, theory, and future research related to understanding community-level ethics in research at research intensive universities in the United States.

Key Themes and Understandings from this Study

In this study, several key themes emerged that contribute new knowledge about CBPR in the context of IRB review. These themes help us understand how two institutions with high levels of community engagement and a history of addressing community-level ethics make meaning about CBPR and the nuances of community-level

protection. The key themes include how environmental cues are a catalyst for IRB sensemaking, how sensemaking forums promote IRB reforms**,** the ways leaders are gatekeepers or facilitators of sensemaking, the critical role of CBPR experts, and the extent of community-based protections offered through IRB Offices. The final theme is that CPBR ethics ultimately remains in the hands of faculty and staff.

Environmental Cues as a Catalyst for IRB Sensemaking

This study yields significant new understandings about how community-engaged research institutions make sense of the ethics of CBPR. Though my analysis of Green and Valley Universities, I learned that IRB staff at the two case sites, especially IRB Managers and Directors, have been much more involved in learning about and understanding CBPR than the reviewed literature at American institutions of higher education acknowledges. This is in line with the study by Guta et al. (2012) outlining how Research Ethics Board stakeholders in Canada showed an unexpected level of understanding of the nuances involved in reviewing CBPR protocol.

The main external influence on IRBs understanding of community-ethics were the federal regulations and their influence on the scope of influence IRB staff and IRBs have in responding to ethical concerns. While federal regulations do indicate a limit to IRBs to consider long-term community effects of research, navigating how to contextualize these regulations while being presented with CBPR protocol also initiated more complex understandings of community-level ethics and internal conversations about how to approach review of CBPR.

An unexpected external influence on IRBs were the ways some community groups' requirements for their involvement in research initiated changes in the IRB

process. This is in some ways surprising because non-IRB participants often described a lack of interest from IRB staff to respond to the distinctive needs of communities involved in research. However, a unique feature of the communities that were able to influence IRBs was that they had organizational structures and formalized leadership which offered their groups the authority to withhold access to research in their communities. These factors motivated IRB staff to respond to their requirements. Green IRB staff members described being initially motivated to respond to requirements from local hospitals for site permission letters to help ensure higher quality data collection. At Valley, the initial motivators were more in line with the tenants of CBPR as IRB staff chose to comply with local tribal leaders and tribal IRBs more robust demands for community protection.

Sensemaking Forums to Promote IRB Reforms

In this study, I learned that both Green and Valley Universities relied on various sensemaking forums to facilitate meaning making about CBPR as it relates to IRB approval. As a result of responding to community, and with increasing levels of exposure to CBPR protocols, (albeit likely fewer at Valley than at Green) IRB leaders have also engaged in collective meaning-making processes to expand understandings of reviewing CBPR protocol effectively. Namely, both at Valley's IRBs and Green's IRB staff developed protocol for best practice in reviewing CBPR protocol which is in line with the type of sensemaking response Guta and colleagues (2012) found in their study. At Valley, the Health Science IRB also brought in outside experts in order to help educate IRB staff on CBPR practices and at the Main campus IRB staff engaged in a deep-dive with local tribal IRB leaders to learn more about their process. At Green, collective

meaning-making has been initiated by IRB staff in the past through institution-wide education events such as a panel discussion on community-engaged research. At certain times in the past, Green's IRB has identified staff members as the CBPR protocol reviewers, which for a short time offered CBPR researchers more support for protocol submission. In short, my analysis of the two cases showed that although IRB sensemaking of CBPR has not resulted in the type of changes many CBPR research teams are hoping for, IRB staff at these institutions have taken an active role in trying to understand some of the unique challenges of CBPR.

Leaders as Facilitators and Gatekeepers of Sensemaking

Another theme that emerged across institutions is that sensemaking and attention to community-ethics largely depended upon the interest of the IRB Director in disseminating information about the topic. Even though IRB participants at both institutions indicated limited ability to change policy and procedure to enact additional community protection, it was clear that the level of understanding exhibited by the Director influenced the flexibility and creativity in the IRB Office's approach to review of CBPR protocol.

Participants at both case sites, including IRB staff and Directors, also expressed a desire and opportunity for institutional leadership to engage with questions related to community protection. A specific example related to data ownership was brought up by participants at both institutions, including an IRB staff member. They identified that questions regarding data ownership are important for institutions to address but they are not and will never be under the purview of the IRB. Instead, institutional policy could require research teams to handle data in a way that offers shared or full ownership to the

community which would then require a response from the IRB in the protocol approval stage. This example highlighted the key role that institutional leadership could play in sensemaking and ways that IRBs could work with institutional leaders to overcome barriers to meaningful and ethical research engagement in communities.

The Critical Role of CBPR Experts

In this study, I also learned that within the subgroup of CBPR research teams, campus CBPR experts had the most influence on IRB understanding of community-level ethics. This is largely because they serve to interpret additional external cues related to evolving best practices in the field and constantly work to push boundaries for protecting communities involved in research. For example, the campus experts at both institutions specifically mentioned utilizing a recent study by Carter-Edwards et al. (2021) about "fiscal readiness" for CBPR partnerships to open up discussions about financial policies at their institutions. They are also involved in generating new research in the field and do so by partnering community partners or faculty and administrative experts across the nation. In doing so, they are able to bring new models for practice to their campuses. The best example of this is the involvement campus experts had in convincing their IRBs to utilize human subject research trainings developed by other institutions specifically for community co-researchers.

Related to collective meaning-making, these leaders are the champions of an ever-growing and diversifying set of researchers, staff members, and community partners who are increasingly interested in incorporating CBPR practices or principles in their work. They offer trainings and consultations on CBPR, they build capacity for community member employment in research roles and also challenge campus leadership on policies

that are unfriendly to community protection. This includes but is not limited to policies and practices related to the research review process (i.e., hiring policies for community members/CBPR faculty and data ownership policies). At their core, these experts see their role as creating a network of individuals on campus, off campus, and across the nation who feel empowered to advocate for themselves and articulate a need for change.

Two Dimensions of Community-Based Protections Within IRB Offices

Regarding the ways and extent to which community-level ethical concerns of CBPR are considered in reforms to IRB processes, I learned that there are two main areas that both Green and Valley are working to provide additional protection for community members and groups. The first is determining whether collaborative sites and individuals are engaged in research, which results in the need for additional human subjects training for community partners. Both institutional IRBs have recently addressed this in a way that is considerate of community needs by allowing the use of contextualized training for community members. The second is ensuring fairness in the selection and recruitment of research participants, which is being addressed in-part through the introduction of site permission requirements. Neither site fully addresses issues related to potential gatekeeping, and Valley currently only has extensive site permission guidelines for tribal communities, but both institutions have acknowledged and acted upon a willingness to understand the community's role in deciding who participants in research.

These dimensions of community protections are in line with Cargill et al.'s (2016) study which outlines seven areas that IRBs can focus on utilizing the current flexibility provided by the federal regulations to alleviate tensions between CBPR best practices. This means that even if there is no change in federal regulations (as suggested by Castro-

Reyes, et al. in their 2017 CCPH report), and IRB's are not considered responsible for any of the broader social goals of CBPR (Cargill et al., 2016), the data from these two cases indicate that there is continued room for growth within IRB staff to learn about, cultivate, and respond to the ethical intricacies of CBPR. This supports previous research as well as data from the current study outlining a desire for continued and increased partnership with IRB staff on review of CBPR protocol.

CPBR Ethics Remains in the Hands of Faculty and Staff

Importantly, data from this study indicated that because IRB staff and IRBs are not addressing the ethics related to the broader social goals of CBPR, much of that work falls within the responsibility of individual research partnerships and faculty and staff across campus (including those identified as well-known experts). According to Cargill et al. (2016) these areas include:

- empowering communities,
- increasing real-world usefulness and relevance of the data,
- building community trust and ownership,
- creating equitable and sustainable partnerships between academic centers and communities, and
- providing local benefit to the communities that are participating in research

The Cargill et al. (2016) study suggested that these responsibilities belong to the community and to the research partnership. However, a clear message in the data from participants within the IRB, on CBPR research teams, and even from research administrators was that to move forward toward increased community protection, these social goals require institutional response. While all goals from the Cargill et al. (2016)

study were considered important, participants most frequently noted institutional barriers in their attempts to take the time to build relationships with community prior to launching a research project and providing benefit to their community partners through sufficient and timely payment or contextually appropriate incentives for participants. Participants in this study indicated that with additional support from leadership, the difficulty in these processes could be mitigated.

Interpreting Findings within Sensemaking Literature

This study provides an understanding of the ways institutional knowledge of community-level ethical concerns fits with literature on sensemaking within higher education institutions. This study is anchored in the work of Weick (1995), Maitlis and Christianson (2014), and Maitlis (2005) on sensemaking in organizations as well as theorists whose specific focus is on sensemaking in higher education to add contextual nuance (Eckel & Kezar, 2003; Gioia & Chittipeddi, 1991; Kezar & Eckel, 2002; Kezar, 2013). Their theories supported the development of a conceptual framework, research questions, and an interview protocol for the study. In this section, I interpret my findings through the sensemaking literature and consider multiple ways that the proposed conceptual framework depicts how community-level ethics are understood by IRBs at community-engaged, research intensive universities and ways the framework can be updated to better capture some of the subtleties revealed in the data.

How Do Events Become Cues for Sensemaking

In this study, environmental cues were defined as environmental jolts, organizational crisis, threats to organizational identity, or planned organizational change initiatives (Maitlis & Christianson, 2014). Sensemaking is then triggered by these cues

which leads to the reduction in incongruence in a previously well-understood process. Cues can be initiated internally or external to the organization. The current conceptual model recognizes how historical events as well as current events all serve as cues that play a role in institutional sensemaking.

A salient theme emerging in this study is that community organizations have more of an influence on IRB staff's understanding of community-level ethical concerns than originally assumed in the framework. The initial framework, as depicted in Figure 3 in Chapter 3, shows that community members influence the IRB only though the research team partnership. In the sensemaking framework, this would be considered an internal cue. What I learned from the data was that community groups and members at times have direct relationships with the IRB and ethical review process which means that their influence is both internal and external. A common example of this was that some organizations and external groups refuse institutional requests for partnership in research (i.e., creating an external environmental jolt) unless certain requirements are met in the research planning and approval process. In many cases, these community members or organizations worked directly with IRB staff to solve their concerns rather than through researchers or research team partnerships.

As multiple participants noted, these historical interactions with communities were the instigators of site permission processes within IRBs. IRB staff learned the requirements of certain community organizations and help to ensure that faculty and research teams are meeting their requirements for research partnership. While one institutional IRB decided to expand these permission requirements to additional community groups (Green) and the other stayed focused on the community group with

the most influence in their community (Valley), they were both responsive to community desires and demands.

This key insight from my study expands my understanding of the original sensemaking framework (see Figure 3) by suggesting that community members and organizations are important to conceptualize as independent decision-makers in the process of protecting community-level ethics in research. This point is important for future studies so that communities are considered as their own unit of identity rather than only as members of research partnerships.

In addition to environmental cues that can be viewed as sudden changes or jolts, I also learned from the data that sensemaking of community-level ethics is influenced by evolving external and internal environmental cues that create dissonance in many university environments. Several participants mentioned shifts in the overall national landscape of CBPR and how its popularization is influencing mainstay academic structures such as major federal funding mechanisms. For example, Clinical and Translational Science Centers have an ever-growing influence on the ways in which the funding is used to encourage faculty to partner with community. The push for translational and community-engaged models of research has encouraged many clinical research entities to alter or transform their health care delivery models.

Additionally, the diversification of individuals who work in university research environments was also a salient environmental cue to participants. Respondents described the way this evolving change in environment influenced their work in CBPR. First, they described that increasing numbers of women and people of color in positions of leadership has helped to create an ease of understanding of values related to CBPR.

Second, they described how influence from an increasingly diversifying faculty pool has led to increased prioritization of and connection to community values in higher education. Finally, respondents noted that when community members are formally employed in research roles, their participation influences effectiveness of study interventions and outcomes. Even for leaders who are fully committed to and supportive of this diversification, changing university personnel and new research models bring new levels of complexity to change management.

Collectively, these evolving external and internal forces can be perceived by campus constituents as either opportunities or threats to typical ways of doing business in higher education. The difference in perception depends on the values and priorities of the person interpreting the environmental cue. While Maitlis and Christianson (2015) describe the influence of environmental cues that are perceived as threats to organizations, they do not describe what happens when individuals perceive cues from different perspectives. Instead, this is in line with Weick's (1995) original understanding of the ways these cues influence individual identity development and, over time, institutional identity development. This expands my understanding of the sensemaking framework as depicted in Figure 3 in Chapter 3. In addition to cues triggering new levels of sensemaking at universities, some cues are an evolving presence that can stall rather than propel sensemaking of a particular issue. The process of stalling is discussed in more detail later in this chapter.

Another theme related to environmental cues also influenced my understanding of the framework. While Maitlis and Christianson (2014) focus on how a changing environment becomes a cue in sensemaking, data revealed that "static" environmental

cues can *either* play a role in facilitating *or* create barriers to understanding and change. One example is the structure of IRBs on campus. Historically at Green and currently at Valley, IRBs that operate separately create barriers to CBPR research teams' ability to successfully submit their studies. Separate IRBs can create a lack of cross-pollination of ideas and strategies between IRB staff who review protocol in different disciplines and also increase administrative burden on multidisciplinary CBPR research teams. Related to sensemaking of community-level ethics, this creates a barrier to the sensemaking processes by increasing burden on research teams and reducing capacity for collective meaning making. At Green, once the IRBs combined and collaborations began, this set the groundwork for an environment that was more supportive of conversations surrounding community-level ethics.

What this example suggests is not that certain environmental factors are static forever, but that some environmental cues *seem* unchangeable, and thus impact an individuals' understanding of what avenues for change are possible. This concept is related to Weick's (1995) idea of "extracted cues" and acknowledges that context matters in sensemaking. Other examples of static environmental cues in the study were unchanged federal regulations, campus finances, and limited support from institutional leadership. While the nuance is slight, a revised framework should consider this detail.

How Collective Meaning is Constructed

Collective meaning making is seen as a "mutually-constituted process, as members jointly engage with an issue and build their understanding of it together" (Maitlis & Christianson, 2014, p. 78). In the sensemaking literature, it is also described as the exchange of ideas between leaders and group members in a process that involves both

sensemaking as well as sensegiving (Gioia & Chittipeddi, 1991). While sensemaking can be understood as acts associated with understanding ambiguous events or new information, sensegiving is the process of influencing others' meaning construction process and moving groups toward a new organizational reality (Gioia & Chittipeddi, 1991, p. 442). This collective meaning making process can either be driven by high level leaders (top-down), by faculty and staff on the ground (bottom up) or driven from both directions. According to Kezar (2013), in top-down and in bottom-up change strategies, sensemaking takes shape as individuals attempt to help others envision and revision an unfamiliar concept, but *sensegiving* looks different between the two. In top-down change, sensegiving involves signaling and energizing, while in bottom-up change, sensegiving involves persuasion and overcoming.

With this in mind, this study illuminates the importance of collective meaning making and supports assumptions made in the initial conceptual framework that change initiatives related to community-level ethical concerns are for the most part driven from the bottom-up at both institutions. Based on coded data, participants almost exclusively described attempts to persuade others and overcome barriers, which is representative of bottom-up sensemaking/sensegiving process. Notably, it was campus CBPR experts who led the way in this bottom-up sensemaking and were able to initiate collective meaning-making that influenced sensemaking across campus and in the community. Examples of persuasion included advocating for additional funding to support partnership development as well as persuading IRB staff to alter their human subjects training for community partners. Prominent examples of overcoming barriers are related to

administrative hurdles such as paying and hiring community members serving in co-researcher roles.

Another key understanding that emerged in this study is that the IRB staff members were involved in collective meaning making process during the mobilization phase of sensemaking at both institutions. Based on the reviewed literature, it was assumed that IRB understanding of community-level ethics began in the implementation phase only after direct influence by CBPR research teams. Instead, I learned that that IRB staff members have been working to understand the ethics of CBPR for just as long as CBPR research teams. This is evident in the ways IRB staff participants described their long histories working with communities on site permission requirements and through the way they feel limited in conceptualizing community benefit and harm due to federal regulations on protection of human subjects.

This aspect of the study aids our understanding of past literature on sensemaking in two important ways. First, it expands the constituencies involved in mobilization of sensemaking beyond CBPR partnerships to include at least, but likely not limited to, community groups and IRB staff. Second, it introduces the idea that IRB staff members are engaging in top-down sensemaking/sensegiving rather that bottom- up sensemaking/sensegiving. This is because IRB staff at both institutions give sense (i.e., influencing others' meaning construction) to the topic of community protection by "signaling" that there are certain areas of community protection (community risk/harm) that they are not able to address.

This isn't to say that IRBs and IRB staff are not or should not be an important component of further sensemaking related to community protections. Participants outside

the IRB certainly identified ways that IRB staff could build a more responsive research review environment. Such ideas included being more intentional about hiring and training of IRB staff and also being more intentional about who represent the "community member" on boards.

Role of Action

The final element to consider in how sensemaking happens are the impact of actions taken by individuals and groups in pursuit of understanding an issue. According to Weick (1995), this is called enactment and is the process of bringing structures or events into reality. Enactment is the main driver behind meaning making and is what makes sensemaking distinct from thought-only driven processes such as interpretation (Maitlis & Christianson, 2014).

According to Kezar (2013), it is possible to identify where on the mobilization, implementation, and institutionalization spectrum an institution lies based on the specific types of enacted sensemaking and sensegiving. Kezar (2013) defined four different phases of sensemaking: 1. Mobilization—focused on gathering support for the change; 2. Early implementation—general support for the initiative garnered, some tangible changes have been initiated, barriers experienced and resulted in stalling; 3. Late implementation—general support for the initiative was garnered, many tangible changes have been initiated including general infrastructure, barriers experienced and overcome; 4. Early institutionalization—initiative becoming part of the general value system, not an innovation or something seen as an add-on to other existing operations.

What emerged from my analysis of the data is that both institutions fall within the early implementation phase of change related to protection of community-level ethics. A

hallmark indicator of a campus moving beyond mobilization into implementation is when individuals or groups begin offering workshops or trainings to enhance and encourage understanding of the issue at hand, which is present at both institutions. Another indication that both campuses are in the early implementation phase is that some tangible change has been initiated related to community-level ethics through IRBs at both institutions. These have been described previously as implementation of site permission requirements and changes to CITI trainings for community researchers.

A final reason both campuses fall within the early implementation phase is because they are both experiencing stalled sensemaking. According to Kezar (2013) stalling is evident when campuses lack a deepness of process, connection to strategies and barriers, or breadth of engagement across departments and campus wide to make real transformational change. While both campuses exhibit a depth of process and a breadth of engagement in academic departments on campus and with community constituencies outside of campus, an inability to connect to potential strategies and overcome barriers keeps both campuses in early implementation.

One reason that CBPR practitioners at both case sites have had challenges connecting to potential strategies related to community protection is because, as previously stated, IRB staff have for the most part decided that this issue is not within the realm of their influence. At Valley, this belief is amplified by the fact that there is a perceived “low-volume” of CBPR research at the institution which perhaps allows for de-prioritization. Several participants acknowledged that this may play a role in the increased expectation for CBPR research teams to solely bear the burdens of community-level protections. At Green, it is amplified by the fact that the IRB staff that deeply

understood CBPR have moved on from the institution. Current staff are considering changes to site permission requirements that would de-emphasize community protection.

Another barrier to sensemaking beyond early implementation is that it is fragmented at both institutions. The four forms of sensemaking are guided (i.e., leaders and stakeholders actively engaged in process), fragmented (i.e., stakeholders raise issues, but leaders do not respond), restricted (i.e., leaders communicate broad vision which stakeholders accept without offering alternate interpretations) and minimal (i.e., leaders and stakeholders wait for the other group to interpret an issue) (Maitlis, 2005). Participants at neither institution indicated that leadership at the highest levels have contributed meaningfully to conversations regarding the protection of community level ethics, regardless of some individuals' attempts to draw attention to the issue. This was a ubiquitous concern at both institutions.

While individuals at each institution have different levels of faith in their current leadership, IRB and non-IRB respondents at both institutions indicated that they believed their Vice Presidents for Research had a specific role to play in this issue and were not taking action. At Green, participants indicated that continued growth in understanding community-level ethical concerns is related to a lack of prioritization by leadership. At Valley, in addition to a lack of prioritization, participants also noted other reasons for stalled progress. First, even though there is a strong sense of understanding of the best practices in CBPR among those who frequently utilize the research model, I learned that leaders in key positions at Valley make sense of CBPR in ways that are not consistent with leaders in the field. Second, Valley recently lost a key high-ranking community-

engaged research position on Main campus, and participants indicate little hope it will be replaced.

These findings do not influence the structure of the conceptual framework originally posed in Chapter 3, rather, they reinforce the stages of sensemaking and offer insight into where these cases are situated on the timeline. What is interesting to note, however, is that while both institutions are in the early implementation phase, their reasons for progress and stalling are nuanced at each institution.

Another key understanding that emerged from my analysis relates to who on campus is most likely to take action in the sensemaking process. Past literature would suggest that advocacy from CBPR partnerships would play the largest role in influencing sensemaking of community-level ethical concerns (see Table 1). Furthermore, IRBs would play a pivotal role in expanding sensemaking across campus as they were seen as a crucial fulcrum in the overall ethical review process.

Previous sections have clarified why IRB staff tend not to see themselves as responsible for transformational change related to community protection, but CBPR research partnerships did play a major role in building momentum at each of the institutions in the study. For example, researchers at both institutions frequently mentioned advocating for lowering burden for CITI training, increasing funding for CBPR researchers to take time to build research partnerships, and reducing burden in administrative processes often related to paying community partners. However, it was also revealed that individuals in these research partnerships do not always have capacity to participate in sensemaking activities that extend beyond advocacy related to their specific research projects.

Instead, sensemaking from thought leaders on both campuses play a large role in continued understanding of community ethics. Their leadership pushes for systemic change, brings in best practices from external sources (e.g., successful models from other campuses and relevant field research that addresses current barriers), and highlights specific research and institutional policies that are not conducive to partnership-based research frameworks. Since the number of participants in this study was limited, it is not fair to say that the thought leaders interviewed for the study are the only change agents on campus, but it is important to note their role in the sensemaking process. Specifically, these individuals were the only participants who described their engagement with community-level ethics in both a bottom-up and a top-down way. In addition to persuasion and working to overcome barriers (strategies used in bottom-up sensegiving), these individuals are also using their positions as departmental heads to re-vision for the future and energize staff and faculty who come to them for advice (strategies used in top-down sensegiving). This has implications for my understanding of the originally proposed conceptual framework. Since moving between early and late implementation requires a connection to strategies and barriers, these change agents are likely key in moving campuses into the late implementation phase.

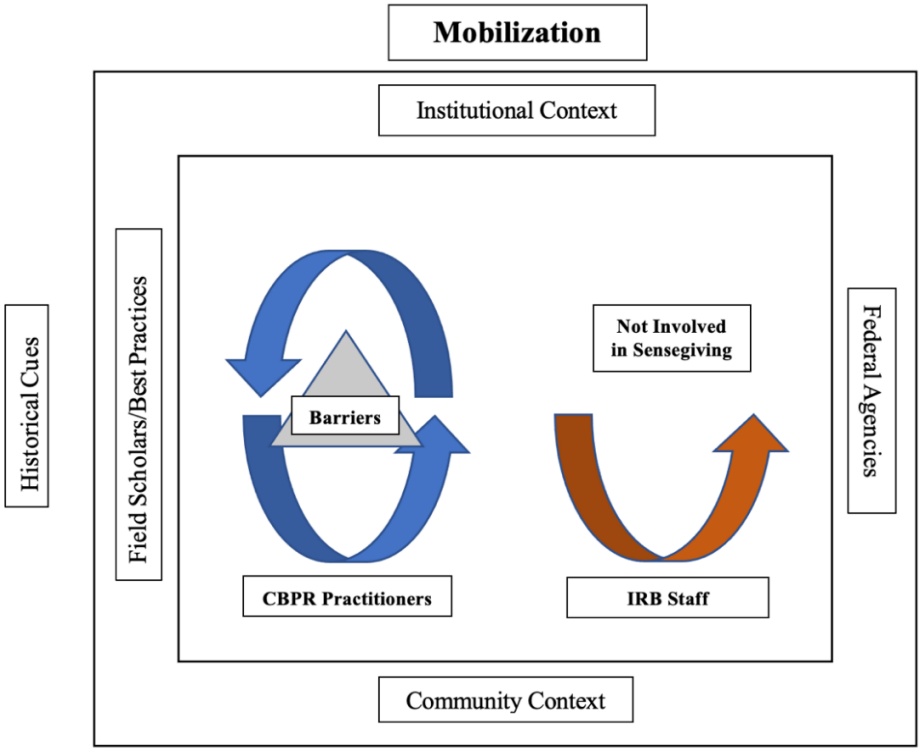
Revisions to Conceptual Framework

The proposed conceptual framework for this study (Figure 3) suggested that sensemaking of community-level ethical concerns is a bottom-up process that is driven by CBPR research partnerships. In this framework, significant external or internal environmental cues that initiate new enacted environments are the main impetus for garnering additional support across campus (e.g., from the IRB in implementation and

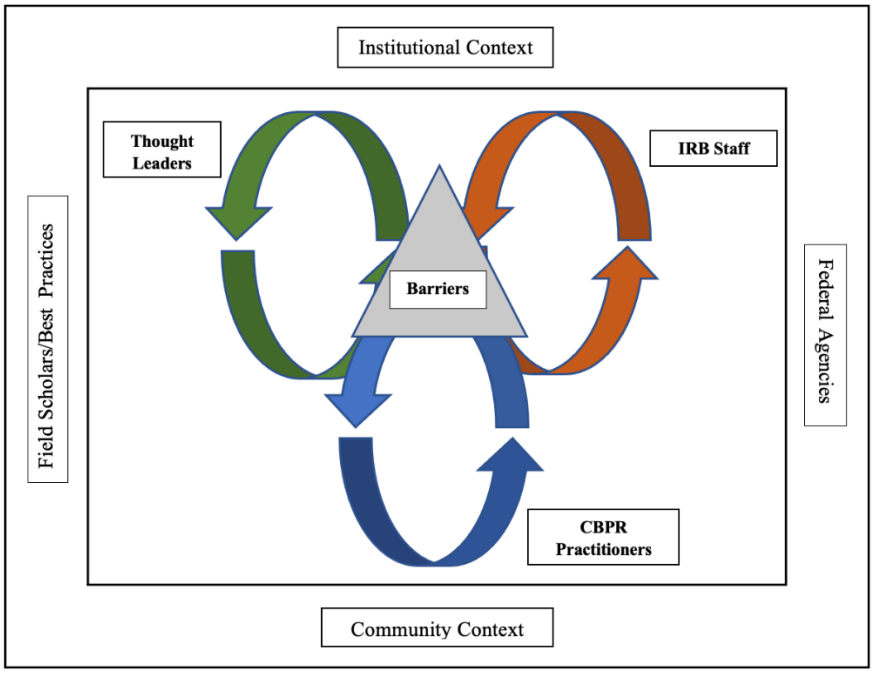
from institutional leadership in institutionalization) and propelling them from mobilization through implementation to institutionalization. In many ways, this original framework was a useful interpretation of previous literature in this area. In other ways, however, the results and interpretations from this study departed from the literature due to the evolving nature of the field, the importance of institutional context, and the recognition of institutional barriers to change. To account for these findings, a revised version of the conceptual framework can be found in Figure 4.

Figure 4

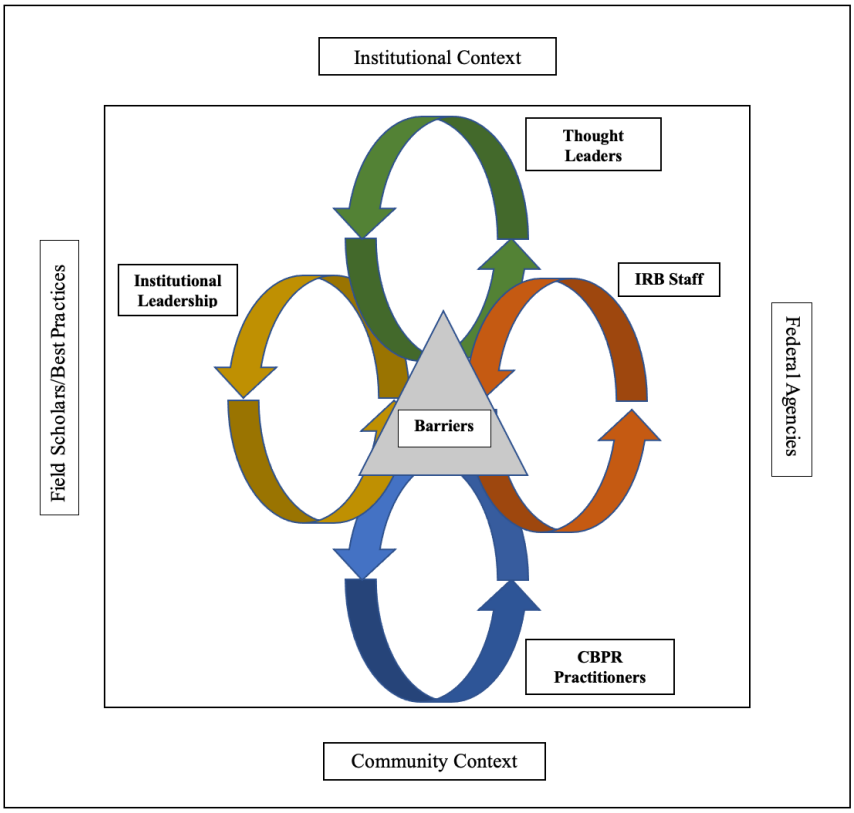
Revised Conceptual Framework for Sensemaking of Community-Level Ethics of CBPR

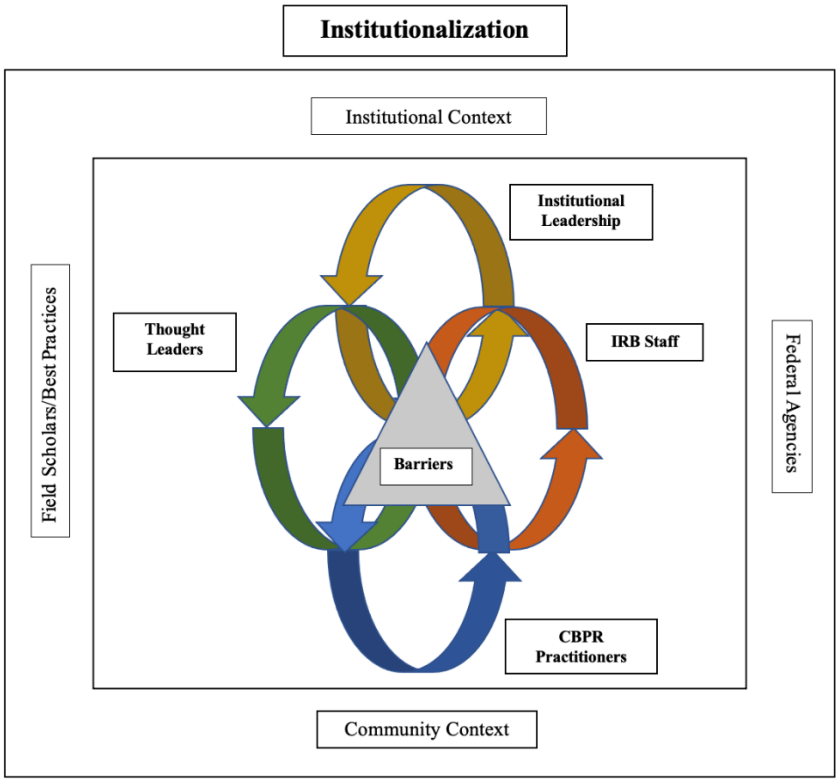


Early Implementation



Late Implementation





The model depicted in Figure 4 alters the proposed conceptual framework that guided this study in several important ways. In doing so, it adds new knowledge to our understanding of the sensemaking process related to community-level ethical concerns at community-engaged research institutions in the United States. First, external groups have even more influence on the sensemaking process of community-level protection than what was initially depicted. In the original framework, it was assumed that best practices developed from outside the institution relevant to community protection were utilized to help in the processes. This is similar to Kezar's (2013) study of interdisciplinary learning environments. In that study, externally developed best practices as well as investments from federal and private agencies influence understanding and propel higher education institutions seeking to invest in interdisciplinary learning environments. The same is true on issues related to community protection. Participants described that external funding

agencies (e.g., NIH, PCORI) as well as groups and scholars committed to CBPR best practices (e.g., CCPH) play a role in sensemaking of community-level ethical concerns.

What is not well-represented in the original model is the way that participants described influences that local communities and federal policy have on defining specific procedures related to CBPR protocol review. The data for this study revealed that local communities and federal policy place more than mere best practice suggestions on institutions, but rather also define exact procedures to follow related to community-protections. This alters perceptions of possibilities as well as actions by those inside institutions in specific ways that are relevant to the sensemaking process.

As such, it is important to depict this influence at every stage of the sensemaking process. Rather than depicting external influence as inputs at the beginning of the sensemaking process, external influence in addition to intuitional context is now depicted by a frame that surrounds each stage indicating that these factors are a constant presence in the sensemaking process. In this model, community and community members have greater influence than just their role as partners in CBPR research. In particular, their influence includes setting standards for site permission practices. Additionally, interpreting federal policy and any relevant changes that occur are also represented as a constant presence for participants to navigate.

The second update was to change the way that environmental cues are acknowledged as relevant to the sensemaking process. As described by Maitlis and Christianson (2014), environmental cues are triggers that initiate new levels of sensemaking to bring clarity to an uncertain reality. In the original framework, it was assumed that environmental cues (either internal or external) would be major events or

threats that propel institutions into deeper levels of sensemaking. In the current model this is depicted by cues that initiate each new stage of sensemaking.

The data also revealed static environmental cues also play a role in participants' understandings of community-level ethics. Examples of these types of cues are institutional features such as the structure of the IRB, institutional resources, and institutional leadership which were described by most participants with a sense of a fixed reality. In this sense, these changes are ever-present, and impact institutional actors' perceptions of or faith in what is possible related to transformational change. While a nuanced difference from the Maitlis and Christianson (2014) model, the differences in this study are substantial enough to warrant a new representation.

Another change to the model has to do with which institutional actors appear in each stage of transformational change as it relates to community-level ethical concerns. The current model assumes that CBPR research teams played a singular role in mobilizing sensemaking of community protection and IRB staff do not participate in sensemaking until the implementation phase. This assumption was based on reviewed literature as it emphasized concerns communicated by CBPR research teams (indicating that they were the ones continually starting conversations) and often proclaimed a lack of engagement in understanding issues from those in IRB offices and more broadly across institutions.

Instead, the data revealed a much wider array of individuals involved in sensemaking at each stage in the process. Many participants at both institutions referenced a history of community members, IRB staff, research staff, faculty, and community co-researchers learning about and responding to issues related to community-

level ethical concerns for decades. This was interpreted to mean that the sensemaking stages all include a broad array of internal and external stakeholders.

A final revision to the framework is the introduction of early and late implementation stages because of their specific relationship to barriers. In a certain sense, the original framework did not incorporate barriers as an important part of the model because it was assumed that the cases chosen for the study would be further along in the transformational change process. The original framework focused on how information flowed to initiate change rather than what was impeding change.

Participants at both institutions agreed, however, that transformational change had not yet happened, and that articulation of and connection to specific barriers by campus leadership would be necessary to continue progress. This is in direct alignment with Kezar's (2013) findings on how institutions become stalled in the implementation process. This stalling of progress is what separates early from late implementation, and participants at both institutions, particularly those considered change agents, specifically indicated a sense of being stalled. According to Kezar (2013):

> Connections to strategies and barriers means that change agents saw and made a connection between sensemaking/sensegiving and specific barriers they are trying to overcome and strategies they are trying to use…The greater intentionality in linking sensemaking and sensegiving to barriers/facilitators, the more likely the campus would move toward transformational change. (p. 768)

Data revealed that change agents at both institutions have exhibited signs of connections to barriers and strategies by communicating with campus leadership through things like initiating their own scholarship on best practices in CBPR as well as leading

groups to initiate campus-wide policy changes on topics such as data justice and financial support when hiring new CBPR faculty. Because both case sites are stuck in the same phase for the same reason, the framework has been expanded to add the nuance a relationship to barriers plays in overall transformational change. The further along the sensemaking timeline that institutions progress, the more campus and community constituents begin to engage with and understand barriers. Based on participant responses, the late implementation stage depicts institutional leadership engaging with barriers and the institutionalization stage depicts an overlapping of the sensemaking process where barriers are discussed and overcome among groups.

To summarize, the conceptual framework guiding this study utilized previous literature on issues related to community-level ethical concerns as well as sensemaking in higher education contexts to guide data collection and interpret participant responses. Since this was an initial study and previous literature on how IRBs make sense of the ethics related to CBPR does not exist, the proposed framework appearing in Chapter 3 was useful as a guide. Data collected from research administrators, IRB staff, community partners, CBPR research support staff, and CBPR faculty leads indicated that my proposed updated framework will enhance this work for future scholars and practitioners.

Implications for Theory

The previous sections of this chapter show how this study confirms and expands the framework for understanding sensemaking in higher education contexts. In the following sections, I will discuss several theoretical implications related to the meaning construction processes of community-level ethical concerns.

First, this study reinforces earlier findings (Kezar, 2013) that bottom-up change includes a sensemaking and sensegiving process that includes persuasion and overcoming barriers that is unique from top-down sensemaking and sensegiving processes. It also confirms the role of change agents in moving institutions closer toward transformational change, particularly in contexts where there is fragmented organizational sensemaking.

A second implication for theory is the acknowledgement of the limitation to Institutional Review Board (IRB) staff in addressing community-level ethical concerns, specifically those related to community risk/benefit analysis, without changes to federal regulations. This is critical to understanding strategies for change and broadens the set of responsible individuals and groups beyond the IRB. This study identifies several ways that IRBs can participate in continued sensemaking and craft strategies for additional community protection, but it also expands the responsibility for community protection to others on campus, in the community, and at external agencies.

Third, this study attempted to provide a basic understanding of how IRB staff understand community-level ethics and the ways in which that understanding translates to changes in policy or practice for CBPR protocol review. Although this study only includes small anecdotal evidence from two institutions, it clarifies that institutional responsibility for community protection extends beyond the IRBs. It also identifies several facilitators and barriers articulated across multiple constituencies at both institutions. Key facilitators include influence from community groups with infrastructure and power, popularization of CBPR and its best practices on a national level, and interpretation and amplification of these practices by experts on campus. Key barriers include a lack of clarity on which constituents are responsible for which types of

community ethics, institutional policies that do not easily accommodate inclusion of community in research practice, and institutional leadership that is either unaware of the nuances of CBPR or unwilling to prioritize changes that would positively influence ethical practice of CBPR. These insights related to barriers can provide additional information for those looking to study this topic further as this topic has not yet been extensively explored in the field of higher education.

Beyond the need for institutions to expand campus-wide strategies, this study provides a foundation for future inquiry regarding the intersection of higher education and external groups that have the opportunity to develop additional strategies for community protection. This work is increasingly necessary given a growing understanding that incorporating community into research in authentic and intentional ways leads to higher quality research. More deeply understanding community as a "unit" worthy of protection similar to understanding the importance of individual protection will only improve research outcomes and the larger goals of higher education to serve the public good.

Implications for Practice

This study has several implications for future practice. Since all participants were familiar with CBPR as well as the IRB review process, they understood the nuances of community-level ethical concerns and agreed with the proposed alignment to the Belmont Report categories of respect/autonomy, beneficence, and justice. Implications for practice can be considered through the lens of what might best amplify *community* autonomy, community beneficence, and community justice.

The first implication for practice is that if an IRB Office chooses to, improved practices surrounding garnering community site permissions can be implemented without federal or institutional policy change. At the chosen case sites, site permissions were originally initiated through requirements from specific groups off campus. Moving forward, IRB staff with an inclination to protect community could prioritize and develop practices surrounding the protection of community autonomy in research without impetus from external groups. This would likely require a focus on training IRB staff in some of the nuances of participatory research. For example, previous literature shows that at times community representatives can gatekeep in a way that does not allow access to participation in research that is equitable to community members. In this way, paying close attention to community autonomy is directly linked to issues surrounding individual access to research opportunities. If IRB staff are aware of this issue, they would be better prepared to clarify these concerns with CBPR researchers. While institutions may choose to implement a site permission request or requirement in various ways, data from this study revealed that it is possible and an area where future development could occur at an IRB level.

Another implication for practice relates to the limitations IRB staff members have in assessing community-level risks and benefits. Given these limitations, there are two avenues for CBPR practitioners to consider. First is to advocate for change at the federal policy level. According to one of the campus experts on CBPR, this option should be a piece of the larger vision for protecting communities in research. Although this is a long-term strategy, a path forward is paved as models for assessment and protection of community risk and benefit already exist within tribal IRB structures.

The second strategy is for CBPR practitioners to focus on issues related to community harm when delivering trainings for research partners. This is because when discussing the framework used for this study, several CBPR practitioners identified that they are more well versed in discussing and identifying ways that their work seeks to amplify benefits to their partner communities but does not always directly address community harm in a tangible way. An example would be research teams that are more well versed in discussing benefits of potential research topics and less equipped to talk through the harms of inquiry on certain topics or harm of particular data gathering processes.

A final area with implications for practice is related to community justice. Based on participant responses, a recent trend in the IRB world is the incorporation of community-friendly IRB training for community member co-researchers. This is an issue of community justice because it is an ethical concern when community researchers must take trainings that are overly academic and unnecessarily difficult to access. IRB staff or CBPR practitioners can suggest approval of previously developed online community-partner trainings to significantly ease the burden on CBPR research teams.

If institutional leaders, particularly those with research under their purview, are looking for ways to invest in community protection, this study suggests two main areas of focus. A first area of focus is the reduction of administrative barriers related to using funds for relationship development activities and ease of paying community partners for the energy they invest in developing and delivering research protocol. The second area is that institutional leadership could initiate conversations around data ownership in community-engaged and CBPR projects (one participant referred to this as a data justice

policy). At the very least, leaders could prompt discussions about institutional responsibility as it relates to returning data to communities in ways that are non-academic and contextually appropriate. These two issues are matters of community justice because they elevate community expertise and create opportunities for shared power, particularly in a world where community knowledge has often been stolen and misinterpreted.

Implications for Future Research

This study is one of the first to explore how IRB staff understand community-level ethical concerns of CBPR and to what extent this influences review of CBPR protocol. As a foundational study, it provides a framework for future research which will become increasingly necessary as CBPR continues to gain popularity while higher education remains scrutinized for a waning commitment to the public good. The qualitative data from this study will help inform future research, but larger scale quantitative studies should be initiated to gain a broader understanding of sensemaking of community protection at other institutions. For example, qualitative findings from this study might be used for developing a survey instrument to more broadly understand how IRB staff and CBPR practitioners across research universities in the United States understand community-level ethical concerns. This type of survey might further inform models of sensemaking in the higher education context and potentially uncover whether statistically significant relationships exist between institutional type or context and propensity to take action related to community-level protections.

Data from participants also revealed that there are a handful of medical centers and medical colleges/universities in the United States and at least one university in Canada that are gaining positive reputations for their commitment to community

protection. Given this information, the present study could be replicated at these institutions with a focus on what factors specifically launched these institutions into the late implementation and institutionalization phases of sensemaking.

Along the same lines, given the implications from this study that the influence of institutional leadership plays a large role in the later stages of sensemaking, high-ranking leaders from the same set of institutions could be interviewed. Studying their belief systems, individual characteristics, professional histories, and institutional strategies would illuminate a path forward for other institutional leaders looking to prioritize community-level ethical concerns in research.

Because this study identifies several barriers and facilitators to making sense of community-level ethics, future research could investigate barriers and facilitators to continued sensemaking in the IRB and across the institution related to particular ethical issues on a more granular level. For example, it would be interesting to know more about successful models for sustainably incorporating non-academic individuals from historically marginalized communities on IRBs. It might also be useful to conduct studies that consider specific institutional concerns related to the development of data justice policies. Finally, it will be important for future research to consider investigating research ambassador programs like the one at Green, as a way to amplify the importance of institutional power and resource-sharing with communities.

The significance of this study is that it provides theoretical context for understanding how and to what extent IRBs have understood and accommodated for community-level ethical concerns. Research in this area is surprisingly rare given the emphasis on vulnerable populations in federal regulations on the protection of human

subjects, the importance of serving the public good for many institutions of higher education, and the increasing popularity of CBPR as a research paradigm and framework. Although there are many potential explanations for this lack of research, any research in this area is useful. If Green University and Valley University are useful as examples, the present study expands understandings of who is responsible for developing community-level ethical protections and in what ways other institutions might consider taking action.

Conclusion

Green University and Valley University are community-engaged research universities that, each in their own ways, show an institutional commitment to community engaged practices. Even with different contexts, sensemaking surrounding the importance of protecting communities in research is widespread, includes IRB staff, and is driven in large part by a small group of change agents and CBPR experts on each campus.

At the same time, each campus is experiencing significant limitations to the opportunity for future growth and understanding of how to further institutionalize community protections. Some of these barriers are external, such as federal regulations, while others are internal, such as burdens presented by administrative procedures.

The unique contribution of this study is that it expands the vision for which constituents internal and external to higher education institutions can be involved in making and giving sense to community-based ethical concerns in research. It also acknowledges several facilitators and barriers in the process. The study provides guidance on how several different constituents can take action for further investment in protecting communities. Although progress is slow and barriers are real, participants

from Green and Valley, as well as their community partners, remain dedicated to a vision of a research landscape that prioritizes community involvement in research. This study also confirms the importance of conceptualizing ethics from a community-level lens.

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Appendix A: Interview Protocol

Each interview began with the interviewer sharing a working definition of Community-Based Participatory Research and Community-Level Ethical concerns.

Opening Questions

--In the chat box, I have provided a list of community-level ethical concerns. These were developed through my review of relevant literature.

a. Are there any from the list that you have questions about?
b. Are there any ethical concerns that are missing from this list?
c. Are there any that your institution tends to focus on more than others?

IRB Review of CBPR

--Do you know when the IRB began to address issues related to CBPR?
--Which of the community-level ethical concerns are addressed by current IRB review?

a. Who was involved?
b. What mechanisms were used to make change? (task forces, open meetings/forums, trainings, emails, documents)
c. Were there motivating factors from the institution or external environments?

--What are challenges that still exist with IRB addressing community-level ethical concerns? How might those be addressed (Through IRB or other mechanisms?)

Historical Context of Sensemaking of Community-Level Ethics of CBPR

--Do you know when [other departments within institution] began addressing community-level ethical concerns? (Follow-up questions below, if necessary)

a. Was this a grassroots effort?
b. Who was involved? [community partners?]
c. What mechanisms were used to make change? (task forces, open meetings/forums, trainings, emails, documents)
d. Were there motivating factors from the institution or external environments?

Current Context of Sensemaking of Community-Level Ethics of CBPR

--What are current strategies by [institution] / [department] to mitigate ethical concerns of CBPR?

a. Who is involved? [community partners?]
b. What mechanisms are used to make change? (task forces, open meetings/forums, trainings, emails, documents)
c. Bottom-up or top-down at this point?
d. Are there motivating factors from the institution or external environments?
e. What have been barriers to change? How were they navigated?
f. Have there been significant facilitators to change?

g. Were there any major turning points to understanding community-level ethical concerns on your campus?

Institutional Identity

--What is it about your institution or department that influenced change or resistance as it relates to protecting community-level ethics in research?
--Can you tell me the degree to which your institution is engaged in this issue? (Does it remain grassroots, is it departmental, are there efforts to engage multiple units across campus?)
--How do you believe institutional identity has changed over the time the institution has been engaged with these questions?

Closing Questions

--Is there anything else you think I should know that would inform this study?
--Are there documents, webpages, reports, meeting minutes, or other documents that might shed light on this process?
--Is there anyone else that comes to mind that could help inform this study?
--May I send any follow up or clarifying questions to you when I am reviewing this transcript?

Thank you again for generously sharing your time with me today.

Appendix B: Participant Recruitment Letter

Dear [Participant],

My name is Kayla Lyftogt and I am a PhD candidate in the Department of Organizational Leadership and Policy at the University of Minnesota. I am collecting data for my dissertation which focuses on the ethical review of Community-Based Participatory Research (CBPR) in higher education contexts. Your name was referred to me as someone with relevant expertise in this area.

It is my hope that this research will inform community members, faculty, and staff involved in CBPR projects about best practices and challenges in adapting Institutional Review Board (IRB) processes to CBPR. Considering [XYZ Universities'] long-term commitment to authentic community-engagement, I would like to investigate your institution as one of the two cases for my dissertation.

I am writing to ask for your assistance by participating in a one-hour zoom conversation about this topic. This conversation will be for research purposes only and published results will not identify you or your institutional affiliation. If you agree to this interview, I will provide you with more in-depth information about the study and measures to ensure confidentiality of your participation and responses.

Thank you in advance for your consideration.

Sincerely,

Kayla Lyftogt
PhD Candidate
xxxxxxxx@umn.edu

Appendix C: Verbal Consent Script

Invitation
My name is Kayla Lyftogt, and I am a doctoral candidate in the Department of Organizational Leadership and Policy Development at the University of Minnesota. You are invited to be in a study about the process that universities use to understand ethical issues related to institutional review of Community-Based Participatory Research (CBPR). I will read this form aloud to you and you are free to ask any questions you have before agreeing to be in the study.

Study Purpose
The purpose of this study is to generate new understandings regarding the ethical review of CBPR in the higher education context. A primary goal of this study is to assist institutional decision makers in learning more about current processes and potential future directions for adapting Institutional Review Board (IRB) processes to CBPR.

Study Procedures
Today you will be participating in an individual interview over zoom which should take approximately one hour. All aspects of your participation are voluntary and may be discontinued at any time.

Risks and Benefits of Being in the Study
There are minimal risks associated with this interview. As a participant in the study, you will be able to reflect on your experiences related to the review of CBPR and discuss those experiences with the researcher. Your participation will contribute to learning more about how institutions are responding to the challenges related to the ethical review of CBPR and may inform institutional efforts to make change in this area.

Confidentiality
The records of this study will be kept private. Your name or any specific identifying information will not appear anywhere in the final write up. If I use a direct quote from you, I will use a vague description to describe you – for example, campus administrator A, or campus staff member B.

With your permission, this interview will be audio recorded. The audio files, as well as data transcription, will be stored in an electronic encrypted locked file until my study is completed; only the researcher and her advisor will have access to the records. The files will then be destroyed. May I have your permission to audio tape this interview? (If yes, keep recording, if no, turn off audio recorder after script is finished).

Contacts and Questions
If you have questions regarding this study, you may ask now. If you have questions later, you may contact me at xxxxxxx@umn.edu or my advisor David Weerts at xxxxxxx@umn.edu.
If you agree to participate in this interview, please say "yes" into the audio recorder. (Wait for response). Your help is greatly appreciated.

Appendix D: Information Sheet for Study

You are invited to be in a study regarding the ways that community-engaged research-intensive universities and their community partners make sense of the ethics and ethical review of Community-Based Participatory Research (CBPR). You were selected as a possible participant because the institution you are affiliated with was chosen as a case site for this study and you have expert knowledge of community-academic research partnerships. I ask that you read this form and ask any questions you may have before agreeing to be in the study.

The protocol was submitted to the University of Minnesota Institutional Review Board (IRB) and was deemed not research involving human subjects as data collected are focused on programs and do not include private identifiable data about individuals being interviewed. Even though this study is considered not human subjects research, I chose to incorporate consent and confidentiality measures as a means to protect participants and encourage transparent interview responses.

Procedures: If you agree to be in this study, I ask you to do the following things: Participate in one, individual, one-hour virtual interview about: (1) your knowledge of ethical issues related to CBPR and how you and/or the entity you are affiliated with responds to those issues, and/or (2) your knowledge of any ethical review policies or procedures related to CBPR protocols at your affiliated organization. The interview will be audio recorded.

Confidentiality: The records of this study will be kept private. In any sort of report I might publish, I will not include any information that will make it possible to identify a participant or their institution. Study records will be stored securely and only the investigator and her advisor will have access to the records. Audio recordings and transcriptions will only be accessible to the investigator and her advisor. They will be deleted upon completion of the study.

Voluntary Nature of the Study: Participation in this study is voluntary. Your decision whether or not to participate will not affect your current or future relations with the University of Minnesota. If you decide to participate, you are free to not answer any question or withdraw at any time without affecting those relationships.

Contacts and Questions: The investigator conducting this study is: Kayla Lyftogt under the advisement of David Weerts. You may ask any questions you have now. If you have questions later, **you are encouraged** to contact them at University of Minnesota, Twin Cities; Organizational Leadership, Policy, and Development. xxxxxxxx@umn.edu; (xxx) xxx-xxxx or xxxxxxx@umn.edu; (xxx) xxx-xxxx

You will be given a copy of this information to keep for your records.

Appendix E: Results of IRB Determination

UNIVERSITY OF MINNESOTA

Twin Cities Campus

Human Research Protection Program
Office of the Vice President for Research

Room 350-2
McNamara Alumni Center
200 Oak Street S.E.
Minneapolis, MN 55455

612-626-5654
irb@umn.edu
https://research.umn.edu/units/irb

NOT HUMAN RESEARCH

January 5, 2022

David Weerts

Dear David Weerts:

On 1/5/2022, the IRB reviewed the following submission:

Type of Review:	Initial Study
Title of Study:	Ethics of Community-Based Participatory Research
Investigator:	David Weerts
IRB ID:	STUDY00014803
Documents Reviewed with this Submission:	• Lyftogt Determination Form, Category: IRB Protocol; • Lyftogt Interview Protocol, Category: Other

As data collected are focused on programs and do not include private identifiable data about the individuals being interviewed, the IRB determined that the proposed activity is not research involving human subjects as defined by DHHS and FDA regulations. To arrive at this determination, the IRB used "WORKSHEET: Human Research (HRP-310)." If you have any questions about this determination, please review that Worksheet in the HRPP Toolkit Library and contact the IRB office if needed.

Ongoing IRB review and approval for this activity is not required; however, this determination applies only to the activities described in the IRB submission and does not apply should any changes be made. If changes are made and there are questions about whether IRB review is required, please submit a Modification to the IRB for a determination.

Sincerely,

Jeffery Perkey, CIP, MLS
Senior IRB Analyst

Driven to Discover℠