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Institutional Review Boards and Writing Studies Research: A Justice-Oriented Study

Johanna Phelps-Hillen
University of South Florida, johannahillen@gmail.com

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Institutional Review Boards and Writing Studies Research: A Justice-Oriented Study

by

Johanna L. Phelps-Hillen

A dissertation submitted in partial fulfillment
of the requirements for the degree of
Doctor of Philosophy with a concentration in Rhetoric & Composition
Department of English
College of Arts & Sciences
University of South Florida

Co-Major Professor: Joseph Moxley, Ph.D.
Co-Major Professor: Norbert Elliot, Ph.D.
Stephen Neely, Ph.D.
Ellen Barton, Ph.D.

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DEDICATION

To my children. I'm so proud to be your mommy.

And to my mom and dad. As I watch your grandchildren grow and learn, I'm beginning to understand, just a bit, how hard you worked to make this all possible.

ACKNOWLEDGMENTS

Andrew, I love you. Thank you for all you gave to our family as I researched and wrote this document, an extension of me. This dissertation is a manifestation of your unwavering support, for which I will be forever grateful.

Norbert, you have steadfastly and patiently nurtured this research and my professional and academic growth. You've both infused my work with confidence and challenged me to make this project the best it can be; nothing more can be asked of a mentor. Joe, thank you for trusting me to get this done from 2314 miles away and for always offering sound advice. Thank you for your guidance throughout the whole of my PhD at USF. Ellen, our conversations in Madison changed the direction of my career and were the start of this project; thank you for all you did then and all you've done since. Stephen, besides your service on this committee, thank you for introducing me to the policy process and encouraging me to join the MPA program. Those two moments of shared history have shaped my research trajectory. And Nicole, you took me on, knowing I would leave when this was done. My time working for you informed this content in unexpected and important ways. *Thank you all for demanding my very best.*

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ABSTRACT

In this multi-method dissertation project I conduct policy analysis and utilize results from a discipline-wide survey ($n=258$) to examine the intersection of Writing Studies researchers' disciplinary affiliation, research context, and personal disposition in relation to the local implementation of federal policy regarding human subjects research. I elaborate on the context of this project, discussing the September 2015 release of the Notice of Proposed Rulemaking (NPRM) to revise and update the Common Rule, 45.CFR Part 46, and the Conference on College Composition and Communication's formal comment in response to the proposed rule's provisions. I discuss the process of designing and implementing the survey used to establish a disciplinary representation of Writing Studies researchers' perceptions of, and experiences with, IRBs. The results of this survey (Chapter 4) indicate how Writing Studies researchers presently interface with the process of local policy implementation. In Chapter 5, data from the survey are set against the Final Rule (released January 19, 2017) to provide a new taxonomy for Writing Studies researchers regarding how to interface with IRBs. Finally, the major theoretical contribution is articulated in Chapter Six: a call for human subjects researchers in Writing Studies to consider IRBs as justice-oriented, rather than positivist, in design and purpose. I argue increasingly reciprocal relationships between IRBs and Writing Studies researchers will help ensure Writing Studies research is not overly influenced by IRB review, nor that Writing Studies researchers are unwilling or unable to interface with IRBs to build more ethical and robust research agendas.

CHAPTER ONE: CONTEXT AND BACKGROUND

The history of our field [Writing Studies], then, shows multiple research methods from the social sciences grafted onto humanistic roots in order to produce the kind of knowledge, predictability, efficacious practice, and useful interventions that give the field its reason for being. The grafting of new methods onto those roots has caused us to reexamine our relationships to research and given rise to the codification of those relationships in the guidelines [CCCC Guidelines for Ethical Research] we took up for discussion that night in New York.

---Barbara Schneider, *CCC* 58.1, 2006, p.76

This multi-method project utilizes a review of public policy and Writing Studies literature, as well as the results of a discipline-wide survey, to examine the intersection of Writing Studies researchers' disciplinary affiliation, research context, and personal disposition in relation to the local implementation of federal policy regarding human subjects research. This confluence impacts the ways in which Writing Studies research proposals and protocols proceed through the Institutional Review Board (IRB) review process.

Federal policy regarding human dignity in research (45 C.F.R. § 46, or the 'Common Rule') serves as a touchstone for analysis and method of analyzing shifting approaches to research ethics nationally, institutionally, and disciplinarily. Situated against a backdrop of feminist research ethics in Writing Studies influenced by Royster and Kirsch (2012), Mortensen

and Kirsch (1996), and Nickoson and Sheridan (2012), this project embraces the expanding justice-oriented research landscape proposed by Elliot (2016), Inoue and Poe (2012), Poe and Inoue (2016), and Elliot et al. (2016). An empirical investigation of the discipline's perception of, and interactions with, Institutional Review Boards is bolstered by interpretations and implications of recently released (January 19, 2017) federal policy updates related to human subjects research. Correlated with survey data collected for this dissertation, these recently released regulations suggest implications about the practice of adhering to, and engaging with, federal policy while conducting Writing Studies research with human subjects.

Throughout this project, "Writing Studies" refers to the Classification of Instructional Programs (CIP) code designation for 23.13 "Rhetoric and Composition/Writing Studies." Like Elliot et al. (2015), when I refer to "Writing Studies" throughout this dissertation, I am referring to all the fields subsumed within 23.13: 23.1301: Writing, general, 23.1302: creative writing, 23.1303: professional, technical, business, and scientific writing; 23.1304: rhetoric and composition; 23.1399: rhetoric and composition/writing studies, other. Rather than "Rhetoric and Composition," I use "Writing Studies" for brevity; it also has the added benefit of being one entity, rather than a combined duality. Hereafter, I refer to *all* these fields as "Writing Studies." It is Writing Studies researchers, both those who enroll human participants in their research, and those who consider doing so, who are the target audience of this project.

Purpose, Goals, and Research Questions

The purpose of this dissertation is to provide narratives, heuristics, and guidelines, to enhance the reader's understanding of what it means to work with human subjects in Writing Studies research. More specifically, this project aims to help (1) expand the discipline's understanding of how federal regulations intersect with disciplinary agendas and (2) reshape

Writing Studies researchers' orientation towards the work of IRBs and provide a deliberative and principled investigation on the challenges, as well as the benefits, that IRB review affords researchers.

Building such a narrative will also serve as an illustration of how public policy shapes disciplinary research, and, as Laura Stark notes, how IRBs "change what is knowable" (Stark, 2012). To build this narrative based on reciprocity rather than animosity or apathy, this project has four goals, which I work toward by asking and investigating related research questions. The goals of this project are to:

- craft a timely overview of the shifting approaches to human subjects protections in Writing Studies Research
- provide analysis of position statements by Writing Studies researchers regarding human subjects protections
- collect narratives from thought leaders in the field regarding research and human subjects protections- past, present, and future
- enhance Writing Studies researchers' understanding of, and ability to navigate, human subjects protections, oriented in more general notions of justice and beneficence

The research questions generated from these goals guided the development of the concept map, survey tool, interview protocol, and interpretation of results. These questions are:

- How do Institutional Review Boards staff, or street level bureaucrats, interact with researchers to shape methods and methodologies in Writing Studies?
- How can we identify pertinent variables of training for Writing Studies researchers related to human subjects protections? What methods can we use to investigate broad categories of influence by IRBs and tailor support for Writing Studies researchers?

- Based on findings, can we create a new taxonomy to explain variables that result in best protections for human participants in Writing Studies research?

Can we provide guidance on modes of crafting documents for IRB review? These goals and research questions are contextualized by the present moment of our disciplinary interaction with federal policy. This project provides broad context via policy, and then, in later chapters, examines the more minute details that impact Writing Studies researchers' experiences with their local IRBs. A table connecting the broad purpose, goals, research questions, and chapters can be found in Appendix A.

Context

On September 8, 2015, the Department of Health and Human Services released a Notice of Proposed Rulemaking (NPRM) in efforts to substantially revise 45 C.F.R. § 46, better known as the “Common Rule.” The Common Rule originally published in 1991, requires IRB review of human subjects research in the United States. Advocates of the NPRM promised it would simplify the Common Rule in line with the current “social, cultural, and technological environment[s]” of today. Initially, this was promising for non-biomedical researchers who rely on IRB review systems generated more than two decades ago and widely critiqued as being predominately designed to work with science and medicine (Klitzman, 2015; Schrag, 2010), rather than sociobehavioral or humanities-based research. The recommended changes in the 2015 NPRM, however, while offering some possible positive outcomes for sociobehavioral and humanities-based researchers, were necessarily required to undergo several evaluations, a public commentary period, and revisions before they would be implemented.

Attendees at Public Responsibility in Medicine and Research (PRIM&R)'s Advancing Ethical Research (AER) conference, November 14-16, 2015, had plentiful opportunities to hear

about the new changes. A flagship conference for IRB staff and members, attendees to the Boston conference heard from Office of Human Research Protections (OHRP) representatives, regulators, policy-makers, and peer street-level bureaucrats. Town-hall meetings brought in the vast majority of conference attendees, who watched as panelists debated the merits and shortfalls of the NPRM.

The NPRM was open for commenting until January 6, 2016. Shortly before the comments period closed, Bradley Dilger compiled,¹ and Joyce Locke Carter, outgoing chair, submitted, the Conference on College Composition and Communication's (CCCC) comments on the NPRM². This work was the effort of scholars affiliated with CCCC and associated professional and academic societies. Carter, Dilger and other researchers shared the request for feedback in social media channels (Twitter, Facebook) in late December 2015; the CCCC comment draft was open for feedback during a quick review process. CCCC was one of the few language-based professional organizations to submit a final comment (for instance, the MLA did not file a comment in the public docket).

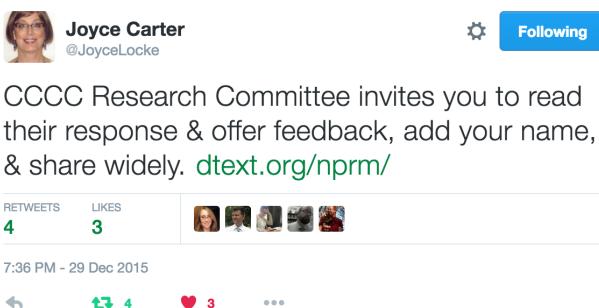


Figure 1. One of Carter's public appeals for review of the CCCC's comments on the NRPM.

¹ See WPA listserv digest, late December 2015-January 7, 2016

² <http://dtext.org/nprm/cccc-public-comment-nprm.pdf>

While it was unclear whether Carter, in her role as chair of CCCC at the time, would endorse the draft, Dilger was able to quickly revise and submit the draft for consideration. The CCCC official comment on the NPRM, requesting revisions and additional considerations before the proposed rule was made law, was submitted to the public docket with a full endorsement from CCCC.

The final comment, memorialized in the public docket HHS–OPHS–2015–000 at regulations.gov, is a textual touchstone of this dissertation project for three primary reasons. First, the CCCC’s comment was drafted and revised by Writing Studies researchers, suggesting a disciplinary awareness of the potential impact of emerging, revisionary policy on the discipline. Second, the comment was endorsed by CCCC, the organization both funding the research of this dissertation and acting as the professional society of the largest number of members of any Writing Studies organization.³ Therefore, the comment is representative of the discipline, broadly construed. Third and finally, the contents of this comment are indicative of areas where Writing Studies researchers can be better educated about the role of this policy in their research.

While the comment is relatively short (approximately 2000 words), the requests therein (1) indicate a confusion by researchers in Writing Studies regarding the policy development, review, and implementation process, (2) suggest that researchers in Writing Studies are concerned with the impact of biomedical revisions to the policy which will not impact socio-behavioral and humanities-oriented research from a federal policy level, and (3) that CCCC and the individuals designing and developing the comment are somewhat unaware of how federal policy is translated into local implementation.

A major goal of this dissertation is to illustrate how these concerns are exhibited more

³ In early 2016, this was over 4,000, which is 2,500 members more than any other reporting organization. RSA did not reply with their membership numbers.

broadly in Writing Studies and not simply in the CCCC's comment on the NRPM. This goal is achieved in part by sharing data from a discipline-wide survey about researchers' perceptions of and experiences with IRBs. These data highlight areas for disciplinary articulation, thereby providing generative space to expand the discipline's understanding of how federal regulations intersect with disciplinary agendas.

Project Outline

The work of this dissertation is situated within regulatory structures, public administration literature, academic publications on IRBs, and Writing Studies publications. These materials frame the boundaries of this project. With this framework constructed, human subjects research in Writing Studies is nested inside. This arrangement represents the unique and fluctuating ecology for Writing Studies researchers, as envisioned in the concept map that provides an overview of this project. This map originated from a thorough literature review conducted in preparation for writing the CCCC Research Initiative Grant that supports this dissertation project. It is also informed by public policy and my personal experience as an IRB coordinator with a sociobehavioral and humanities-oriented IRB at a large western university. In the context of this dissertation, the map provides a visualization of the interactions of the variety of moving components that fed into this project, shaped the project's inception and implementation, and moderated the project's outcomes. It aims to capture the diverse and multitude of elements that impact human subjects research in Writing Studies.

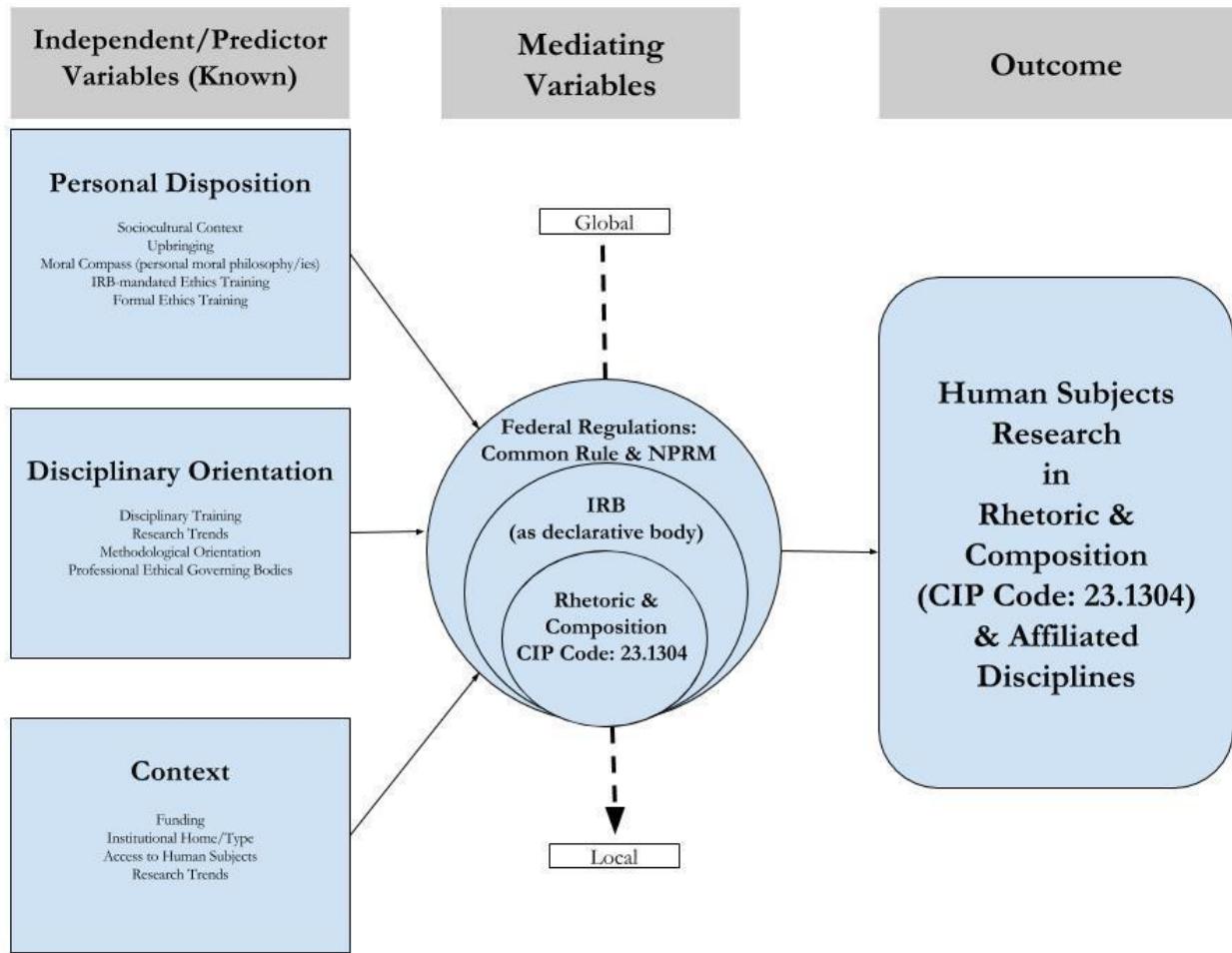


Figure 2. Project Concept Map.

This project concept map is foundational for understanding the organization of this dissertation. It provides context for understanding the ways in which the research questions posed in this introduction are answered, and how the research goals, articulated earlier in this chapter, are met. For that reason, explicating each component before identifying how they impact, and appear in, discrete chapters, is important.

To the far left are three categories of what are identified as independent, or predictor, variables. These variables were identified via the literature review (Chapter Two). Variables within the “Personal Disposition” box speak to researchers’ pre-dispositions regarding the

fundamental tenets of IRB review: justice, beneficence, and autonomy. One's moral compass, formal ethics training, socio-cultural context, and upbringing all influence their approach to these fundamental ethical positions. Variables within the "Disciplinary Orientation" box, such as disciplinary training, research trends and methodological position all shape the type of research projects that researchers generate. Variables within the "Context" box impact IRB review of protocols. A researcher's funding situation, the trends in their (sub-)discipline, their institutional home, and their access to human subjects all impact their research design and their experience interfacing with IRBs.

Together, these variables coalesce to represent the ways in which Writing Studies researchers' projects are experienced by IRBs, and how IRBs review Writing Studies protocols and interface with Writing Studies researchers. This step is represented in the vertical "Mediating Variables" category, where federal regulation, local IRB review, and the discipline's guidelines exist. The outcome, then, represented on the far right, is human subjects research in Writing Studies. This process is not a straightforward trajectory from left to right, however. Rather, it is a complex, recursive, and iterative process. Therefore, the following explanation of how the chapters of this dissertation will proceed will reflect some of these complexities.

In Chapter Two, the literature review and analysis, I begin broad and then narrow my focus. Honoring the reality of federal policy as overarching, and Writing Studies research as only one of many, many components of that policy's oversight in implementation, this literature review integrates Writing Studies research more effectively within public policy and institutional infrastructures. Chapter Two focuses almost exclusively on the mediating variables from Figure 2, the project concept map. Specifically, the federal regulations, local IRBs, and the discipline are nested to narrow the focus of this project before presenting the methods and data associated

with the examination of how Writing Studies researchers interface with IRBs.

An overview of the present state of human subjects research in Writing Studies and affiliated disciplines is provided in the literature review as well. Therefore, Chapter Two addresses those right-most two columns in the concept map, specifically the mediating variables and the outcome. The outcome represented on the far right of the concept map is recursive, especially after the release of the finalized, updated regulations in January 2017. The literature review focuses on present outcomes and sets the stage for future outcomes, which will be presented in Chapters Five and Six.

Chapter Two also continues the work of establishing both the legitimacy and necessity of this dissertation. In this chapter, I focus on the multi-disciplinary swath of literature undergirding this project. I delve into the literature and history of IRBs both writ large, as well as in Writing Studies specifically. My professional and academic personas are also heavily influenced by public policy and administration, as I am trained as a public administrator. For this reason, Chapter Two is grounded with not only a section on public policy, but another on broad academic scholarship on IRBs, and finally a section specific to Writing Studies. The CCCC comment on the NPRM makes it clear that Writing Studies researchers may not fully understand their position in the broad scope of what it is that IRBs do, and how it is that IRBs have come to exist. Essentially, Chapter Two works to remediate this and examine the “mediating variables,” from the concept map. In doing so, it frames the analysis and presentation of data collected for this project in a way that acknowledges the vitality and importance of Writing Studies research, while determining methods of best approaching human subjects protections regulations efficiently and effectively from a disciplinary standpoint.

The major contribution of Chapter Two to Writing Studies is to critique of disciplinary

positions on policy while opening the space to contribute implications drawn from survey results and findings to improve IRB↔researcher interactions. Moreover, this section addresses notions of generalizability and rigor as complex and somewhat fraught, in Writing Studies. Finally, Chapter Two introduces the theoretical goal of the project, which is to move from a traditional disciplinary approach towards IRBs as positivist to an approach that is justice-oriented.

Chapter Three outlines the methodology and methods of the research done for this project. I define my methodological standpoint as a justice-oriented, feminist researcher. The data collection methods utilized in this dissertation embrace the long-standing, widely accepted methodologies used in Writing Studies. By way of examining the policy constraints that apply to researchers interfacing with humans, this project utilizes accepted methodologies, seeks rigor and replicability, and works to encourage useful research that contributes to the nebulous concept of “generalizable knowledge” addressed in the Common Rule. At the same time, it is guided by premises often claimed by feminist researchers; it is participant-oriented, emancipatory, non-hierarchical, mutually beneficial, and collaborative (Kirsch, 1999, p.46). Therefore, in many respects, the methodology adopted is Intemann’s (2010) feminist standpoint empiricism, which is contextualist, normative, and social (p. 782), and adopts feminist standpoint theory’s positions on diversity and social and political values (p.793).

Within this feminist empiricist standpoint framework, Chapter Three provides an overview of the design, development, and use of the survey tool, as well as the sampling plan design, calculations for the population sample sizes, and information about the release and closure of the tool. Materials about these tools can be found in Appendix C (IRB Approval), Appendix D (Consent Documents), and Appendix F (Survey Tool). The data from the survey are

the foundational dataset for this dissertation; however, Chapter Three also provides information about the development of the subsequent interview protocol, its final design, and the use of the protocol in interviewing selected participants.

Essentially, the methods discussed in Chapter Three focus on examining the predictor variables in the concept map: variables such as personal disposition, disciplinary orientation, and context. The data collected from the survey tool and interviews inform the discipline's understanding of these predictor variables. This, in turn, is indicative of the ways in which these variables are influenced by the mediating variables of policy, local IRBs, and disciplinary policy. The intersection of these two variable types result in outcomes to complete the concept map.

In Chapter Four, I share results from the discipline-wide survey "IRBs and Writing Studies: Disciplinary Perspectives." The results are generalizable to the broader population of Writing Studies researchers. Chapter Four is divided into two sections that map directly to the predictor variables (disciplinary orientation and context are one section, personal disposition is the second) and a third section that maps onto the mediating variables (federal regulations, local IRBs, and disciplinary policy), followed by a final, brief, comparative section.

First, the general "demographics" of participants are shared. These fall under the predictor variable categories of "Context" and "Disciplinary Orientation." Data about respondents' disciplinary affiliation, their title and highest level of education, and information about their institutional home are examples of what is covered in this section. Participants' personal dispositions, the third predictor variable set, are exhibited in data from case studies and open-ended replies about ethical principles (beneficence, justice, and autonomy). The third major section of this chapter provides an overview of respondents' perceptions of, and work with, IRBs, which align with the intersection of the known variables and the mediating variables. This

section also outlines the ways in which respondents work with students as research participants.

Chapter Five provides generalizations from the data presented in Chapter Four and elaborates on common themes identified in the surveys and interviews. This chapter provides the “findings” of the dissertation; these findings are correlated with the recently released updates to federal policy on human subjects research, which I refer to throughout this dissertation as the “Final Rule.” Chapter Five specifically takes the results shared in Chapter Four and feeds them through concept map to provide a new representation of the mediating variables considering the survey data and updated regulations. Chapter Five is organized by research question (each research question has a specific section) to exhibit how the newly collected data about known variables interface with mediating variables, sending us back through the concept map for a second time with new data, beginning with the predictor variables and pushing them through the mediating variables.

Chapter Five explores the implications of the discipline’s current knowledge in the months before federal regulations were updated, alongside updated policy. This chapter is organized into four primary sections. These four sections are mapped directly to the project’s research questions: (1) how we learn about and from IRBs, (2) how we understand IRBs and our roles in relation to IRBs, (3) how our discipline engages with the IRB review process and policy commentary and revision, and finally, (4) how we are impacted by IRBs and the policy that mandates them. The findings from the survey are supplemented with narratives from interviews with thought leaders. Essentially, Chapter Five takes the results from Chapter Four about the independent/predictor variables and pushes them through the concept map flow chart one step further, setting the stage for Chapter Six.

Chapter Six pushes the data from the survey tool through the concept map one step

further to result in implications for practice, particularly in relation to the newly released federal regulations regarding human subjects research. This results in the concept map being once more complete and layered with the final complexity of the major theoretical contribution of this dissertation: providing guidance on how and why researchers should shift their mindset from deficit to asset-based, from positivist to justice-oriented, regarding IRBs. It highlights the shifting policies and implementation as a ripe environment to engage with the local processes by participating on boards and engaging with the review process in a meaningful way.

Chapter Six utilizes the results from Chapter Four and the findings in Chapter Five to provide a synthesis of the project, offering a novel approach, divided into theoretical and pragmatic components, for human subjects research in Writing Studies. This Chapter concludes the dissertation with recommendations for future research, planned projects, and a final reflective conclusion on the project.

Conclusion

This chapter provided an articulation of the goals and purpose of this project by illustrating both the policy exigence (the NPRM and Final Rule) and the discipline's response to these policy proposals. As Chapter Four demonstrates, only 12% of the 269 survey respondents to the survey tool indicated any familiarity, or even awareness, of the NPRM. Yet the implications of the maneuverings of the Office of Human Research Protections (OHRP) impact the entire discipline; the policy updates will influence IRBs, and IRBs, as Laura Stark pointed out, are declarative bodies. They will determine what is knowable to Writing Studies researchers, to the field. The updated federal policy, and the discipline's reaction to iterations of this update, have created a space for thoughtful and critical analysis. The remainder of this dissertation guides readers through the process of that investigation and charts directions for future research.

CHAPTER TWO: HUMAN SUBJECTS RESEARCH AND WRITING STUDIES

IRBs are declarative bodies because they are empowered to turn a hypothetical situation (this study *may be* acceptable) into shared reality (this study *is* acceptable). It is a testament to the power of their words that IRBs rarely disapprove studies but regularly change them. In so doing, they change what is knowable.

---Laura Stark, *Behind Closed Doors: IRBs and the Making of Research*

As much as this dissertation project is about Writing Studies, it is also an examination and inquiry into the ways in which Writing Studies *presently* fits within the larger infrastructure of higher education, federal funding, federal policy, and institutional organization. Throughout this project, I show how as the landscape of policy changes, so, too, will our situatedness shift and change. Therefore, this chapter follows Hart's (2000) recommendations on framing a literature review: providing historical context, identifying key sources and authors, establishing context for the work of this dissertation, and identifying what this dissertation contributes to the literature.

Providing historical context requires not only an overview of the policy that governs human subjects research in Writing Studies (and across disciplines), but also a description of the legacy of research ethics and, more specifically, literature on IRBs in Writing Studies. But because public policy literature spans disciplines, and extra-disciplinary touchstones are important to contextualize this project, this literature review is built from three distinct, yet interrelated, sections. Each section follows this model: readers are provided the sampling plan

for the selection of literature, an exposition of the literature, and an analysis.

The first section covers the history of the policy governing IRBs (45 C.F.R. § 46), along with an overview of the Notice of Proposed Rule-Making (NPRM). No other literature on IRBs would exist without these technical documents and the resultant social ramifications, so they are treated in some detail. The CCCC comment on the NPRM is discussed in this section as well. Second, inter- and multi-disciplinary literature regarding IRBs, rather than the regulations that mandate their existence, is reviewed to provide a broad socio-cultural context wherein Writing Studies can be situated. Finally, the history of research ethics and literature on IRBs in Writing Studies is discussed, and an introduction to emerging literature on ethics, fairness, and justice (Elliot, 2016) in Writing Studies, are presented in efforts to situate the theoretical contribution found in later chapters.

Policy

As a significant volume of history about the evolution of IRBs already exists, this section focuses instead on the federal policy governing human subjects research. This policy, 45 C.F.R. § 46, known colloquially as the “Common Rule,” is the crux of policy interpretation and local implementation. This document is a foundational component of both the pragmatic work done by researchers under the regulation, but also a fundamental document to establish context for theoretical work.

Given the importance of the policy language regarding its implementation, I focus this section around the federal policy, 45 C.F.R. § 46, finalized in 1991. This section also discusses and analyzes documents produced by the government since that time, including the Advance Notice of Proposed Rulemaking (ANPRM), released in 2011, and the Notice of Proposed Rulemaking (NPRM), released September 2015, as well as the CCCC comment on the Final

Rule. Discussion of the final regulation released January 17, 2017 is reserved for Chapters Five and Six.

Exposition on Common Rule (1991). 45 C.F.R. § 46, “Protection of Human Subjects,” outlines the ways in which institutions are required to protect human subjects while conducting and supporting research. If federal monies are utilized to conduct research, and if the research involves humans, organizations are required to adhere to 45 C.F.R. § 46; some organizations opt to apply these regulations to research not necessarily funded by federal dollars, especially if they receive federal funding for other purposes (this is called “checking the box”).

Key portions of this code include how to form and utilize Institutional Review Boards, guidelines on informed consent processes, requirements for use of federal funds, and specific regulations regarding prisoners, fetuses, pregnant women, and children. Subparts A and E of 45 C.F.R. § 46.101-505 articulate the specific requirements for protection of human subjects in federally funded research initiatives.

These guidelines have largely been accepted, and even built upon, by industries engaged in human subject research, regardless of whether they receive funding from the federal government (Schneider, 2015; Schrag, 2010). 45 C.F.R. § 46 is now considered the standard by which organizations gauge research ethics awareness. Health and Human Services (HHS), one of the 16 federal agencies signed on to the Common Rule, state that the policy offers, verbatim:

1. Requirements for assuring compliance by research institutions.
2. Requirements for researchers’ obtaining and documenting informed consent.
3. Requirements for Institutional Review Board membership, function, operations, review of research, and record keeping.
4. ...Additional protections for certain vulnerable research subjects.

5. Specific DHHS and FDA regulations.

45 C.F.R. § 46 is a protective regulatory policy (Birkland, 2010). It implements the requirements of the National Research Act of 1974. According to the brief history of the revised Common Rule (2017):

The Department of Health, Education, and Welfare first published regulations for the protection of human subjects in 1974, and the Department of Health and Human Services (HHS) revised them in the early 1980s. During the 1980s, HHS began a process that eventually led to the adoption of a revised version of the regulations by 15 U.S. federal departments and agencies in 1991.

The 1974 National Research Act alluded to in this narrative prompted the work of the National Commission on the Protection of Human Subjects of Biomedical and Behavioral Research conducted between 1980 and 1983. This organization released the renowned Belmont Report, a document focused on human subjects research and concerned with the ethical issues of beneficence, justice, and respect for persons. Per the very text of the Common Rule itself, the Belmont Report served as groundwork for the construction of the final regulation, which was released in 1991. Until January 18, 2017, this portion of the CFR remained unmodified and widely promulgated.

The National Research Act of 1974 spurred the development of a number of official committees on research ethics and, ultimately, 45 C.F.R. § 46. Challenges emerged initially with the implementation of the policy simply because prior to 1990s, there was no formal mandate like 45 C.F.R. § 46. Acclimating “street level bureaucrats” (Lipsky, 2010) to the new regulations entailed creating policies and procedures to maintain and document the implementation process.

It is important to note that by engaging with IRB at an institutional level, researchers are

accepting an “informed consent” to do research for the federal government. Information they produce in protocols is collected, collated, and assessed by IRBs and, when necessary, monitored by regulatory agencies. One major criticism of IRBs, however, is that the potential to harness this wealth of data to make empirical claims about IRBs’ efficacy is not utilized (Schneider, 2015; Schrag, 2010).

45 C.F.R. § 46 has largely been successful in its aims. While there is not a “control group” that can indicate the outcomes of research without 45 C.F.R. § 46, it stands to reason that the well-being of many human subjects is sustained because of the checks and balances mandated by 45 C.F.R. § 46. Indeed, prior to the implementation of these regulations, the U.S. government ran studies, and more studies were conducted in academic settings without federal funding, which are now considered to be tremendous violations of human dignity. For instance, the Tuskegee Syphilis Experiment (originally titled “Tuskegee Study of Untreated Syphilis in the Negro Male”) was funded by the U.S Department of Health; black men were provided “free health care,” but were provided no meaningful treatment. Rather, the course of their disease was simply observed so that researchers could examine the natural progression of syphilis, despite treatment being available. Corollary narratives in socio-behavioral research (such as Laud Humphrey’s “Tearoom Trade”) exhibit how even into the mid-1900s, some researchers’ work was an affront to human dignity.

While 45 C.F.R. § 46 may have been adept at tackling and confronting the issues facing science and federally funded research in the 1990s, it is not currently well-equipped to handle the whole of modern science, nor, more generally, research initiatives undertaken by social science disciplines, or by researchers working in fields such as technical writing, sociology, and composition. Increasing pressure both inside, and external to, the rulemaking process informed

updates to the policy, which were implemented January 2017. The longevity of these new regulations, however, remains unclear.

While complaints and concerns about the policy itself have been leveled, and will be discussed in relation to the Notice of Proposed Rulemaking shortly, another tremendous variety and volume of concerns about the Common Rule are specifically concerns about implementation. There are two major issues covered in the policy specific literature regarding the implementation of the Common Rule. First, that IRBs lack a level of necessary efficiency, and second, IRBs are increasingly guilty of “mission creep.” Both are a result of the implementation of a federal policy in local environments. The individuals who implement such policies are referred to as “street level bureaucrats” in public policy literature.

Lipsky (2010) offers a comprehensive overview of his theories related to street-level bureaucrats and suggests that across fields, in order to cope with their workload and constant backlog, “street level bureaucrats invent benign modes of mass processing that more or less permit them to deal with the public fairly, appropriately, and successfully” (p. xii). This best-case scenario is also the worst-case scenario – some street level bureaucrats commit acts of “favoritism, stereotyping, and routinizing- all of which serve private or agency purposes” (p. xii), for instance, IRB reviewers opting to prejudice their review of a protocol based on its poor grammar (Stark, 2012). Lipsky notes that those who implement policy are in a unique position because

[T]he decisions of street-level bureaucrats...effectively *become* the public policies they carry out...public policy is not best understood as made in legislatures or top-floor suites of high-ranking administrators, because in important ways it is actually made in the crowded offices and daily encounters of street-level workers. p. xi-xii

When considered cumulatively, individual street level bureaucrats' behaviors congeal to represent policy to the public, and their specific governing body (federal/state/county/etc) that authorized their role. As community members themselves, and as manifestations of public policy, street level bureaucrats shape the very communities in which they circulate. Lipsky notes that it is not possible to remove the human factor that street level bureaucrats implicitly incur on the implementation of policy, but it is possible to examine their impacts on the public.

Analysis of Common Rule. While it stands to reason that as a preventative regulatory policy the Common Rule is generally effective, many researchers can articulate how often the process can be unwieldy when it comes to efficiency. Some institutions warn researchers that a wait of three months is not unwarranted (research.unl.edu/researchresponsibility, 2014). The same street level bureaucrats who work in IRB offices and make initial determinations about projects are the individuals that design, create, and manage the systems for the routine processing of protocols. The unique setting of each street level bureaucrat may result in different concerns or responses to a submission for research. Given the volume of research conducted in the United States, and the fact that many organizations opt to apply these federal standards to all research (FWA, 2016), even research not funded by the federal government, the administrative and bureaucratic burden can be significant.

Of late an important notion troubling scholars on research ethics is the notion of equity related to the implementation of the policy. While 45 C.F.R. § 46 provides particular considerations for three specific populations in Subparts B, C, and D, it is important to note that since the 1990s, vulnerable populations have been redefined and reconsidered in implementation, but not in policy. Individuals with disabilities, minorities, and even veterans (Cohen and Lynch, 2014) may not be given specific protections from a regulatory standpoint, but local IRBs may be

more or less attentive to specific populations at the local level; while the Common Rule mandates certain populations be considered vulnerable, at the institutional level (for instance, a given university) different populations may be interpreted to be “vulnerable,” problematizing a researcher’s interaction with an IRB requiring additional protections in addition to the federal regulation (Federal Register, 2017).

Due to this “mission creep,” critiques have been leveled at IRBs for impeding research, and even access to clinical trials, which some scholars argue is against the best interest of human subjects (Schrag, 2010; Schneider, 2015). This is because of the predominant interpretation of the Common Rule that defines justice as protection, rather than as access. Therefore, some patients who may benefit from clinical trials are unable to do so (Mastroianni & Kahn, 2001). Biomedical researchers, confronted with problematic interpretations of the Common Rule, are not unwarranted in reconsidering the representations of equity in 45 C.F.R. § 46. Moreover, the more ubiquitous and alarming concern seems to be the policy’s (in)ability to mandate behavior and review at a local level.

In this context, sociobehavioral and humanities researchers, such as those doing work in Writing Studies, may find it difficult to design a just, generalizable study with available study populations. For instance, control groups are a component of biomedical programs to show efficacy of a given treatment. In pedagogy-based research, having a control group may be impossible (for instance, when only one section of a course is being taught); additionally, while certain institutions may have specific demographics (an HBCU, for instance), the findings from research in those classrooms may be generalizable because the setting or demographics are similar to another institution. Opting to not examine a course, or changing the study population because it is composed of traditionally marginalized populations would, in this instance, be a

determination an IRB could make, and one a Writing Studies researcher could (and should) question as an example of mission creep and outdated representation of equity.

The Common Rule has been due for a reconsideration by policymakers, both official and unofficial actors, to ensure that the health and well-being of human subjects is maintained well into the 21st century. This reconsideration came in the form of the NPRM released September 2015.

Exposition of Notice of Proposed Rulemaking (NPRM). The Notice of Proposed Rulemaking is not only a sort of addendum to the Common Rule, but it is also its own unique and important document, deserving a section of its own in this literature review.

Released on September 8, 2015, the Notice of Proposed Rulemaking, was opened for comment over four years after the Advance Notice of Proposed Rulemaking (ANPRM) that the Office of Human Research Protections (OHRP) released in July 2011. The four-year gap between the ANPRM and NPRM was not lost on IRB professionals, research ethics scholars, or regulatory agencies. Moreover, the changes between the two documents suggest not only a significant change over time, but also significant reconsideration of the ANPRM's proposals (Menikoff, 2011).

The NPRM is a 131-page PDF, endorsed by the Departments of Homeland Security, Agriculture, Energy, Commerce, Justice, Labor, Defense, Education, Veteran's Affairs, Health and Human Services, Transportation, the National Science Foundation, the Environmental Protection Agency, the Agency for International Development, the Social Security Administration, and NASA. Unsurprisingly, all of these entities also endorsed the original Common Rule, released in 1991, save for the department of Homeland Security, which was established in 2002 (DHS.gov, 2016).

A summary of the NPRM, release by OHRP on September 8, 2015, suggests that the new Final Rule will (these are abbreviated from the material found at HHS.gov [2015] and synthesized from the NPRM, which can be found in the Federal Register [2015]):

1. Improve informed consent by increasing transparency and by imposing stricter new requirements regarding the information that must be given to prospective subjects.
2. Generally require informed consent for the use of stored biospecimens in secondary research ... That consent would generally be obtained by means of broad consent (i.e., consent for future, unspecified research studies) to the storage and eventual research use of biospecimens.
3. Exclude from coverage under the Common Rule certain categories of activities that should be deemed not to be research, are inherently low risk, or where protections similar to those usually provided by IRB review are separately mandated.
4. Add additional categories of exempt research to accommodate changes in the scientific landscape and to better calibrate the level of review to the level of risk involved in the research....
5. Change the conditions and requirements for waiver or alteration of consent such that waiver of consent for research involving biospecimens (regardless of identifiability) will occur only in very rare circumstances.
6. Mandate that U.S. institutions engaged in cooperative research rely on a single IRB for that portion of the research that takes place within the United States, with certain exceptions....

7. Eliminate the continuing review requirement for studies that undergo expedited review and for studies that have completed study interventions and are merely analyzing data or involve only observational follow-up in conjunction with standard clinical care.
8. Extend the scope of the policy to cover all clinical trials, regardless of funding source, conducted at a U.S. institution that receives federal funding for non-exempt human subjects research.

The NPRM was open for comments until January 6, 2016. 2,189 comments were received, and by law, policymakers are required to consider each and every one (FederalRegister.gov, 2011).

Hudson and Collins (2015) published “Bringing the Common Rule into the 21st Century” shortly after the NPRM was released September 2015. Despite the positive press, the NPRM has been a point of contention already in published scholarship, too, (Lynch et al., 2016) with industry lauding the updates and requesting better processes for research in the 21st century (Jackman and Kanerva, 2016). Concerns codified in the 2,189 registered comments on the NPRM during the comment period in early 2016 exhibit the unease with which many IRB professionals, organizations, and individuals greeted the NPRM. A fundamental issue was that the NPRM provided allusions to tools and policies that were not provided for public evaluation (Final Rule, preamble, January 19, 2017).

At the Public Responsibility in Medicine and Research (PRIM&R)’s Advancing Ethical Research (AER) conference in November 2015, there was a slew of panels (mostly in the “Hot Topics” track), town halls, and keynotes related to the NPRM and its implications for IRB staff and reviewers (PRIM&R, 2015). Jerry Menikoff, Director of the Office of Human Research

Protections, presided over a town-hall (AER, 2015), answering questions about the proposed updates, including the option for researchers to make determinations about whether or not their work was “excluded” from IRB review, OHRP providing informed consent templates for mandatory use, and updating exemption criteria.

Analysis of NPRM. Comments on the NPRM came from a variety of sources and are available for review in the public docket at regulations.gov. Many are uploaded on formal letterhead from universities and organizations impacted by the changes. Research administrators, the general public, IRB staff, participants, the terminally ill and their advocates all had a great number and variety comments.

Policymakers took note of the public’s concern that it was impossible for the public and stakeholders to adequately assess the proposed policy with unclear and ill-defined components. This in turn indicated that those components of the proposed legislation were in violation of the Administrative Procedures Act (2017), which resulted in the necessary removal of a number of proposed sections. The Council of Government Relations, in their synthesis of the comments *prior* to the release of the final regulation noted there was:

significant opposition to most major proposals, with mixed support for mandated use of a single IRB and extending the Common Rule and greater support for the concept of standard security safeguards. In addition, a number of responses suggested that the NPRM is overly complex, poorly written, and not supported by data; highlighted areas that could have a substantial impact on a Final Rule but were not included in the NPRM (e.g., proposed security safeguards, a consent template, a list of minimal risk studies and a decision tool); and suggested that some of the proposals would adversely affect human health with little perceived benefit. (2016, p. 1)

The proposed and finalized new regulations also did not attend to the shifting landscape of international research. Notably, neither the NPRM, nor the Final Rule released in January 2017, addresses the increasingly bureaucratic complexities researchers face when engaging with international research opportunities. Where one governing body begins and the other ends remains in question.

Exposition of CCCC comment on NPRM. Like many other professional organizations, the Conference on College Composition and Communication (CCCC) also designed and contributed a formal comment on the NPRM. The comment was divided into three sections relevant to this review. First, CCCC indicated their agreement with some new policies: (1) eliminating continuing review of expedite studies, (2) changing the term “exempt” to “registered” and (3) streamlining the IRB review of multi-site studies (this is referred to as the move towards single IRB review by NIH and IRBs). CCCC also expressed support for the requirement of appeal mechanisms and an improved informed consent template/guidelines.

CCCC also provided “areas of concern” in section two of their document. The CCCC response articulates reservations regarding the definitions of the proposed excused/registered categories, the requirement for HIPAA security requirements for all research, and updated regulations regarding the use of what they call “archival,” but what is specifically referred to in the NPRM, as biospecimens. The CCCC comment calls upon updated policies regarding how the regulations should apply to students, and laments the loss of concern regarding IRB mission creep that appeared in the ANPRM in 2011 but was removed from the 2015 NPRM.

CCCC offered the following recommendations in their third section: that funding opportunities be available to evaluate the impact of the new policy, and that panels composed of diverse constituencies be brought together three years from the release of the final revised rule to

review the impact of the new policy. The comment is clear that a representative from CCCC should be in attendance.

Analysis of CCCC comment on the NPrM. As stated in Chapter One, there are three primary concerns from a policy perspective regarding this comment. The comment creates a space to examine Writing Studies' researchers perceptions and understanding of the policy and function of IRBs. The three primary concerns are that the comment: (1) indicates a confusion by researchers in Writing Studies regarding the policy development, review, and implementation process, (2) suggests that researchers in Writing Studies were concerned with the impact of biomedical revisions to the policy which will not impact socio-behavioral research from a federal review level, and (3) that CCCC and the individuals designing and developing the comment are unclear regarding how federal policy is translated into local implementation. Let me articulate these positions further.

These concerns are based on the following observations and correlation to the policy process and the function of local IRBs. For instance, requests within the CCCC's NPrM comments to reconsider the role of student researchers are indicative of a misunderstanding regarding how students are perceived at the level of federal policy. In terms of broad, national policy, there can be no discrimination of *who* a researcher is. If any given individual is producing generalizable knowledge and interacting with human subjects, that individual is considered a researcher. Local IRBs make determinations about how to support faculty and students in the research process while adhering to regulations. Many treat students as equals to faculty and research staff (e.g. the University of South Florida); others require faculty to serve as the Principal Investigator, with the student as a Co-I (e.g. Utah State University). These are unique to local IRBs and are not a complaint related to federal policy.

Moreover, suggesting *after* the NPRM had been released that further revisions should be made to bolster the new policy (including re-integrating concerns about mission creep) suggest that academics affiliated with the CCCC comment process misunderstood the stage of the policy design represented by the NPRM. No additional information can be considered once the NPRM is released. Policymakers must necessarily conform to the Administrative Procedures Act to determine which updates cannot be implemented because they are not clear and accessible to the public for deliberation. Because such changes were not included in the NPRM, suggesting them in a formal comment is indicative of the discipline's lack of attunement to the policy process and the impact of proposed revisions. Therein lies the crux of this project: to examine, explicate, and imagine ways in which the discipline can more effectively interact with the policy and local implementation.

Policy review conclusion. While a Final Rule looking like a much-streamlined version of the NPRM without notable concerning updates was finalized on January 19, 2017, IRB administrators are hedging their bets as they continue their day-to-day practices. It would make good sense to incorporate these new rules into the system, yet given the new administration, and open statements from policy makers with the intent to repeal Obama's late-term policy updates via the Midnight Relief Act, the new rule may be dismantled. The implications of this new rule, and the longevity of its impact on Writing Studies researchers, will be addressed in Chapter Six.

Extra-Disciplinary Literature

This section of the literature provides a brief overview of some of the literature that has emerged in recent years related to both federal policy and local IRBs. These pieces represent a variety of disciplines: some situated in the humanities, some in law, some in medicine, some authored by practitioners, and others by research ethicists. Books are supplemented with journal

articles, op-eds, and other materials found in journals such as the *Human Research Report*, *Journal of Empirical Research on Human Research Ethics*, and *IRB: Ethics & Human Research*. Without the policy, these documents and texts would not have been produced; therefore, this component of the literature review is made sense of only in context of policy. They identify, and were produced because of, the larger social implications of the policy, and contextualize concerns expressed in Writing Studies research with human subjects.

This section of the literature review is built from materials published after 2004. This date was chosen for a number of reasons. First, Schrag suggests that oversight of social science researchers became more stringent again in the 1990s, meaning the realities of researcher oversight beginning at that time would have become apparent by the early 2000s. Second, given the wealth of literature, the more recent material noting increasing changes in the human subjects research landscape is the most appropriate for this project.

Exposition of extra-disciplinary critique. In recent years, IRBs, and the policy behind them, have been the subjects of a number of manuscripts and articles. Much of the early literature constituted articles, but as frustrations and critiques of the policy and IRBs mounted, books were published on the topic. This section follows a variety of extra-disciplinary materials chronologically, beginning in 2005.

Hamburger argued in a 2005 *The Supreme Court Review* article that IRBs are unconstitutional, violating the first amendment by censoring researchers' initiatives and research agendas. Not long after, in 2007, two more critical pieces were published. Gunsalus et al. published a white paper on IRB mission creep (the tendency for IRBs to enforce local policies that are an outgrowth of the federal policy). This team questioned the ability of IRBs to adequately handle their workload. They also argued that IRBs are primarily concerned with

litigation and audits, rather than ensuring the ethical treatment of humans. Also in 2007, Bledsoe et al. published “Regulating Creativity: Research and Survival in the IRB Iron Cage.” They offer a laundry list of complaints, bolstered, as much of the critical literature seems to be, with the claim that “there is [not] any persuasive evidence that research subjects’ rights or welfare have benefited, overall, in exchange for this damage [of IRB oversight]” (594).

In 2009, Hamersley critiqued IRBs in his piece “Against the ethicists: on the evils of ethical regulation.” Hammersley’s concern was regarding the UK frameworks more specifically, but he argues that regardless of location, both the regulation, and the people who implement it, do not increase the ‘ethical standard’ of social science research, and rather make the outcomes of research a poorer quality.

In 2010, one of the landmark book length pieces on IRBs was released; Zachary Schrag, moderator and author of the popular blog institutionalreviewblog.com, published *Ethical Imperialism: Institutional Review Boards and the Social Sciences, 1965-2009*. He levied perhaps one of the most vicious attacks against IRBs from a humanities perspective; his continuing publication on his blog, often berating other scholars who come to the defense of IRBs (Schrag, 2016, 2016, & 2016), is indicative of his general approach to IRBs. Schrag’s complaints are epitomized in the last paragraph of his book. The tone and emphases are indicative of his approach to IRBs:

When wise people, fairly selected, craft policies based on careful investigation and deliberation, their decisions deserve respect, whether the result is a constitution or a humble regulation. But when policymakers deny power to experts and to representatives of those most affected by the restrictions, when they ignore available evidence, when they rush regulations into print along with empty promises of future revision, and when

they restrict freedom simply as an afterthought, their actions deserve little deference. IRB review of the social sciences and the humanities was founded on ignorance, haste, and disrespect. The more people understand the current system as a product of this history, the more they will see it as capable of change.

Schrag's book was released before both the NPRM and the ANPRM. Yet he's addressed both the ANPRM and NPRM on his blog with some regularity. His latest post, as of this writing, was one indicating his decade long fight against the regulatory constraints was over, based on his reading of the Final Rule released in January 2017; his reading of the rule suggests that the rule excludes common practices and methods in history, oral history, and journalism from IRB review. The implications of these updates will be addressed in Chapter Six.

Two years after Schrag's book was published, Laura Stark, an anthropologist, published *Behind Closed Doors: IRBs and the Making of Ethical Research*. Stark's project was critiqued often by Schrag (Schrag, 2016); like Schrag, Stark ventured into studying IRBs through her dissertation work. While she suggests that there are merits to the present system, she, like Schrag, suggests that IRBs should be examined and critiqued. Her book, focused on the collection of ethnographic data from IRB meetings, examines the narratives of board members. Her greatest contribution to mediate the dissensus regarding IRBs are represented in her concepts of local precedent (making decisions about specific protocols based on the board's prior experience with similar concerns or research, rather than direct appeal to 45 C.F.R. § 46) and IRBs as declarative bodies (Stark states that "because [IRBs] are empowered to turn a hypothetical situation [this study *may be* acceptable] into shared reality [this study *is* acceptable]." [p.v]). These concepts are important in addressing the variation of how IRBs implement policy and contribute to "mission creep."

Stark buffers verbatim conversations from board meetings with recognition of rhetorical moves made by board members. For instance, she argues, after presenting one conversation between a chair and a faculty board member that “The language of weighing risks and benefits is more rhetorically useful, perhaps, than actual attempts to compare incommensurable things,” for instance, the risk/benefit ratio, and moreover “members of declarative bodies invoke regulatory language to show that they are aware of what they are doing, especially when they use their discretion to interpret the rules creatively” (13).

Schrag finds Stark too sympathetic to boards (Schrag, 2016), but Stark effectively reminds readers that IRBs are not simply a three-letter hurdle. Rather, they are composed of humans that do have a variety of backgrounds, expertise, and practical experience. She calls upon Boltanski and Thevenot, noting that “for board members, the style and tidiness of researchers’ documents offer a snapshot of the person behind the application” (16), and she pre-empts Schneider’s policy oriented complaints by noting that her description of local precedents “contrasts with the assumption that expert bodies deliberate within the framework of what has been called legal positivism” (52), i.e. board members with specific qualifications and specific education make predictable decisions based on ubiquitous precedents.

A couple years later, Cohen and Lynch (2014) published an edited collection that offers a variety of perspectives and approaches to modern issues in human subjects regulations. *Human Subjects Research Regulation: Perspectives on the Future* provides essays by both Schrag and Stark in their respective areas of expertise. Moreover, there are suggestions of expanding the scope of vulnerable populations, the evolving concerns regarding data and privacy, and discussions of the paradigm shift in research ethics. While Cohen and Lynch’s collection certainly exhibits critique of the system, they also consider ways in which the protections of the

policy should expand and evolve in coming years.

Echoing Schrag, Musoba et al. (2014) suggest that there is not enough “empirical” research to suggest IRBs are useful; they also argue that IRBs can have a “chilling effect” on research. Rather than having an IRB or federal policy, they consider that perhaps disciplines should self-regulate. Yet they provide no heuristic or recommendations to bolster this position of disbursing the obligation to uphold even the most minimal of ethical standards in human subjects research. Their commentary, along with their predecessors, follow the trend which led to the most recent scathing book length piece on IRBs: Carl Schneider’s *The Censor’s Hand: The Misregulation of Human-Subject Research*.

Schneider’s 2015 book is a rigorous attack on Institutional Review Boards. Unlike Schrag’s affiliation with the humanities, however, Schneider suggests that his area of expertise is policy (Chapter Six, footnote #1, p. 244). As such, his book, published in 2015, just five months before the release of the NPRM, takes a different approach to the “problem” of IRBs. He suggests “the IRB system is a bad tool.” Schneider leaves no question as to whether any of the current system can be salvaged or repurposed. He claims was research was effectively and ethically conducted before IRBs were implemented as a result of 45 C.F.R. § 46, and would be done well without IRBs should they be abolished. While IRBs may not be the best vehicle for managing the oversight of ethical research with human subjects, they remain the legislatively mandated mechanism for doing so in the latest revised policy.

Also released in April 2015, Robert Klitzman’s *The Ethics Police: The Struggle to Make Human Research Safe* took a more moderate, yet still critical approach to IRBs. Klitzman, a psychotherapist and trained physician, offers another unique approach to IRBs. By opening his book with a personal narrative about standard of care treatment for his ailing father, he

immediately recognizes the deep impacts that IRB decisions, and physicians' decisions, can have on individuals, families, systems, and policy. Citing a plethora of articles, Klitzman argues that "Evidence suggests that many IRBs review too much, too quickly, and with too few experts; conduct minimal continuing review of approved research; and provide little training for members and investigators; and that too little attention is paid to evaluating these committees or their effectiveness" (8). Yet what constitutes effectiveness is left for the reader to decide.

Klitzman also utilized ethnographic methods, approved by his IRB, to interview a variety of board members, chairs, and administrators. Like Stark, Klitzman openly aims to provide a balanced approach to critique, noting that the bureaucrats in IRB offices, and the expert reviewers on the board, are bound by federal regulation. Klitzman also acknowledges a dichotomy between IRB review and "science," namely that "conducting science is ostensibly objective, whereas defining, interpreting, and balancing ethical notions involves inherent ambiguities" (11). Aligned with the literature in Writing Studies specifically, this notion of "ostensibly objective" becomes increasingly important as the work of IRBs intersects with disciplinary agendas in Writing Studies.

Most recently, in Spring 2016, an entire special issue of *PS: Political Science and Politics*, was dedicated to concerns amongst political scientists regarding IRB oversight. One piece was written by an NSF officer, recommending that researchers interested in NSF funds and working with human participants should seek out approval from their IRB as soon as possible. In one scathing piece in this collection, Mayer (2016) noted that rather than applying the "reasonable person" concept to anticipate board reviewers' approaches, she told her colleagues to anticipate the "unreasonable bureaucrat."

Extra-disciplinary literature has, until this point, been largely critical. The recent release

of the new regulatory revisions to the Common Rule will undoubtedly produce more literature on the issues surrounding IRB review of research, federal policy, oversight of human subjects protections in research, and the interactions of federal policies surrounding funding of research and the revised Common Rule.

Analysis of extra-disciplinary critique. Not all scholars suggest that IRBs are inefficient or ineffective. Instead, authors like Redman and Caplan (note that Caplan is the editor of the press that produced both the Cohen and Lynch collection, as well as Schneider's book) argue that IRBs do not, in fact, do enough. Redman and Caplan suggest that IRBs should serve as a more rigorous check on the potential reproducibility of all studies they review: "Institutional Review Boards (IRBs) ought to require that research protocols contain explicit probability statements about likely risks and benefits, based on a comprehensive review of prior studies and meta-analyses addressing reproducibility." (p. 9).

Stark exhibits a more moderate approach; she notes that "inside IRB meetings, that process [regulating decision making individually and as a board] tends to encourage research that fits with existing personal and local sensibilities about the appropriate limits of research on people. Those limits are worth considering over time" (166). This concept of local precedents in some ways excuses poor IRB behavior, but the recommendation for further research is vital to understanding the general literature surrounding IRBs: more research, specifically empirical research, should be done.

Schrag's primary critique (via his blog) and later pieces by Stark herself (2014) suggest that the existence of local precedents is not sufficient to justify their use. As many IRB personnel state, "the regulations are the floor, not the ceiling;" for this reason, many IRBs rely on regulations, but may make requests of researchers unfounded in federal policy, but perhaps

codified in institutional policy. These may be specific to unique research populations or communities with which the IRB must regularly interface. This, in a nutshell, is the frustration of IRB “mission creep.” When federal policy is further informed by local precedents and implemented by street level bureaucrats, the implications of baseline federal policy can be exacerbated. For instance, one western research institution requires all researchers working in public schools to provide a letter of support from the relevant district; this is not a requirement of the Common Rule, specifically, but it is a derivative of the regulations specific to this institution (USU IRB Standard Operating Procedures, Chapter 10). Mission creep like this, more than anything else, appears to be the target of critiques in extra-disciplinary literature, save for those authors like Schneider’s, who wish to abolish the policy altogether. And this mission creep is often defensible. For instance, the policy mentioned above was articulated because of conversations amongst districts and with the USU IRB requesting to be informed when research was being conducted in schools (personal communication, 2015).

While Scheinder’s book reads as a rallying cry to re-envision research ethics without IRBs, like Schrag, he offers little by way of recognizing the policy process and the inevitable locality of IRBs and their researchers. However, removing the policy and resultant IRBs would clearly eliminate the issue of mission creep. It would also open the door of ethical malpractice such as that seen funded by the federal government prior to 45 C.F.R. § 46.

More than efforts to successfully interface with their local IRB, authors such as those discussed above instead stoke disciplinary flames regarding specific concerns with IRBs’ policy implementation. Job ads for IRB administrators regularly request applicants who can “build and maintain positive relationships with researchers,” suggesting that negative stereotypes, and stereotype threat, consume a great deal of time and effort in IRB offices- time and effort that

could be used to make the review process more expedient.

The voices of IRB staff, board chairs, and members are, save for in Stark and Klitzman's texts, largely unrepresented. IRB personnel and members are generally not the subject of these more theoretical critiques. While their narratives appear in Stark and Klitzman's books, they are certainly not the crux, nor the point, of these texts. They do, however, exhibit how local precedents can tremendously influence researchers experiences with IRBs. Schrag and Schneider suggest that the culprits are the federal government, rather than individual IRBs, and the lack of concrete guidance leads to mission creep. Yet neither offers tangible, actionable methods of improving the policy. As such, these texts are theoretical in nature, rather than practical, in their critique. One thing that can be done is to look at IRBs from a discipline specific standpoint to determine the best methods of interfacing with public policy.

Writing Studies

Compositionists', rhetoricians', and technical communicators' growing attendance to the place of the *polis* in ancient rhetoric calls upon the importance of rhetor's attendance to public policy. Poulakos (1997) suggests that Isocrates' rhetorical education model shows "how he looked to pressing issues of the day for rhetoric's subject matter and to the welfare of the polis...how he adjusted rhetoric so as to address successfully issues of vital importance to the citizenry and deliberate effectively questions of public policy" (p. 4). Having situated human subjects protections more broadly in the *polis* in the prior two sections of this literature review, this third and final section of the literature review crystallizes a discipline specific representation of how human subject research appear in methodologies, methods, and publications in Writing Studies.

This section of the literature review covers discipline-specific literature regarding (1)

traditional literature on research ethics in the field, including specific publications regarding human subjects research and policy on such activities and (2) emerging issues and areas of concern regarding human subjects research. Because this project is situated in Writing Studies, and the history of Writing Studies approach to methodologies and methods that engage human subjects is a vital component of this project, this literature review begins in the late 1990s, when the impact of the 1991 Common Rule on research ethics became increasingly represented in discipline specific literature.

Exposition of traditional scholarship on human subjects research in Writing Studies. Publications in Writing Studies, particularly those appearing in disciplinary and professional organizations' publication outlets, suggest that researchers are attuned to the necessity of IRB review (NCTE, 2015; ATTW, 2016). Yet at the same time, researchers such as Johnson-Eiola (2012), Frost (2015), and Frost and Eble (2015), problematize the prescriptive approach of Institutional Review Boards in governing human subjects research.

Schneider (2006) notes that the “grafting” of social science methods onto the rich humanistic tradition of Writing Studies is relatively recent (beginning in the 1980s). The increasingly rich tradition of Writing Studies research now includes not only the traditional work of historians, philosophers, and critics (North, 1987) but also an increasing variety of “experimentalists, clinicians, and formalists” who work in predominantly qualitative or mixed methods framework; these frameworks often require researchers to engage directly with their human subjects via methods such as ethnography, interviews, classroom engagement, or surveys. It is in both this research on the texts themselves, as well as the direct interactions with human subjects, that Writing Studies researchers rely on both disciplinary and institutional frameworks to manage their research efforts. These are informed by federal (45CFR46, 1991) and

disciplinary policies (CCCC Guidelines for the Ethical Conduct of Research, 2015; ATTW Code of Ethics, ND) that recommend how research with humans be most ethically conducted. Writing Studies researchers' engagement with human subjects protections in research are also tempered and influenced by a robust literature on the impact of human subject protections and IRBs.

In 1996, Anderson called for greater attendance to the ethical treatment of human subjects and his continued publication in this area through the mid- to late- 1990s brought voice to a federal policy within Writing Studies. While Writing Studies is not a discipline that relies on modification of the human body to achieve research aims (for instance, providing patients novel drugs or therapies) it does conduct research that interfaces with the human subject at a different level: as creator and generator of texts. Moreover, these creators are asked about their creations; sometimes, these questions can be deeply personal, even invasive. They can shake a writer's affinity with their own self (Anderson, 1998).

In some instances, when texts could be used outside their intended purposes, or when a subject's very worldview is shaken in the process of research on behalf of Writing Studies, the importance of ethical considerations are readily apparent. Moreover, digital technologies increasingly foster novel research (Gurak, L. & Silker, 1997) yet simultaneously complicate the representations and rights of "the unfortunate human factor" (Johnson, 1994) in Writing Studies research. McKee noted in 2003 the increasing complexities of conducting research with human participants. She called upon CCCC to not only encourage adherence to policy, but to improve discipline specific guidance that interpreted policy on behalf of researchers. She also encouraged researchers to push back against mandates made by IRBs accustomed to doing primarily bio-medical research.

Wallace (2003) shared his narrative of suggesting to the Series in Writing Research

(*SWR*) Editorial Board that “IRB policies come out of a positivistic, masculinist tradition of research” (31) and that, in line with Harding, “feminist calls to reexamine the power relations in research have led to much more substantive ethical considerations” (33). He is dismissive of IRBs as “rarely address[ing] the complexities of the kinds of qualitative research designs I engage in and that the procedures too often seem designed primarily to cover the university’s collective ass and protect its eligibility for federal funding” (33). What McKee offers in the same year, however, was to suggest that the policies are a fruitful way of establishing whether the design *itself* is ethical. This can be done within the framework of novel feminist theory. Wallace exhibits the stresses of inhabiting the “story-teller” role many oral historians and other humanities-based scholars displeased with IRB policy share: “however, it’s also true that I did not say some things that I felt were true, things that I’m fairly sure would have been provocative reading in the pages of a journal” (36), and “I had a good story about her mixed-race identity to tell...” (38), “articulating myself as a gay man to Mark was hard and made me feel exposed, and I want/need to tell that story” (41). While largely critical of the CCCC position, Wallace also critiques federal policy, encouraging “informed dissent,” given his experience being harmed by a research participant, from whom he did not solicit consent. Wallace introduces a complex issue in Writing Studies research with human subjects.

For Writing Studies researchers, invasive research may not be a material project, but it can have material consequences. In Wallace’s case, these consequences appear to be a burden for the author, rather than the participants. However, Wallace, *as a researcher* opted to ignore fundamental principles of ethical behavior in research. Because the range of Writing Studies work can extend beyond simply examining archival research of deceased authors (McKee & Porter, 2012), researchers may ask deeply personal questions of writers in an online space, or

conduct ethnographic studies of private online spaces reserved for individuals who identify with a marginalized population. Regarding human subjects research in the humanities and social sciences, the regulations are quite clear that the risk is not of an immediate physical nature; rather, the risk of harm “is largely informational, not physically; that is, harms could result primarily from the inappropriate disclosure of information and not from the research interventions themselves. Nonetheless, these harms can be significant” (Federal Register 82.12, 2017, p.7151). This concern regarding the material consequences of human subjects research in Writing Studies will be more broadly addressed in Chapter Five.

Ten years prior to the preamble above from the new regulations, in 2007, McKee further developed her name as a leading scholar on ethical research in Writing Studies with her book, edited with DeVoss, *Technologies, Methodologies, and Ethical Issues*. This collection featured a chapter by Banks and Eble, who offer a guide for Writing Studies researchers as they interface with Institutional Review Boards. This is one of the most specific instances wherein Writing Studies scholars published methods of engaging with the IRB process. More broadly, the text addresses the ways in which research design and research ethics are vital to a researcher’s interaction with an IRB; the IRB review process, just as it was a specific chapter in the book, is only one specific component of the broader undertaking of conducting ethical research.

The next year, Barton (2008) published on the ethical turn in Writing Studies research. She examined the consent process used in two medical studies and their relation to the prescribed and federally mandated consent process. As an IRB chair herself, Barton offered not only her linguistic expertise, but also her legal and regulatory expertise, to the project. She notes consistency in review is a “well-recognized problem in the IRB literature” (p. 622), indicative of the more recent extra-disciplinary literature regarding “localism” and local implementation of

policy, discussed earlier. Her approach is also, perhaps most vitally, pragmatic, a function I'll revisit in the analysis of this section of literature.

McKee and Porter's 2009 *The Ethics of Internet Research: A Rhetorical, Case-Based Approach* speaks most specifically to the discipline, and both tangentially in support of Stark and in critique of the variety of complaints leveled against IRBs. Specifically, they note that a rhetorical (with emphasis on a specific context) and casuistry-based approach (examining general principles in relation to specific cases) of analyzing the increasingly complex research projects in digital environments "avoid(s) the problem of ethical relativism in research" wherein "every new research context [is] distinct and, thus, that leaves every researcher's own justifications as ... unassailable" (xxii). McKee and Porter argue that a rhetorical approach affiliated with casuistry will provide space for the development of heuristics. These ensure that "ethical decision-making for research [is] systematic, deliberative, collaborative, and multidisciplinary in order to be valid." (xxii).

A few years later, McKee and Anderson built upon Anderson's previous work and enhanced the project by addressing the day-to-day implications of researchers using texts outside their designated purpose (McKee and Anderson, 2011). In this way, ethical considerations of texts extend beyond research and into the classroom. The maintenance of digital files and years worth of student work further expands ethical concerns related to student texts. Anderson and McKee ask: At what point are we able to use this for work without discussing its use with (former) students? A functional question asked by a number of scholars, including Wallace, this represents an important component of Writing Studies research: studying the texts of students.

Paralleling these concerns in composition, rhetoricians grew equally interested in the effects of technology on research. Selber's (2012) *Rhetorics and Technologies: New Directions*

in Writing and Communication included a chapter by Johnson-Eilola: “Among Texts.” While the book copes with the larger opportunities related to the integration of technologies into disciplinary production of knowledge and subjects of study and research, Johnson-Eilola’s piece speaks most directly to how texts become “*actively social*” (emphasis in original). He questions:

If you are reading my article, do I have the right to know that you have read it? That you have passed it on to someone else with a snarky comment? That you have quoted it in a text you are writing, agreeing or disagreeing with me? What ethical obligations does a reader have to an author? (53)

Johnson-Eilola’s pointed concerns apply not simply to traditional texts, but more to those texts produced by and with emerging technologies. These technologies afford us the possibilities of *doing* new things such as tracking readers and authors and engaging in a dialogue through formal and backchannel means. The ethical concerns, then, rests not so much in the novelty of possibility but in the manifestation of current technologies’ impact on disciplinary research.

In 2012 CCC released a special issue on research methodologies. In this special issue, McKee and Porter (2012) discussed archival research in the context of digital archives. Inherent in the conversations about disciplinary methodology were conversations about harnessing both technology, as well as recognizing the necessity of ethical practice, in Writing Studies research. McKee and Porter’s piece developed a response to the somewhat more constructive heuristic McKee and Anderson had published the year prior, and situated pedagogical implications of using texts in the work of Writing Studies research more broadly.

Within this literature, McKee and Porter, like Banks and Eble, provide the clearest set of resources and heuristics for a discipline lacking both theoretical and pragmatic approaches to IRBs. While Anderson’s work in the 1990s brought research ethics to the attention of scholars,

these later texts pushed those concerns into the 21st century, where composing, and researching composing, became a far more nebulous agenda.

Analysis of traditional scholarship on human subjects research in Writing Studies.

In the 1990s, Paul Anderson called for greater attendance to the human subject component of composition research. Anderson's "Simple Gifts" offered a paternal approach to the student and text's author, mimicking federal regulations; Wallace (2003) was one of the first scholars to push back against this approach, titling a section of his piece "Complex Gifts." Still today, some scholars are currently calling for a reconsideration of federal policy to mitigate this paternal approach to human subjects protections (Frost, 2015).

Similarly, scholars have noted that Writing Studies can inform and support the use of documents and governance guidance used by Institutional Review Boards. For instance, Wright (2013) noted that documents such as Informed Consents often need to be re-tooled by researchers to ensure they meet the needs of human subjects. For instance, by updating a template consent into a set of multi-modal tools for use during the consent process, prospective participants better understand what they are being asked to do as research participants. Given Writing Studies scholars' training and skill sets, he suggests researchers in Writing Studies are particularly well-equipped to re-tool these documents to enhance comprehension. Utilizing this unique avenue to critique and engage with policy is an asset for the discipline and could indicate an increased space for research.

In recent years, Writing Studies researchers' considerations regarding the construction of ethical research, while presumably attended to in previous years, was codified in disciplinary policy. This policy shaped a small facet of publication in the field, and supported the development of policy statements for organizations such as CCCC and ATTW. This, along with

increased criticism of IRBs and policy from peers across disciplines, and the proposals to update federal policy, have spurred ongoing debates, presentations, and publications on human subjects research in Writing Studies.

As was noted in the NPRM (2015), technologies and new methodologies continue to shape the work of researchers. The early part of the 21st century witnessed a number of technological advances that reshaped writers' relationships to writing both materially and theoretically. Writers now compose with increasingly novel technologies and embrace the possibilities of communicating across vast spaces with ease, thanks in large part to modern technological innovations such as email, instant messaging, and social networking applications. Researchers in rhetoric, technical communication, and composition therefore have unique and exciting possibilities to examine writers' modes of composing in these new technological environments. However, continued research entails a conscious examination of how emerging technologies influence ethical considerations in existing Writing Studies research practices and methodologies.

The most prominent voice in this collection of scholars is one that recognizes the implications of local IRB review on unique research proposals. Barton offers a pragmatic approach to IRBs and the broader ethical concerns in the field regarding the methodological shifts in the field:

I realize that some scholars may critique my effort to define ethical persuasion in terms of generalizations and guidelines as putting a context-based framework in a marginalized or hierarchically diminished role, but I would respond that it is an attempt to work productively with the critical perspective of our field within the realities of research regulation in the university. (624).

I align the methodology of this project, and the general contribution of this chapter, with Barton's 2008 example. As an IRB coordinator and Writing Studies researcher, my work done for this dissertation reifies the lasting importance of Barton's observations, nearly a decade later, and with new federal policy to which the discipline to acclimate.

Exposition of recent trends regarding the ethics of human subjects research in Writing Studies. Emerging trends are addressed in this section regarding human subjects research in Writing Studies. Specifically, shifting methodological frameworks provide unique affordances and concerns for Writing Studies researchers interfacing with IRBs. Additionally, the increased attendance to social justice as a theoretical frame, and assessment as a practice, are influencing disciplinary literature on IRBs. These emerging trends have already produced a body of literature influencing how policy is perceived in the field.

In recent years, philosophical frameworks such as those oriented towards justice, social justice, fairness, and ethics suggest shifting trends in the impact of theoretical ethical concerns on pragmatic activities such as research and teaching in Writing Studies. Specifically, in relation to the scholarship of teaching and learning (SoTL), researchers have worked to examine the legal ramifications and ethical implications of enrolling one's own students in research.

Schneider (2006) offered approaches to this in her *CCC* piece dovetailing federal policy and the CCCC Guidelines for the Ethical Conduct of Research (which have since been updated). More recently, Hassel (2014), an associate editor for *TETYC*, noted that "for many English instructors, formal training in organizing systematic research that includes what is called "human subjects" research in many science disciplines was not part of their graduate training, and the process for approaching such a project is unfamiliar" (p. 404). Moreover, "a further challenge can be that some two-year colleges may not have a constituted IRB." Both authors note

trepidation in enrolling students in research, given the field's only recent turn towards research traditionally seen in the social sciences. Scheider writes:

The gap that appears between the research ethics we take as our own and those we teach emerges as an effect of the conflicted history of the field. Ours is a profession with deep roots in the humanities, a field of inquiry that has not historically conceived of its research in the same ways that either the physical or social sciences have conceived of their inquiry. The physical sciences have been invested in the production of knowledge that provides for greater predictability of and intervention in human and social systems.

(72)

The turn she identifies- as the arm of research North (1987) identified as being constituted by the experimentalists, clinicians, and formalists:

shows multiple research methods from the social sciences grafted onto humanistic roots in order to produce the kind of knowledge, predictability, efficacious practice, and useful interventions that give the field its reason for being. The grafting of new methods onto those roots has caused us to reexamine our relationships to research and given rise to the codification of those relationships. (76)

This synopsis of the shifting methodological landscape represents an ongoing trend in the field of Writing Studies. Adoption of more rigorous methods and quantitative explorations are occurring with greater frequency with the availability of larger data sets. From a disciplinary standpoint, even collections of such things as syllabi, publications, or genre-specific compositions within sub-disciplines have grown large enough to serve as viable data sets that articulate the boundaries of the field (e.g. Hall, 2015; Meloncon & Henschel, 2013). In this area of research, too, traditionally qualitative approaches to data analysis can now be conducted with quantitative

tools. Harnessing the power of these datasets both reifies disciplinarity, but also suggests those places where the discipline may increase its scope and better align methodology with novel methods and theoretical approaches. Such opportunities broaden methodologies, methods, and data sets, thereby expanding the discipline's theoretical knowledge such that new practices- and entire programs (White, Elliot, & Peckham, 2015) -- can be effectively assessed. The increasing attention to assessment, and the ethics of assessment, are an important change in what was, and remains, discussions surrounding the SoTL. Assessment offers researchers the opportunity to make claims about specific populations within a larger dataset; these datasets can be composed of thousands of students' data comprising an exponentially greater number of data points (Moxley, 2013; Moxley & Eubanks, 2015). Yet claims about individuals, or subpopulations, if made without attention to justice and fairness, can reify stereotypes of systematically marginalized populations. This work has been taken up by a collection of researchers, including Poe, Elliot, and Inoue in particular.

These theoretical frames have widely been applied to assessment in relation to human subjects research: assessment as social justice was the theme of a recent *College English* issue edited by Poe and Inoue (2016); a theory of ethics for writing assessment was proposed by Elliot (2016) in the *Journal of Writing Assessment* special issue edited by Kelly-Riley and Whithaus. These pieces return to a “humanities-based approach” to justice and fairness (Kelly-Riley and Whitehouse, 2016), with recognition of the increasing rigor and quantitative nature of research occurring in Writing Studies. This specific approach marries the call for more RAD research (Haswell, 2005) in Writing Studies with recognition of the importance of the human element that is studied in our humanities-based and increasingly justice-award scholarship. The intersection of these research agendas with justice as a theoretical framing device is a unique space to further

examine IRBs.

Elliot's 2016 article examines opportunity structures and articulates a vision of ethics in writing assessment based on "maximum construct representation under conditions of constraints...to the extent which benefits are realized for the least advantaged." This piece served as the groundwork for subsequent articles in the special issue by Slomp (2016), who advanced Elliot's theory and illustrated his work with case studies, Poe and Cogan (2016), who focused on the legal aspects of civil rights and the disparate treatment and impact in writing studies, Broad (2016), who looks at ethical blindness via case studies of large testing organizations, and Cushman (2016), who calls for a decolonization of assessment. Together, this special issue serves as a landmark collection on justice in writing assessment; the work of revisionsing an ethics of writing assessment is no small feat.

Given the need, and willingness of the discipline to support, growth in this area, Poe, Inoue, and Elliot's forthcoming edited collection *Writing Assessment in Social Justice: History and Practice* (In Press) provides a collection that "bring[s] together threads of writing assessment scholarship as related to ethics, anti-racism, fairness, and social justice from a range of perspectives and sites" (Poe, 2017). The movement towards fairness in assessment a critical space for examining the intersection of Writing Studies research and IRBs. Even large-scale assessment traditionally requires IRB review and/or approval, as those researchers conducting the assessment, unless managed by an outside researcher, have access to individually identifying information. This necessitates a level of IRB review and consideration of big data research that was, until recently, unheard of in Writing Studies. For instance, Moxley's research on the MyReviewers corpus has been designed such that consent from participants is still integrated into the research and tool-use process, but it is altered under the federal regulations to ensure the

balance of benefit and respect for persons (“Research,” 2017). The opt in/opt out still resulted in a substantial drop in data points, as individuals indicated they did not want their material being used for research purposes (Personal Communication, 2016). The frustration with ensuring autonomy while still collecting data to make generalizable claims has grown as the datasets afforded to Writing Studies researchers have grown.

Beyond program assessment, social justice initiatives and projects are pervasive in Writing Studies, broadly construed. In technical communication alone, social justice is represented widely, for instance in Walton and Jones (2013), Colton and Walton (2015), Redd et al. (2014), Moore, Jones, and Walton (2015) Agboka (2013, 2014), a *connexions* 2016 special issue on Technical Communication, Social Justice, and the Global South. These publications incorporate both pedagogy and/or research, both of which require IRB oversight. The representation of social justice in publication has implications for the ways in which Writing Studies researchers ethically design, implement, and evaluate their human subjects research.

Elliot (2016) suggests that social justice in Writing Studies is a concept that relies heavily on Rawlsian notions of justice: distributive justice based on social advantage, as a rebuttal of Mill’s (2011) utilitarianism, satisfying equal rights before re-distributing goods, and finally, in contrast to Kant’s (2012) deontology, justice in this iteration is communal. Advancing (social) justice in the scholarship, then, is of great value, as it displaces responsibility from the individual to the community, engages process for re-distribution of goods, and articulates the satisfaction of equal rights.

Justice-oriented agendas like those outlined above, big data methods (Moxley and Dixon, 2013), internet-based research (McKee and Porter, 2009), and the implications of increasingly globalized research can constructively problematize human subjects research in Writing Studies.

As networks increase in size, the prospective participant population base also increases; the world may be large, but the internet is making it smaller. This grows even more complicated as nations have unique and varying approaches to reviewing research (HHS.gov, 2016). Internet-based research that is also international exhibits some of the serious changes that the discipline is working to manage, as transnational partnerships require attendance to institutional, local, and national policies for multiple stakeholders.

These changes are primarily a result of methodological shifts in the discipline. Methodology serves as a disciplinary touchstone. Accepted methods and methodological frameworks define disciplines (Rude, 2009; Miller, 2014; Sullivan et al., 2000; Ross and Arnett, 2013). Therefore, the sorts of research conducted within a given discipline suggest the epistemological constraints within which a discipline, or field, circulates. Research in Writing Studies' sub-disciplines can be situated, for instance, in methodologies expressed through hermeneutic (e.g. Tillery, 2011; Haller, 1997; Collings Eves, 2005) or qualitative (North, 1987; Teddlie & Tashakkori, 2009; Creswell, 2014) methods, and (occasionally still positivist) methods related to cross-purposes such as pedagogy. Methodological design influences the way in which researchers present themselves to their IRBs. For instance, the CCCC Guidelines on the Ethical Conduct of Research in Composition was recently updated to reflect the shifting methodological scope of the field.

Over a decade after their release of the original position statement “CCCC Guidelines on Ethical Conduct of Research in Composition” (November 2003), CCCC formed a committee to update the guidelines, which were re-released in 2015. These guidelines (Appendix I) provide a baseline for assessing whether disciplinary constituents represent CCCC’s goals. In many instances, the CCCC guidelines, while suggesting researchers interface with IRBs to introduce

methodologies and novel methods, are restrictive beyond the federal regulations (for instance, the recruitment of one's students into one's research). Moreover, the CCCC guidelines suggest multiple times that "we...make determinations"; for instance:

When studying unpublished writing samples that have been collected outside of a study approved by an IRB or other process, we, (and, when applicable, our undergraduate/graduate researchers, collaborators, and colleagues), determine whether our planned use of these samples is consistent with the policies governing research at our institutions and, if different, the institution at which the samples were collected.

In many ways, the CCCC's updated guidelines regarding use of archival materials, acknowledgement of the multiple roles researchers and participants can play, as well as their contemplation of assessment and digital materials, suggests that the discipline remains on the forward trajectory of human subjects research in Writing Studies. Yet still, their response to the proposed updates to the Common Rule, as well as their suggestion that researchers themselves can make determinations about whether something is "research" are indicative of remaining issues in the discipline's approach to policy.

Analysis of recent trends regarding the ethics of human subjects research in Writing Studies. With the growing capabilities of born-digital and digital reformatting tools, Writing Studies is increasingly able address Haswell's (2005) call for more RAD (replicable, aggregable, and data supported) research. RAD research is aligned with "rigorous" empirical, data-driven research to discuss how digital and new media tools extend and expand Writing Studies' methodological approaches. Regardless of qualitative, quantitative, or mixed methods representations, however, empirical research conducted in Writing Studies is heavily imbued with the contexts of research as a social construction (Herndl & Nahrwold, 2003). While this

project is empirical, it is also an effort to model a specific feminist methodology, particularly Intemann's (2010) feminist standpoint empiricism, which combines the assets of modern feminist empiricism, which is contextualist, normative, and social, as well as modern feminist standpoint theory. Therefore, the analysis and critique of the recent trends in human subjects research will be substantiated with data to make generalizable claims about the spaces for innovation and implications. But it also relies on interpretation of literature.

One piece of literature worth drawing out further in this analysis is the short "Inquiry" piece by Hassel (2014). She noted:

Some concepts are important to understand, including the terms *exempt* and *expedited*. SoTL work should be categorized in most cases as *exempt*...However, this does not mean that the project is exempt from review by the IRB. Instead, it simply means that it is exempt from *full board review*, which means that an aspiring researcher may have a proposal reviewed and approved by a designee of the committee. The determination of whether a project is exempt must be made by a member of the IRB committee. There are other distinctions that may be important -- for example, an *expedited* review can take place, which means a proposal can be evaluated by a qualified reviewer, rather than at a full board meeting. (405)

This quote, alongside previously articulated concerns with disciplinary approaches to federal policy, further conflates federal policy with local implementation by specific IRBs. For instance, protocols that are exempt are, actually, exempt from IRB review- not simply the committee, but the staff and Chair of the IRB as well. The Common Rule (1991) does not indicate who at an institution has to make these determinations, but the individual who does make the determination does not need to be a member, or even an affiliate, of the IRB!

In her description, Hassel is conflating expedited and exempt protocols, making their designations meaningless. While individual IRBs may implement their own procedures to assess whether a study is exempt, for instance by recommending that a committee member, or staffer, review to ensure a project is exempt (as is the case at many institutions that seek AAHRPP accreditation (AAHRPP, 2017)), it is not required by federal regulation. While Hassel's experience may be one shared by a number of individuals in the Writing Studies research community, particularly relating to SoTL and the broadening scope of assessment, it is not an accurate representation of federal policy, nor a comprehensive representation of how the policy could be implemented.

Research conducted through a justice-oriented lens is not new. However, its proponents increasingly design research to bring in, and/or represent, marginalized populations such as those from the Global South, and those who are, by definition in their focus as participants in social justice research, traditionally marginalized in scholarship (e.g. LGBTQ, persons of color). These collaborative research designs can be troublesome as they move through the IRB review process, particularly for Community-Based/Participatory Action Researchers. While researchers can redefine their populations, they cannot redefine any populations' status as vulnerable. Nor can Writing Studies researchers, in these instances, easily define what true benefits or risks exist for these populations.

Besides the expanding environments and populations for research, Writing Studies researchers have increasing access to, and the expertise to use, a number of born-digital tools. Yet tool-use is helpful only when such tools align with a researcher's overarching methodological frame. Because of their function, and sometimes open-sourced nature, the tools require attention to both their usefulness and appropriateness, but also their cultural situatedness.

In many ways, conversations about tool use, what researchers decide to study, and how they decide to study it are all ethical concerns with justice-oriented aims. Marrying novel policy implications with the increasingly breadth and complexity of disciplinary methodological affordances invites the empirical examination discussed in the coming chapters.

Conclusion

This chapter provided an overview of the nested components of mediating variables from the concept map. Specifically, the chapter began with an overview of current federal policy and examined forthcoming policy. Human subjects research in Writing Studies within these contexts was then filtered through both the lens of policy and the broad scope of multidisciplinary research and literature on IRBs.

Given the literature, I propose that there are three identifiable gaps in the Writing Studies literature on IRBs and federal policy related to human subjects research. First, it is clear that the discipline's federal policy process knowledge is limited, as exhibited by the CCCC comment on the NPRM. Second, while it is important to know policy well enough to advocate for one's projects, and one's students, Writing Studies researchers cannot exclusively rely on federal policy and/or disciplinary guidance, as exhibited by the CCCC Guidelines on the Ethical Conduct of Research and the fallacies within critical literature by Wallace, for instance, and educative literature, such as that by Hassel. These two components will be the groundwork of the investigation established in Chapter Three; the results will be shared in Chapter Four, and the findings in Chapter Five.

Finally, in relation to these two conclusions and the turn towards justice-oriented mind-sets in assessment and the broader design of ethical research in Writing Studies, one remaining contribution can be made in this dissertation. Writing Studies researchers have not only failed to

recognize that while policy is the threshold, local implementation is the way in which they must learn to interact with policies regarding human subjects research. They also approach the review process in many instances in publication with frustration regarding the vestiges of positivist research design expectations in the IRB review process. Re-orienting Writing Studies researchers' perceptions of policy (and, in many cases, IRBs) to one that is justice-oriented will prove generative to the field. This theoretical position is taken up in great detail in Chapter Six.

Together, these gaps represent the unique and constructive work to be done in the remainder of this dissertation: to transition Writing Studies' narratives about the policy and implementation of federal policy via IRBs from one that is punitive and positivist to one rooted in justice.

CHAPTER THREE: METHODOLOGY AND METHODS

This chapter provides an overview of the methodology and methods utilized for this dissertation project. I furnish the primary research goals and questions of this project to contextualize these choices. I also provide the variable map used to demonstrate how the core research questions of the study were designed. I then discuss the specific methods used in this project by identifying both the affordances and challenges of each method: a survey and interviews. I describe the development of each tool, and discuss the target populations of each method. Finally, I provide a brief outline of how the data will be analyzed and interpreted before moving into providing the results in Chapter Four.

Methodological Frame

I identify as an action-oriented (pragmatic), theory-informed researcher (Teddlie & Tashakkori, 2009). A justice-oriented, feminist methodology is well situated in this broad identification.

Soliciting IRB review suggests, at the outset, that one's work is (1) generalizable, and therefore in some way pragmatic and intended for consumption by a public-facing audience and (2) seeking to better understand the human condition by studying some aspect of humans. Therefore, this work is pragmatic and action-oriented because I hope to both provide a course of action to examine and influence the ways Writing Studies interact with IRBs, and, moreover, I am *examining* pragmatic research.

Work done and reviewed by IRBs suggests some goal of generalizing knowledge to impact the broader landscape of what is knowable, and what is understood, about the human

condition. A healthy, human-oriented research project should, I believe, be necessarily justice-oriented, too, because of the enrollment of participants. Utilitarianism has been proven to be a poor method of determining the risk/benefit ratio in the United States. Therefore, this project is justice-oriented, I suggest, for the following reasons: (1) this research is governed by policy that specifically calls upon justice-oriented goals, and (2) this research, towards Rawlsian notions of fairness, is designed to contribute more just outcomes not only for participants, but also for future populations.

My methodology is not novel, but it is articulated in a specific theoretical space. IRBs work to assess risk to participants, as researchers seek to increase and add to generalizable knowledge. Marrying this, and public policy, to Writing Studies methodologies leads me to suggest that the space of the discipline, and research, in respect to IRBs, is service-oriented and pragmatic. Specifically, when researchers engage human participants in their research, they are deeply interested in assessing the outcome of some intervention on their fellow human, for instance: students, clients, or the general population. When researchers conduct research with IRB approval, presumably they do so to make the world, and Writing Studies classrooms, a better place.

This dissertation straddles the multiple and competing demands of our roles as teachers, researchers, and scholars. To best do so, I've employed a mixed-methods approach, with a justice-oriented feminism at its core. I'd like to elaborate on each of these claims.

First, *that this project is mixed-methods*: While considered mixed methods in Writing Studies, in political science, public policy, and research ethics, the quantitative approach of this project would still be considered largely qualitative, given the relatively small sample size of the participant population. Generally, however, the methods here are mixed; survey participants

provided thousands of data points. Different, yet equally important, data were collected from a smaller population during the interview phase. Describing this work as “mixed-methods” is indicative of how this project is influenced by positivist overtones, yet postpositivist in methodological application. I address this more in the paragraphs below; what I mean to say is: this started as, and remains, a deeply pragmatic project. With a purpose of increasing protections of human participants in research, and increasing the ease of researchers’ interactions with their IRBs, I firmly situate this project in the “mixed-methods” camp. These mixed-methods provide a robust empirical standpoint from which to interpret (Chapter Four) and analyze (Chapter Five), and thereby provide predictive (Chapter Six) material.

Second, *that this project is justice-oriented*, as defined earlier, with Elliot’s (2016) use of Rawls’s theory of justice. There is a definite tension between feminist methodologies and research ethics. For instance, Cross et al. (2015) and Huisman (2008) question the effect of IRB review for ongoing feminist methodologies such as community-based participatory research. Given the increased representation of feminist/queer rhetorical research methods such as those discussed in *Rhetorica in Motion*, the methods in design and practice are aimed towards notions of justice as fairness. This is parsed out in descriptions of findings and in Chapters Five and Six as I address implications for researchers.

My justice-oriented approach is most clearly seen in the methods I used to collect and interpret data. For instance, the survey development process, data disaggregation, sub-group analysis, and hypotheses use methods to examine these issues from a justice-oriented standpoint.

It is noteworthy, however, that the survey and interview methods did not include strategic approaches to non-United States settings. While data from non-U.S. settings may be provided by participants, the regulatory framework exists in the U.S. and impacts U.S.-generated research.

Some may suggest that this inhibits a justice-oriented approach, as I am focused on one of the strictest human subjects protections policies in the world (Angell, 2007). Rather, I'd suggest that this project encourages critical reflection on the “paternalistic” systems that constrain research in our nation before engaging in projects abroad, especially with nations that have non-existent, lame-duck, or rubber-stamping ethics commissions. The U.S. policies, while strict, rely on a robust history of maltreatment of marginalized populations by the U.S government itself. In addition, a rich tradition of moral philosophy and scientific rigor undergird the current regulations. However, as Elliot (2016) notes, “While scientific realism may be thought of as the pursuit of truth gained through objective reality, constructive empiricism holds that such beliefs need not go, as Rawls put it in his treatment of concepts of justice, “all the way down” (Rawls, 2001, §13. p. 32).” Thereby, Elliot suggests, and I rely on, the notion that “empiricism is perceived as a shared point of view, a key principle of community” which Broad and Boyd (2005) defined as “a rhetorical and democratic process for establishing knowledge, value, and meaning.”

This, as Elliot (2016) states, means that empiricism is no longer relegated to logical positivism. Therefore, rigorous empiricism is accessible to projects with a variety of non-objectivist positionalities. These are reflected in my claim that *this project is situated in (a) feminist methodology*, specifically Intemann's (2010) feminist standpoint empiricism, which is contextualist, normative, social, and honors diversity in social and political values.

But the site of this project exists in a traditionally positivist epistemological framework for determining change and establishing generalizable knowledge. Frankly, all work done that must be vetted by an IRB rests within a dominant theory of knowledge creation, one that generally values a pre-scribed understanding of what entails “good research,” (yet, to be fair,

can, at times, resist positivist overtones). Even researchers in Writing Studies working on the fringe of the field, in the dark web, for instance, or anonymous, public forums about gender-identity, still seek out IRB approval for their work (Personal Communication, 2016). McKee and Porter (2010) note that “it is possible for researchers to pursue feminist methodologies without studying gender primarily, although attunement to power in gender relations ...asymmetry and ...inequity must certainly be strongly present.” (154). I work to follow McKee and the many other feminist scholars by participating in ongoing critical reflexivity, dialogism, and transparency during my research process.

Yet I also must recognize the sometimes contradictory issues with the feminist ethics of care identified by Barton (2008) within an empiricist framework. I work to mitigate these concerns by applying a feminist standpoint empiricism (Intemann, 2010) that honors the goals of feminist empiricists by adopting the kind of diversity recommended by standpoint theory and embracing the importance of ethical and political values of standpoint theory.

When Writing Studies researchers seek out IRB approval, they are doing so as a function of how higher education, and federal funding dollars are used to promote tenure and promotion, and therefore research, at many institutions across the nation. It is indicative of how public policy impacts work in Writing Studies. This project aims to pull apart of all these particulars that, while researchers do the work of filing and revising their protocols, may not seem to impact the knowledge they produce.

This is to say: I am reflective and attuned to the fact that this methodology may not seem, at its surface, to be “feminist” or “justice-oriented” in nature. However, I suggest that making effective change in the constraints of promotion and tenure culture, and ensuring that feminist methodologies become more mainstream, we must learn to work within, while subverting, the

system. I suggest, in later chapters, how this is best done.

In this way, in my attempts to explicate the methodology that undergirds this project, I hope it is clear that rigorous processes were used to establish an ecology, a heuristic, and a *map* that will guide researchers towards ethical, care-full research practices in the discipline. While the project works to consider non-U.S. based researchers, its target audience is both researchers enmeshed in the traditional and current scholarship models dictated by tenure in the U.S. This work is for the researchers in our field working on the fringes of theory and human-based studies that push the boundaries of what it means to research and be just.

Research Goals and Questions

Before establishing the research questions, I elaborated the following goals for the human-subjects based research for this project: (1) craft a timely overview of the shifting approaches to human subjects protections in Writing Studies Research, (2) provide analysis of position statements by Writing Studies researchers regarding human subjects protections, and (3) collect narratives from thought leaders in the field regarding research and human subjects protections- past, present, and future to enhance Writing Studies researchers' understanding of, and ability to navigate, human subjects protections, oriented in more general notions of justice and beneficence. Out of these goals came the following research questions:

- How do Institutional Review Boards staff (who I call street-level bureaucrats), interact with researchers to shape methods and methodologies in Writing Studies?
- How can we identify pertinent variables of training for Writing Studies researchers related to human subjects protections? What methods can we use to investigate broad categories of influence by IRBs and tailor support for Writing Studies researchers?
- Can we provide guidance on modes of crafting documents for IRB review?

- Can we create a new taxonomy to explain variables that result in best protections for human participants in Writing Studies research?

Together, these goals, research questions, and the literature review resulted in the development of the variable map (Figure 2, discussed at length in Chapter 1) used to tie each survey question to the project.

The research questions specifically address this variable map in multiple ways. The survey tool and interview protocol were both constructed based on not only the research questions but also the connection of those questions to discrete components exhibited in the variable map.

For instance, in examining how to identify pertinent variables of training for Writing Studies researchers related to human subjects protections, and considering what methods can be used to investigate broad categories of influence by IRBs (RQ 2), participants were asked about their experiences with IRBs and their understanding of fundamental principles that undergird IRB review. This in turn helps answer the research question regarding whether or not Writing Studies, as a discipline, can provide guidance on modes of crafting documents for IRB review (RQ 3). The results from the survey will be interpreted as findings that help create a new taxonomy to explain variables that result in best protections for human participants in Writing Studies research (RQ 4). And finally, while survey data may not address it as specifically, interview data and open-ended replies to the survey provide information about how IRB staff interact with researchers to shape methodologies in Writing Studies (RQ 1). The connection of survey questions to the concept map, and thereby the research questions, are articulated in Appendix G.

Methods

The data collection tools used for this dissertation were a discipline-wide survey, targeted interviews, and close reading and text analysis. This section of the remainder of this chapter outlines the survey and interview data collection and analysis components.

In addition to findings from the survey, interview transcripts also provide narratives and initial findings from the second phase of the CCCC grant project affiliated with this dissertation: interviews. This subset of the general population of Writing Studies researchers was built by researchers working also with federal grants (per the funded CCCC Research Initiative) or individuals who had a legacy of working with IRBs in the field (five or more years). The most generative data for this dissertation comes from the surveys; however, the interview data will supplement these findings.

Thus far, the project has provided an analysis of IRB literature, attention to disciplinary narratives related to research, and an explication of the methodological frame. What follows is a representation of how the survey tool was built, refined, and disseminated, and a brief introduction to the use of interviews as a qualitative method. The finalized survey tool (Appendix F), as well as the feedback survey on the tool for expert committee members (Appendix E), can be found in the appendix.

Survey. The following section discusses the benefits and limitations of surveys as a data collection method both in broader methodology literature, as well as within the field of Writing Studies. An overview of the construction and validation of the survey tool is provided, as well as information about the target population and the sampling plan.

Benefits and limitations of survey as data collection method. Surveys are widely used in Writing Studies both for research and program evaluation purposes. Articles across journals in Rhetoric and Composition, such as those by Miller et. al (1997) and Chapman and Tate (2007),

utilize surveys as a method for collecting data and making knowledge claims about the field and its practices and pedagogies.

Effective surveys with adequate response rates allow researchers to make generalizations about a large population based a smaller portion of that population (Rea & Parker, 2014). Cresswell (2014) notes that surveys provide a “quantitative or numeric description of trends, attitudes, or opinions of a population” by examining a sample of the population (p. 155). The advantages of surveys also include rapid turnaround times (Fowler, 2009), especially for those delivered online (Rea & Parker, 2014). As the goal of the survey component of this project was to make broad claims about the discipline’s approach to IRBs, and it needed to reach thousands of potential respondents across the nation in a rapid amount of time, an online survey tool was designed.

Qualtrics online software was free to use as a student at the University of South Florida. An online survey was the most obvious way to collect a large number of replies to a variety of questions. While the survey length approaches 30 minutes for respondents who have interacted with IRBs and have federal grants, it was reasonably short for individuals who have worked only in passing with IRBs.

The fundamental limitations of using a survey for this project were three-fold. First, almost in violation of the Belmont Report, the survey asked questions of individuals who may never work with IRBs again. Indeed, more folks may have been bothered by the survey than need be. Because there is no central database indicating how many individuals consider themselves *part of* Writing Studies, it was difficult to establish a baseline sample size and determine adequate power for this project. Indeed, as is ever the case, final response tallies suggest a higher response rate would have provided more power to make stronger claims.

Second, while incentives were offered for participants, the response rate, as it tends to be, was quite low. Incentives were originally \$5, and this was increased to \$10 shortly after the soft-release of the survey in mid-September 2016. While budget constrained compensation, it is not clear how response rates could have been improved. Compensation was increased to mitigate selection bias amongst the population under study.

Finally, the survey was clearly subject to fatigue. 270 participants completed the survey. 22 respondents started the survey and did not complete it; that being said, a 92.5% persistence rate is quite good given the length of the survey tool.

Survey construction and validation. The original survey was built based on several inputs: (1) feedback on pertinent issues and concerns by expert committee members⁴, (2) common themes experienced by the researcher as a both an IRB staff and IRB member, (3) questions stemming from the literature review in Chapter Two, specifically about IRBs more generally and (4) questions stemming from the literature review in Chapter Two, specifically about Writing Studies and IRBs. As no similar survey exists, this tool was built specifically for this research.

I used an IRB approved survey⁵ that was reviewed and co-constructed with an expert committee. The survey was divided into five major components besides the Letter of Information and compensation sections. Participants were asked about their professional roles/affiliations, their interactions with IRBs, their familiarity with federal regulations that govern IRBs, a selection of case studies, and finally, a section on the intersection of any federal grants they may have received and IRB policy. Survey questions are attached in Appendix F.

⁴ This committee was composed of members of the dissertation committee, IRB administrators, and external reviewers focused on ethics in Writing Studies and statistical work in assessment

⁵ The survey was submitted to USF's IRB in early April, 2016 and was approved a week later after minor revisions; the approval letter can be found in the Appendices.

The survey tool was titled “IRBs and Writing Studies: Disciplinary Perspectives” and underwent pilot testing and review by an expert committee to (1) ensure the questions matched the variable map, (2) check for fatigue, (3) look for errors, and (4) solicit recommendations for improvement. Along with a second evaluative survey, reviewers evaluated the “IRBs and Writing Studies: A Disciplinary Perspectives.”

The process for updating the survey after receiving feedback from the expert committee was as follows. First, all feedback was printed and correlated. All data was pulled down from feedback survey. Eight complete and three partial responses to the actual tool (under evaluation by the committee) were pulled down from Qualtrics; these responses were saved to a harddrive and wiped from Qualtrics. The survey then sat clean, with zero respondents, until its soft release on September 16.

Sampling plan design. The target population of this survey was any individual who considered/s themselves a part of Writing Studies, writ large. Even if these individuals did not conduct human subjects research, they were still part of the target population. Because prior to the release of this survey, there was not a way of assessing how many individuals within the field work with human participants, the survey was intended to be discipline-wide, rather than focused on the sub-set of Writing Studies researchers who interface with IRBs.

Sample size. Initial sample size calculations, using very general estimates as to the total population of Writing Studies researchers, and a low confidence level (80%) and reasonable margin of error (5%) suggested that a survey population of a little over 250 respondents was necessary. After receiving reported professional memberships at national organizations across the United States (WPA, CCCC, ATTW, etc), as well as examining previous studies collecting data on disciplinary affiliation (Consortium, 2004; Miller, 2014; Skeffington, 2011; Brown et al.,

2008), the estimated affiliated researcher base was increased to approximately 4,500. It was not possible before releasing the survey to determine the probability that participants identified with, or were members of, multiple organizations, nor was it possible to know the exact number of individuals in the discipline who conduct research.

Using the equation seen below in Figure 3, I estimated a total population of 5,000, which is a generous 927 individuals more than the reported CCCC membership (4,083) at the time of this examination. The CCCC population was used as a basis, with a near 25% addition to ensure results were generalizable within the population of Writing Studies researchers. With a z score of 1.65 and a margin of error of 5% and an expected p value of .5, a sample of 257 individuals was necessary, where $N = 5,000$; $z = 1.65$ (90% confidence level); $e = \text{margin of error (.05)}$, and $p = 0.5$ (percentage value at .5, normal distribution).

$$\text{Sample Size} = \frac{\frac{z^2 \times p(1-p)}{e^2}}{1 + \left(\frac{z^2 \times p(1-p)}{e^2 N} \right)}$$

Figure 3. Sample Size Equation.

Eliciting the sample. A multistage, or clustered, procedure was used for this survey; groups were identified that met the qualification criteria (Creswell, 2014). Specific individuals within these groups were not identified individually in the listservs used for recruitment; therefore, random sampling was not possible in this study. Individuals were identified through their largely anonymous participation on public listservs. As neither random sampling or systematic sampling procedures were used to recruit participants (Creswell, 2014), a nonprobability sample was utilized, wherein selected respondents opted in of their own accord

due to their availability (Creswell, 2014). Compensation was offered in efforts to decrease response bias and self-selection to ensure adequate data from a variety of respondents was received.

The survey was distributed at first with a “soft-release” September 16, 2016 only via social media. This levied a mere 5 respondents. Immediately, IRB approval was sought to increase compensation amounts (doubling what had been offered- \$5 to \$10). As soon as approval was levied for the increased compensation, the survey was pitched again using personal social media channels, as well as released on listservs to all populations above. Following Dillman’s (2014) tailored design method, emails were sent to the WPA-L on September 28, 2016 and again on October 24, 2016. Emails were sent to the CPTSC and ATTW listservs on October 8, 2016 and November 3, 2016. IEEE also posted the link to their website, and emails were shared on various social media channels (Twitter, Facebook) by both the researcher and colleagues. On November 4, 2016, the survey had over 310 responses, 269 of which were usable. The survey was closed, as nonsense replies were being submitted by individuals not affiliated with Writing Studies.

The modest target of this project was an 80% confidence interval with a low margin of error (<5) for each targeted sub-population. The following chapters provide specific information related to the confidence level and margin of error for the population as a whole, as well as for each sub-population examined.

Ensuring quality sample sources. An alternative check was utilized to check for response bias (Fowler, 2009). Additionally, as data collection was ongoing, the researcher received email updates with full data sets for each respondent. These were scanned to ensure that the internal checks within the survey (i.e. prompts about position at institution in comparison to percentage

of time spent on tasks) were consistent. On November 4, over 20 responses were submitted where these internal checks were not met. It became quickly apparent that individuals had collected the URL and were hoping to receive compensation, despite not being part of Writing Studies. These data sets were deleted and those individuals were not compensated.⁶

Some interviewees were nonrespondent to the survey; their interview protocol involved prompts from the survey to check for response bias (Creswell, 2014); their responses indicated that nonrespondents' replies would not have varied from the compiled data.

Interviews. This section provides information on the benefits and limitations of interviews as a method of inquiry in both Writing Studies and the broader methodological literatures. Additionally, information about the selection of interview participants, as well as design and deployment of the interview protocol are discussed.

Benefits and limitations of interviews as a data collection method. Interviews and data collection from protocols provides aural and visual data to supplement the findings from the more generalizable materials of the survey. These speak to the specific, nuanced experiences of interviewees. As such, they provide a legacy of interpretation and understanding of both federal regulatory policy and local institutional knowledge that is invaluable for the growing and evolving field of Writing Studies. The interviews selected for representation in this dissertation contextualize findings from the survey and provide innovative narratives for moving forward in Writing Studies research.

As with any method, but particularly important in implementing qualitative methods such as interviews, it is vital for researchers to reflect on their "biases, values, and personal

⁶ This issue, along with the data plan and the solution (scrubbing data and not compensating these respondents) was submitted to the IRB as an unanticipated problem report. The IRB deemed the action taken (closing the survey, cleaning the data, and not compensating participants who ignored the specifications in the LoI) were sufficient and no further action was necessary.

background” (Creswell, 2014, p. 167.). As an IRB coordinator at a mid-size campus with high research intensity, I am bound in my research by the work that I do, day-to-day. This certainly impacted the interview protocol designed for this project. While prompts were (1) an extension of the survey tool, (2) tied to the concept map and research questions and (3) served to elicit replies from individuals with a clear knowledge of IRBs, other questions may have been generated had a different population (besides assistant, associate, full, or emeritus professors) replied to the survey tool.

Interview protocol development. After survey results were collected, the interview protocol was developed to highlight clear areas of tension and concern in survey responses. The construction of the interview itself underwent two primary phases. First, a draft of questions was developed, including individual-specific questions addressing the respondent’s replies to survey prompts. Other document-based questions were designed with three approaches in mind: regulatory, ethical, and disciplinary. Finally, a set of questions general for all interviewees supplemented these other two categories.

Once the first draft of the interview protocol was finalized, it was tested with the project consultant. It was mapped to the concept map and re-worked to better exhibit the goals of the research and collect usable data for this project.

Target population and deployment. As an IRB Coordinator, or a professional “regulationist” (as Schneider characterizes us), my understanding of and allegiance to the work of IRBs should not be taken at face value. Rather, familiarity with policy and day-to-day experiences with countless researchers greatly informed my interest in the interview component of this project. My experiences certainly shaped my approach to the development of the interview protocol. My work with an IRB helped me recognize the lack of historical legacy about

IRBs in Writing Studies.

Therefore, interviewees with both expertise in human subjects research and at least a decade of legacy in the discipline, were able to fill this void. Interviewees were purposefully selected for the interview component of data collection.⁷ Because I used the interviews as a method of “studying up” rather than “studying down” (Kirsch, 1999), I believe interviewees were frank and honest in their responses.

Interviewees were solicited via direct email one of two ways: either they were asked to participate because of the responses they supplied in the survey, or they were asked to participate given their publications on projects that underwent IRB review or their service on IRBs at their institutions. Six interviews supplement the survey data. The researcher conducted skype interviews with participants; these were audio recorded and transcribed.

Data Analysis and Interpretation

Survey data analysis and interpretation. Ultimately, 269 of responses were collected. Chapter Four provides a descriptive analysis of the data for all variables. Qualtrics provided visualizations for data, both correlated across questions and prompts, as well as for individual survey questions. These are used to represent the results in Chapter Four. Opened-ended replies to prompts about the principles of beneficence, autonomy, and justice, as well as responses to case studies, were loosely organized in word clouds to display general approaches to the prompts.

Interview data analysis and interpretation. Interviews were recorded by both audio

⁷ This component of the research was approved alongside the survey approval by USF’s IRB. Because the potential exists for personal or professional harm should an individual respondent’s data be released alongside their name (especially if they suggest something negative about their institution, research community, or IRB), great care was taken to dissociate data and re-confirm with participants regarding the use of verbatim quotes and attribution.

recording software on an iPhone (Voice Memo App). No video recordings were made. The recordings were run through Dragon, a transcription service. Transcripts were cleaned. These transcriptions created a corpus, which will be used in future projects related to this dissertation. For the purposes of the dissertation, these transcripts are used, with permission, to frame the data and findings from the survey. They provide a narrative description throughout this dissertation of the interactions Writing Studies researchers have had not only historically, but also at present, and their future expectations.

Interview data will be presented in context, representing the participant as wholly as possible. As the interviews were participant specific, and the goal was to create a broad understanding of the scope of Writing Studies researchers' perceptions of Institutional Review Boards, the data from these interviews will be presented as both Klitzman (2015) and Stark (2011) presented their interview data: as a narrative.

Conclusion

As an action-oriented researcher, using a traditional survey method to obtain answers to research questions seems like an obvious choice, yet one seemingly made in contradiction with a feminist methodological frame. Utilizing open-ended response options in the survey, as well as interviews, afforded a more qualitative approach to enhance findings. In efforts to broker honest findings and determine a discipline-wide understanding of interactions with IRB, as a required component of human subjects research methods, I endeavored to use those methods most familiar to researchers using these methods. The methodology and methods have set the stage to provide a representation of the data in Chapter Four and a variety of analyses of findings in Chapter Five. These provide the foundation of Chapter Six, which offers general heuristics for Writing Studies researchers.

CHAPTER FOUR: SURVEY RESULTS

This chapter presents the results from the survey “IRBs and Writing Studies: Disciplinary Perspectives.” This survey was administered via Qualtrics between September 14 and November 4, 2016. Participants were able to opt-in to receiving compensation- a \$10 Amazon giftcard. Over 300 responses were received, but after data cleaning, only 269 responses were complete enough to be useable. The results are provided in tables, figures, and images. Descriptive narratives accompany each of these representations; reports of how the results answer research questions, and their implications, will be addressed in Chapter Five.

The results are divided into four sections. First, the descriptive traits, what I refer as “demographics” of respondents are shared. These map onto the project concept map as the two predictor variables “context” and “disciplinary orientation.” The second section of this chapter provides results from the major components of the survey that map on to the project’s “personal disposition” variables, which are exhibited in data from case studies, open-ended replies about ethical principles, and some Likert scale questions. This section details both representative and unique solutions to the case studies, as well as other detailed open-ended responses. These are represented in word clouds. The third section provides results from the survey regarding participants interactions with the “mediating” variables from our concept map, specifically the federal regulations, local IRBs, and disciplinary ethical standards. Finally, the fourth section of Chapter Four provides an initial comparative analysis of a variety of variables from the general population’s responses.

Narratives that accompany data representation are imbued, of course, with the author's situatedness within the realms of Writing Studies and the work of IRBs. However, claims about the data, as well as narratives from the interviews, are saved for the next chapter. Note also that not all totals in all tables equal 269. This is for two primary reasons. First, all questions were, in the spirit of completely voluntary engagement by participants, optional. This means that participants could skip questions. Additionally, Qualtrics skip-logic feature was used; therefore, respondents who indicated, for instance, that they had not filed any protocol with their IRB, would not be prompted to answer questions about the sorts of protocols they filed.

Predictor Variables Associated with Context and Disciplinary Orientation

This section provides an overview of the characteristics of the 269 respondents' data collected via the "IRB and Writing Studies: Disciplinary Perspectives" survey tool. These questions were asked primarily to support the analysis of data across different characteristics. However, they provide a unique look at the general "demographic" of respondents.

Education. Participants were asked to select their highest degree of education. The plurality of respondents has a PhD, and the second largest population of respondents hold a Master's degree. In line with responses to prompts about position titles, it appears that most of those with Master's degrees are presently PhD students or candidates. The one individual who selected "Other" noted they have an MFA. The individual who responded that they had "some college credit, no degree" was screened out of the survey in a subsequent question about their institutional affiliation. All respondents had at least a Bachelor's degree. Less than 5% of respondents had only a Bachelor's degree. No respondent indicated that they had a technical degree or Associates.

After removing the single respondent who indicated "some college credit and no degree,"

this count represents 96.3%, 258 respondents, which is 2 more than the minimum needed for generalizable data in the sample size calculated in Chapter Three. Therefore, this breakdown appears to be representative of the population as a whole.

Disciplinary affiliation. The plurality (45%) of respondents identified with the National Center for Education Statistics (NCES) classification of “Rhetoric and Composition” as their disciplinary affiliation. “Professional, Technical, Business and/or Scientific Writing” was represented by 27% of respondents, and 21% of respondents identified with the classification “Rhetoric and Composition/Writing Studies, Other.” Much like level of education, these data represent the large majority of respondents; 96% of respondents replied to this prompt. While ambiguity exists regarding the 11 individuals who did not reply, those who selected “None of these apply” represent individuals from second language acquisition, philosophy, and linguistics. All other responses affiliated with “Rhetoric and Composition” or “Professional, Technical, Business, and/or Scientific Writing,” indicating those percentages are marginally higher than the data suggest. Noteworthy is that no respondent suggested an affiliation with “English Language and Literature/Letters, Other” or “Literature.” The data do suggest therefore that the target population, specifically researchers working in Writing Studies, responded to the survey.

Professional activities. Respondents were prompted to articulate percentages of time spent on a variety of activities traditionally associated with academics: research, teaching, scholarship, and service. These data are represented as means; teaching, research and publication, and administration were articulated by respondents as a whole to compose 100% of their work activities. However, obviously, individual respondents may have indicated higher or lower than average amounts of time spent on any one of these activities.

Respondents replied to the “Other” designation again with a number of replies that

correlated directly to provided prompts, suggesting that these means are at least representative of the respondent base. Other tasks not represented in the options, and entered by participants, were: co-directing centers, coursework, tutoring, dissertating, professional development of junior staff, web development, marketing, staff duties, public outreach, advising, and technical writing. The bars represent the average amount of time spent on specific activities, with the total equaling 100%. Respondents spend the most time teaching undergraduate students, but research and publication- which, when human subjects are involved ties directly to interfacing with the IRB- was the second most common activity amongst respondents collectively.

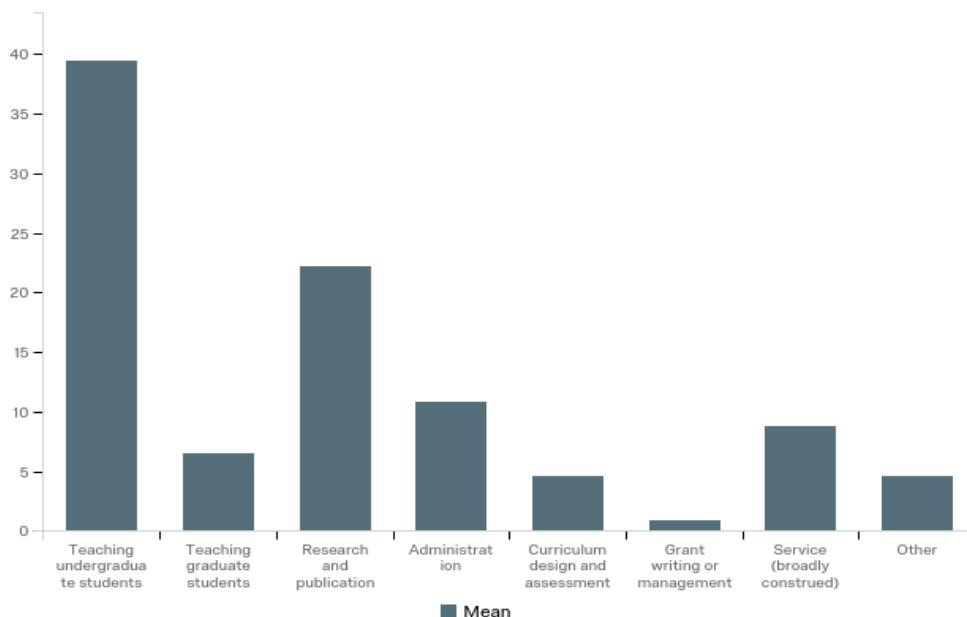


Figure 4. Percentage of time spent on activities.

**This graph shows the percentage of time (y-axis) spent on activities (x-axis); together, these designations equal 100% and are the mean of all respondents.*

Highest degree offered by institution. To gauge the level of research activity of institutions, and correlate such data with time spent by survey respondents on research,

participants were asked to select the highest degree offered by their institution in a variety of categories. This data is best represented in the table below. Forty-nine percent of respondents work or are affiliated with institutions that offer a Ph.D. in Rhetoric and Composition specifically. Many institutions offer a full spectrum of programs in Professional, Technical, Business and/or Scientific Writing, and many respondents indicated their institutions also granted MFAs. Literature and General Writing programs were also consistently represented throughout respondent replies.

Table 1. Degrees granted by respondents' respective institutions (abbreviated)

	Undergrad Certificate	Undergrad Minor	BA/BS	MA/MS	PhD	Graduate Certificate
Writing, General	3%	5%	24%	11%	14%	2%
Professional, Technical, Business, and Scientific Writing	5%	10%	15%	13%	17%	7%
Rhetoric and Composition	0.5%	3%	6%	12%	49%	1%
Literature	0.9%	0.45%	18%	28%	45%	0%
Creative Writing (MFA select MS)	0.5%	7%	18%	44% (23% MFA)	15%	0%

Current job title. To determine the primary population of respondents, individuals were asked to identify, via a drop-down menu, what their current job title was. While “Other” was presented as an option, participants were not able to provide a text entry to this field. The plurality (47%) of respondents were along the spectrum of tenure-track or tenured faculty. 28% of respondents were assistant professors, 14% were associate professors, 4% were professors, and 1% were emeritus. PhD students and candidates were well represented at 29% of the total respondents, while instructors (7%), adjunct faculty (4%) and MA/MS students (5%) made up the smallest percentages of respondents.

Based on comparative analysis with text entry from other early questions in the survey

regarding professional roles, and text entry fields later in the survey related to case studies, those who selected the “Other” category appear to be affiliated with institutions who support research, but who are not in faculty or student roles. They also have graduated from MA/MS/MFA or PhD programs, but are not “traditional academics.”



Figure 5. Respondents’ Rank.

**This bar, totaling “100%” shows the breakdown of respondents’ job titles/positions. Blank spots from left to right: Adjunct, 4%; MA/MS 5%; Research Fellow 1%; Full Professor 4%; Professor Emeritus 1%*

Affiliations. Because this project was funded by a CCCC research initiative, and participants were solicited via a variety of listservs specific to sub-specializations within Writing Studies, participants were prompted to select with which professional organization(s) they were affiliated. This question also helped determine whether generalizable claims about sub-groups could be made. Participants were able to select as many options as applied, and “Other” was listed twice so that individuals could add multiple additional affiliations.

Given the relative chaos of the open-ended replies, it can be generally determined that:

(1) The generalizability of results to the broader population of Writing Studies affiliated folks, enough responses were gathered to make generalizable claims. (2) Only two sub-groups’ data can be generalized to the broader sub-group populations: CCCC and ATTW members. Not enough data was collected from members of CPTSC, CWPA, or IEEE to make substantive,

grounded claims about these populations' interactions with IRBs. 75% of respondents indicated they were members of CCCC. ATTW members also were well represented; 35% of respondents indicated they were affiliated with ATTW. A similar number of respondents indicated affiliation with RSA, while CWPA members represented about 27% of total respondents. CPTSC, a smaller professional organization, was represented by about 19% of all respondents. Note that these percentages are higher for the specific question, as only 231 of the 269 respondents replied to this question.

The “Other” options were flooded with a variety of sub-disciplinary options that will not be parsed for the purposes of this dissertation; the representation was too small for each subgroup to allow the data to support effective or meaningful claims. Some “Other” options were filled in with identical affiliations listed in the options, such as CWPA, or parent organizations, such as the NCTE in the case of CCCC. For these reasons, given the broad scope of Writing Studies, generalizable claims can be made about the population of Writing Studies affiliated researchers and about CCCC and ATTW members more specifically. While the aim of the survey was to, if possible, make claims about subgroups, this was not feasible given the data collected. The table below provides information about membership numbers for each organization used as a sub-group for the purposes of the survey. The column to the far right provides the final number of participants for that organization, and the column directly to the left of this provides the z-score, confidence interval, and margin of error for that subpopulation, if generalizations about that sub-population are possible given the data.

Table 2. Membership and Response Rates for Professional Organizations

Org	Membership	As Of	# of Responses	Z-Score	Confidence Level	Margin of Error	Generalizations Possible?
ATTW	246	5/31/16	96	1.44	85%	6%	Yes
CCCC	4083	2/16/16	203	1.44	85%	5%	Yes
CPTSC	225	8/22/16	51	N/A	N/A	N/A	No
IEEE	790	8/29/16	25	N/A	N/A	N/A	No
CWPA	551	8/22/16	73	N/A	N/A	N/A	No

IRB membership/chairing. Participants were also asked whether they had served on an IRB either as a member or as the Chair. Just a little over 6% of respondents who replied to this prompt had participated in such a way with an IRB. Several left comments to a follow-up prompt requesting information about their position, whether they were compensated, etc. While few participants indicated they had served or are serving, those who did indicated only positive experiences. Only Chairs suggested they were compensated, and all respondents in the open-ended replies stated it changed their outlook on IRBs tremendously.

Do you, or have you ever, serve(d) as a member and/or chair of an IRB?

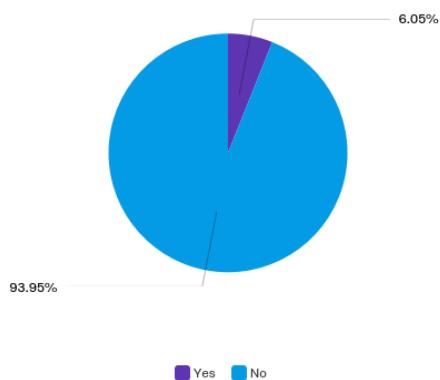


Figure 6. Representation of Writing Studies Researchers on IRBs.

Predictor Variables Associated with Personal Disposition

This section addresses a variety of components respondents were prompted to reply to related to such things as formal ethics training, number and types of protocols filed, and opinions about training, IRBs, human subjects research, and participants in their own research.

Formal ethics training. The large majority of respondents completed formal ethics training. Many indicated they completed the Collaborative Institutional Training Initiative (CITI) training program run out of the University of Miami. CITI offers a standardized training that is often accepted across institutions, making it a common tool used by many IRBs. Some respondents indicated they did not recall taking a formal ethics training program, but just about 13% noted they had not done such training.

Because trainings like these are often a prerequisite for filing protocols or participating as a member of a study team,⁸ these individuals' data was compared to their responses to prompts related to number of protocols filed in the comparative analysis section of this chapter. The pie chart below displays the responses to the prompt "Have you ever completed an IRB-required formal ethics training/course, like CITI?"

⁸ See, for instance, University of South Florida's policy on CITI training, Utah State University's policy on training, and transcripts from interviews validate this requirement.

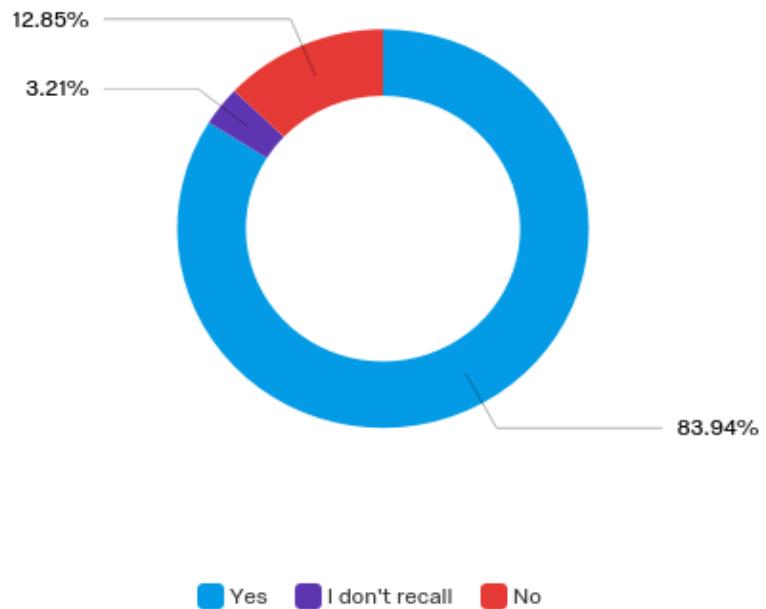


Figure 7. Respondents' Formal Ethics Training.

Only those respondents who indicated they had taken a training course were routed to the next question regarding their perceptions of the training. 208 respondents (93% of the 223 qualified) completed their reply to this question. They generally agreed that while the training was rote and took too long, it was straightforward, comprehensive, addressed ethical principles, and helped them better understand human subjects protections in research. Respondents were ambivalent about whether the training prepared them to interact with their IRBs; this prompt resulted in a clear spread across the Likert scale.

Table 3. Respondents' perceptions of their institution's training program.

Question	Strongly Agree	Agree	Somewhat Agree	Neither Agree nor Disagree	Somewhat Disagree	Disagree	Strongly Disagree
The training took too long	8.65%	17.31%	24.52%	20.67%	11.06%	15.87%	1.92%
The training was comprehensive	5.29%	29.33%	27.40%	12.02%	17.79%	6.73%	1.44%
The training was rote	17.31%	36.54%	23.56%	12.50%	7.69%	1.92%	0.48%
The training discussed the Belmont Report	43.75%	26.44%	5.77%	18.75%	0.96%	4.33%	0.00%
The training helped me prepare to file with my IRB	6.25%	20.19%	29.33%	9.13%	14.42%	12.98%	7.69%
The training was straightforward	9.62%	43.27%	32.21%	6.73%	5.77%	2.40%	0.00%
The training addressed ethical principles	34.13%	49.52%	13.94%	1.44%	0.48%	0.48%	0.00%
The training helped me better understand human subjects protections	20.19%	41.35%	19.71%	9.62%	5.77%	1.92%	1.44%

Principles. This section discusses results from the case studies in the survey and the three prompts that addressed the primary ethical principles expressed in the Belmont Report: beneficence, justice and autonomy. Each ethical principle was represented with “In research ethics, and as described in the Belmont Report, _____ is described as _____. What is your understanding of how the principle_____ manifests in Writing Studies research with human subjects?” Common to all of the open-ended replies collectively was the use of students in explaining perceptions of these principles in research in Writing Studies. Note that the prompts did not state anything about classroom research. Specifically, respondents were asked to address how the principle manifests in Writing Studies research with human subjects.

Given the high proportion of responses focused on students, all text from open-ended replies was entered into a word cloud builder and the top 50 words were made into a word cloud.

The words with higher incidence appear larger, based solely on *n*.

Beneficence. In the survey, beneficence was defined as: “having the welfare of the research participants as a goal of any research study. In other words, the goal is not only do not harm, but also to maximize possible benefits for participants while minimizing possible harms.” A number of respondents suggested that improved teaching and curriculum is one way beneficence manifests in Writing Studies research. This is somewhat problematic in terms of *time*, however, unless immediate improvements to curriculum are being made, or immediate updates to teaching behaviors. This will be addressed further in Chapter Five. All respondents’ open-ended replies were fed into a word cloud generator at N=1, and the top 50 words were represented by increasing size within the word cloud based on their representation. This can be seen below. Interesting words which appeared included “direct(ly),” “instruction,” “learn” and “don’t.” Noting that “goal,” “benefits,” and “pedagogy” also appear, it can be concluded, along with the size of the word “students,” respondents’ interpretations of the term “beneficence” in research in Writing Studies, broadly construed, were framed around students.



Figure 8. Word Cloud of Open-Ended Replies for “Beneficence” Prompt

Justice. Justice was defined for participants in the survey as: “ensuring equivalent representation of all types of individuals enrolled in a given study, and that folks who won’t benefit from the study findings won’t be enrolled. This ensures both the burden and benefits of research are equally distributed.” This definition stands in direct contrast to responses from participants regarding beneficence, as students in a given class may not directly benefit, but students in later sections of the course may. This, of course, applies to a small percentage of the general respondent population, but given that 49% of respondents indicated they enroll their own students, this is a substantial issue that will be further addressed further in Chapter Five. All respondents’ open-ended replies were fed into a word cloud generator at N=1, and the top 50 words were represented by increasing size within the word cloud based on their representation. This can be seen below. The word cloud does not provide any suggestive interpretations, save for the representation of the terms “equivalent” “demographics” and “sample” which speak to the issues of justice addressed in the prompt. It appears that participants largely interpreted this prompt in relation to the use of students as participants, which was not the intent of the question. It does suggest which population may be the one most studied by Writing Studies researchers.

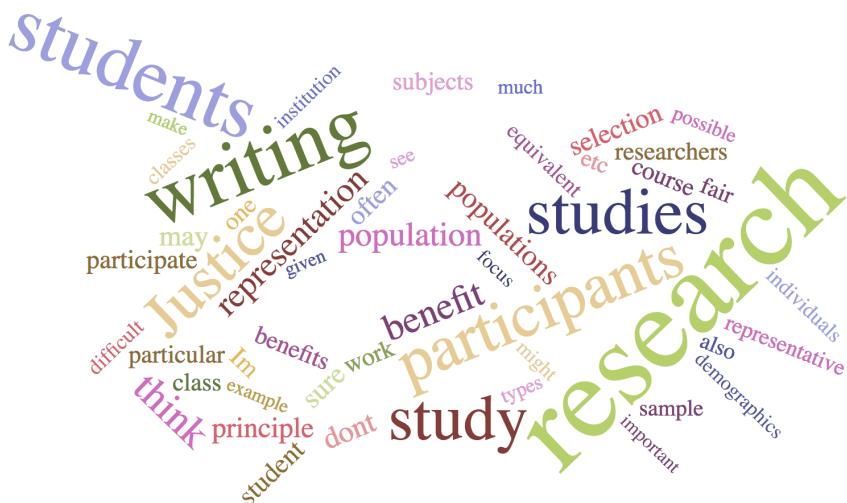


Figure 9. Word Cloud of Open-Ended Replies for “Justice” Prompt

Autonomy. Participants were provided the following definition of autonomy, or respect for persons, in the survey. “In research ethics, and as described in the Belmont Report, respect for persons (also called “autonomy”) dictates that even in situations where it is not obvious, participants enter research voluntarily and with sufficient information.” This speaks specifically to the requirement for consent from participants. All respondents’ open-ended replies were fed into a word cloud generator at N=1, and the top 50 words were represented by increasing size within the word cloud based on their representation. This can be seen below. This figure suggests that survey respondents were aware of the context for the use of students as participants/subjects in studies, including the implications of using student writing and the solicitation of Informed Consent from students. Notably, the words “always” “respect” and “withdraw” appear; withdraw is a function of the principle of autonomy. Words like “clear” “need” and “make” also suggest respondents’ awareness of the complex interactions that result from using students as participants.



Figure 10. Word Cloud of Open-Ended Replies for “Autonomy” Prompt.

Results from case studies. This section discusses results from the case studies in the survey. Four case studies were presented to respondents. Each case study was followed by a series of Likert scale rated statements and the prompt: “Please tell us how you would resolve this scenario.”

Case study 1. Nonprofit case study: Respondents were asked to read a prompt designed to make explicit the “program evaluation” and “research” divide. Because this applies often in classrooms, providing respondents with a different setting, yet fundamentally similar context, allowed for these components to be clearly addressed. Generally, respondents indicated that while their disciplinary training, IRB training, and personal philosophies/moral compass would help, they would work with a colleague or the IRB to resolve this issue.

Table 4. Likert Scale Responses Regarding Case Study 1, Nonprofit Prompt

Question	Strongly Agree	Agree	Somewhat Agree	Neither Agree nor Disagree	Somewhat Disagree	Disagree	Strongly Disagree
My disciplinary training would help me adequately resolve this scenario	7.46%	22.37%	30.70%	6.14%	12.72%	16.67%	3.95%
Training provided by my IRB would help me adequately resolve this scenario	3.07%	10.53%	22.81%	17.98%	17.11%	16.67%	11.84%
My moral compass/personal philosophies would help me adequately resolve this scenario	7.89%	33.33%	29.82%	19.30%	6.58%	2.63%	0.44%
I would consult with a colleague about this scenario before moving forward	50.00%	28.07%	15.35%	3.51%	0.88%	1.75%	0.44%
I would consult with my IRB before moving forward	54.39%	28.51%	11.84%	3.51%	1.32%	0.00%	0.44%

Case Study 2. The purpose of this case study was to identify a morally ambiguous research opportunity and the attendant ethical concerns. Respondents indicated slightly different beliefs about their own disciplinary training, IRB training, and moral compass in regard to the second case study, which detailed the use of student data collected through students' mandated use of a for-profit submission system (for instance, TurnitIn). Generally, they were more confident that training and their personal philosophies would guide them in the right direction. They indicated less reliance on peers for a determination and reliance, to a similar degree as was seen in the first case study, on their IRB for support and consultation.

Table 5. Likert Scale Responses Regarding Case Study 2, Student Work.

Question	Strongly Agree	Agree	Somewhat Agree	Neither Agree nor disagree	Somewhat Disagree	Disagree	Strongly Disagree
My disciplinary training would help me adequately resolve this scenario	13.97%	27.51%	24.02%	9.17%	11.79%	8.30%	5.24%
Training provided by my IRB would help me adequately resolve this scenario	13.97%	24.45%	27.95%	11.79%	6.11%	9.61%	6.11%
My moral compass/personal philosophies would help me adequately resolve this scenario	21.40%	31.44%	25.33%	12.66%	5.68%	2.18%	1.31%
I would consult with a colleague about this scenario before moving forward	39.47%	30.70%	14.04%	7.02%	3.95%	3.51%	1.32%
I would consult with my IRB before moving forward	57.21%	26.64%	8.30%	3.06%	1.75%	1.75%	1.31%

Case study three. In the third case study, participants were prompted with a scenario wherein they and colleagues would like to use former graduate students' papers to develop

materials for publication. Another ethically ambiguous case for some respondents, this case was intended to explicitly have participants parse the concerns of using existing data from identifiable individuals. This case used graduate students specifically, as there are fewer of them than graduate students, and presumably faculty maintain relationships with graduate students over a course of years and decades after graduation. This case worked to determine if individuals felt they could work directly with their IRB, or if they felt they had the right to use the data, since it already existed.

This case was also tricky for respondents because an underlying issue is FERPA, the Family Educational Rights and Privacy Act. Without explicit consent from students, use of work produced for a grade at an institution could also be a violation of FERPA. Most IRBs have FERPA liaisons outside of, or experts within, their offices to help researchers make these determinations.

Respondents replied to this case with even greater certainty that their disciplinary training, and IRB training, alongside their moral compass, would guide them to make the most appropriate determinations. While respondents were somewhat less willing to interface with colleagues about this project for support, they were clearly drawn to the option to discuss this with their IRB. The response rate at this case dropped, and this drop was also reflected in Case 4.

Table 6. Likert Scale Responses Regarding Case Study 3, FERPA

Question	Strongly Agree	Agree	Somewhat Agree	Neither Agree nor Disagree	Somewhat Disagree	Disagree	Strongly Disagree
My disciplinary training would help me adequately resolve this scenario	18.26%	28.70%	21.30%	6.09%	11.74%	9.57%	4.35%
Training provided by my IRB would help me adequately resolve this scenario	19.13%	23.48%	23.48%	10.87%	5.22%	11.74%	6.09%
My moral compass/personal philosophies would help me adequately resolve this scenario	25.76%	35.37%	15.72%	12.23%	6.55%	3.06%	1.31%
I would consult with a colleague about this scenario before moving forward	41.92%	27.51%	12.23%	10.04%	3.93%	2.18%	2.18%
I would consult with my IRB before moving forward	56.77%	23.58%	10.04%	3.06%	1.75%	3.06%	1.75%

Case study 4. The fourth case study provided a unique example of the movement of research practices from in-person to online and the attendant concerns of collecting data in digital environments. In this case, respondents were asked to address the use of data gathered in a private online forum, in conjunction with data gathered from publically available sources. A noticeable drop occurred in respondents' confidence in their own training from their discipline and their IRB, but they remained generally confident in their own personal philosophies to guide their ability to resolve the issue. Again, respondents indicated they would consult with their IRB before moving forward.

Table 7. Likert Scale Responses Regarding Case Study 4, Digital Research.

Question	Strongly Agree	Agree	Somewhat Agree	Neither Agree nor Disagree	Somewhat Disagree	Disagree	Strongly Disagree
My disciplinary training would help me adequately resolve this scenario	10.92%	27.95%	24.02%	11.35%	7.86%	11.79%	6.11%
Training provided by my IRB would help me adequately resolve this scenario	10.04%	25.33%	23.58%	14.41%	10.04%	8.73%	7.86%
My moral compass/personal philosophies would help me adequately resolve this scenario	16.16%	34.50%	22.71%	17.03%	5.24%	3.49%	0.87%
I would consult with a colleague about this scenario before moving forward	36.24%	27.51%	12.23%	12.66%	6.11%	3.93%	1.31%
I would consult with my IRB before moving forward	52.84%	24.45%	11.79%	7.86%	2.18%	0.44%	0.44%

Case studies summary. Interestingly, in all the case studies, respondents indicated that they strongly or somewhat agreed, or directly agreed, that their moral compass and personal philosophies would help them adequately resolve the scenario. The table below shows trends in respondents' indication that their personal philosophies would help them make determinations about a given case.

Table 8. Trends in “Personal Philosophy” Impact on Case Decisions

	Case 1	Case 2	Case 3	Case 4
Strongly Agree	7.89%	21.40%	25.76%	16.16%
Agree	33.33%	31.44%	35.37%	34.50%
Somewhat Agree	29.82%	25.33%	15.72%	22.71%

Interestingly, the two cases that relied on scenarios perhaps considered “unethical” for other reasons: use of data from for profit companies, and use of students’ work, had the clearest indication from respondents that their moral compass would guide them. However, while one’s moral compass can direct the course of research, it cannot be interpreted as a replacement for making accurate determinations about the implementation of policy.

Participants’ Experiences with Mediating Variables

Filing protocols. After answering questions about the training they received on human subjects research, participants were prompted to reply to a series of questions about their activity filing protocols with their respective IRBs.

Like the section before, those who replied that they had not filed a protocol were not asked to complete subsequent questions specifically about protocol development and filing. Therefore, besides the first pie chart, the data represented here are indicative of a subset of the total population. Only 216 of the 269 respondents (80%) replied to the first question “Have you ever filed a protocol (a research project or proposal) with an Institutional Review Board?” Of these, 205 (76% of the total survey respondents) replied “yes;” these respondents were triaged into the section about their protocol development. Others clearly skipped this question and moved into the next set, because there are 239 replies to the second prompt in this section. The graph below is a breakdown of the responses to the prompt “Have you ever filed a protocol (a research project or proposal) with an Institutional Review Board?”

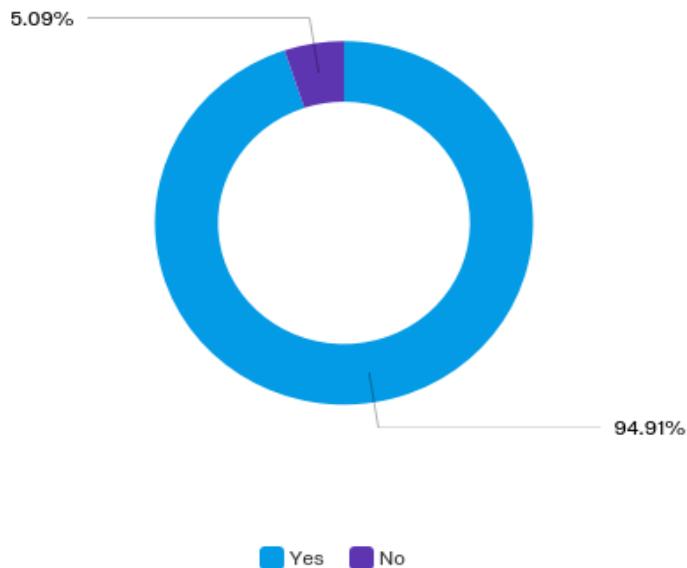


Figure 11. Replies to “Have You Ever Filed a Protocol with an IRB?”

Number and types of protocols filed. The plurality of respondents (68%) indicated that they had filed between one and five protocols with an IRB. A significant percentage had filed none (18%) and a handful (five respondents) had filed more than 15. For full professors working with graduate students, this level of proficiency with the IRB process is not unusual, although it is rare. As a reviewer at a mid-sized university in the west with a high research activity designation, there are a number of Principal Investigators across disciplines who have over 25 active protocols. This is to say, such high numbers are rare, but not impossible, given the span of a full professor’s career.

Below are the total numbers of types of protocols filed by all respondents who completed this portion of the survey. Of particular interest for this study’s interview phase are those respondents who indicated they had protocols that underwent either expedite or full board review procedures. Because these levels of review are more involved (expedite reviews traditionally require two board members to review the protocol, and full board protocols go to, as one would

expect, the full IRB), participants for interviews were selected partly based on their experience with these levels of review as a researcher. The large majority of protocols filed were Exempt protocols, which require a determination, and often small revisions are necessary, but these are generally processed quickly, are low-risk, and do not engage with vulnerable populations. The pre-2018 (original Common Rule) criteria for Exempt categories and Expedite approvals can be found in Appendix I. The images below show the number of protocols filed for each type from the respondents collectively. Exempt protocols were by and large the most significant set of protocols filed within the discipline.

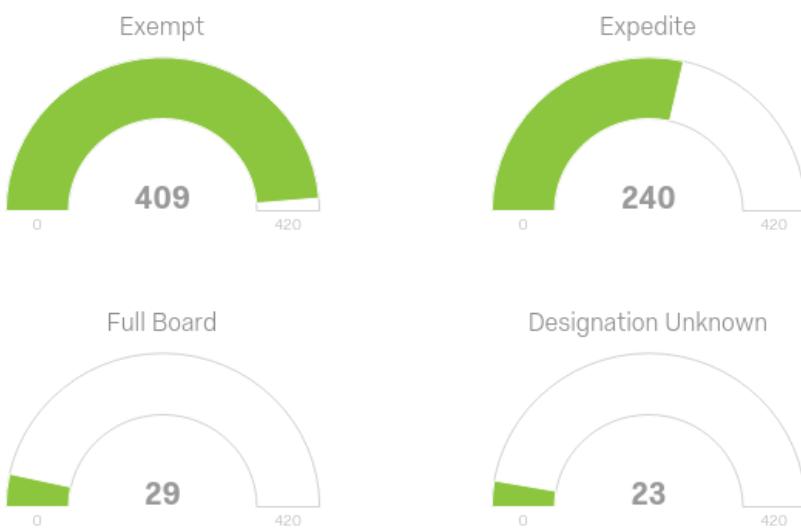


Figure 12. Number of Protocol Types Filed Collectively by Respondents

After answering questions about the number and type of protocols they had filed, participants were asked to select their perception of their IRBs in relation to a number of prompts. For the most part, participants were largely positive about their IRBs, suggesting that they are well-equipped to make determinations about the ethical components of research in

Writing Studies. However, respondents were less certain that their IRBs were attentive to the challenges and affordances of digital research environments, and generally suggested that the educative components offered by their IRBs was not exceptional, merely sufficient.

Table 9. Respondents' Perceptions of their IRBs

Question	Strongly Agree	Agree	Somewhat Agree	Neither Agree nor Disagree	Somewhat Disagree	Disagree	Strongly Disagree
My IRB is well-equipped to review the sort of research I do	14.51%	30.57%	22.28%	6.22%	13.47%	7.25%	5.70%
My IRB is well-equipped to make determinations about the ethical components of my research	16.58%	33.16%	21.76%	7.25%	14.51%	3.63%	3.11%
My IRB is attentive to the challenges of digital research environments	8.81%	16.06%	15.03%	34.20%	9.84%	9.84%	6.22%
My IRB is attentive to the affordances of digital research environments	8.81%	14.51%	16.58%	33.68%	9.33%	11.92%	5.18%
My IRB has a good relationship with researchers on campus	19.17%	25.39%	19.69%	22.28%	5.70%	3.11%	4.66%
My IRB offers effective training for researchers	7.77%	16.06%	19.69%	26.42%	16.06%	6.74%	7.25%

Similarly, when prompted to share whether they had experienced many of the common complaints about IRBs, in all cases, save for amendments and continuations, the majority of participants indicated they had never encountered negative experiences such as frustrating or lengthy review processes, delays in funding or research initiation, or issues with the software IRBs used. That being said, while the majority had for the most part not indicated problems, a noteworthy percentage had experienced a negative IRB influence at least once, and some respondents noted that these negative issues occurred on multiple occasions and/or with multiple protocols. Notably, 18% of participants indicated that unnecessary revisions and edits were

requested multiple times.

Table 10. Respondents' Experiences with IRBs

Question	I've never experienced this	I've experienced this once	I've experienced this multiple times
Reviews take too long	32.81%	45.31%	21.88%
Unnecessary edits and revisions requested	34.38%	37.50%	28.13%
Review doesn't seem to protect participants	79.69%	10.94%	9.38%
Interfacing with reviewers was frustrating	40.63%	40.63%	18.75%
Seeking IRB approval delayed my research	34.38%	43.75%	21.88%
There was too much red tape	31.25%	40.63%	28.13%
Not enough training on what the IRB is looking for	39.06%	35.94%	25.00%
Seeking approval delayed funding	90.63%	6.25%	3.13%
Seeking approval prevented me from getting funding	92.19%	6.25%	1.56%
Requirements to submit amendments and/or continuations	32.81%	31.25%	35.94%
The software I have to use was unwieldly/difficult to use	51.56%	25.00%	23.44%

Participants were asked to provide any particular experiences or explanation of their negative experiences with the IRBs in a text box. 99 substantive text entries were supplied. These were a mixed bag of positive, negative, and neutral commentaries, including horror stories, positive experiences, and notes about in-progress projects.

Participants were also asked to articulate changes they believe could be made to improve the way their institution implemented the federal regulations. This prompt also generated a number of replies, many of them noting one or more of three primary concerns which appeared multiple times: (1) the IRB was STEM focused (2) reviewers unable to understand Writing Studies research or (3) some category of exemption for Writing Studies research should be standard.

Besides collecting information about participants' perceptions of IRBs, one survey question also requested information about the populations that respondents worked with in their research. This question was framed around the term "vulnerable populations" which has specific regulatory definitions. However, researchers often consider additional populations to be considered "vulnerable." The list below is indicative of this. For instance, prisoners, pregnant women, and individuals under 18 are the only "vulnerable" populations listed in this prompt, per the regulatory definitions.

First generation, low SES, and students in one's classroom are considered susceptible to coercion, and are therefore, in some ways, "vulnerable." Over 40% of respondents who conduct research with humans indicated they work with these populations. Because participants were able to select multiple options, the percentages cannot be combined for these populations. Over 60% indicated they work with their own students.

Replies to the prompt "Other vulnerable population (please explain):" generated replies such as "individuals with disabilities" and "senior citizens" (both regulatory vulnerable populations), patients, genocide survivors, transgender people, minority groups abroad, African American student-athletes, first-time technology users, and individuals diagnosed with HIV (not a group defined by regulations as vulnerable). Some of these responses outside the scope of the regulatory definition of "vulnerable" suggest that respondents are aware of different vulnerabilities in their study populations. IRB members who are familiar with the study populations and procedures make determinations on projects involving such populations, but the review criteria can change substantially if those defined in the regulatory definition of "vulnerable" are prospective participants.

Design of research to avoid mediating variables. At the conclusion of this section, participants were asked a straightforward question. Do they design their research such that they won't have to seek IRB review and approval? Interestingly, over 35% of respondents said "yes."

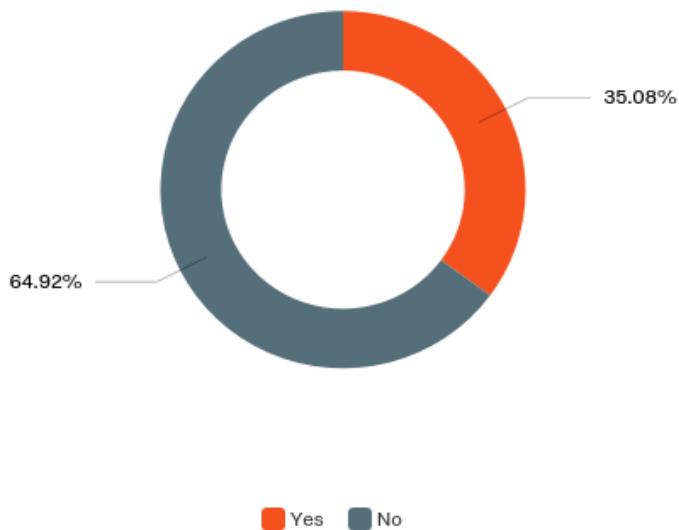


Figure 13. Designing Research to Avoid IRB Review.

**Question: Do you actively work to develop projects that do NOT require IRB review?*

Familiarity with regulation. Participants were also asked what their self-perceived familiarity with human subject protections regulations was. The vast majority of respondents, approximately 90%, indicated they are either educated or have at least completed their institution mandated educative components. Very few suggested they were experts (4%) and nearly 6% said they were not familiar with the policies, regulations, or practices.

Awareness of NRPM. As would be expected, only a handful of respondents (approximately 12%) had heard of the Notice of Proposed Rule-Making. At the time of the survey, the NPRM had been available for over a year and had opened and closed for public commenting.

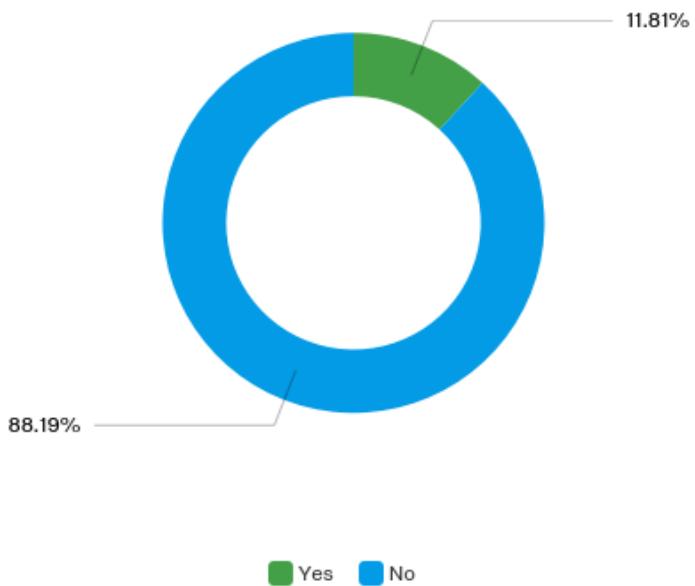


Figure 14. Are you familiar with the NPRM?

Students in research. The final bit of this section addresses how respondents indicated they work with students, both the students and students' work, in their research. Over 45% of respondents who have interfaced with IRBs indicated that they had enrolled students in their research, whereas 51% indicated they had not. Because the classroom can serve cross-purposes in Writing Studies, spanning the intersecting nodes of research, teaching, and curricular improvement, it is expected that a number of respondents would have enrolled, or do enroll, students as participants. IRBs often have special considerations for the use of students as participants in research, particularly if the students' professor, instructor, or grading/teaching assistant are PIs or part of the study team.⁹ The relationship of rank and tenure can be correlated with the number of respondents who indicated they enroll student participants to provide a

⁹ For just one example of policy- MSU Denver's policy is often referred to by institutions without formalized policy looking to express the concerns regarding students as subjects:
<http://www.msudenver.edu/irb/guidance/studentsasresearchsubjects/>

clearer picture of whether students are considered “low-hanging fruit” with which to establish a participant pool. IRB reviewers call these populations “populations of convenience,” which suggests, rather negatively, that (1) findings cannot be generalized¹⁰ and therefore (2) students’ autonomy is being violated.¹¹

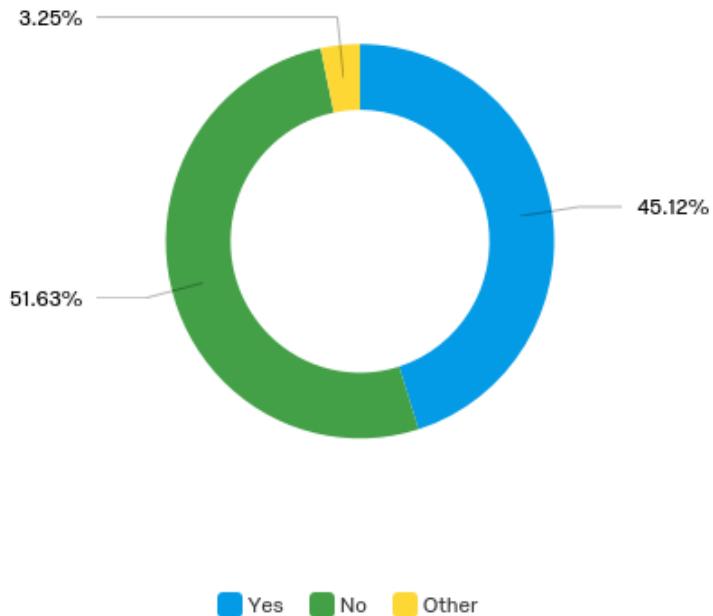


Figure 15. Enrolling Students in Research.

**Have you ever enrolled your students as participants in your research?*

A similar breakdown between those who have and have not used student texts in research is exhibited as well; 48% of respondents had used student-produced texts as part of their research, whereas nearly 50% had not.

Unlike students themselves, texts rest in a more nebulous space. If instructors plan to use texts for research purposes before the class begins, or even while it is underway, they are

¹⁰ For more information, read about the WEIRD sample: here <http://blogs.worldbank.org/impactevaluations/weird-samples-and-external-validity> or here <https://ideas.repec.org/p/rsw/rswwps/rswwps139.html>

¹¹ Because being troubled to participate in research is a disruption to the classroom and/or a violation of students’ expectations for the space.

required to receive IRB approval. But what about those files of composition papers from decades ago? Can those be used without explicit permission of the authors? These are some of the complicating aspects of text use in the field, as produced texts are often a subject of study. Texts produced by students require special considerations, for the same reason students often require special consideration by IRBs.

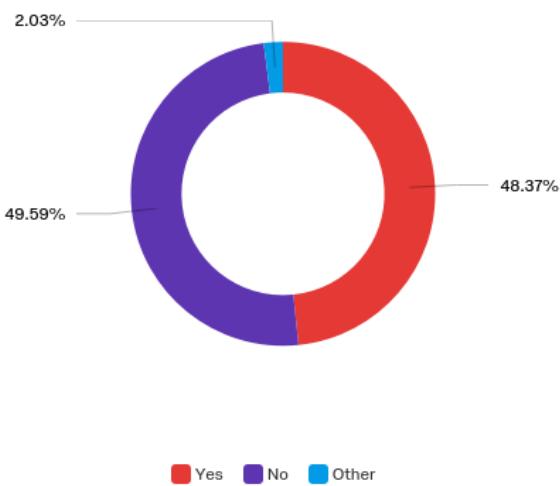


Figure 16. Using Student Produced Texts in Research

**Have you ever used student-produced texts as part of your research?*

Participants were also prompted with the Likert scale requests presented in Table 11 on the following page.

Table 11. Teaching, Classrooms, and Student Texts in Writing Studies Research

Question	Strongly Agree	Agree	Somewhat agree	Neither agree nor disagree	Somewhat disagree	Disagree	Strongly disagree
In order to improve my teaching, it is acceptable to use my students in my research without IRB review or approval.	4.86%	10.12%	12.55%	14.98%	14.57%	19.84%	23.08%
In order to improve my teaching, it is acceptable to use my students in research only with IRB review or approval.	18.29%	22.36%	16.26%	17.48%	13.41%	7.32%	4.88%
In order to publish an article, chapter, or book, it is acceptable to use my students in research without IRB review or approval.	0.81%	2.44%	4.47%	3.66%	10.57%	28.46%	49.59%
In order to publish an article, chapter, or book, it is acceptable to use my students in research only with IRB review and approval.	40.89%	29.96%	10.53%	6.88%	4.86%	2.43%	4.45%

The purpose of this prompt was to parse apart the difference between research and program/curriculum evaluation. While the majority of participants clearly understood that they should not publish on research done on students without IRB approval, they also seemed to believe that they needed IRB approval to do curricular assessment activities. IRBs do not make determinations about non-research projects, such as program evaluation. However, because publication on pedagogy is such a tremendous component of the Writing Studies community,¹² these may be intertwined for a number of respondents. Survey respondents did not miss the nuance of the question, but the dichotomy between improvement of pedagogy and the

¹² For instance, in journals such as *Assessing Writing*, *Composition Forum*, *Journal of Basic Writing*, *Journal of Teaching Writing*, etc.

publication on that work, is a component of this survey that will be addressed heavily in Chapter Five.

Relation Between Data Points for General Population

Who completed training and who filed protocols. All individuals who indicated they had not completed IRB training also had not filed an IRB protocol. Seven individuals noted that they did not recall completing something like CITI, but had filed a protocol(s) with their IRB. Approximately 10 individuals had completed training but not filed a protocol; perhaps these individuals are study staff or were preparing to file.

Purposefully designing studies to avoid IRB & perception of IRBs. Those who indicated that they purposefully designed studies and research that did not require IRB had markedly higher percentages of responses to prompts soliciting negative experiences with IRBs. While some were only marginally higher, the difference is distinct. Those who do design research such that they can avoid the IRB are shaded. Their results should be compared to the percentages in the cells to the immediate left.

Table 12. Respondents Who Avoid IRBs and their Experiences with IRBs

Do You Actively Design Protocols that Don't Need to Go Through IRB Review?	No/I've experienced this once	Yes/I've experienced this once	No/I've experienced this multiple times	Yes/I've experienced this multiple times
Reviews take too long	28.66	43.31	10.85	21.86
Unnecessary edits and revisions requested	29.69	37.50	13.28	28.13
Review doesn't seem to protect participants	10.08	10.24	1.55	9.38
Interfacing with reviewers was frustrating	19.38	40.63	10.08	18.75
Seeking IRB approval delayed by research	30.23	43.75	12.40	21.88
There was too much red tape	19.38	40.63	14.73	28.13
Not enough training on what the IRB is looking for	36.43	35.94	12.40	25.00
Seeking approval delayed funding	3.91	6.25	0	3.13
Seeking approval prevented me from getting funding	3.91	6.25	0	1.56
The software I have to use was unwieldy/difficult to use	16.28	25.00	19.38	23.44

Job titles of those who enroll students. Also of interest is the respondent types that indicated the highest enrollment of students in research, given the stark divide between those who believe it's appropriate and those who do not. Notably, while assistant and associate professors and PhD students and candidates were the largest percentages of respondents to the survey, assistant professors were more likely than any other cohort, by far, to enroll students. While speculation, it is worth considering if this increase is due to the demands made on these specific faculty members to produce research.

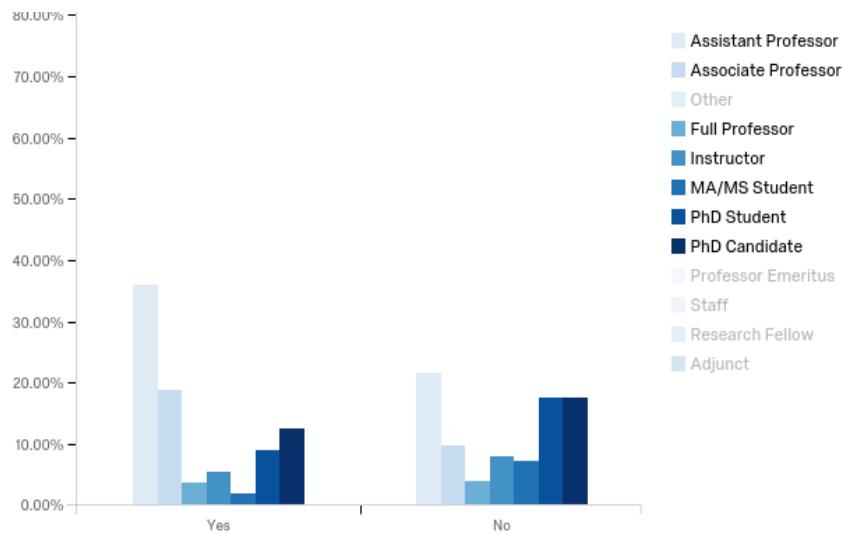


Figure 17. Rank/title of Those Who Enroll Students in Their Research.

Conclusion

This chapter has provided an overview of the results of the survey “IRBs and Writing Studies: Disciplinary Perspectives.” The data provided indicate the “demographics” of the respondents, general data related to the respondents’ perceptions of, and interfacings with, their IRBs. Also provided were respondents’ data about working with students, and baseline (non-interpreted) results from the case studies and open-ended prompts about respondents’ perception of the three primary principles outlined in the Belmont Report. While some correlative data was included in this chapter, the majority of interpretation for the purpose of establishing findings will occur in Chapter Five, which presents generalizations and extrapolations from this data alongside interview data. This in turn will provide a robust groundwork upon which to build a predictive model and methods of successful interfacing with IRBs for researchers across Writing Studies.

CHAPTER FIVE: ANALYSIS AND FINDINGS

Since the Common Rule was promulgated, the volume and landscape of research involving human subjects have changed considerably. Research with human subjects has grown in scale and become more diverse... Yet these developments have not been accompanied by major change in the human subjects oversight system, which has remained largely unaltered over the past two decades... The Final Rule is designed to more thoroughly address the broader types of research conducted or otherwise supported by all of the Common Rule departments, and agencies such as behavioral and social science research.

---Introduction to the Revised Common Rule, Federal Register, Vol 82, No. 12, January 19, 2017, p. 7149

Alongside the promulgation of the Common Rule and shifting “volume and landscape of research involving human subjects,” Writing Studies researchers, too, have integrated their adopted methodologies and methods (Schneider, 2006) from social sciences and other disciplines. As these shifts influence the field, Writing Studies researchers also find themselves responsible for embracing the federal policy mandating IRB oversight of some aspects of their research. While the term “generalizable” and “knowledge” remain vague in the federal regulations, the increasing publications by Writing Studies researchers aimed to share knowledge

about one group of individuals (such as a classroom of students) to make claims about a population (such as “students at xyz institution in abc course”), are indicative that 45 C.F.R. § 46 requires increasing attention in the discipline. This interpretation of “generalizable” is applied by IRBs dealing with sociobehavioral and humanities-oriented research. While traditionally one interpretation of “generalizable” certainly encompasses studies with a large n , and is now, generally, equally applicable for those with a small n , such as ethnographies. Taking any amount of data, from any methodological design, and generalizing to make claims about any population, is to produce research, and therefore generalizable knowledge. In essence, this chapter helps researchers understand their accountability to IRBs. It sets the stage for Chapter Six, where predominant interpretations of IRBs as positivist are set aside for a justice-oriented, asset-based approach to policy and local implementation.

While survey data suggest that only a small contingent of respondents remained obstinate regarding the policy’s impact on their work with human subjects, the literature shared in Chapter Two, and the overwhelming awareness of Institutional Review Boards’ impact on Writing Studies research, are indicative that much of the discipline (76%) is aware of and have worked with IRBs. While segments of the field investigate topics where human subjects research is outside a scholar’s methodological scope, given the shifting federal landscape, and our shifting methodological breadth, these findings suggest ways for the majority of Writing Studies researchers to engage with the rather ubiquitous federal policy while encountering it at a local level.

In Chapter Five, the results shared in Chapter Four are set in relation to the research questions driving the investigation conducted and discussed in the four previous chapters. However, the data presented in Chapter Four was strictly data from the survey tool. This chapter

incorporates narratives from the interview components of the research, as well as a synthesis of the “Final Rule” released in the Federal Register January 19, 2017. These are set in relation to each research question and supplement the results from the survey.

In the context of the shifting political climate in the United States, the results do allow for generalizations from the data and an assertion of some new and novel methods of engaging with IRBs in the coming years, as final regulations are implemented. For the purpose of claiming the results of this survey are generalizable, and also to further support the claim that Writing Studies research can, and often does, produce generalizable knowledge, I’d like to propose two disciplinary definitions of generalizable: one by Kane (2013) “Generalization is the study of information regarding a defined construct as that information is useful across time and setting” and the other by Elliot and Katz (2016): “Generalization inferences take us from the observed sample of performances (as reflected in the test score) to claims about expected performance in the construct sample (e.g., that the test score reflects expected performance not only on the current …assessment tasks, but on similar … assessment tasks)” (107).

Because the Final Rule was codified in the Federal Register after the survey was conducted for this dissertation, the data are best represented in correlation with specific research questions and corollary interpretation and application of the updated regulations. The research questions for this project are:

- How can we identify pertinent variables of training for Writing Studies researchers related to human subjects protections? What methods can we use to investigate broad categories of influence by IRBs and tailor support for Writing Studies researchers?
- Can we create a new taxonomy to explain variables that result in best protections for human participants in Writing Studies research?

- Can we provide guidance on modes of crafting documents for IRB review?
- How do Institutional Review Boards staff, or street level bureaucrats, interact with researchers to shape methods and methodologies in Writing Studies?

This chapter is organized by using the research questions as broad categories to create subsections in this chapter. In each of these subsections, “findings” related to the specific research questions will be presented. These findings are constructed based on (1) survey results, (2) the recently released Final Rule (the update to the Common Rule), and, when applicable, (3) narratives from interviews.

The first major section of this chapter addresses the first research question: *How can we identify pertinent variables of training for Writing Studies researchers related to human subjects protections? What methods can we use to investigate broad categories of influence by IRBs and tailor support for Writing Studies researchers?* This section addresses the independent/predictor variables regarding how researchers in Writing Studies are trained to disciplinary and contextually interface with human participants. This section, titled “How We Learn,” details the ways in which Writing Studies researchers can educate and be educated about best practices in human subjects research, in response to the call for more effective and engaging training from the survey data. This section concludes with a description of the broad sorts of influence IRBs have, and how Writing Studies researchers can best be supported in their pursuit of IRB review and approval.

The next major section of this chapter addresses the second research question: *Can we create a new taxonomy to explain variables that result in best protections for human participants in Writing Studies research?* This section pulls upon data from the survey to determine where the discipline can learn more about the limits and affordances of the governance of human subjects

research in the United States. It also correlates U.S. laws with laws from other nations with similar, equivalent, or even more strict interpretations of internationally recognized protections documents. This comparative analysis between policies will provide options to integrate new taxonomies to better address the variables Writing Studies researchers encounter while pursuing ethical, rigorous research. This work is furthered in Chapter Six, where a new justice-oriented taxonomy is articulated.

The third major section of this chapter discusses the third research question: *Can we provide guidance on modes of crafting documents for IRB review?* This section draws upon data from the survey and interview narratives to make claims about how experts in written communication can both design documents for review by IRBs (i.e. building protocols for IRB determinations and review), as well as offer recommendations to IRBs on methods of strategically revising methods of filing and reviewing protocols. These findings have implications regarding the ways researchers can improve experiences for all parties on a given human-subjects research focused campus.

And finally, the fourth major section of this chapter addresses the fourth research question: *How do Institutional Review Boards staff, or street level bureaucrats, interact with researchers to shape methods and methodologies in Writing Studies?* This section of Chapter Five relies on interviews conducted with individuals well-versed in both research with human subjects, as well as a significant tenure within Writing Studies and/or its sub-disciplines. These narratives are augmented with policy changes and survey data. Together these frame the final finding offered in this chapter: that while street-level bureaucrats can, and have, influenced Writing Studies researchers' methods and methodologies, this need not, and should not, be a one-way street.

This chapter concludes with a brief discussion of the general findings and segues into Chapter Six, which addresses how the goals of the project were met and implications, future research directions, and the conclusion of the dissertation project.

Situatedness

I would like start with an illustration of both my, and my discipline's, situatedness by sharing an anecdote concerning another discipline in the humanities. This anecdote illustrates three primary take-aways from this chapter: first, that researchers being better educated on human subjects protections policy and local implementation is important and useful. Second, that Writing Studies' scholars awareness of the policy process is important, should the discipline wish to enter public policy dialogue. And finally, that reciprocity in the review process is vital. These three points support this project's aims to (1) expand the discipline's understanding of how federal regulations intersect with disciplinary agendas and (2) reshape Writing Studies researchers' orientation towards the work of IRBs and provide a deliberative and principled investigation on the challenges, as well as the benefits, that IRB review affords researchers.

As an IRB coordinator, reviewer, and member at a mid-size research institution in the West, the office I work in often encounters protocols and questions from faculty in Oral History. Often, when they are querying whether they need to file a protocol with us, they cite position statements from the Oral History Association, which tells this narrative about seeking approval from OHRP to have Oral Historians not seek IRB approval:

Responding to increasing concerns about the lack of congruence between the terms of Common Rule and the practice of oral history, in 2003 the OHA [Oral History Association] and the AHA [American History Association], after a series of discussions, secure the Office of Human Research Protections' concurrence with a policy statement

that excluded most oral history interviewing from IRB review on the grounds that it does not conform to the regulatory definition of researchers seeking “generalizable knowledge,” that is to say historians “do not reach for generalizable principles of historical or social development; nor do they seek underlying principles or laws of nature that have predictive value and can be applied to other circumstances for the purpose of controlling outcomes. (“Oral History and IRB Review,” 2016)

This is often quoted verbatim, as oral historians have clearly educated each other that if they cite OHRP to IRBs, then (perhaps) IRBs will listen. The last time one of these was received by our office, our director stated “Well. They don’t work for the OHA. They work for USU. USU’s policies are clear that their work does fall under our purview” (Personal Communication, 2016).

I share this case to illustrate three themes that will help contextualize the findings presented in this chapter. First, disciplines such as Oral History often call for discipline-specific review. Many principal investigators I have interacted with suggest that their disciplinary training, and their peers’ review, would provide better protections against harms towards their human participants than existing IRB policies. This is one proposed option, then, to resolve frustrations noted by Writing Studies researchers in the survey related to lengthy reviews, and useless requests for revisions. Abolishing the IRB as an institution (as Schneider recommended), and requiring disciplines to manage their own ethical attitudes towards research, seems to be one possible option. This includes both the design and the implementation of research with humans; while CCCC has a policy on ethical conduct of research, this would entail some level of disciplinary oversight not currently present: training, tracking projects, determination of punitive measures, etc. This possibility is one I will show is not useful to the discipline in this chapter.

Second, this case is indicative of the locality of IRBs. Just as there are sixty major

Classifications of Instructional Programs (CIP) codes, with hundreds of discrete sub-disciplines nested within each that form academic disciplines (NCES, 2017), there are thousands of IRBs (Health and Human Services, 2017). They are local for a number of reasons, which were best articulated by Stark in 2012. Their locality, while a frustration, can also be viewed as an asset. An asset-based approach may also help researchers in Writing Studies feel more confident about their interactions with IRBs. This recommendation is one I further parse out in Chapter Six, but it is addressed in the subsections of this chapter.

Finally, and perhaps most importantly, oral historians are happy to part ways with their IRBs under the auspices of suggesting they are not doing “research,” or not contributing to “generalizable knowledge:” a fundamental and foundational concept in the regulatory language. The definition of “research” in the regulations is notoriously vague

a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes (45 C.F.R. § 46.102 Subpart D).

For example, some demonstration and service programs may include research activities. Yet within a framework of higher education, of knowledge generation and discipline building, suggesting that one’s discipline does not contribute to generalizable knowledge, as defined earlier in this chapter, can be a very dangerous claim. Exhibiting disciplinary and/or individual hubris regarding the oversight of the IRB is a dangerous prospect on a number of levels.

I believe the themes identified here: being under-educated regarding both local implementation and the policy process, as well as having a deficit-based orientation towards and

positivistic perceptions of IRBs, represent the contemporary situation in Writing Studies, as a discipline. As readers engage with the findings, I recommend they consider these three factors: previous disciplinary dissensus with federal regulation has resulted in disciplines such as Oral History (1) publically suggesting they do not contribute to “generalizable knowledge” (2) still being required to undergo IRB review at a number of local institutions, and (3) despite their best efforts, being unable to establish disciplinary management of these issues outside of regulation and internal to the field.

Given the recently released Final Rule, which includes significant updates to the Common Rule instituted, promulgated, and familiarized to Writing Studies researchers since 1991, Writing Studies researchers should know that now, more than ever, their local regulationists (as Schneider calls them), not their discipline,¹³ are the best entities to ask about protecting human subjects.

Specifically, local IRBs are governed by the same federal mandates, but have unique methods of incorporating those regulations into their structural boundaries. Therefore, it is vital, as these narratives are shared, that readers be aware that their local IRB can mitigate any number of these recommendations. But given the literature, survey findings, interview data, and experiences of the author, these are interpretations that can apply to the large majority of Writing Studies researchers.

How We Learn

RQ #1: How can we identify pertinent variables of training for Writing Studies researchers related to human subjects protections? What methods can we use to investigate broad categories

¹³ Note the WPA-L queries such as “Here’s what I am doing. Do you think I need IRB review?”--- see the WPA-L Special Issue December 3-4, 2015 #2015-456

of influence by IRBs and tailor support for Writing Studies researchers?

A goal of this project was to find specific mechanisms to support Writing Studies researchers as they engage with their IRBs. Figure 2, presented in Chapter One, represents the initial design of a model, and Appendix G (the map of survey questions to the variables in Figure 2) indicates the model was field tested and recorded valuable results. These results can be translated into generalizable findings and indicates the identification of pertinent variables for training for Writing Studies researchers.

One response to an open-ended question in the survey rings loudly: “[IRBs] require too much revision.” While this comment does not reflect Writing Studies researchers as a whole, a large percentage of them do agree that there are issues and concerns in the pursuit of IRB approval. At the intersection of one’s own pursuit of IRB approval, which may result in frustrations experienced during the review process, researchers can interface in educative ways with their IRBs in ways that can allow them to support and enhance the IRB review process. This can only have positive ramifications for researchers’ individual projects and those of their peers.

This is to say: Writing Studies scholars circulate within worlds of drafting and brainstorming, revision and reading, contemplating and conceptualizing and review. This, alongside publications across our discipline about effective technical and professional communication, effective writing- and teaching to write- strategies, suggest Writing Studies scholars have established the skills to meaningfully manage and navigate the demands of IRB review. It is important to harness the expertise scholars in the field collectively have, as a discipline, and examine the ways in which they can ease the burden of IRB review. Both IRB specific training, as well as methods of engaging with training on federal policies (such as CITI), appear to be useful recommendations for Writing Studies researchers, 35% of whom suggested

their mandated training did not prepare them to file with their specific IRB and 77% of whom suggested the training was rote.

IRB as legitimating factor. Given that 35% of survey respondents purposefully design studies so as not to have to interface with IRBs, I'd suggest one goal of undergoing IRB review and receiving approval is indicative of a commitment to rigorous and ethical research. This approach will be further substantiated in Chapter Six. But the specific goal of this section is to encourage that 35% of respondents to reconsider their research design and encourage them to not be hamstrung by their frustrations with, or concerns regarding, IRB review.

IRBs are built from a regulatory structure put in place to protect the most vulnerable within communities of interest. IRB review may not simply be sufficient, or necessary, but pursuing IRB approval is also a researcher's duty as they work to ensure they are effectively using their expertise and training to make the best use of the time and information their participants share with them. IRB review suggests researchers are collecting data from a source close to the experiences and information they need, in order to improve the work they produce. Therefore, conducting research outside of the purview of the IRB suggests one of two primary issues. Either one: research is being conducted-- however ethically-- outside the rules determined by one's own society, or two: humans are not involved in Writing Studies research. These are both concerns for Writing Studies researchers, scholars who inhabit a relatively new discipline.

In the first instance, where researchers make determinations outside the bounds of established bureaucracy, the researcher is proposing that they alone are a better judiciary about what is best and right for society at large; this, rather than a committee of their peers from both within the discipline and from the human community in the US. Unilateral thinking such as this is a way to quickly dismantle the legitimacy of not only a single project, while potentially

harming those who researchers aim to serve (Interviewees BE and MK, January 2017). This can also discredit a discipline or department at a single institution, manifesting as an intensely adversarial and problematic relationship between administration and individual faculty (Personal Communication, 2016); this spirals out into the larger disciplinary community as individuals train undergraduate and graduate students and interface with colleagues.

In the second instance, when humans are not engaged in the sort of work a researcher does, they are suggesting the discipline's closeness to the human community is not immediate. While I do not wish to suggest that Writing Studies researchers *must* work with humans to gather important information about their community and worlds, to *purposefully* design studies which do not require IRB review suggests a grave disconnect with a healthy mission for any invested discipline in higher education. Given that the aims of Writing Studies as a whole, and sub-disciplines within the field, work to improve communication through writing, and design more egalitarian, justice-oriented societies, it is vital that the discipline continue to be human-centered, even as researchers work to re-orient their perspectives through novel theoretical lenses which decenter the human component.¹⁴

For these reasons, IRB review serves as a method of legitimating the work done in disciplines. IRBs can, and do, decline to review a variety of projects that appear to be research. While being told that our work “is not research” may sting at first (Interviewee MK & GS, January 2017), accepting the IRB’s determination is one step in understanding how IRBs determine work with human subjects to be research and learning to navigate the vocabulary of claiming the importance of the work to the field and one’s academic community.

While the NPRM offered the promise of reprieve for some Writing Studies researchers doing minimal risk research, the Final Rule does not incorporate the concept of “excluded”

¹⁴ For instance, such as Latour’s Actor Network Theory or posthumanisms.

research that was discussed in the NPRM. This means that while there was promise of a less stringent federal mandate for IRB review of projects that were, and remain, considered “exempt,” Writing Studies researchers are still obliged to interface with their IRB about the exempt determination. Making those determinations on one’s own is a dangerous game and can delegitimize the work done elsewhere in the discipline (Interviewee GS, January 2017).

IRB as educator. Interviewees indicated that training programs like CITI can provide excellent background education to researchers about human subjects protections in research (BE & MH, January 2017), broadly speaking. Yet CITI is context-specific and focuses on federal regulation and narratives rather than functioning as institution-specific training.

On the other hand, survey responses indicate that IRBs that offer educative experiences were 43% more likely to have good relationships with researchers. In open-ended replies, respondents generally agreed that requesting help and support, and soliciting guidance from their IRB, was the most effective method of solving tricky problems in human subjects research.

Therefore, viewing the IRB process not so much as an application, review, and approval process, but rather an educative and meaningful engagement with experts in human subjects protections, Writing Studies researchers may be able to mitigate their general frustrations with the IRB processes.

However, neither researchers, nor interviewees who had served on an IRB, viewed their role as educative (Interviewees BE, MH, GS, and SG, January 2017). While, for instance, Utah State University’s IRB often puts the onus on researchers to learn and understand regulations, they do often work with researchers on projects that push the regulatory structure in place. This is of increasing importance given the release of the Final Rule in January 2017.

While the Final Rule considers the shifting landscape of research¹⁵ discussed in Chapter Two, concerns about international research, and research in digital environments and with massive datasets, were not contemplated with great rigor prior to 2015. The attention OHRP gives in the Final Rule to “more thoroughly address the broader types of research conducted...such as behavioral and social science research” (p. 7150) is indicative of the increasing attention IRBs will give disciplines such as Writing Studies and other fields that continue to adopt methodological frames from the social sciences. For this reason, I recommend that researchers and IRBs work together to interpret the Final Rule and educate one another about disciplinary practices and local IRB policies. This notion of reciprocity is a common theme throughout the findings.

While the burden to crack open new avenues of research may be frustrating to many PIs, those who step in during this year of buffer between the release of the Final Rule and the implementation (required, for most components, by mid-January 2018) will (1) be able to provide information to colleagues about the implications of the new rule and (2) provide a Writing Studies specific approach and expertise to their institution. Much like students, IRBs are willing to learn and navigate new territory (Interviewees, MH, BE, January 2017; personal experience), if what a researcher is proposing is, for a given IRB, indeed, unprecedented. With the release of the Final Rule, some research being done in Writing Studies can be reconsidered in relation to new policy. For instance, exempt categories have expanded, and vulnerable populations have changed. Therefore, IRBs serve as educator to faculty who are always learning, and faculty and researchers can serve as educators to IRBs, too. Democratic engagement with one another is another way to ease the burden of compliance with regulatory structures, and to enhance the research environment at one’s institution.

¹⁵ See epigraph for this chapter, as well as the updated policy

Finally, researchers should consider the fact that IRB staff and reviewers often review hundreds, if not thousands, of different protocols each year. They also review the federally required closure report forms and continuation documents for these protocols.¹⁶ They see amendment requests to update protocols. This gives them a bird's-eye view of how research looks; while some IRBs use this knowledge to more effectively review and analyze their function, they are at a minimum a useful resource for researchers with technical question about their chosen methodologies: are my sample sizes too ambitious? Will certain types of research take longer than planned? Will I be hamstrung by my own data destruction timelines? Do certain methods of using surveys or interviews prove ineffective at answering research questions?

Synthesis. Given their ability to see the lifespan of projects, IRBs are also helpful resources in the broad design considerations- not simply regarding human protections. While their primary mindset is human subject protections, they are also effective analyzers of design and implementation. They must be able to judge whether a project is feasible, for if it is not, the claim can be made that it is unethical (Common & Final Rule, 1991 and 2017; MH and BE interviews). While IRBs would rarely make such a determination, IRB members may have stories and ideas about how to best ensure one's needs as a researcher are met.

Considering one's IRB to be one's best resource on IRBs and federal policy is useful. Because of issues of "localism" [EN, interview Jan 2017], the most efficient way to educate oneself about regulations and implementation at unique IRBs across the country is to interface with one's own IRB. While many Writing Studies researchers are clearly pleased with their IRBs, the fact that several others restrict their research avenues to avoid IRBs suggests that recognizing IRBs as an asset, rather than a gatekeeper, may open numerous research possibilities

¹⁶ Note that the requirement for IRBs to conduct Continuing Reviews was not included in the Final Rule for expedited protocols and further limited for Full Board protocols.

previously unexplored. Expanding the scope of the discipline's research should not be limited by bureaucracy. Given the opportune time to work with IRBs during their process of revising and updating their policies and procedures to comply with the Final Rule, Writing Studies researchers should consider the IRB process as mutually beneficial.

How We Understand

RQ #2: Can we create a new taxonomy to explain variables that result in best protections for human participants in Writing Studies research?

Contemplating the data's relationship to this research question, I'd like to focus this section specifically on the intersections of pedagogy and research. Given the CCCC's request, in the comment on the NPRM regarding student researchers, there is a clear concern about two issues involving students, which Schneider pointed out in 2006: first, students as researchers, and second, students as participants in top-down (Kirsch, 1999) research, i.e. students enrolled in a researcher's course who are also asked to enroll in their educator's research. Interestingly, the "mission creep" of IRBs somewhat parallels the "mission creep" of teaching into the Scholarship of Teaching and Learning, where classrooms function as generators of research agendas. While the Final Rule does not offer any significant modifications that impact existing policy, the data from the survey suggest, and interviewees noted, that discussing students as participants is an important mode of examining the ways researchers approach human subjects research in Writing Studies.

Particularly in composition, students are, perhaps, the most vulnerable population. Given that they are often of the age of majority, and do not fall into any of the former, or new, criteria of the federally identified vulnerable populations, they are a unique and illustrative population when researchers consider their methods of data collection. While the regulations protect

individuals subject to coercion, not all IRBs interpret the regulation to apply to students.¹⁷

Over 45% of survey respondents indicated they enrolled their own students as research participants. Publications by Anderson (1996; 1998), McKee and Porter (2009), McKee and Anderson (2011) clearly articulate the concerns with the use of students as participants from an ethical standpoint. Because the literature is minimal, or provides false (Hassel, 2014) or inflammatory (Salvatori & Donahue, 2009) information, and because survey data indicate that respondents were unclear regarding the difference between evaluation and research in their teaching (57% of respondents stated they believed that they must have IRB approval to use students as respondents on how to improve their teaching and a shocking 12% believed it was appropriate to publish - an academic interpretation of “generalizable”- on their students without IRB approval), in this section, I work to explain how the variables in Writing Studies research can result in best protections for students, and other participants.

IRB as participant advocates. Like experts in any field, IRBs have access to limited knowledge; while IRB staff may often not be experts in a specific field, they are often uniquely trained with advanced degrees; over 50% of all IRB professionals have an advanced degree (PRIM&R, 2015). While the knowledge of how the IRB review process works is not, in fact, accessible only by a few, it is a difficult body of knowledge to develop by the non-affiliated. Without consistent engagement with policy and practice interpreting the impact of policy on a variety of cases, it is difficult for a researcher to achieve the same familiarity as an IRB board reviewer or staff person. IRB professionals are required to critically apply their knowledge and expertise to each unique study. Because reviewers come from different backgrounds and institutions with different influences and concerns, complaints about the differences in the IRB

¹⁷There is no federal regulation protecting higher education students specifically; however, many IRBs have local policies to protect students as participants.

review process for similar protocols are pervasive not only in the literature, but also in Writing Studies researchers perceptions of IRBs. These local precedents (Stark, 2012), however, can be considered an asset to researchers.

The fundamental components of the IRB review process, and considerations by reviewers and staff, relate to the three principles outlined in the Belmont Report: justice, autonomy (respect for persons), and beneficence. These are weighed in relation to the benefit and risk incurred by participants. For instance, if the study is high risk, but protections are in place for those three principles, and the expected outcomes for society are exceptional, reviewers may consider the study acceptable.

In relation to these issues, IRBs can also be considered advocates for students; in many ways, while their role is compliance related, their obligation can be interpreted as advocates for participants. While the recently revised CCCC Guidelines for the Ethical Conduct of Research in Composition Studies provides disciplinary expectations and guidelines, these must serve as additional protections to those articulated by local IRBs. Interviewees noted that our disciplinary approach to research ethics, broadly construed, are the umbrella, of which IRB review is only one component (MH, BE, & SG January 2017). Yet specific IRBs may have contradictory allowances, for instance, regarding the use of students' verbatim work with attribution (CCCC, 2015).

Many IRBs have explicit policies about the use of one's students as research participants (MSU, 2017). Chief among these are efforts by researchers to minimize feelings of coercion (such as having someone besides the PI present the research to the students and maintain files until grading is done). Interviewees were largely aligned with these concerns, or actively worked to conduct research *outside* of their classrooms- in other classrooms, for instance (Interviews

with SG, MH, BE, January 2017). As representatives of the discipline with a collective 120 years of human subjects research experience, and some with IRB board experience, these narratives are compelling.

For all number and manner of reasons, unless excellent outcomes from the research are expected, and can overturn concerns about the principles discussed above, particularly autonomy, students should engage in research only in a fully voluntary fashion. Often, students are a sample of convenience; especially in my experiences with reviews, use of students in research can be indicative of poor research design, lazy protocol development, and confused PIs. While this is not always the case, when researchers explicitly point out that “if I cannot enroll students during the semester, none will provide consent after,” they are speaking directly to concerns about coercion.

In the age of big data, sites of research such as Turnitin, MyReviewers, and Eli Review host rich opportunities to examine student data. However, much like HIPAA, FERPA protects the use of identifiable¹⁸ student work without the express permission of the student. When the data is de-identified and provided to researchers outside of these databases, the review process can be considered under the former, and current, Exempt 4 criteria¹⁹ (updated criteria now

¹⁸ The updated regulatory definition of human subject does not change the regulatory concept of “identifiable”- if data are collected with identifiers, or if they can be re-identified by the research team with the available data, they are identifiable.

¹⁹ The updated policy language: (4) Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met: (i) The identifiable private information or identifiable biospecimens are publicly available; (ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects; (iii) The research involves only information collection and analysis involving the investigator’s use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of “health care operations” or “research” as those terms are defined at 45 CFR 164.501 or for “public health activities and purposes” as described under 45 CFR 164.512(b); or (iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the

include language regarding biospecimens). However, when students are asked to turn over their identifiable data from these tools for research purposes, especially as they are interfacing with the databases and tools in real time, IRBs and researchers often have tricky issues to work out. This does not eliminate projects from consideration, however.

If researchers plan to use the data for research purposes and have such an expectation of this data, participants must be consented. Interviewees noted that amongst peers, the notion that researchers can decide whether their project is “exempt” is pervasive (GS, 2017). However, while the Final Rule does not provide more clear clarification regarding who is responsible for making this determination, it does align with the verbiage in the 1991 Common Rule which suggests that the department (note, not in the sense of an “academic department”) or agency retains final authority as to whether a study is exempt. Therefore, most IRBs have policies in place²⁰ that require the submission of an exempt project outline to solicit a determination by the IRB or Human Subjects Protection Program.

The introduction to the Final Rule also notes, harkening back to the claim in Chapter Two, that while Writing Studies research involving humans may not be a material project, but it could have material consequences:

as technology evolves, so does the nature of the risks and benefits of participating in certain types of research. Many studies do not involve interaction with research subjects, but instead involve secondary analysis of data...Risks related to these types of research studies are largely informational, not physical; that is, harms would result primarily from the inappropriate disclosure of information and not from the research interventions

identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

²⁰ See, for example, USU’s IRB’s Standard Operating Procedures and Investigator Handbook for this information.

themselves. Nevertheless, these harms can be significant. (7151)

This leads to a conflict between the potential amount of data available to researchers and the actual amount of data they are able to use for research purposes without consulting their IRB. For instance, program directors, system administrators, and faculty can use data to improve pedagogy and conduct program evaluation without working through the IRB process. Only 25% of survey respondents understood this delineation between research and assessment and where those boundaries break down. But as soon as researchers seek to produce generalizable knowledge (for which many institutions offer guidance) and is, in academic contexts generally, to produce something publishable, those requests do need to go through the IRB process.

To illustrate this intersection of teaching and researcher, consider the role instructors have over students in the classroom in the context of a Conflict of Interest (CoI). Perhaps a PhD candidate would like to conduct research on his curriculum to develop publishable material to increase his chances of being well-placed in the job market, or an assistant faculty member would like to do something similar to improve her tenure chances. When researchers are prompted to disclose “Conflicts of Interest,” the conflict between researcher and teacher in the academic setting is never one that must be disclosed, but is rather assumed in the regulations (“because of the potential conflict of interest, investigators not be given the authority to make an independent determination that their human subjects research is exempt” [7183]).

It is in the PhD candidate's interest to conduct the research and produce publishable material. It is not, however, in the student's best interest to participate in the research. Indeed, simply being bothered with an Informed Consent process is an intrusion for students, who would otherwise not be bothered by research. Using his privilege as the instructor, as someone better versed in the academic setting, and in his role as grade-giver, this researcher has negatively

conflated his duties to his students. His students have no duties to him, especially not to further his career. If researchers consider the relationship of higher education and communities as one that is largely one where communities contribute to support research, and higher education returns those findings, the discrete research conducted in a specific classroom may be justified if it will positively impact future students. Can these researchers make such a claim? Given the large number of survey respondents who indicate they work with students, and the publications in the field on conducting this sort of work ethically, it is important to consider whether one's sample is merely a sample of convenience and whether one has fully considered the implicit coercion concerns in classroom research.

Synthesis. Data sharing, and the identifiability of data, were tremendous thrusts behind the NPRM. Yet because the NPRM did not allow for several these policies to be fully vetted by the processes outlined Administrative Procedures Act, many proposals were dropped in the Final Rule. However, in their goal to improve the regulations with attendance to the changes to research landscapes, the Final Rule perpetuates frustrations about these issues, while minimizing IRB oversight of some specific activities usually conducted by Oral Historians, journalists, and historians.²¹ This is not an asset for Writing Studies researchers, who must remain vigilant about ensuring the diversity of their research population, ensure their participants are not coerced to participate (especially students) and that participants' data is protected and honored.

While the discipline has rigorous ethical guidelines, the literature on working with students is limited, in some cases, out of date, or, in others, inaccurate. I recommend that researchers honor the protections set by the CCCC Guidelines for the Ethical Conduct of

²¹ Among three other otherwise non-related categories, the new rule reads: "For purposes of this part, the following activities are deemed not to be research: (1) Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, *that focus directly on the specific individuals about whom the information is collected.*" Emphasis mine.

Research in Composition Studies, while also recognizing their institution's unique methods of reviewing projects where one's students are one's participants. This further establishes that disciplinary guidelines are applicable only insofar as they can be couched within federal and local guidelines related to the ethical conduct of research. The best case to represent these issues relates to engaging one of the discipline's more vulnerable populations: students subject to coercion.

How Our Discipline Engages

RQ #3: Can we provide guidance on modes of crafting documents for IRB review?

Responding to this research question requires attendance to new and novel research spaces, which have expanded greatly as methods and methodological frames expand within Writing Studies. Technological innovations require thoughtful consideration, as they provide unique affordances in research. This section works to articulate two major spaces for Writing Studies researchers to consider methods of engaging with the process of IRB documentation and review to expedite and enhance the review process.

Like interpretations of data represented in relation to the two prior research questions, it is vital to remember that the locality of each IRB will greatly influence the specific documents IRBs use. Many IRBs use systems designed specifically for IRB review processes; others use home-grown systems that are part of the larger institutional matrixes. And still others continue to use hard copy documents.

This section aims to provide language and explication of major and emerging issues in Writing Studies research. This language, in turn, can be integrated into any given IRB's specific documentation for consideration by reviewers. While IRBs are often receptive to new techniques and methods, they may also prohibit some activities, or require major levels of review. In this

case, communicating with one's specific IRB is the best course of action.

IRBs and international research. As Writing Studies researchers increasingly take advantage of comparative and exploratory research outside of the United States, it is vital to be educated about the protections for human subjects in other countries. The U.S. policies are welcoming of other levels of review and protections, but researchers should note that only stricter protections can be used; the threshold, the baseline, is U.S. standards.²² Therefore, even though other nations may have more relaxed protections related to, for instance, confidentiality, the level of protection expected in U.S. policy applies.

As a counterpoint to this, many countries, and the E.U., have different regulations that focus on issues such as privacy. For example, research conducted in Sweden that is generated out of the U.S. requires explicit consent from Swedish participants to (1) acknowledge that the data is being collected and housed in a country outside of Sweden and (2) manage protections to possess data about that person (contact information, etc.) in the first place (PRIM&R, 2016). The first is not a consideration of any stateside research; it is not a U.S. requirement of researchers to disclose where servers and data live. However, many E.U. nations remain deeply concerned for their citizen's privacy, given the U.S.'s passage of the Patriot Act in 2001 (Qualtrics, 2016).

While many IRBs have reviewers or staffers who have reviewed or conducted research outside the U.S., the labor involved in examining and balancing regulatory structures of both the

²² This is the text from the updated rule released January 19, 2017; the bracketed content was removed from the Common Rule during revisions. "When research covered by this policy takes place in foreign countries, procedures normally followed in the foreign countries to protect human subjects may differ from those set forth in this policy. [An example is a foreign institution which complies with guidelines consistent with the World Medical Assembly Declaration (Declaration of Helsinki amended 1989) issued either by sovereign states or by an organization whose function for the protection of human research Redline of Unofficial Final Revised Common Rule (January 18, 2017) Against Health and Human Services Common Rule at 45 C.F.R. Part 46, Subpart A 5 subjects is internationally recognized.] In these circumstances, if a department or agency head determines that the procedures prescribed by the institution afford protections that are at least equivalent to those provided in this policy, the department or agency head may approve the substitution of the foreign procedures in lieu of the procedural requirements provided in this policy. Except when otherwise required by statute, Executive Order, or the department or agency head, notices of these actions as they occur will be published in the Federal Register or will be otherwise published as provided in department or agency procedures."

U.S. other countries entails a significant investment on the part of the IRB. For this reason, educating oneself before submitting to one's IRB is paramount to a smoother review process. Understanding the baseline protections surrounding broad ethical concerns regarding consent, privacy, and risk for one's research site is an effective way to negotiate with IRBs as they seek to effectively and efficiently review research being conducted outside the United States.

The Final Rule does include updates to components of international research, though they are administrative rather than practical. The primary update was to remove reference to the Declaration of Helsinki as a landmark document on research ethics which could serve as a touchstone for researchers. The introduction to the Final Rule suggests that because this document could change and shift out of line with U.S. baseline requirements, referencing it could eventually cause a contradiction in policy (Final Rule, 7159). If a researcher's IRB does not have a policy or process for engaging with international research, providing language from the Final Rule, or OHRP guidance,²³ and presenting oneself as well-educated regarding the research one plans to do is an excellent way of navigating these issues.

IRB as mediator of user agreements. One interesting point, as these venues for research grow increasingly common, is the concern between user agreements and human subjects protections. Per their federal prerogative, IRBs are less concerned with researchers access to a given data set than they are with what the data set contains and how it will be used. However, meeting minutes from a series of USU's board meetings in 2016 make clear reviewers' concerns with data collection from sites that the researcher does not have purview over.

In summer 2016, a researcher submitted a protocol to build a scraper to pull data from Facebook posts by potentially incarcerated individuals from a specific town in the U.S. Prisoners are a vulnerable population; as such, the protocol was brought to the board.

²³ For instance, <http://humansubjects.stanford.edu/research/documents/OHRP-intlcomp.pdf>

Some companies will allow researchers to use data only once they have secured IRB approval. However, Facebook is a company that (1) does not allow for the use of tools such as scrapers to be used on their data and (2) they have a policy that research must be reviewed and approved by their own internal board before it can begin.²⁴

When the USU IRB was confronted with these pieces of information, and it became clear the researcher had not read Facebook's terms and conditions and policies about research using even public data, they returned the protocol to the PI and requested that the resubmitted protocol include documentation of Facebook's approval to use the data. While this level of review may not have been required for a study enrolling individuals who were not part of a vulnerable population, the laws around prisoners' use of social media, and Facebook's own careful consideration after the "contagion study,"²⁵ made clear that the PI did not have access to the data he intended to use. Moreover, he had not read policies from the local jails regarding the use of social media by incarcerated individuals, nor had he communicated with Facebook about their policies for sharing data with researchers.

In this case, the IRB declined to review until the PI indicated they had done their due diligence regarding the collection and use of data. When researchers propose projects that suggest they will need access to data they do not personally possess, the assumption by the IRB is that they have an ethical means of soliciting that data. For this reason, IRBs may request a letter of support from the company or organization to be on record for such a protocol (Personal Communication, Aspire IRB, 2017). Yet, IRBs have no authority to compel companies to update their policies. Therefore, while PIs expect to be able to conduct a great deal of research with the new and novel spaces and digital communities, they may find themselves breaking laws not

²⁴ See, for instance, <https://www.facebook.com/policy.php>

²⁵ Here is the link to the published piece: <http://www.pnas.org/content/111/24/8788.full> For examples of public backlash, simply google "facebook contagion study"

related to human subjects research in the process. Doing one's due diligence before pursuing a course of research can prevent time wasted on inaccessible projects. IRBs can support the navigation of new procedures under which research could be possible, so seeking their guidance may be an asset in complicated situations such as these.

IRB as learners. As articulated in the first section related to RQ1, and throughout this section, IRBs are not only a source of education about any number of components related to the review process, research design, and ethical protections for participants. They are also resourceful and recognize the expertise of researchers. If an IRB notices a researcher's exceptional skill in interfacing with the policy implementation process, they may ask that researcher to serve on the board.

Writing Studies researchers can support their IRBs, and the IRB's review of their work, not only by being well educated in the shifting venues for research. They can also serve on boards; interviewees and survey respondents who serve, had served on, or served as a Chair of an IRB, all indicated only positive experiences. Service to one's institution in this capacity is one important way Writing Studies researchers can work with their local IRBs to better understand policy and, thereby, produce heuristics and recommendations for their discipline. One interviewee shared a story about criticizing their IRB's collection of research protocols; the IRB invited this individual to serve on the board and help with an initiative to revise the materials. They did so, and helped produce technical documents that did not have such a strict biomedical focus as prior versions, opening a space for their colleagues to submit materials more easily through the IRB (MK Interview, 2017).

Synthesis. All interviewees noted that conversations with IRBs either expedited the review and interactions between researcher and IRB. Some interviewees noted that while the

process of designing an IRB protocol for review required them to “think through” their research in ways they had not before, this process occasionally resulted in improved research designs. They noted that some researchers are frustrated by IRB review because their study design is not adequate, or complete enough, for IRB review. In exceptional cases, IRBs did not simply help researchers formalize their work; they offered novel methods and even contacts for other researchers using similar methods or research populations.

Approaching each unique IRB with a methodologically sound and well-designed study in line with the principles of beneficence, autonomy, and justice will result in a more efficient review. It may also result in connections amongst academic peers one’s IRB also works with, and, perhaps a request to serve on the board. Serving on a board has a positive impact on researchers’ own interactions with IRBs, and this service also informs the work and scholarship that subsequently appears in the field; see for instance Eble and Banks (2009), Barton (2008), McKee (2003).

Because the regulatory landscape will rapidly shift over the next year, and the implications of the updated policies are not yet clear, Writing Studies researchers have unique opportunities to interface with their local IRBs as institution specific policies regarding international policy, data use, access, and storage are revised for implementation of the new rule in January 2018.

How Writing Studies Researchers Are Impacted

RQ #4: How do Institutional Review Boards staff, or street level bureaucrats, interact with researchers to shape methods and methodologies in Writing Studies?

Discussing the fourth research question generated by the goals for this project requires significant insight from individuals with a considerable tenure in the field. The narratives shared

in interviews with a selection of five Writing Studies researchers, who have more than a collective century of experience in the field.²⁶ While not traditionally coded or interpreted with quantitative methods, these narratives (as part of the goal to collect narratives from thought leaders in human subjects research in Writing Studies) do inform the overarching narrative of how Writing Studies as a discipline has seen the IRB review process emerge, grow, shift, and change over time. These individuals also represent a wealth of experience with the methods and methodologies used within Writing Studies, and the shifts and changes in those over time as well.

IRB as partner/complicating factor. While interviewees largely identified IRBs as a mechanism for supporting the ethical design of research, many pointed out that these issues should be resolved by good disciplinary training and thoughtful methodological design. IRBs are but one component of a broad process of engaging with the variety of independent variables in the concept map: disciplinary training, research trends, methodological orientation, professional and ethical governing bodies, funding, institutional home, access to human subjects, and one's personal disposition all influence the ethical design of research. Interviewees responded unanimously that IRBs did not guarantee that a project is ethical. Rather, IRB approval indicated that a researcher's project was in line with the national expectations for ethical research with human subjects, and that disciplines, departments, and colleagues may have unique expansions on the minimum expectations of the IRB. As may IRB administrators note, the policy "is the floor, not the ceiling."

This notion, which tremendously impacts the local precedents of specific IRBs, can result in IRBs being a complicating factor for many researchers. When disciplinary standards may be different, but within the scope of regulatory standards, researchers can push back, as McKee

²⁶ At present, about 120 years.

proposed in 2003. Having had some experience with the IRB process, and being willing to ask questions rather than demand acceptance, are good indicators that a researcher can push back against IRB “mission creep” or overreach.

One interviewee noted that an IRB indicated their proposed compensation was “coercive” for a specific subject population. The researcher, rather than changing this, instead sent the IRB specific guidance regarding the day-rates for specific professionals, and the IRB correlated this to assure that the compensation was appropriate. In this instance, the IRB had a policy in place that was not contextual for this researcher (GS Interview, 2017). Another interviewee recalled removing specific data collection methods (photos and audio recordings) because they needed approval sooner and did not have time to build out the disciplinary justification for the IRB. In this instance, the researcher recalled that while this shifted their methodology, it was something that could have been negotiated (SG Interview, 2017). Another interviewee shared how their IRB requested they remove a specific survey question because it didn’t seem to fit the proposal for the research; the researcher responded with evidence that the question was a common one and important for delineating data amongst subgroups of respondents (EN Interview, 2017).

While there is evidence, then, that IRBs can *attempt* to shift methods and methodologies, interviewees were aware of how to make appropriate rhetorical arguments, in the context of federal policy and disciplinary appropriateness, to convince their IRBs to make alternate determinations. Two interviewees (one who served as a Chair and one as a IRB member) also shared their experiences working with their own IRBs. One noted that the IRB review process was generally positive unless a researcher is dealing with a “nightmare” IRB; generally, she noted, because the IRB proposal process requires researchers to contextualize and “think through” the whole research process before implementing it (KM Interview, 2017), IRB review

can be positive. EN also noted the way in which IRB review can result in a “whole cloth,” comprehensive research design sharing the story of two review processes: one, where the instruments had been validated, and the second, which required revisions. The latter required revisions and resulted in various frustrations.

Synthesis. Even though there are success stories from Writing Studies researchers pushing back on methods and research procedures here are instances, however, when IRB staff, Chairpersons, or even the board itself will make determinations about research. Therefore, when IRBs do become a complicating factor (beyond perhaps a long timeframe for review), there is often little to no recourse. Being well-educated about institutional policies, in addition to federal policies, is an important step in finding a healthy process for engaging with one’s institutional home. While a small percentage of Writing Studies researchers (11%) believe they are fully exempt from federal regulations, and others suggest that they do not believe they produce what the regulations refer to as “generalizable knowledge,” interviewees resoundingly agreed that pursuing something like the OHA’s exemption is dangerous because it is not applicable to *all* research in Writing Studies. Therefore, conferring with one’s IRB is important.

Conclusion

Chapter Five extrapolated generalizations from the survey data introduced in Chapter Four. These generalizations provide inferences that extend across settings: institutional types, researcher positions and job descriptions, individual research agendas, primary populations of study, etc. The findings provide a guide for all Writing Studies researchers who rely on human subjects in their research. This chapter also introduced findings from interviews conducted with participants in conjunction with references to new policy (the Final Rule) and survey data. These findings were framed in relation to the research questions that served as the foundational

guidance for this project. In this chapter, findings were broken down to represent Writing Studies researchers' perceptions of IRBs from a variety of standpoints: IRB as Partner, Complicating Factor, Learners, Educators, Participant Advocates, and Legitimizing Factor. These characteristics are not exhaustive of the discipline's experience with IRBs, but they are suggestive of the experiences with local precedents and individual IRBs.

While this chapter dealt with the major challenges apparent in Writing Studies research literature regarding IRBs, specifically in relation to navigating the local implementation of federal regulation and methods of understanding and engaging with the policy process, it only began to address the larger theoretical underpinning of this project: re-orienting the discipline's approach to IRBs as one that, rather than being deficit based, or positivist in nature is, rather, asset-based and justice-oriented. This is further developed in Chapter Six.

CHAPTER SIX: IMPLICATIONS FOR PRACTICE

Regarding the concerns expressed that the Common Rule departments and agencies are not authorized to regulate humanities and social science research, this challenge has been asserted previous against the 1981 HHS protection of human subjects regulations, as well as the 1991 Common Rule, and in each case the regulatory agencies concluded that the regulation of humanities and social science research is justified. We continue to assert the authority to regulate humanities and social science research that falls within the scope of the Final Rule.

----Federal Register, Vol 82, No 12, Thursday January 19, 2017, p7153

After this dissertation had been fully drafted by late 2016, and while revisions were underway, the Final Rule was released. The text was published in the Federal Register, Volume 82, Number 12, on Thursday, January 19, 2017; these updates to the Common Rule are intended for broad promulgation and implementation, or, in another word, compliance, by January 19, 2018. Save for one component of the regulation, cooperative IRB review (otherwise known as single IRB review), all IRBs are expected to be compliant with the Final Rule within the year.

The impact and applicability of the 1991 Common Rule on Writing Studies research has been well-outlined throughout this project (for instance, the explication of the Common Rule and the NPRM in Chapter Two and the use of the Final Rule in Chapter Five); these positions were also integrated into the design of the study presented in Chapters Three, Four, and Five. Similarly, the discipline's response to the NPRM, and the CCCC's standards of ethical conduct

of research, have been textual touchstones.

In this chapter, I seek to extrapolate the relation of localism, federal policy, and disciplinary guidance on the individual Writing Studies researcher. Specifically, I make the argument that (1) because Writing Studies research is generalizable, (2) and therefore federal regulations are applicable, though not positivist, as frequently claimed, (3) a justice-oriented approach to the responsibility of IRBs is a fruitful, generative way to engage with the IRB process. The logical processes at work in the statement above are discussed in the first section of this chapter; this argument, I suggest, re-oriens the discipline's approach to and understanding of IRBs in important ways. This theoretical argument is the contribution of this chapter to the dissertation.

This chapter also proposes four considerations for further research: extended research on the impact of IRB members and reviewers on protocol and procedure development, international implications, theoretical avenues for exploration, and broader inter- and multidisciplinary research on the empirical implications of IRB review. Finally, I offer a brief synthesis of the contents of this dissertation project. I suggest future research is necessary to build out Writing Studies' researchers relation to not only IRBs, but public policy more broadly. Understanding one's situatedness not only within one's departments and disciplines, but the university and state and federal environments, can only improve a researcher's odds of ensuring the impact and longevity of their discipline within the ever-shifting world of higher education.

Moving Forward: Federal v. Local Policy

Writing Studies research as generalizable. As discussed in the introduction to Chapter Five, while the term “generalizable” and “knowledge” remain vague in the federal regulations, the increasing representation of work by Writing Studies researchers aimed to share knowledge

about one group of individuals (such as a classroom of students) to make claims about a population (such as “students at xyz institution type in abc course type”), are indicative that 45 C.F.R. § 46 requires attention from researchers in Writing Studies. This interpretation of “generalizable” is commonly applied by most IRBs dealing with sociobehavioral and humanities-oriented research. While traditionally one interpretation of “generalizable” certainly encompasses studies with a large n , it is now, generally, equally applicable for those with a small n , such as ethnographies. Even small populations can provide researchers data they can use to generalize findings, make claims, or even- in the case of federal policy- lobby for revisions and updates (for instance, petitioning from one small field such as Oral History resulted in changes to a federal, overarching policy).

Production of knowledge, especially in publication in peer-reviewed journals, is a functional component of the work many Writing Studies researchers do. Publication in a journal suggests the work contributes to generalizable knowledge; pursuit of research to earn a Ph.D. or M.A. also, often, functions as a contribution to generalizable knowledge.²⁷ If, therefore, IRBs have oversight of human subjects investigations and research conducted by Writing Studies researchers, the negative characterizations of IRBs in the literature as positivist, or not applicable, should be further addressed.

While the Institute of Education Sciences (IES) provides rigorous guidelines and standards regarding study design and reporting on findings (2014), the IES methodological considerations are not without limitations, as Elliot et al. (2017) note:

...it is difficult, if not impossible, for any institution to meet the [IES] intervention design standards; and, while the single case study design standards are addressed in the present study, there is no deliberate manipulation... While the effort of the Institution of

²⁷ See, for instance, USU’s policy 582.6 regarding what is considered research.

Education Sciences may be seen as an extreme case of misplaced rigor, it is important to recognize that such standards reflect known methodological challenges... (Section 8.2)

Similarly, any critique of IRBs as positivist ignores the important cases upon which they established their leverage and exhibited the necessity for oversight; even those studies enrolling many individuals in traditional biomedical examinations represented policymakers concerns with the notion of “objectivity” (Tuskegee, for example). Moreover, given the recent updates to the federal policy, considering the shifting research landscape, including feminist, post-modern, post-positivist, and participatory action methodologies suggest that despite complaints of positivism at its core, the federal policy can be characterized as justice-oriented, rather than positivist. This characterization relies on three components of the policy: (1) the (shifting) vulnerability categorizations, which align with the discipline’s increasing attendance to justice (2) the justification OHRP provides for their oversight of human subjects research, and (3) the fundamental principles which undergird the policy: beneficence, autonomy, and justice.

(Shifting) vulnerability categorizations, which align with disciplinary approaches to justice. Federal policy is justice-oriented in the recognition of the shifting categories of vulnerable populations. For example, in the 2017 revisions, pregnant women are no longer considered “vulnerable.” While there remain specific protections for pregnant women in the regulations, their former designation as a vulnerable population was removed due to comments suggesting that pregnant women don’t need specific protections if their participation in research that is not specifically related to their pregnancy. It also recognizes a shifting trend in the paternal approach of federal policy to research participants. Specifically, while the policy aims to provide protections for marginalized populations, they also seek to recognize the ways in which individuals categorized as vulnerable can be prevented from contributing to the knowledge-

making process. The redlines between the original 1991 Common Rule and the updated Final Rule are provided in an image below. Deletions from the original are in red; additions are in blue. Note the revised language regarding not only pregnancy, but also regarding “handicapped or mentally disabled.”

§ 46.107 IRB membership.

(a) Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members (professional competence), and the diversity of ~~the~~its members, including~~-consideration-of~~ race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. ~~In addition to possessing the professional competence necessary to review specific research activities, the~~The IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments (including policies and resources) and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a ~~vulnerable~~ category of subjects that is vulnerable to coercion or undue influence, such as children, prisoners, ~~pregnant women, or handicapped or mentally disabled~~individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these categories of subjects.

Figure 18. Redline of Vulnerability Categories in Updated Rule

As these revisions indicate, policymakers are attentive to shifting language regarding traditionally marginalized populations. They are also attentive to issues of justice appearing in the field; recognizing that economically or educationally disadvantaged individuals are a unique and important group of individuals, and perhaps subject to coercion, parallel calls for ethics in assessment and increasing attention to social justice in the discipline.

OHRP justification for federal oversight of human subjects research. OHRP's justification for the existence of the Common Rule rests not only in a series of policy changes during the late 1900s, but also on a mandate that's often grounded in contextualized narratives regarding abuses by U.S. researchers. More than this, however, is the OHRP's own acknowledgement of the negative impact of studies such as Tuskegee (Register, 2017, p. 7175); codified in the federal register. These narratives have designed a human subjects protection program as a direct affront to the notion that "science" is or can be "objective," rather than deeply contextual. This is not an uncommon approach within the discipline (Herndl and Narhwold, 2003), and the increasing reflexivity of feminist methodologies (Kirsch, 1999; McKee and Porter, 2009) reify this shift in the discipline's understanding of knowledge-making.

Intemann's feminist standpoint empiricism, articulated in her 2010 piece, combines the empiricism sought after in more traditional positivist methodologies (such as those rejected by Writing Studies researchers who do not believe IRB review pertains to them) while acknowledging the situated, contextual components of any research and researcher. This model is one that I've followed throughout this project, and I propose is applicable to Writing Studies researchers' approach to IRB review. Specifically, both feminist standpoint theory and feminist empiricism are:

implicitly empiricist as [they] take experience to be central to justification of our beliefs. Each is contextualist, recognizing that justification occurs within a context of assumptions, including assumptions about aims, appropriate methods, and criteria for theory choice. Both views are socialized epistemologies that take groups, rather than individuals to be the locus of justification and objectivity. Both views recognize that social and political values can sometimes enhance, rather than hinder, objectivity and

reject traditional distinctions that have supported the “value-free” view of science.

Finally, both views take diversity, equality of intellectual authority, and other democratic mechanisms to be crucial for promoting objectivity within epistemic communities. (790)

Intemann further suggests that feminist empiricism should adopt the feminist standpoint presupposition that:

oppression is unjust, revealing gender is valuable, and that hierarchical power structures ought to be abolished. In this way, certain ethical and political views are intrinsically valuable...The reason that sexist values and androcentrism are bad for science is not because they are values that give rise to *partiality*. Rather, the problem is that they are *unjustified* value judgement. (793)

Together, these positions- feminist standpoint theory and feminist empiricism- reflect a binary previously applied in Writing Studies research. Specifically, that either IRB review was required, or not, and that the process of review was based in a positivist system, or not. Yet together, a feminist standpoint empiricism suggests the unique positionality of the Writing Studies researcher within a hierarchical power structure of federal and local policy. Such an approach embraces Writing Studies researchers’ concerns about the vestiges of adopted positivism, while recognizing the federal policy as hierarchical. Yet at the same time, this work can be justice-oriented by exposing oppression. This is parallel to how the federal policy has been built and revised. Writing Studies researchers recognition of this in the hierarchical structure can be a boon during their interactions with their local IRBs.

The fundamental principles which undergird the policy: beneficence, autonomy, and justice. As one interviewee noted, ethical research is also good research. The implication here speaks specifically to the three principles that undergird the policy. When research is

methodologically sound, it is indicative of *beneficence*. It suggests respect for participants' time, contribution, and the risk, however minimal, that they undertake. When research is well-designed, it is indicative of an orientation towards *justice* regarding the broader human community; it suggests a recognition of participants' socio-cultural context, the historical oppression of certain groups, and the faults of prior researchers who did not take these important factors into account. It acknowledges the risk undertaken by a specific group on behalf of a larger population. And when research is ethical, it is done with informed consent. *Autonomy* of each individual participant is honored and respected, and their willingness to participate determines their engagement with the research.

Functionally, all these components from the Belmont Report, a foundational text for the original Common Rule, remain similar in the 2017 revisions. These are aligned with a feminist standpoint empiricism, with a justice-oriented perception of research, and reflect an alignment with the disciplines' contextualist approach to RAD research.

Thoughts on implications. While discipline specific guidance exists regarding research with human participants (CCCC, 2015; ATTW, 2017), this guidance (as CCCC aptly notes) is not a substitute or replacement for adherence to federal policy. While the survey results indicated that most respondents were familiar with federal regulations, only 4% claimed to be experts. The concerns discussed and levied in the survey were closely aligned with the local implementation of policy; this, it seems, is the crux of researchers' complaints with IRBs. Interviewees GS and MH both had experience with multiple IRBs, sometimes simultaneously. They specifically discussed their frustrations with IRBs' inconsistent implementation of policy. There are several layers of gradation between the floor and the ceiling; this inconsistency is not unusual.

Calls in the comments on the NPRM, and professional organizations levying complaints

and formal interactions with OHRP prior to the NPRM, suggest that disciplinary critique and advocacy regarding the federal policy can have tangible impacts. For instance, the updated regulations regarding the definition of research exclude activities common to history, oral history, and literary criticism. These exclusions are new to the 2017 rule and were the result of heavy lobbying by actors such as Schrag and the Oral History Association. The question then arises as to whether, due to Writing Studies researchers' frustration with local implementation, Writing Studies as a discipline should lobby for changes at the federal level. Despite the confusion regarding this process exhibited in the CCCC comment on the NPRM, this is not to say that such work could not meaningfully be done. At present, I do not recommend such lobbying.

This is because since “final” regulations have been released, they will likely not be revisited for some time. From a practical perspective, the investment of time to examine and critique the Final Rule to align it more closely with Writing Studies researchers would result in very little tangible recommendations for updates; nor would it result in updates to policy in the near future. Given the 26-year timeframe between the release of the original Common Rule and the release of the Final Rule, by the time further revisions are made, the discipline’s research landscape will have evolved substantially. This is not to say that commenting on proposed legislation is not important; it is something the discipline should continue to do. However, lobbying in ways to make federal regulations bend to specific concerns (like the CCCC request regarding student researchers) will have little meaning to legislators who cannot generalize this policy.

Rather, focusing on the impact of forthcoming interpretations of the Final Rule is the most effective way to ensure Writing Studies researchers are prepared to interface with updated

regulations. This is work that can be done at the disciplinary level, but is contingent on researchers engaging with their local IRBs to assess the process. Re-orienting the approach to IRB review as asset-based and justice-oriented from a federal standpoint will enhance Writing Studies researchers ability to interface with the street-level bureaucrats they encounter in their local IRBs.

Should the discipline more broadly wish to critique, and propose modifications to, the federal policy, further research with Writing Studies researchers would need to be conducted to effectively examine the regulatory components and impact of updated policy. This is addressed in the final section of this chapter on future research directions.

Future Work and Research

The work done in this study, exhibited in the variable model and validated with survey results, provides the first step in work towards further empirical examination and expansion. Utilizing the data to further parse out differences among sub-groups, especially the differences between those who identify with technical communication specifically, will be a useful avenue of research. Utilizing tools such as SPSS and latent semantic analysis tools to analyze the growing corpus of transcribed interviews will prove useful to the discipline. Additionally, assessing data among groups regarding status at universities, university type, research roles, and federal grant awards will all provide useful data to generate broad categories of influence of federal policy on Writing Studies practice.

The variable model can be used as a basis, alongside the survey data, to develop a training model for Writing Studies researchers so they can achieve expert proficiency, something only 6% of survey respondents indicated they have. Designing such training, and suggesting means and methods of promulgating it throughout the discipline is a rich area for furthering the

work done in this dissertation.

This study is but a small component of the work done examining IRBs in Writing Studies. Other studies, both inside and outside Writing Studies, have provided a variety of perspectives on the relevance, impact, and day-to-day work of IRBs. Attendance to IRBs may not seem to be a vital research agenda for the discipline, as it's clear that many of the discipline's researchers are effective at navigating and engaging with IRBs. However, the updates in federal policy regarding some methods traditionally used in humanities disciplines could mean major changes in coming years. For these reasons, examining, and sharing resulting findings and information with these groups, could positively (or negatively) impact the discipline. Therefore, maintaining an interest in, and a rigorous research agenda around, the workings of IRBs is important for the discipline. The following recommendations for further research build upon the study presented in this dissertation, and offer rich avenues for generative projects.

International implications. As research grows in scope methodologically, physically, and theoretically, it is important for researchers to engage with human subject protection policies from partnering researchers at other non-US institutions. These regulations are often not as comprehensive or strict as U.S. regulatory structures from a general perspective, but many nations, and collations of countries such as the E.U., have policies about certain components, such as privacy, that are far more elaborate and vital to their human subjects protections programs than the U.S. Attention to these specific components is important for researchers who may be even intimately familiar with U.S. policy, but unprepared for the intricacies of non-U.S. based research. A second major concern is the use of communities for research which are not appropriate, or that the researchers are, in effect, taking advantage of.

Straightforward comparative work can be done to examine differences and similarities

between the United States' policies and those of other nations, particularly those with which researchers in the discipline tend to do significant work. Theoretical work can be done to establish baseline international ethical research considerations for the field of Writing Studies, given that human participants from a large majority of non-U.S. institutions speak and write English as a second, third, or even fourth language and may not have the same standard of living or expectations of researchers as their U.S. counterparts. The implications for documents such as Informed Consents, translation of research materials, and data collection efforts are not only impacted by regulations, but also by the practical experience of collecting data and researchers' familiarity with and care for their participants.

Specific gains from this sort of research would be numerous. For instance, the impact on policy re-design, should it occur, could be influenced by the practical and theoretical examinations provided by Writing Studies researchers. Moreover, the implications for active researchers exploring this increasingly attractive and generative environment for research are vast. Providing peers workable heuristics, in the meantime, is a mechanism for increasing the scope of Writing Studies and examining our work's impact on the rest of the world.

Impact of IRB review on protocol and procedures. An outgrowth of this project is the examination of protocols filed by researchers who participated in the survey component and indicated they had filed either (1) a large number of protocols (2) worked with a significant number of vulnerable populations/participants or (3) interfaced with IRBs during their pursuit of a federal grant. This particular form of research will allow writing studies researchers, and, more specifically, technical communication specialists, to examine the ways in which IRB reviewers and staff members interface with researchers to make changes to methods, and perhaps even methodologies, in Writing Studies research.

In my own work as a reviewer, oftentimes requested revisions are made specifically to comply with regulations. But because I review a tremendous number of studies, and work with a number of researchers in any given discipline, there are common strategic recommendations that can be made to (1) improve compliance with regulations once the study is underway (IRBs may not have resources to police all the studies they've approved, and are traditionally primarily concerned with prospective review) and (2) improve data collection and ensure data integrity, facilitate healthy participant interactions, and retain participants.

Specific gains from this sort of research would include heuristics on working with IRBs to determine whether recommendations are necessary or preferred by a given IRB, and to determine if there is a common method in which IRBs enshrine these recommendations in their own Standard Operating Procedures (another source of data for research in Writing Studies) to compel researchers at specific institutions to engage with policies in a given way. Gains also include the ability to examine the ways in which institutions differ in their implementations of the regulations and thereby how researchers can produce more specific guides and methods for working with colleagues at different institutions; for instance, a guide for researchers working at an AAHRPP accredited institution, or one with a biomedical IRB, would be useful for researchers.

Understanding how institutions can implement the regulations in different ways, and how researchers can either prepare or push back, would be a tool useful as comparative projects between, for instance, first year composition programs, are researched. The impact of policy refers to theoretical concerns regarding the obligation of a discipline to engage with the policy process.

Interdisciplinary research agendas. Research opportunities are endless when Writing Studies researchers consider partnering with fellow researchers outside of the discipline. Discipline specific research on IRBs is common; however, collaborative projects amongst researchers in multiple disciplines is lacking. IRBs affect all disciplines that are oriented towards improving or examining the human condition. Humans are needed to make claims about knowledge and the human condition; therefore, these disciplines all have something in common. They are bound by specific regulations.

The impact of these regulations on projects outside Writing Studies likely manifests differently. However, rather than considering this a complicating factor, working with fellow scholars and researchers with diverse and effective analytical and theoretical insights and expertise affords Writing Studies researchers both (1) unique and rich locations of research and (2) opportunities to expand the scope of the discipline to impact policy, both locally and nationally.

Specific gains for Writing Studies researchers are plentiful. It is no small undertaking to pursue interdisciplinary projects. IRBs inherently are such projects, as they involve examining entire institutions. Much disciplinary research seeks to understand specific impacts IRBs have on research and work; this project, for instance, while imbued with policy and administrative analysis, is situated squarely in Writing Studies, and is intended to support Writing Studies *as a discipline*. In reality, it is bound by the localism observed by interviewees and a number of survey respondents.

Were researchers across disciplines to collaborate on projects that examine the tangible impact of IRBs on specific subsets of disciplines, the strength of any argument to shift or influence policy- both locally and nationally- increases substantially. Specifically, on certain

campuses, collaboration across disciplines allows for researchers to levy collective expertise to petition for changes and updates to local Standard Operating Procedures, systems and tool use for the protocol development process, and increased representation of like-minded individuals on the IRB itself.

Conclusion

This dissertation was intended to serve multiple purposes. In crafting a timely overview of the shifting approaches to human subjects protections in Writing Studies research, this project provided a disciplinary perception of the status of human subjects in research. Additionally, it also allowed for space to provide a clear indication of how and why IRBs are perceived the ways they are by Writing Studies researchers. The survey data, and collected narratives from thought leaders in the field provide an analysis of Writing Studies researchers' positions regarding human subjects protections, while also offering guidance to enhance researchers' understanding of, and ability to navigate, human subjects protections that are justice-oriented. The work is far from over; because of the recent changes in national leadership, it is unclear whether the Final Rule revisions to the Common Rule will remain in place.

Yet the CCCC's response to the NPRM, which served as a formative textual springboard for this project, and initiated the avenues of investigation examined in the survey and interviews, served as a rich document through which to examine how IRBs impact research in Writing Studies. While higher education, decades old public policy, and the many institutions across the U.S. face uncertain futures, the findings from this project offer something small, yet tangible. Writing Studies researchers have developed methods of coping with the regulatory framework *as it is*; this dissertation represents those efforts, developed over the past two decades as the discipline has taken shape, adopted non-traditional methods into the humanities, and acclimated

to the onus of federal policy. This project also provides a baseline of data and questions for reference in future research, especially perhaps once new policy has been implemented. The material here may be used as comparative data to determine the shifts and changes in the impact of policy and/or perceptions of Writing Studies researchers towards human subjects protections.

The future of federal human subjects protections remains uncertain during this tumultuous time for policymakers; because institutions, such as those where Writing Studies researchers work, use those regulations as a baseline for local implementation, Writing Studies researchers should recognize the situatedness of their work, their context. Within this context, approaching the IRB review process with a justice-oriented approach, and a general knowledge of federal policy and local implementation, can enhance the discipline's research and broaden our areas of investigation. I urge researchers who avoid engaging human subjects because of IRBs to reconsider their position, and I urge those with interest in learning more about IRBs to offer their service to their local board. Increasing Writing Studies' representation on IRBs and expanding the discipline's engagement with the review process will only enhance local IRBs' understanding of what Writing Studies scholars do.

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APPENDICES

Appendix A: Table Connecting Goals, Purpose, Research Questions, and Chapters

PURPOSE: Provide heuristics, guidelines, and narratives to enhance the reader's understanding of what it means to work with human subjects in Writing Studies research by (1) reshaping Writing Studies researchers' orientation towards the work of IRBs and provide a conscientious and thoughtful meditation on the faults, as well as the assets, that IRB review affords researchers and (2) expanding the discipline's understanding of how federal regulations intersect with disciplinary agendas.

Goals	Associated Research Questions	Associated Chapters
Craft a timely overview of the shifting approaches to human subjects protections in Writing Studies Research.	How can we identify pertinent variables of training for Writing Studies researchers related to human subjects protections? What methods can we use to investigate broad categories of influence by IRBs and tailor support for Writing Studies researchers?	<ul style="list-style-type: none"> • Chapter One, introduction and setting of dissertation • Chapter Two, literature review • Chapter Three, design of survey and interview • Chapter Four, results • Chapter Five, findings from survey on variables • Chapter Six, implications
Provide analysis of position statements by Writing Studies researchers regarding human subjects protections.	Can we create a new taxonomy to explain variables that result in best protections for human participants in Writing Studies research?	<ul style="list-style-type: none"> • Chapter Two, exposition of policy and statements through December 2016 • Chapter Five, intersection of survey data with policy released January 2017
Collect narratives from thought leaders in the field regarding research and human subjects protections- past, present, and future.	Can we provide guidance on modes of crafting documents for IRB review? & How do Institutional Review Boards staff, or street level bureaucrats, interact with researchers to shape methods and methodologies in Writing Studies?	<ul style="list-style-type: none"> • Chapter Five, findings from survey data are correlated with updated policy and narratives from interviews • Chapter Six, findings suggest implications for future interaction with IRBs during the phase of implementation and promulgation of the revised Common Rule
Enhance Writing Studies researchers' understanding of, and ability to navigate, human subjects protections, oriented in more general notions of justice and beneficence.	How can we identify pertinent variables of training for Writing Studies researchers related to human subjects protections? What methods can we use to investigate broad categories of influence by IRBs and tailor support for Writing Studies researchers?	<ul style="list-style-type: none"> • Chapter Three, survey and interview design • Chapter Four, data from survey • Chapter Five, findings • Chapter Six, implications

Appendix B: CCCC Public Comment on NPRM

Conference on College Composition and Communication (CCCC)
1111 W. Kenyon Road, Urbana, Illinois 61801-1096

U.S. Department of Health and Human Services (HHS)
Office for Human Research Protections (OHRP)
Attn: Jerry Menikoff, M.D., J.D.
1101 Wootton Parkway, Suite 200
Rockville, MD 20852

Dear colleagues,

We write on behalf of the Conference on College Composition and Communication (CCCC), a division of the National Council of Teachers of English (NCTE). We are a group of teachers and scholars deeply invested in empirical research on writing. Our work concerns not only writing in education, but in everyday life: we study writers and writing from diverse contexts, and we seek to build and share knowledge about writing best practices, writing processes, and the relationships between writing and other profound human activities. Our teaching, informed by research, seeks to provide students with skills, experience, and knowledge appropriate for their particular writing lives, meaning that it is as diverse and varied as our research. In classrooms and beyond, we rely on research methods derived from both the humanities and social sciences, some long-standing, some cutting-edge, and most directly engaged with writers and their writing. Our research has illuminated, for example, articles in the natural sciences (Bazerman 1988), connections young people make between literacy and identity (Kinloch 2009), writing with social media in distributed work (Pigg, 2014), college students' writing for school and other purposes (Sternglass, 1997), relations between writing for school, at workplaces, or in community organizations (Cox et al., 2009), writing and communication in medicine (Dautermann, 1997) — and much, much more.

For these and other reasons, research ethics are deeply important to us, and the proposed changes to the Common Rule have broad implications for our work, our students, and the institutions in which we study and teach. This comment is organized in three sections: (A) proposed changes we support; (B) concerns we have; (C) concerns about implementation of proposed tools and processes. References are attached.

In 2011, the CCCC commented (80f5ccf2) on the Advance Notice of Public Rulemaking published at that time (HHS-OPHS-2011-0005-0001). Many of the changes proposed at that time are repeated in the current NPRM. We repeat our support for them below. While some of our 2011 concerns were addressed in the current NPRM, many remain. For these reasons, we note that portions of this comment are repeated directly from the 2011 comment made by the CCCC.

A) Support for proposed changes

1. Elimination of continuing review requirements for some research

We support elimination (§46.109(f)) of continuing review requirements for research approved by expedited review, and for research which has reached data analysis.

2. Making informed consent “more meaningful and transparent”

As above, research in our field has also acknowledged that informed consent processes can become complex and counterproductive, especially for internet-based research (McKee & Porter, 2008) or research with participants who might struggle to understand traditional consent forms and language (Wright 2012). We support efforts (§46.116) to improve the consent process while maintaining its integrity, especially specific reforms such as waiver of signature requirement and/or alternative means for obtaining consent when appropriate.

B) Concerns about research methods common in writing research

1. “Not research” language may undermine credibility and funding for writing research

We are generally in favor of the proposed exclusion of certain types of research such as history, journalism, and biography from research regulated by the Common Rule, in §46.101(b). Writing research engages these methods in both writing assessment and other forms of research which focus on individual writers. However, we are concerned that the language “not research” will lead to the perception that these forms of inquiry do not contribute to generalizable knowledge, as “research” regulated by the Common Rule does. We fear this exclusion, coarsely applied, could further limit the already thin funding opportunities for writing research as grantmakers would be less likely to see this work as legitimate scholarly inquiry.

We ask that HHS avoid the potentially misleading language “not research,” and explicitly emphasize that the term “exclusion” is limited to exclusion from regulation under Common Rule, not a determination these important activities are not research. Public comment questions #12 and #21 address the differences between “exemptions” and “exclusions;” we note the difference between these two forms of research is one possible confusion of the term “exclusion.”

2. New exclusions may lead to proliferation of external standards or regulations

Here we consider not only the research methods mentioned in §46.101(b)(1), but the exclusion of “low risk” human subjects research and educational tests in §46.101(b)(2).

As above, we support this exclusion given the nature of these research activities and the minimal risks to participants. However, we expect that some institutions will seek to regulate this research in some manner given that risks are still present. Institutions may develop rules which seek to maintain oversight of this type of research activity.

One possibility is that common best practices may become adopted by institutions who seek to regulate excluded research, perhaps because they lack the resources or staff to ensure oversight, but are not comfortable with the prospect of unsupervised research. For example, in supporting exclusions in §46.101(b)(1), the American History Association (AHA) refers to the best practices and ethical codes they have developed over time, suggesting these aggregated experiences work well for the specific methods they have developed. We agree, and indeed, writing researchers have our own similar documents, such as the “Conference on College Composition and Communication Guidelines for the Ethical Conduct of Research in Composition Studies” (2015). However, we also note the AHA writes in a public comment on the

NPRM, “Individuals *in any discipline* who plan to do oral history interviews should follow the practices and ethical codes developed by the Oral History Association” (our emphasis). We feel this type of disciplinary creep is not appropriate and, ironically, threatens to reproduce the conditions the AHA and other professional organizations have long objected to, when regulations designed for research in one discipline are applied wholesale to another.

To the extent that research oversight may come to mean the imposition of best practices, ethical codes, or similar rules in contexts where they are a poor fit, we suggest that the HHS clarify the purpose and nature of these exclusions from regulation by Common Rule.

3. Definition of “benign interventions” is broad

Section 46.104(d)(3) establishes a specific category of exempt “benign interventions” which involve “the collection of data from an adult subject through verbal or written responses.” As written, this definition seems very broad: for example, risky or embarrassing subject matter is rightfully explicitly excluded, but how is that line drawn? We recommend the HHS seek to clarify the definition.

4. Diverse research methods should be better represented in OHRP decision-making

Writing research often draws on non-experimental qualitative methods such as interviews, case studies and ethnography (Brice Heath et al., 2008). The human subject protection efforts of the Office for Human Research Protections (OHRP) focus on experimental medical research, and with good reason, given its legal mandate. However, we note that few of the materials prepared by OHRP staff in support of the NPRM address the methods writing researchers frequently engage. We are concerned that development of the NPRM, and its upcoming implementation, will exclude perspectives unique to qualitative research. For example, we note that the October 20 town hall, questions about ethnographic research were largely deflected.

We recommend that the OHRP seek to address non-experimental and qualitative research methods more vigorously, consider the impacts of proposed changes for broad types of research, and consult with and/or include a broad diversity of researchers in decision-making processes. Please see below (C3 and C4) for specific suggestions.

5. Student research is not explicitly addressed

The public comment made by the CCCC in 2011 noted the ANPR did not address student-conducted research (§II.4). Since 2011, student research has become ever more important, as more students, educators, and institutions have recognized its value (Kuh, 2008). Unfortunately, the length of time necessary for IRB review can make it impossible to complete in courses. For this reason, we echo the CCCC’s 2011 request for development of IRB review provisions which minimize the time necessary for review of faculty-supervised student research integrated into courses.

C) Implementation: concerns and suggestions

1. Implementation of decision tools and other centralized support systems is not described

We welcome the proposed development of centralized tools intended to make research oversight more efficient, such as the decision tool to aid in determining which research qualifies as exempt (§46.104(c)), and the proposed repository of informed consent materials (§46.116(h)). We agree that these resources will help institutional staff and researchers alike better understand and follow the intent of the Common Rule. However, the lack of discussion of implementation of these and other tools raises questions about the design of these tools and the manner of their operation. For us, questions for public comment #27–33 reflect the considerable variation possible. Given that much writing research qualifies as exempt, that tool, in particular, will be important for us.

We suggest the HHS publish more information about plans to develop and implement these decision tools and resources. We request that writing researchers be included, especially for the exempt research decision tool, given our expertise in technical communication. We also request that development include a public beta testing period and request for public comment.

2. Implementation of streamlining IRB review of multi-site studies is not described

Research in our field has noted the labor intensity, complexity, and chilling effects of obtaining multiple IRB approvals for inter-institutional research (Lunsford & Lunsford, 2008). The shift to a single IRB could provide adequate oversight far more efficiently, and we generally support this change. However, we note that public comment questions #74–78, and many NPRM comments already submitted, raise concerns about implementation which we share. As above, given the considerable room for variation here, we request the HHS further clarify its vision for single IRB approvals with a request for public comment.

3. Provide funding opportunities to initiate changes and to track their impact

We quote at length from the 2011 comment by the CCCC:

Many of the proposed reforms will require substantial reorganization for local IRBs and for disciplinary societies. We request that the OHRP provide grants to support the development of more streamlined review processes, informed consent forms, and ethics guidelines among academic societies; as well as for the re-education of IRB members. We also request that the OHRP provide grants to allow research communities to track the impact of the proposed changes.

Given continued declines in state support for higher education, we find the establishment of these funding opportunities even more important today.

4. Convene a panel with diverse constituencies, including writing researchers, to review the impact of the changes in three years

Again, we quote the CCCC comment from 2011, emphasizing the need for inclusion of writing researchers given the issues we observe in section B, above:

As with any large-scale endeavor, the proposed reforms will likely have unintended consequences. We ask that, three years after the reforms are implemented, the OHRP should convene a panel with diverse constituencies to review their impact. We ask that a member from the CCCC be included on the panel.

We thank the OHRP for the opportunity to comment on the NPRM. Please contact us if you have any questions.

Respectfully submitted,

Conference on College Composition and Communication (CCCC)
Joyce Locke Carter, Chair
Associate Professor of English
Texas Tech University

Primary Contact:
Bradley Dilger, CCCC Research Committee
Associate Professor of English
Purdue University
dilger@purdue.edu
309-259-0328

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Appendix C: IRB Approval Letter



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RESEARCH INTEGRITY AND COMPLIANCE
Institutional Review Boards, FWA No. 00001669
12901 Bruce B. Downs Blvd., MDC035 • Tampa, FL 33612-4799
(813) 974-5638 • FAX (813) 974-7091

April 8, 2016

Joanna Hillen
English
Tampa, FL 33612

RE: **Expedited Approval for Initial Review**

IRB#: Pro00025347

Title: Federal Grant Programs and Corollary Institution; Review Board Protocols: An Analysis of Reciprocity in Policy Determination, Implementation, and Impact on Writing Studies Research

Study Approval Period: 4/7/2016 to 4/7/2017

Dear Ms. Hillen:

On 4/7/2016, the Institutional Review Board (IRB) reviewed and **APPROVED** the above application and all documents contained within, including those outlined below.

Approved Item(s):
Protocol Document(s):

Consent/Assent Document(s)*:

[Consent for Interview, Data, & Quotes \(Phase 2\).pdf](#)
[Survey LoI/Consent](#)

*Please use only the official IRB stamped informed consent/assent document(s) found under the "Attachments" tab. Please note, these consent/assent document(s) are only valid during the approval period indicated at the top of the form(s).

It was the determination of the IRB that your study qualified for expedited review which includes activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the categories outlined below. The IRB may review research through the expedited review procedure authorized by 45CFR46.110. The research proposed in this study is categorized under the following expedited review category:

(5) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).

(6) Collection of data from voice, video, digital, or image recordings made for research purposes.

(7) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

Your study qualifies for a waiver of the requirements for the documentation of informed consent as outlined in the federal regulations at 45CFR46.117(c) which states that an IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either: (1) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or (2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context. (Online consent).

As the principal investigator of this study, it is your responsibility to conduct this study in accordance with IRB policies and procedures and as approved by the IRB. Any changes to the approved research must be submitted to the IRB for review and approval via an amendment. Additionally, all unanticipated problems must be reported to the USF IRB within five (5) calendar days.

We appreciate your dedication to the ethical conduct of human subject research at the University of South Florida and your continued commitment to human research protections. If you have any questions regarding this matter, please call 813-974-5638.

Sincerely,

John Schinka, Ph.D., Chairperson
USF Institutional Review Board

Appendix D: Consent Documents



Informed Consent to Participate in Research

Information to Consider Before Taking Part in this Research Study

Pro # 25347

Your participation is being requested in a research study called *IRBs and Writing Studies Research*. The person who is in charge of this research study is Johanna Hillen; she is the Principal Investigator and a PhD candidate at the University of South Florida. Her advisor is Dr. Joseph Moxley. This study is sponsored by the 2015-2016 CCCC Research Initiative. The purpose of this study is to learn more about how Writing Studies researchers interact with their Institutional Review Boards.

Why are you being asked to take part?

We are asking you to take part in this research study because you are over 18 years old and are a part of the discipline of Writing Studies, broadly conceived. For instance, you may be studying composition pedagogy, rhetorical theory, or technical communication. We are looking for a diverse set of viewpoints on the topic of IRBs. Even if you haven't dealt with an IRB, we hope you'll consider participating, especially if you work or teach at a research-intensive university, a community college, or a private liberal arts school. Your input will help future researchers in Writing Studies by providing information about federal regulations that impact researchers and participants.

What are you being asked to do?

If you take part in this study, you will be asked to complete the survey via Qualtrics. This survey, depending on your replies, will take between 15 and 30 minutes of your time. You will be asked questions about your experience as a researcher and teacher in Writing Studies, and your perceptions of Institutional Review Boards. This study has other components, and participating in this online survey will prompt you to indicate whether you would be willing to participate in further interview and data collection procedures.

Alternatives / Voluntary Participation / Withdrawal

You have the alternative to choose not to participate in this research study. You are free to participate in this research or withdraw at any time. There will be no penalty or loss of benefits you are entitled to receive if you stop taking part in this study, however you will not be compensated for your time if you withdraw before you complete the survey and provide your contact information for compensation purposes.

Benefits and Risks

We are unsure if you will receive any benefits by taking part in this research study, but researchers will learn more about how Writing Studies as a discipline can interact with Institutional Review Boards to conduct thoughtful, vibrant, and ethically sound research. This research is considered to be minimal risk, meaning that the risks of participating are no more than what you'd experience in your everyday life. There is a risk of loss of confidentiality, but the research team has made efforts, as described in the "Privacy and Confidentiality" section of this document, to minimize those risks.

Compensation

To thank you for your time, you will be compensated with a \$5 Amazon gift card. After you complete the survey, you will be asked to provide your email address. Each Saturday, new participants will be emailed their claim code for their \$5 Amazon gift card. If you do not receive an email the Saturday after you complete the survey, please email the PI at jhillen@mail.usf.edu.

Privacy and Confidentiality

We must keep your study records as confidential as possible. It is possible, although unlikely, that unauthorized individuals could gain access to your responses because you are responding online. It is possible, although unlikely, that unauthorized individuals could gain access to your responses. Confidentiality will be maintained to the degree permitted by the technology used. No guarantees can be made regarding the interception of data sent via the Internet. However, your participation in this online survey involves risks similar to a person's everyday use of the Internet. Since we are collecting personally identifiable information alongside your opinion on what some consider a contentious issue, you should be aware that breach of confidentiality could be a risk for you if you participate.

Certain people may need to see your study records. By law, anyone who looks at your records must keep them completely confidential. The only people who will be allowed to see these records are the Principal Investigator and her faculty advisor, and other members of the research team, and the projects sponsor, CCCC. The University of South Florida Institutional Review Board (IRB) is allowed access to study data to ensure this research is being conducted ethically and in accordance with federal regulations.

Contact Information

If you have any questions about your rights as a research participant, please contact the USF IRB at 813-974-5638. If you have questions regarding the research, please contact the Principal Investigator at jhillen@mail.usf.edu. We may publish what we learn from this study. If we do, we will not let anyone know your name. We will not publish anything else that would let people know who you are. Please print a copy of this consent form for your records.

Participant Consent

I freely give my consent to take part in this study. I understand that by proceeding with this survey that I am agreeing to take part in research and I am 18 years of age or older.



Informed Consent to Participate in Research Involving Minimal Risk

Pro # 25347

You are being asked to take part in a research study. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below.

We are asking you to take part in a research study called:

IRBs and Writing Studies Research

The person who is in charge of this research study is Johanna Hillen. This person is called the Principal Investigator. However, other research staff may be involved and can act on behalf of the person in charge. She is being guided in this research by Dr. Joseph Moxley.

The research will be conducted via online interviews, on the USF campus, or in a place where we can meet to conduct the interview.

This research is being sponsored by the NCTE's 2016 CCCC Research Initiative.

Purpose of the study

The purpose of this study is to learn more about how Writing Studies researchers interact with their Institutional Review Boards. We are collecting information from surveys, interviews, and technical documentation between researchers like yourself and their Institutional Review Board for analysis. This will help us support Writing Studies researchers as we move into a new era of Human Subjects Protections.

Why are you being asked to take part?

We are asking you to take part in this research study because you are over 18 years old and are a part of the discipline of Writing Studies, broadly conceived. You have also been asked to participate in the interview and document sharing process because you indicated in your survey responses that you've filed a number of IRB protocols OR are otherwise affiliated with your institution's IRB OR are otherwise familiar with the impact of human subjects protections on research in Writing Studies. We are looking for a diverse set of viewpoints on the topic of IRBs, regardless of your sub-discipline(s) in Writing Studies. Your input will help future researchers in Writing Studies by providing information about federal regulations that impact researchers and participants in future studies.

Study Procedures:

If you take part in this study, you will be asked to participate in an interview via skype or G-Chat or your preferred method of video conferencing. If the PI can reasonably come and meet with you in person, we will conduct the interview that way. The interview will ask you questions about your Social Behavioral

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interaction with your IRB. These questions will ask you to address both your interactions with personnel as well as with any databases or software that you use to interface with your IRB. The interview questions will also ask you conceptual questions about the federal regulations that require IRB oversight of your research. Interviews will be both video and audio recorded for transcription and coding purposes. The interview will take approximately 60-90 minutes of your time. At the end of the interview, you will be provided instructions on how to share your protocols with the PI and study team, also for coding and analysis purposes. All identifiable data will be destroyed by July 2020- perhaps sooner depending on the transcriptions and coding- and de-identified data will be kept indefinitely. Interviews will take place at a time and location of your choosing, ideally prior to March 1, 2017.

If you are willing to allow the research team to use direct quotes from your interview please initial below. Before using them, the PI will email you and request to use specific quotes or information. You would be able to review the content before submission, in context. Please initial here if you are willing to allow the research team to use direct quotes: _____

Please also initial here if you are willing to send and share your communications and database interactions with your IRB via screen capture: _____

Total Number of Participants

About 70 individuals will take part in this part of the study across the US, specifically for the interview component of this research. Approximately 500 total participants will be engaged in this research in other ways, such as surveying.

Alternatives / Voluntary Participation / Withdrawal

You do not have to participate in this research study. You should only take part in this study if you want to volunteer. You should not feel that there is any pressure to take part in the study. You are free to participate in this research or withdraw at any time. There will be no penalty or loss of benefits you are entitled to receive if you stop taking part in this study

Benefits

We are unsure if you will receive any benefits by taking part in this research study but researchers will learn more about how Writing Studies as a discipline can interact with Institutional Review Boards to conduct thoughtful, vibrant, and ethically sound research.

Risks or Discomfort

This research is considered to be minimal risk. That means that the risks associated with this study are the same as what you face every day. There are no known additional risks to those who take part in this study.

Compensation

We appreciate your time and would like to compensate you for your participation, up to \$75 either as a VISA gift card (sent via post) or an Amazon gift card (redemption code delivered via email). You will be compensated \$25 for your time for participating in the interview, and \$50 for your time in collecting and sharing your IRB related documentation.

Costs

It will not cost you anything to take part in the study.

Privacy and Confidentiality

We will keep your study records private and confidential. Certain people may need to see your study records. Anyone who looks at your records must keep them confidential. These individuals include:

- The research team, including the Principal Investigator, study coordinator, the project consultant, and all other research staff.
- Certain government and university people who need to know more about the study, and individuals who provide oversight to ensure that we are doing the study in the right way.
- Any agency of the federal, state, or local government that regulates this research, such as the OHRP.
- The USF Institutional Review Board (IRB) and related staff who have oversight responsibilities for this study, including staff in USF Research Integrity and Compliance.
- The sponsors of this study, the Conference on College Composition and Communication and their parent organization, the National Council of the Teachers of English.

We may publish what we learn from this study. If we do, we will not include your name. We will not publish anything that would let people know who you are.

You can get the answers to your questions, concerns, or complaints

If you have any questions, concerns or complaints about this study, or experience an unanticipated problem, call Johanna Hillen at 719.321.0097.

If you have questions about your rights as a participant in this study, or have complaints, concerns or issues you want to discuss with someone outside the research, call the USF IRB at (813) 974-5638.

Consent to Take Part in this Research Study

I freely give my consent to take part in this study and understand that the PI will be audio and video recording the interview. I understand that by signing this form I am agreeing to take part in research. I have received a copy of this form to keep.

Signature of Person Taking Part in Study

Date

Printed Name of Person Taking Part in Study

Statement of Person Obtaining Informed Consent

I have carefully explained to the person taking part in the study what he or she can expect from their participation. I confirm that this research subject speaks the language that was used to explain this research and is receiving an informed consent form in their primary language. This research subject has provided legally effective informed consent.

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Signature of Person obtaining Informed Consent

Date

Printed Name of Person Obtaining Informed Consent

Social Behavioral



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Appendix E: Feedback Survey on Survey Tool for Expert Committee

Feedback Form: "IRBs and Writing Studies: Disciplinary Perspectives" Q13 This is a feedback form for the survey "IRBs and Writing Studies: Disciplinary Perspectives." The form is organized to solicit feedback on three of the survey's attributes: usability, the inclusion of case studies, and variable mapping. Please keep this form open while you complete the survey "IRBs and Writing Studies: Disciplinary Perspectives." You can change your answers at any point before you submit.

Q8 Please select your level of agreement with the following statements:

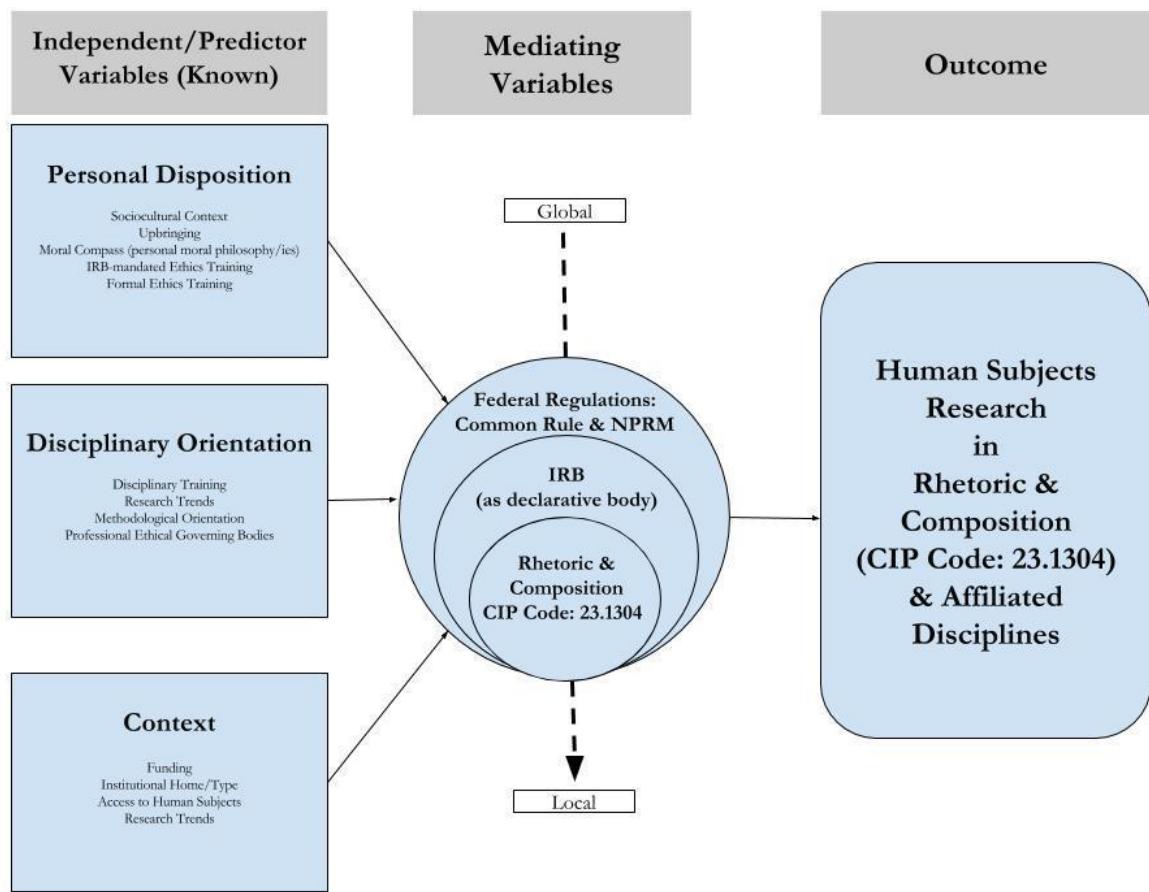
	Strongly Agree (1)	Agree (2)	Somewhat agree (3)	Neither Agree or Disagree (4)	Somewhat disagree (5)	Disagree (6)	Strongly disagree (7)
the questions are clearly worded (1)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
the survey is free of mechanical errors (2)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
the skip logic functions correctly (3)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
the sections of the survey are logically organized (4)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
the questions within each section are logically organized (5)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
the survey design minimizes	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

the likelihood of fatigue (6)	<input type="radio"/>						
the headings/ descriptive texts for each section are comprehensive (7)	<input type="radio"/>						
the headings/ descriptive texts for each section are clear (8)	<input type="radio"/>						
the answer categories (multiple choice/ranking/open reply) are appropriate each question (9)							

Q9 Please share any comments, suggestions, or recommended revisions related to the survey design here.

Q10 Below is an embedded version of the concept map for this project. Please refer to it as necessary for this set of prompts.

Q11



Q1 Please select your level of agreement with the following statements regarding the relation of the survey questions to the project concept map.

	Strongly Agree (1)	Agree (2)	Somewhat Agree (3)	Neither agree no disagree (4)	Somewhat Disagree (5)	Disagree (6)	Strong Disagree (7)
the survey questions rely on variables identified in the concept map (1)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
the survey questions elicit information related to how IRB staff interact with respondents (2)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
the survey questions about IRBs are tailored towards Writing Studies researchers (3)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
the survey questions allow for investigation of the	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

broad categories of influence by IRBs on Writing Studies (4)							
--	--	--	--	--	--	--	--

Q3 Please share any comments you have regarding the survey related to its relation to the concept map. Are there variables missing? Are some over- or under-represented?

Q4 Please select your level of agreement with the following statements regarding the case studies.

	Strongly Agree (1)	Agree (2)	Somewhat Agree (3)	Neither Agree nor Disagree (4)	Somewhat Disagree (5)	Disagree (6)	Strongly Disagree (7)
the case studies are understandable (1)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
the case studies map onto the independent variables in Figure 1 (2)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
the replies to the case studies are comprehensive (3)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
the purpose of the case studies is clearly explained (4)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
the method of soliciting replies to case studies are sufficient to reveal	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

responde nt's justificatio n for their choices (5)							
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Q7 Please share any comments or concerns you have regarding the case studies.

Q12 Please share your name and email/best method of contact for any follow-up questions.

Appendix F: Final Survey Tool

Writing Studies and IRBs: Disciplinary Perspectives

Q1.1 Please review this Letter of Information before proceeding into the survey.

- I am 18 years of age or older and would like to participate. (1)
- I am not 18 years of age or older and/or do not want to participate (2)

If I am not 18 years of age or... Is Selected, Then Skip To End of Survey

Q2.1 This survey is divided into five parts. This first section of the survey prompts you for information about your professional roles and affiliations. Depending on your replies, this section will take you approximately 2-5 minutes to complete. The whole survey will take you between 15-30 minutes depending on your experiences with IRBs.

Q2.2 Are you, or have you ever been, affiliated with an institution of higher education? For example (this list is not exclusive): as a student, faculty, staff, or administrator.

- Yes (1)
- No (2)

If No Is Selected, Then Skip To End of Survey

Q2.3 Please select your highest level of education. If you are currently enrolled, please select the highest degree received.

- High school graduate, diploma or the equivalent (for example: GED) (1)
- Some college credit, no degree (2)
- Trade/technical/vocational training (3)
- Associate degree (4)
- Bachelors degree (5)
- Masters degree (6)
- Professional Degree (7)
- Doctorate Degree (8)
- Other (9) _____

Q2.4 Please select the National Center for Education Statistics (NCES) Classification of Instructional Programs (CIP) code that best describes your disciplinary affiliation.

- Writing, General (1)
 - Rhetoric and Composition (2)
 - Professional, Technical, Business, and/or Scientific Writing (3)
 - Rhetoric and Composition/Writing Studies, Other (4)
 - English Language and Literature, General (5)
 - English Language and Literature/Letters, Other (6)
 - Creative Writing (7)
 - Literature (8)
 - None of these apply (if this is the case, please type your affiliation in the text box) (9)
-

Q2.5 With which institution are/were you affiliated?

Q2.6 Are you presently employed or studying at this institution?

- Yes (1)
- No (2)

If No Is Selected, Then Skip To What is your current job title?

Q2.7 What percentage of paid time do you spend on:(note: your total should equal 100)

- _____ Teaching undergraduate students (1)
- _____ Teaching graduate students (2)
- _____ Research and publication (3)
- _____ Administration (4)
- _____ Curriculum design and assessment (5)
- _____ Grant writing or management (6)
- _____ Service (broadly construed) (7)
- _____ Other (8)
- _____ Other (9)

Q2.8 What is the highest degree offered by your institution in the following areas?

	Undergraduate Certificate (1)	Undergraduate Minor (2)	BA (3)	BS (4)	Graduate Certificate (5)	MA (6)	MS (7)	PhD (8)	N/A (9)
Writing, General (1)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Professional, Technical, Business, and Scientific	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Writing (2)									
Rhetoric and Composition (3)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Literature (4)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Creative Writing (MFA please select MS) (5)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Other field related to Writing Studies (6)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Q2.9 What is your current job title?

- Assistant Professor (1)
- Associate Professor (2)
- Full Professor (12)
- Instructor (3)
- MA/MS Student (4)
- PhD Student (5)
- PhD Candidate (6)
- Professor Emeritus (7)
- Staff (8)
- Research Fellow (9)
- Adjunct (10)
- Other (11)

Q61 Please select all of the organizations with which you are affiliated:

- ATTW (1)
- CCCC (2)
- CPTSC (3)
- IEEE (4)
- RSA (5)
- CWPA (6)
- PRIM&R (7)
- Other (8) _____
- Other (9) _____

Q3.1 This is the second of five sections of the survey. This section gathers information about your interactions with IRBs. Depending on your replies, you can expect to spend between 2-10 minutes on this section.

Q3.2 Have you ever completed an IRB-required formal research ethics training/course, like CITI?

- Yes (if you recall the name of the program, please type it here) (1)
- Maybe; I don't recall. (2)
- No, I have not. (3)

If Maybe; I don't recall. Is Selected, Then Skip To Following successful completion of yo...If No, I have not. Is Selected, Then Skip To How many protocols (research projects...)

Display This Question:

If Have you ever completed an IRB-required formal research ethics training/course, like CITI? Yes (if you recall the name of the program, please type it here) Is Selected

Or Have you ever completed an IRB-required formal research ethics training/course, like CITI? Yes (if you recall the name of the program, please type it here) Is Not Empty

Or Have you ever completed an IRB-required formal research ethics training/course, like

CITI? Yes (if you recall the name of the program, please type it here) Is Empty

Q3.3 Please select your level of agreement with the following statements about your IRB mandated ethics training.

	Strongly Agree (1)	Agree (2)	Somewhat Agree (3)	Neither Agree nor Disagree (4)	Somewhat Disagree (5)	Disagree (6)	Strongly Disagree (7)
The training took too long (1)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The training was comprehensive (2)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The training was rote (3)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The training discussed the Belmont Report (4)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The training helped me prepare to file with my IRB (5)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The training was straightforward (6)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The training addressed ethical	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

principles (7) The training helped me better understan d human subjects protection s (8)	<input type="radio"/>						
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Q3.4 Have you ever filed a protocol (a research project or proposal) with an Institutional Review Board?

- Yes (1)
- No (2)

If No Is Selected, Then Skip To Have you ever done research on or wit...

Q3.5 How many protocols (research projects) have your filed with your current Institutional Review Board?

- 0 (1)
- 1-5 (2)
- 6-10 (3)
- 11-15 (4)
- 16-20 (5)
- 21 or more (6)

If 0 Is Selected, Then Skip To Have you ever done research on or wit...

Q3.6 Approximately how many of each sort of protocol (research project) have you filed?

- _____ Exempt (1)
- _____ Expedite (2)
- _____ Full Board (3)
- _____ Designation Unknown (4)

Q3.8 Please select your level of agreement with the following statements.

	Strongly Agree (1)	Agree (2)	Somewhat Agree (3)	Neither Agree nor Disagree (4)	Somewhat Disagree (5)	Disagree (6)	Strongly Disagree (7)
My IRB is well-equipped to review the sort of research I do (1)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
My IRB is well-equipped to make determinations about the ethical components of my research (2)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
My IRB is attentive to the challenges of digital research environments (3)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
My IRB is attentive to the affordances of digital research environments (4)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
My IRB has a	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

good relationsh ip with researche rs on campus (5)							
My IRB offers effective training for researche rs (6)	○	○	○	○	○	○	○

Q3.9 IRBs are unique to each institution. Some researchers have written about the following concerns with their IRBs. Please select the option that applies to your experience with your IRB.

	I've never experienced this (1)	I've experienced this once (2)	I've experienced this multiple times (3)
Reviews take too long (1)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Unnecessary edits and revisions requested (2)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Review doesn't seem to protect participants (3)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Interfacing with reviewers was frustrating (4)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Seeking IRB approval delayed my research (5)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
There was too much red tape (6)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Not enough training on what the IRB is looking for (7)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Seeking approval delayed funding (8)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Seeking approval prevented me from getting funding (9)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Requirements to submit amendments and/or continuations (10)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The software I have to use was unwieldily/difficult to use (11)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Q3.10 Is there anything you'd like us to know about your experience with your IRB?

Q3.11 If you could modify the way your institution implements the policy (45 CFR 46/the Common Rule) that governs human subjects research, what would you change?

Q3.12 Have you ever done research on or with any of the following populations? (please select all that apply)

- First generation college students (1)
- Prisoners (2)
- Pregnant women (3)
- Individuals under 18 (4)
- Individuals not citizens of the United States (5)
- Veterans (6)
- Students in your course (7)
- Students in a program you administer (8)
- Other vulnerable population (please explain) _____

Q3.13 Do you actively work to develop research projects that do NOT require IRB review so that you do not need to submit protocols for consideration?

- Yes (1)
- No (2)

Q4.1 This is the third of five sections of the survey. This section of the survey asks questions related to federal regulations and foundational principles in research ethics. Depending on your replies, it will take between 5-10 minutes to complete.

Q4.2 How would you describe your familiarity with Human Subjects Protections in research?

- I am an expert in the regulations, policies, and practices of human subjects protection in research (1)
- I consider myself educated regarding the regulations, policies, and practices of human subjects protections in research (2)
- I've done my institution's required ethics training and abide by their regulations (3)
- I am not familiar with the regulations, policies, and practices of human subjects protections in research (4)
- Other (5) _____

Q4.3 Do you, or have you ever, served as a member and/or chair of an Institutional Review Board?

- Yes (1)
- No (2)

If No Is Selected, Then Skip To Please select your level of agreement...

Display This Question:

If Have you ever served as a member or chair of an Institutional Review Board? Yes Is Selected

Q4.4 Please briefly describe this experience: how were you recruited? were you compensated for your time? do you still serve on the board? was this a useful professional experience for you? did this service alter your perceptions of the role of IRBs?

Q4.5 Please select your level of agreement with the following statements

	Strongly Agree (1)	Agree (2)	Somewhat Agree (3)	Neither Agree nor Disagree (4)	Somewhat Disagree (5)	Disagree (6)	Strongly Disagree (7)
Human subject protections apply to the sort of research I conduct (1)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Education on human subjects protection s in research should be included in undergraduate curricula (2)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Education on human subjects protection s in research should be included in graduate curricula (3)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
There are some instances when research should be	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

conducted even if there is no direct benefit to participants/students (4)						
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Q62 Please select your level of agreement with the following statements

	Strongly Agree (1)	Agree (2)	Somewhat agree (3)	Neither agree nor disagree (4)	Somewhat disagree (5)	Disagree (6)	Strongly disagree (8)
In order to improve my teaching, it is acceptable to use my students in my research without IRB review or approval. (1)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
In order to improve my teaching, it is acceptable to use my students in research only with IRB review or approval. (2)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
In order to publish an article, chapter, or book, it	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

is acceptable to use my students in research without IRB review or approval. (3)							
In order to publish an article, chapter, or book, it is acceptable to use my students in research only with IRB review and approval. (4)	<input type="radio"/>						

Q4.6 Have you ever enrolled your students as participants in your research studies?

- If yes, please briefly describe the research (1) _____
- No (2)
- Other (3) _____

Q4.7 Have you ever used student produced texts as part of your research studies?

- If yes, please briefly describe the research (1) _____
- No (2)
- Other (3) _____

Q4.8 In research ethics, and as described in the Belmont Report, beneficence is generally defined as having the welfare of the research participants as a goal of any research study. In

other words, the goal is to not only do not harm, but to also maximize possible benefits for participants while minimizing possible harms. What is your understanding of how the principle of beneficence is manifested in Writing Studies research with human subjects?

Q4.9 In research ethics, and as described in the Belmont Report, justice is considered the fair selection of participants, i.e. ensuring there is equivalent representation of all types of individuals enrolled in a given study, and that folks who won't benefit from the study findings won't be enrolled. This ensures both the burden and benefits of research are equally distributed. What is your understanding of how the principle of justice manifests in Writing Studies research with human subjects?

Q4.10 In research ethics, and as described in the Belmont Report, respect for persons (also called "autonomy") dictates that, even in situations where it is not obvious, participants enter research voluntarily and with sufficient information. What is your understanding of how the principle of respect for persons manifests in Writing Studies research with human subjects?

Q4.12 If you could modify federal regulations about human subjects protections in research, what would you change? Why?

Q4.11 Are you familiar with the Notice of Proposed Rule Making (NPRM) for revisions to the Common Rule that was released in September 2015?

- Yes (1)
- No (2)

Q5.1 This is the fourth of five sections. This section of the survey asks you to respond to four hypothetical scenarios. It will likely take you between 10-15 minutes to read and respond to the prompts.

Q5.4 Recently you've begun enhancing your teaching and research by working with nonprofit organizations. When you submitted your latest protocol to your IRB, requesting approval to develop and run analyses of satisfaction feedback without consenting the nonprofit's clients (since the nonprofit would be collecting the feedback and would technically be owners of the data), the IRB replied and asked you to remove a portion of the project from your protocol. The specific section they asked you to remove was providing feedback to the organization, calling it program development and evaluation. However, key to your findings, and therefore ability to publish, is what sort of feedback you provided to the organization. This feedback is based on your analysis of surveys and interviews. You believe this component to be an integral part of the research, and an integral part of your partnership with your nonprofit partner. Please select your level of agreement with the following:

	Strongly Agree (1)	Agree (2)	Somewhat Agree (3)	Neither Agree nor Disagree (4)	Somewhat Disagree (5)	Disagree (6)	Strongly Disagree (7)
My disciplinary training would help me adequately resolve this scenario (1)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Training provided by my IRB would help me adequately resolve this scenario (2)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
My moral compass/personal philosophies would help me adequately resolve	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

this scenario (3) I would consult with a colleague about this scenario before moving forward	<input type="radio"/>						
(4) I would consult with my IRB before moving forward	<input type="radio"/>						
(5)							

Q5.5 Please tell us how you would resolve this scenario:

Q5.6 Your university requires first-year writing students to use a for-profit service where they submit their work, conduct peer reviews, and receive feedback from instructors online. You contact the company and ask what their policy about data sharing is, as you'd like to be able to use the comments, content, and materials in their database to conduct research on peer review. They are happy you're interested in conducting research, and they let you know that users of the system agree to the use of their de-identified data for these reasons in the end-user agreements. Information such as race, gender, SES, and first-generation status are all collected as well. It's reasonable that you'll be able to breakdown the data and make inferences about these populations. In casual conversation, a colleague suggests that before you move forward you need to consider whether this project falls under the purview of the IRB. Please select your level of agreement with the following:

	Strongly Agree (1)	Agree (2)	Somewhat Agree (3)	Neither Agree nor disagree (4)	Somewhat Disagree (5)	Disagree (6)	Strongly Disagree (7)
My disciplinary training would help me adequately resolve this scenario (1)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Training provided by my IRB would help me adequately resolve this scenario (2)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
My moral compass/personal philosophies would help me adequately resolve	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

this scenario (3) I would consult with a colleague about this scenario before moving forward	<input type="radio"/>						
(4) I would consult with my IRB before moving forward	<input type="radio"/>						
(5)							

Q5.7 Please tell us how you would resolve this scenario:

Q5.8 You and two colleagues at different institutions have a cache of student papers from the past decade of teaching your respective graduate level research methods course each year. You'd like to use these papers to publish a journal article exhibiting how the discipline's incoming scholars have shifted/enhanced the field in terms of methods and methodology. Your students were never informed that their writing may be used for research purposes, and it was never discussed in seminar. One colleague suggests that perhaps you must fully consent all past students before beginning to develop your manuscript. Please select your level of agreement with the following:

	Strongly Agree (1)	Agree (2)	Somewhat Agree (3)	Neither Agree nor Disagree (4)	Somewhat Disagree (5)	Disagree (6)	Strongly Disagree (7)
My disciplinary training would help me adequately resolve this scenario (1)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Training provided by my IRB would help me adequately resolve this scenario (2)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
My moral compass/personal philosophies would help me adequately resolve this scenario (3)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

I would consult with a colleague about this scenario before moving forward (4)	<input type="radio"/>						
I would consult with my IRB before moving forward (5)	<input type="radio"/>						

Q5.9 Please tell us how you would resolve this scenario:

Q5.10 You have a graduate student interested in researching how narratives about pregnancy loss have changed over time in online spaces. She has personally participated in both public and private forums for over 5 years and has a collection of digital articles and archives she'd like to analyze. She comes to you with questions regarding the IRB review of this project, given that her target journal for publication requires a letter of approval. Please select your level of agreement with the following:

	Strongly Agree (1)	Agree (2)	Somewhat Agree (3)	Neither Agree nor Disagree (6)	Somewhat Disagree (7)	Disagree (8)	Strongly Disagree (9)
My disciplinary training would help me adequately resolve this scenario (1)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Training provided by my IRB would help me adequately resolve this scenario (2)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
My moral compass/personal philosophies would help me adequately resolve this scenario (3)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I would consult	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

with a colleague about this scenario before moving forward (4)	<input type="radio"/>						
I would consult with my IRB before moving forward (5)							

Q5.11 Please tell us how you would resolve this scenario:

Q6.1 This is the fifth of five sections of the survey. This section asks questions about funding you've received for research projects. It should take between 1-2 minutes to complete this section. After this section you will be prompted for information on compensation and follow-up interviews.

Q6.2 Have you ever received federal grant funding for research, or worked on a project funded by federal monies?

- Yes, on one project (1)
- Yes, on multiple occasions (2)
- No (3)

If No Is Selected, Then Skip To End of Block

Q6.3 Did (any or all of) the project(s) require Institutional Review Board review?

- Yes (1)
- No (2)

Display This Question:

If Did (any or all of) the project(s) require Institutional Review Board review? Yes Is Selected

Q6.4 Did you solicit IRB approval before or after the project was funded?

- Before (1)
- After (2)

Q6.5 Please tell us about this/these project/s.

Q6.6 Which agency funded your project(s). Please select all that apply. Please note this list is not exhaustive. Please list any federal funding agencies in the 'Other' text entry box, if applicable.

- NIH (1)
- NSF (2)
- FDA (3)
- USDA (4)
- DOD (5)
- DOC (6)
- ED (7)
- HHS (8)
- DHS (9)
- Other (10) _____
- IMLS (11)
- EPA (12)

Q5.12 Do you often participate in research studies?

- Yes, I do (please share your experience, if you'd like) (1) _____
- No, I do not (and, if you're willing, please share with us why you don't) (2) _____

Q7.1 Would you be interested in participating in a 60-90 minute follow up interview related to this survey? Compensation up to \$75 is available for participating in an interview related to your experiences with Institutional Review Boards.

- Yes, please contact me if I'm eligible. (1)
- No, I'm not interested. (2)

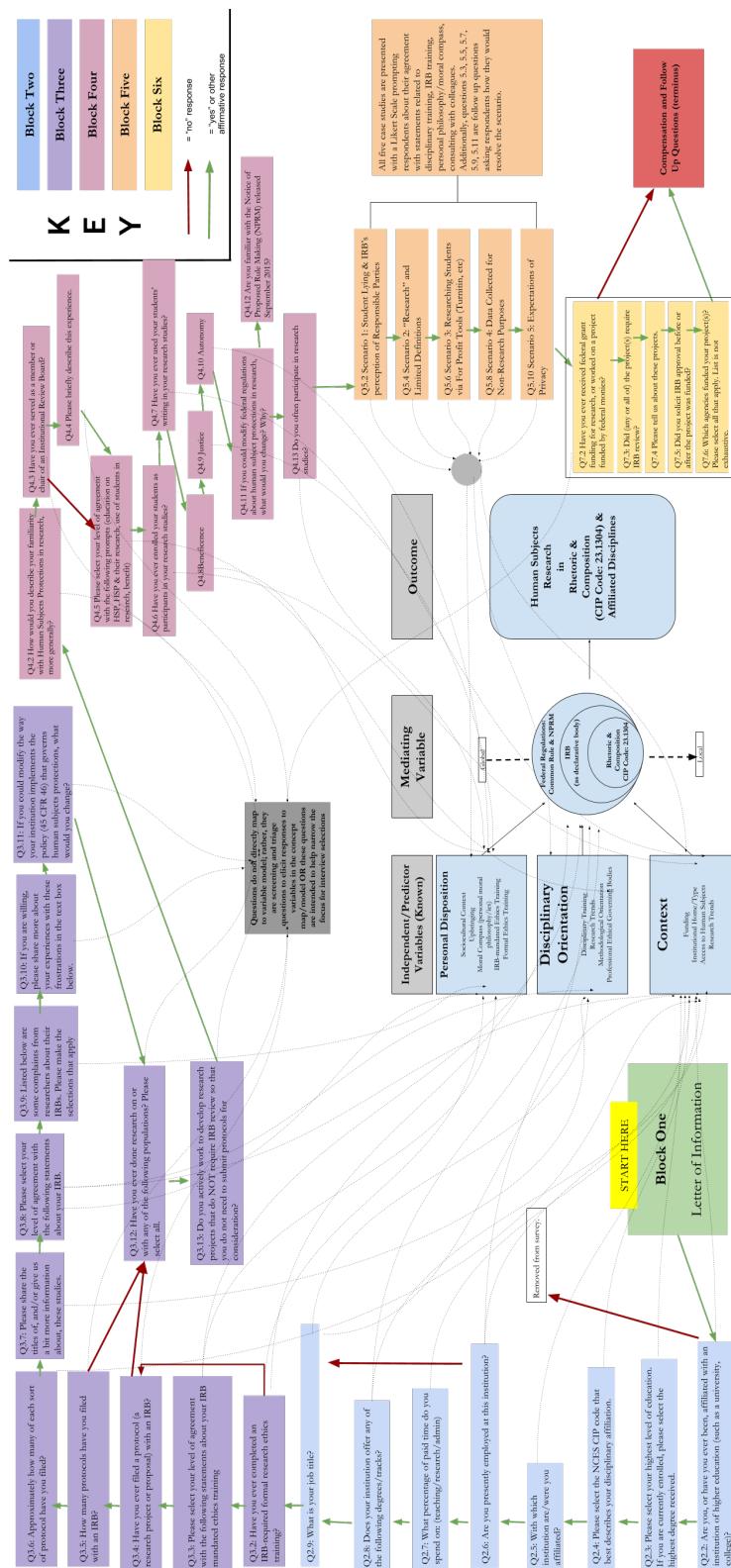
Q7.2 Would you like to receive a \$10 Amazon gift card code in compensation for your time today?

- Yes, that'd be great (1)
- No, I'm all done. (2)

Q7.3 Please enter your name and email address below. If you've indicated you'd like to be compensated, please note that codes are emailed each Saturday. If you do not receive the code within one week, please email jhillen@usf.edu. Thank you for your time and for sharing your expertise!

Preferred Name (1)
Preferred Email (2)

Appendix G: Map Connecting Survey Questions to Variables



Appendix H: CCCC Guidelines for Ethical Conduct of Research

2/5/2017

CCCC Guidelines for the Ethical Conduct of Research in Composition Studies

CCCC Position Statement

A statement on an education issue approved by the CCCC Executive Committee

CCCC Guidelines for the Ethical Conduct of Research in Composition Studies

Conference on College Composition and Communication, November 2003, revised March 2015

Preamble

The CCCC represents teachers and researchers of composition and communication in all possible genres, media, contexts, and exigencies; for the purpose of these guidelines, "writers" and "writing" will be all-encompassing, and the term "researcher" will refer to anyone who undertakes a study. We embrace numerous subfields, many of which have also issued their own ethical statements and have published commentary about conducting research that should be consulted. As members of the CCCC, we share a commitment to protecting the rights, privacy, dignity, and well-being of the persons who are involved in our studies, whether as participants or co-researchers. These guidelines are intended to assist researchers in fulfilling this commitment.

The following guidelines have been informed by U.S. Federal policies, regulations, and laws on the ethical conduct of research;¹ however, they do not replace or supersede them. Researchers who conduct studies outside of their home countries should also refer to the policies, regulations, and laws that govern the locales where the research takes place. The U.S. Office of Human Research Protections maintains a listing of international standards that may be consulted.²

The following guidelines apply to all efforts by scholars, teachers, administrators, students, and others that are directed toward publication of a book or journal article, presentation at a conference, preparation of a thesis or dissertation, display on a website, or other general dissemination of the results of research and scholarship. The guidelines apply to formally planned investigations. They likewise apply to emergent studies that discuss the writers and unpublished writing that researchers encounter in other ways, such as when teaching classes, holding student conferences, directing academic programs, conducting research in nonacademic settings, or going about their professional, civic, and personal lives.

U.S. Federal policy allows an exception for studies that researchers conduct solely for the purpose of improving their own practice, or solely for discussion within their own institution. To confirm that a study falls under the exception, researchers should follow local review processes. Moreover, even in studies confirmed as exceptions (granted an exemption), CCCC members carefully protect the rights, privacy, dignity, and well-being of their participants and co-researchers. These guidelines suggest ways to accomplish this goal.

Compliance

As researchers, we learn about and comply with all policies, regulations, and laws that apply to our studies. Many institutions have an Institutional Review Board (IRB)³ or alternative review process to which we submit our plans for advance review and approval. We then conduct our studies in accordance with the approved research plans. We also confirm with the IRB or alternative review committee if we believe a proposed study should be allowed an exception (granted an exemption). If we work at or are students at an institution without an IRB or alternative review process, then we contact colleagues at other institutions so we can learn about and follow procedures that IRBs require.⁴

Although we comply with the final decision of our IRBs or alternative review processes, we recognize that members of the review committee may need to be educated about the particular methods and methodologies of writing research. As researchers, we negotiate with committeees about IRB requirements or restrictions that hamper research unnecessarily and without benefit to participants. Moreover, we engage in ongoing conversations with regulatory agents to advise them in developing policies, regulations, and laws that take into account the methods and methodologies of writing research.

We acknowledge that mere compliance with policies, regulations, and laws does not necessarily guarantee the ethical conduct of research (see Maintaining Competence).

Maintaining Competence

<http://www.ncte.org/ccccc/resources/positions/ethicalconduct>

1/7

As researchers, we strive to refine our competence and to keep apprised of ongoing ethical discussions for several reasons:

1. Understandings of and definitions of ethical research practices are constantly negotiated among members of a discipline or subfield;
2. New experiences among researchers and participants may raise new ethical issues; and
3. Formal policies, regulations, and laws continually evolve (See the "Selected Bibliography" section).

We assure that we are appropriately trained and prepared to conduct the studies we undertake, and we likewise assure that our co-researchers and assistants are appropriately trained and prepared. Training and preparation may include activities such as enrollment in classes, review of relevant published research and methodological discussions, and consultation or collaboration with other experienced researchers.

Researchers who are supervisors of and/or collaborators with novice researchers (such as undergraduates, graduate students, postdoctoral scholars, colleagues new to a discipline/subfield, and participant-researchers) should maintain frequent and open discussion of research procedures with those in their charge as the studies are conducted and disseminated.

Recruiting

Some studies may include populations who may be considered vulnerable and protected, including but not limited to children and adolescent minors, students, prisoners, pregnant women, military veterans, disenfranchised groups, persons with disabilities, and adults with legal guardians. In these cases, as researchers, we consult carefully with the IRB/reviewing agencies, colleagues, and (when allowed) with prospective participants to develop a protocol that protects their rights, privacy, well-being, and especially, dignity.

When conducting studies with individuals who are perceived to have less institutional power or others whose well-being depends on the researcher's opinions, decisions, or actions, we take special care to protect prospective participants from adverse consequences of declining or withdrawing from participation.⁵

To avoid situations in which students feel that their decision to participate (or not) in a study might affect their instructor's treatment of them, we recruit participants from other classes or other sources. If the topic of the research or other special circumstances require that the study involve our own students, then we use measures to avoid coercion or perceived coercion, such as confirming students' voluntary participation after grades are submitted or asking colleagues to conduct the actual data collection.

Obtaining Informed Consent

When asking people to volunteer to participate in (or in the case of co-researchers or novice researchers, collaborate in the design and execution of) a study, we provide participants a copy of the consent document and explain the study in a way that enables the participants to understand the following points:

1. The purpose of the research and its possible benefits.
2. Why the participant was recruited.
3. What the participant will be asked to do and how long it will take.
4. What we plan to do with the information or data obtained from participants.
5. Any potential discomforts, harms, or risks one might incur as a result of participating and how we plan on minimizing any potential discomforts, harms, or risks.
6. Any potential benefits (separate from compensation, if any) participants may experience from the study.
7. Whether or not we intend to include data in research reports that would render participants identifiable. (We always honor participants' requests that disseminated reports contain no personally identifiable information, including data that would make them identifiable to persons familiar with the research site. We acknowledge that sometimes a conflict may emerge when some participants want to remain anonymous and others want to be recognized, and we resolve the issue before presenting, publishing, or reporting on the study.)
8. How confidential data will be stored and who will have access to confidential data and materials, particularly in the case of research teams/co-researchers. If data and materials are to be included in an archive, we receive explicit consent (see "Conducting Studies Involving Archival Work").

In addition, we emphasize the following points:

1. Participation is completely voluntary.
2. Participants can decline to answer any questions instead of withdrawing from the study.
3. Participation is an ongoing and constantly negotiated process between the participants and the researcher or research team.

4. If anonymity for participants is not possible, then we are explicit about this constraint.
5. Participants may withdraw at any time without penalty or loss of benefits to which they are otherwise entitled.

For studies involving vulnerable populations who have parents or legal guardians, we obtain written permission from the parents or legal guardians in addition to the assent of the prospective participant or we seek permission from IRBs for a waiver of consent. If required, we also gain the permission of sponsoring institutions, such as public schools or private workplaces. We are careful to determine that whatever terms of access we agree to are consistent with the stipulations of applicable IRB regulations and the provisions of these guidelines.

We always provide those invited to participate in a study an opportunity to ask questions. When asked questions by participants during or after a study, we reply in a timely manner.

In the case of classes in which undergraduate and graduate students are collaborators in research projects, we guide their work toward best practices and acknowledge their collaboration in any presentation, publication, or report.

These guidelines concerning informed consent are intended to complement (not replace) any additional requirements of applicable policies, regulations, and laws.

Conducting Studies Involving Classes

When conducting studies involving classes, we give primary consideration to the goals of the course and fair treatment of all students. Toward that end, we take the following measures, whether the students are members of our own classes or are from classes taught by colleagues:

1. We design our studies so that participation is completely voluntary.
2. We assure that volunteering, declining to volunteer, or deciding to withdraw after volunteering will not affect a student's grade.
3. We assure that pursuit of our research goals will not hinder achievement of the course's educational goals.
4. We assure that all students will receive the same attention, instruction, support, and encouragement in the course. For example, studies may be conducted so that instructors do not know who participated or not until the class is over.
5. We assure that reports on the research do not include information about students who did not volunteer.
6. If there is a possibility that one or more of the volunteering students have changed their minds since the study began, we obtain confirming consent at the end of the course.
7. In the case of classes in which undergraduate and graduate students are collaborators in research projects, we guide our work toward best practices and acknowledge their collaboration in any publication.

Conducting Studies Outside the Classroom

When conducting studies in sites outside the classroom, we give primary consideration to the contexts of our research and to the fair treatment of all participants. Toward that end, we take the following measures:

1. We design our studies so that participation is completely voluntary.
2. We assure that volunteering, declining to volunteer, or deciding to withdraw after volunteering will not affect participants or a participant's standing at the research site.
3. We assure that pursuit of our research goals will not hinder achievement or operation at our research site.
4. We coordinate and discuss our research plan with site leaders/administrators before proceeding with research.
5. We assure that reports on the research do not include information about participants who did not volunteer.
6. In the case of research projects in which participants, undergraduate, and/or graduate students are collaborators, we guide our work toward best practices and acknowledge their collaboration in any publication.
7. When conducting research with protected/vulnerable populations, we follow federal guidelines to ensure our research is ethical and legal.

Conducting Studies Involving Digital/Online Media

When conducting studies involving digital/online media, we are particularly aware that researchers' and participants' expectations regarding the public/private, published versus unpublished documents, informed consent, sensitivity of the data, vulnerability of the participants, identifiability of the data, and other aspects of the research study must be negotiated.⁶ We recognize that these expectations are often contingent and may shift in response to revised trajectories in disciplinary research practices; newly introduced, innovative technologies; and the multifaceted histories that specific digital/online communities have experienced. As a result, we should explicitly justify our research choices and our positioning as

researchers when we plan, conduct, and publish our studies.

We do not assume, for example, that all digital/online communications are available for research studies simply because they can be accessed. Nor do we assume that we must always receive express permission from authors before citing their digital/online materials. A balance must be struck between these extremes, a balance that is informed by institutional regulation, consultation with published research and other researchers, discussion with members of the online communities themselves, and sensitivity to and understanding of the expectations that authors (including student authors) may have had in posting their materials.

We are also aware that promising anonymity to participants may be impossible when conducting certain digital/online studies. Communication technologies may not be secure enough for discussing sensitive topics. Likewise, search engines have become increasingly powerful in their capacity to locate text strings. Materials that are protected behind a firewall or password today may become readily available tomorrow as passwords are compromised, the mode of access changes, a database is archived, or other modifications in technology occur that are beyond the researcher's control. Instead, we may need to integrate practices that take into account these possibilities, such as finding alternate means of communicating with participants; turning off the collection of IP addresses in online survey services; asking participants' permission to use real names; allowing participants to review interview data before employing them; and so on.

Researchers interested in digital/online media are encouraged to consult the more extensive ethical guidelines published by researchers in these subfields, including those by the Association of Internet Researchers. In addition, they are encouraged to consult the many and lengthy discussions found in the provided Bibliography.

Conducting Studies Involving Archival Work

Conducting Studies Involving Archival Work As researchers, we often consult library resources, museums, and other archival materials. These already collected materials are not governed by IRB review. However, we are aware that some archival materials may have been assembled without ethical consideration for all cultural stakeholders involved, and that understandings of ethical standards may shift over time. As researchers, we are alert to these concerns and debates, and when we choose to use these archival materials, we strive to represent them and their multilayered, multivoiced contexts accurately and fairly.

The following guidelines speak to studies that involve living participants, plus the intent to generate, construct, and curate an archive. Such a study typically requires an IRB's/review committee's approval. For example, as researchers, we may collect and analyze a large sample of student or professional documents, and then make the documents available for use by other researchers. When we plan to build a new archive as a component of a study, we need to negotiate several considerations:

1. As researchers, we are sensitive to our participants as cultural stakeholders in a long-term archive of materials. We explicitly ask for permission to include a participant's materials in an archive. In some cases, stakeholders may actively collaborate on building the archive. Negotiations over what materials to include and exclude should be explicit, and they may need to consider the archival materials' impact on the descendants of those whose work is included.
2. Libraries and other institutional repositories may not be able to accept materials from studies involving human participants unless their own versions of permission forms are collected in addition to informed consent letters. (These additional permissions often address intellectual property and access issues.) As researchers, we consult early in the process with the intended host to determine what conditions may apply and what procedures to follow.
3. We must balance accessibility to the archive with both the participants' and the future researchers' rights to privacy. When we create archives, we organize the artifacts and the information about their provenance so that the organization is clear and consistent. If we create or adopt data-mining tools for digital archives, we facilitate access to the artifacts without violating the researchers' privacy. When we compile culturally sensitive records, we are careful to follow procedures to maintain participants' anonymity when permission to use real names is not granted (for example, by removing identifying information and/or by embarguing materials until an agreed-upon date).
4. We acknowledge the impact that different cataloging, data-mining, coding, and other software may have in shaping our access to and interpretation of archival information. When building an archive, and when reporting on materials in an archive, we explicitly name and justify the relevant software used.
5. We strive to ensure the proper long-term storage and preservation of artifacts, whether they are physical or digital materials.

Conducting Studies Involving Assessment Data

Studies involving assessment data may include outcomes data, portfolio evidence, survey data, directed self-placement scores, interviews, and so on. According to U.S. Federal policy, if such studies are conducted solely for the purpose of internal assessment (e.g., placement testing, improving a program), they are typically considered exceptions. As researchers, we confirm the exception (request an exemption) as well as any local requirements (e.g., anonymity of data) with our

IRB/review committee.

If we plan to present, publish, or report on assessment data beyond the local institution, then we submit a protocol for advance review and approval by the IRB/review committee.

Using Unpublished Writing Collected Outside of an IRB-Approved Study

When studying unpublished writing samples that have been collected outside of a study approved by an IRB or other process, we, (and, when applicable, our undergraduate/graduate researchers, collaborators, and colleagues), determine whether our planned use of these samples is consistent with the policies governing research at our institutions and, if different, the institution at which the samples were collected.

When using unpublished writing samples for reasons outside of research purposes (e.g., textbook samples, writing samples collected for writing consultant or teacher training), we determine whether our use of these samples is consistent with the policies governing student privacy at our institutions, and, if different, the institution at which samples were collected.

We continue to apply to these materials the same ethical guidelines we employ when analyzing and reporting on data collected under the auspices of an IRB-approved study. We are also mindful that copyright regulations may apply to these materials.

Quoting, Paraphrasing, and Reporting Statements

In our publications, presentations, and other research reports, we quote, paraphrase, or otherwise report unpublished written statements only with the author's permission. That permission may be indicated by written consent, or (in digital/online research) through click-through approval on a form, and/or through another procedure approved by an IRB or alternative review process. We likewise seek permission to quote, paraphrase, or otherwise report a spoken statement that a participant has made with the expectation that it will remain private. U.S. Federal policy allows an exception to be made for spoken statements made while participants are speaking in or attending a public forum (the definition of which may be contingent upon institutional regulation, previously published research, and the expectations of the participants involved).

When quoting, paraphrasing, or reporting unpublished writing and when reporting (with permission) oral statements made in private, we respect the writer's or speaker's wishes about whether or not to include the writer's or speaker's name or identifying information. When the writer or speaker is a member of a vulnerable/protected population with a parent or legal guardian, we obtain permission from a parent or legal guardian in addition to the assent of the prospective participant. When we use an informed consent process approved by an IRB or similar committee, we have obtained the necessary permission.

We do our best to represent language/meaning accurately, understanding that meaning-making is often negotiated, shifting, multivoiced, and changeable over time. We report written and spoken statements in ways consistent with the collected data, and avoid deliberately misrepresenting participants' words. We provide contextual information that will enable others to understand the statements the way the writer or speaker intended. When in doubt, we check the accuracy of the reports and interpretations with the writer or speaker. We are especially sensitive to the need to check interpretations when the writer or speaker is from a cultural, ethnic, or other group different from our own.

When discussing the statements that we quote, paraphrase, or otherwise report, we do so in ways that are fair and serious, and that avoid harm.

Describing Individuals and Groups

We describe individuals and groups fairly and accurately, in ways that are accountable to the data, observation, or other evidence on which the descriptions are based. We describe people in ways that are fair and serious, avoid harm, and protect privacy.

Using Video, Audio, Photographs, and Other Identifiable Representations of Participants

Because video, audio, photographs, and other representations (e.g., cartoons) of participants in the studies that we conduct allow individuals to be identified, we include them in conference presentations, publications, or other public displays only with written consent (or other approved procedure for receiving consent) from all persons whose voices and/or images were recorded or shown. When the person recorded is a member of a vulnerable/protected population with a parent or legal

guardian, then we obtain permission from the parent or legal guardian in addition to the assent of the prospective participant. When we use an informed consent process approved by an IRB or similar committee, we have obtained the necessary permission.

One exception allowed by U.S. Federal policy are instances when the recording was made while participants were speaking in or attending a public forum (the definition of which may be contingent upon institutional regulation, previously published research, and the expectations of the participants involved).

Working with Co-Researchers and Co-Authors

Research studies often rely upon the assistance of many people, not only the participants, but also those who organize and perform data collection, those who assist with coding, those who analyze information, and so on. We are generous in acknowledging these contributions, whether by name or general category (e.g., reviewers of the manuscript).

In some cases, participants in and/or other contributors to a study should be considered co-researchers and/or co-authors. Determining who should be a co-researcher and/or co-author depends on disciplinary convention, institutional regulation, and local expectations. Ideally, participants who become co-researchers and/or co-authors benefit, learn, and gain insight/knowledge through the collaborative process. We strive for reciprocal relations. Participants who become co-authors should be made aware that a designated "author" on a publication has legal privileges (e.g., copyright) and ethical obligations for the acceptable conduct, representation, and/or dissemination of the study.

Co-researcher status and/or co-authorship may be determined at the beginning of the study, or they may emerge during the course of the study. In either case, expectations about who can use what data, and under what circumstances, should be negotiated and made explicit. Many institutions have a representative, committee or office (such as the IRB office or Ombuds Office) that can assist in negotiating these expectations to avoid conflicts.

Working with Editors/Publishers

When accepting manuscripts for publication or other public display, editors and publishers should assist in maintaining ethical standards without unduly burdening the researcher. For example, editors/publishers should doublecheck for occasions where identifying information has been incorporated accidentally into a manuscript, or for representations of participants that may be misunderstood.

Publishers also recognize the difference between informed consent letters (as approved by an IRB or other reviewing committee) and copyright release permissions. If anonymity has been promised to participants, it is inappropriate to demand copies of the signed informed consent letters.

Indicating Possible Financial Conflicts of Interest

In accordance with U.S. Federal guidelines, for any presentation, publication, or report on a study, the researcher(s) shall make full disclosure of all possible financial conflicts of interest with an entity connected to the research topics. (Research conducted under the auspices of other nations should accommodate those nations' regulations regarding conflicts of interest as well.) The following exceptions are allowed:

1. Amounts less than \$5,000 per calendar year per entity and associated entities
2. Book royalties
3. Instances when an author's or speaker's stated affiliation is with the entity or associated entities.

This policy applies to all researchers associated with the study. Presenters at a conference will also disclose if an interested entity has paid some or all of the expenses related to performing the study and/or attending the conference.

Full disclosure can consist of statements in the methods section, acknowledgements, footnotes/endnotes, or, in the case of a presentation, a statement on a slide or handout. The exact amount of financial remuneration need not be disclosed, but, except for the cases indicated above, the fact that remuneration was received must be stated.

Selected Bibliography

CCCC has compiled a selected bibliography of sources on the ethical conduct of research involving human participants. It is available at <http://www.ncte.org/ccccc/resources/positions/ethicalconductbiblio>

Notes

¹Information about these policies, regulations, and laws can be found at the U.S. Department of Health & Human Services, Office of Human Research Protections, [\[http://www.hhs.gov/ohrp/\]](http://www.hhs.gov/ohrp/)

²The International Compilation of Human Research Standards, [\[http://www.hhs.gov/ohrp/international/index.html\]](http://www.hhs.gov/ohrp/international/index.html)

³An institutional review board is a committee established under the federal regulation for the protection of research participants (45 CFR 46). Each IRB is legally responsible for assuring that all research involving human participants that is conducted under the aegis of its institution complies with this regulation. For more information, visit the website of the federal Office for Human Research Protections: [\[http://www.hhs.gov/ohrp/\]](http://www.hhs.gov/ohrp/)

⁴In several cases, institutions without IRBs have made arrangements with a local institution with an IRB to conduct the reviews.

⁵This sentence is adapted from the American Psychological Association Ethics Code, 3.08. [\[http://www.apa.org/ethics/code/\]](http://www.apa.org/ethics/code/)

⁶This section has been informed by work by Heidi McKee & James E. Porter. "The Ethics of Digital Writing Research: A Rhetorical Approach." College Composition and Communication 59.4 (2008): 711–749, and by the Association of Internet Researchers' 2002 and 2012 reports, Ethical decision-making and Internet research: Recommendations from the AoIR ethics working committee, located at [\[http://aoir.org/ethics/\]](http://aoir.org/ethics/). Researchers may also be interested in the Statement of Principles and Best Practices by the Oral History Association, located at [\[http://www.oralhistory.org/about/principles-and-practices/\]](http://www.oralhistory.org/about/principles-and-practices/)

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Appendix I: Criteria for Exempt & Expedite Approvals, pre-2018 Rule

2/5/2017

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(b) Unless otherwise required by department or agency heads, research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from this policy:

- (1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
- (2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
 - (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
- (3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if:
 - (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
- (4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
- (5) Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:
 - (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.
- (6) Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant

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Office for Human Research Protections

OHRP Expedited Review Categories (1998)

Categories of Research That May Be Reviewed by the Institutional Review Board (IRB) through an Expedited Review Procedure[1]

Applicability

- A. Research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review procedure authorized by 45 CFR 46.110 and 21 CFR 56.110. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.
- B. The categories in this list apply regardless of the age of subjects, except as noted.
- C. The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects= financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.
- D. The expedited review procedure may not be used for classified research involving human subjects.
- E. IRBs are reminded that the standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review--expedited or convened--utilized by the IRB.
- F. Categories one (1) through seven (7) pertain to both initial and continuing IRB review.

Research Categories

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

§46.406 Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition.

HHS will conduct or fund research in which the IRB finds that more than minimal risk to children is presented by an intervention or procedure that does not hold out the prospect of direct benefit for the individual subject, or by a monitoring procedure which is not likely to contribute to the well-being of the subject, only if the IRB finds that:

- (a) The risk represents a minor increase over minimal risk;
- (b) The intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations;
- (c) The intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition; and
- (d) Adequate provisions are made for soliciting assent of the children and permission of their parents or guardians, as set forth in §46.408.

§46.407 Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.

HHS will conduct or fund research that the IRB does not believe meets the requirements of §46.404, §46.405, or §46.406 only if:

- (a) the IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children; and
- (b) the Secretary, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, education, ethics, law) and following opportunity for public review and comment, has determined either:

- a. (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
- b. Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

- a. (a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
- b. from other adults and children [2], considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

3. Prospective collection of biological specimens for research purposes by noninvasive means.

Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject=privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)
6. Collection of data from voice, video, digital, or image recordings made for research purposes.
7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)
8. Continuing review of research previously approved by the convened IRB as follows:
 - a. where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or
 - b. where no subjects have been enrolled and no additional risks have been identified; or
 - c. where the remaining research activities are limited to data analysis.
9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

[1] An expedited review procedure consists of a review of research involving human subjects by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB in accordance with the requirements set forth in 45 CFR 46.110.

[2] Children are defined in the HHS regulations as "persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted." 45 CFR 46.402(a).

Source: 63 FR 60364-60367, November 9, 1998.

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