SIGNs, SHOCKs, AND EFFECTS OF INSTITUTIONAL REVIEW PROCESSES ON 
QUALITATIVE RESEARCH: COMPLEXITIES ALL THE WAY DOWN

DISSERTATION

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This dissertation research investigates the concept and practices of ethical responsibility in the conduct of research at universities. Recently enacted federal mandates for institutional accountability require individual researchers to demonstrate responsibility in the conduct of research by complying with prescriptive procedures that define ethical practices according to ostensibly objective standards and assume that responsibility is demonstrable. Federal policies and regulations do not address the ways qualitative researchers working in educational settings might respond to more nuanced questions of ethical responsibility. There exists, then, a gap between federal and institutional requirements and the behavior researchers demonstrate as they interpret and apply standards for human subject research within their own work. In this study, I consider consistencies and disparities between researchers’ obligations to comply with federally mandated standards as well as institutional requirements and researchers’ ethical responsibilities to foreground the protection of human subjects in research.

The study is multi-sited and takes a postmodern emergent approach to investigating questions of what is meant by the notion of responsibility in research, how ethical responsibility might be demonstrated by researchers in academic communities, and in what ways institutional review processes affect underlying ethical principles in responsible conduct of research. Standpoint epistemologies inform the construction and
interpretations of researchers’ actions, beliefs, and values. The empirical work traces
effects of institutional review boards in an ethnographic study carried out for more than
two years and across three subject positions.

The study concludes with a case study focusing on a teacher education program
that balances ethical principles of justice and autonomy. The case study report is
grounded in earlier fieldwork and translates theoretical knowledge into action. The goal
of culminating project is to demonstrate an empirically based model for initiating
change in the often troublesome relationships between IRBs and education researchers.
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CHAPTER 1

INTRODUCTION

This study begins with a question of what it means to be responsible\(^1\), progresses as a somewhat desperate effort to hold together impossible things that all seem true and necessary simultaneously\(^2\), acknowledges that we can have no easy answers to what counts as acting responsibly\(^3\), thinks and unthinks\(^4\) concepts of responsibility and accountability, and concludes by generating a distinctive account\(^5\) of the nature of responsibility in the conduct of research. I find that a study of what it means to be responsible in the conduct of research can be described as a becoming of discontinuities and uncertainties. This study reveals complexities inside, outside, and all the way down.

As the study progressed and as data emerged, I refined the research questions, returned on numerous occasions to research sites, and adopted an iterative approach to research methods. The research design evolved in a similar fashion. The overall complexity of the study called for a “moving-beyond-postmodern” organization to

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\(^1\) Gayatri Spivak asks “What is it, then, to be responsible to a changeful thought on the question of responsibility?” (1994, p. 19).

\(^2\) Donna Haraway asserts: “The Cyborg Manifesto was…a somewhat desperate effort in the early Reagan years to hold together impossible things that all seemed true and necessary simultaneously” (2004, p. 3).

\(^3\) Naomi Scheman argues that for “Those with perverse identities…can have no easy answers to what counts as acting responsibly; we have no straight paths to follow” (1991, p. 196).

\(^4\) Corlann Gee Bush (1983, p. 151) proposes thinking, to be, and unthinking, to free.

\(^5\) Sandra Harding makes a case that standpoint theorists work from different and naturally occurring locations of social relations. “They do not determine [the accounts], but only ‘tend to generate’ accounts different from the dominant ones in distinctive ways” (1997, p. 384).
presentation of the data and of the reporting. Details, repetitions, and even redundancies, saturated the study.

The study is ethnographic in that I “attempt to understand another life world” (Buch & Staller, 2007, p. 187), and I serve as the primary research tool. I engaged myself over an extended period of time and immersed myself into settings where discourses naturally occurred as the ground from which practices and themes related to ethical responsibility emerged.

The context for the study, the research methods for investigation, the presentation of projects reports, and the meta ethnographic accounting are marked by tensions between “what might be” and “what is.” I adapted the research methods and practices to transform the flowing and productive tensions into a responsible accounting of the research. There was no straight path to follow for this investigation of responsible conduct in research. Thus, research questions guided my methods and practices, and this writing, although encumbered by the risks of being outside traditional norms, traces my path, my lines of flight.

Stating the Research Problem

This dissertation research investigates the concept and practices of ethical responsibility in the conduct of research at universities. Recently enacted federal

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6 Patti Lather works tensions between “getting smart” and “getting lost” in Getting Lost: Feminist Efforts toward a Double(d) Science, 2007. Lather discusses “turn[ing] life into a means to knowledge, fuller of future by risking not being understood as one writes outside traditional norms” (p. 18).

7 Deleuze and Guattari (1987) describe the developmental relationship between rhizomes and lines of flight in their discussion of rhizomes. They write: “There is a rupture in the rhizome whenever segmentary lines explode into a line of flight, but the line of flight is part of the rhizome. These lines always tie back to one another. That is why one can never posit a dualism or a dichotomy, even in the rudimentary form of the good and the bad” (p. 9).
mandates for institutional accountability require individual researchers to *demonstrate* responsibility in the conduct of research by complying with prescriptive procedures that define ethical practices according to ostensibly objective standards and assume that responsibility is demonstrable. Federal policies and regulations prioritize randomized trials and experimental methods as privileged ways for educational researchers and institutions to design studies and conform to regulations, thereby making assumptions about the nature of knowledge and purposes of research. Federal mandates do not address the ways individuals working in educational settings might respond to more nuanced questions of ethical responsibility.

There exists, then, a gap between federal and institutional requirements and the behavior researchers demonstrate as they interpret and apply standards for human subject research within their own work. In this study, I consider consistencies and disparities between researchers’ obligations to comply with federally mandated standards as well as institutional requirements and researchers’ ethical responsibilities to foreground the protection of human subjects in research. I investigate operations of institutional power, authority, and accountability mechanisms (ways in which mandates are translated into practice requirements) in relationship to individual responsibilities in the conduct and practices of research. This gap that I investigate between requirements and practices carries forward to the distinctions I draw between accountability and responsibility, and to the proposal I make to entertain a notion of *recounsability* in the conduct of research.

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8 The online *Oxford English Dictionary* (1989) gives five definitions for *demonstrate*. The one I use in this study states: “To show or make evident by reasoning; to establish the truth of (a proposition, etc.) by a process of argument or deduction; to prove beyond the possibility of doubt.”
Asking Questions

In the face of persistent demands for accountability, such as those in federal mandates, and increased calls for responsibility in the conduct and practices of research, I cannot not consider both if, and how, regulatory and institutional demands for accountability are related to individual perceptions of responsibility. Public policy writers suggest that the word accountability has the “capacity to stand in for” responsibility (Dubnick & Justice, 2004, p.5), treating the words as synonymous. This idea moves against the way Gayatri Spivak “formalize[s] responsibility: it is that all action is undertaken in response to a call (or something that seems to us to resemble a call) that cannot be grasped as such” (1994, p.22).

In her writing, Spivak (1993/1996; 1994) identifies elements of complexity and ambiguity in responsibility and states, “ethics is not a problem of knowledge but a call of relationship” (1993/1996, p. 186). Naomi Scheman warns that there are “no easy answers to what counts as acting responsibly; we have no straight paths to follow” (1991, p.224). Donna Haraway insists, “Feminist objectivity is about limited location and situated knowledge, not about transcendence and splitting of subject and object. In this way we might become answerable for what we learn to see” (1988/1991, p. 190). Lorraine Code claims that responsible knowing and actions that count as responsible are complex ideas, but posits, “‘responsibility’ can allow emphasis upon the active nature of knowers/believers” (1987, p.51).

Spivak’s opening question and her suggestion of a changeful thought in regard to responsibility provoked the emergence of empirical, theoretical, and methodological
questions that guided the research along pathways to exploration. Research questions for the study responded to concerns of researchers who were in some ways situated in positions of marginality (Harding, 1992). As a researcher, I investigated from insider and outsider positions (Collins, 1986; Okin, 2000) in order to develop an understanding of the complicated workings (Fuss, 1991) of how responsibility and accountability operate in and through institutional review processes; in so doing, I focus attention on the processes and procedures of institutional review boards (IRBs). As the study progressed, I adopted a feminist standpoint for theorizing about the provisional constructions that evolved from the “historically shared, group-based experiences” of my own and the participants in the study (Collins, 1997).

Holding Together Concepts of Responsibility and Accountability

This research study has empirical and theoretical aspects. There are five projects involving human subjects, data gathering, and analysis which constitute the empirical components of the study. The empirical projects take an active approach to knowing and believing. I theorize complexities and ambiguities of both responsibility and accountability as assemblages of multiplicities. I consider demonstrations of responsible actions and behaviors to investigate smoothing flows and intensities in the practices and conduct of education research. My continuing goals are to theorize and describe an assemblage where smooth spaces of responsibility are striated and striated spaces of accountability are smoothed. I take as my guiding theoretical question Spivak’s (1994, p.19) call: “What is it,

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9 Philosophical theorists, Gilles Deleuze and Felix Guattari (1987) develop the concept of smooth and striated spaces. Smooth and striated spaces “…in fact exist only in mixture; smooth space is constantly being reversed, returned to a smooth space” (Deleuze & Guattari, 1987, p. 474).
then, to be responsible?” I respond to the call of responsibility as a researcher by investigating the actions and behaviors of students, faculty members, and administrators involved in education research.

My interest in studying the concept of responsibility in relationship to traditional understandings of scientifically based research emerged as part of my interest in ethics. This interest in ethical questions and the ways that individuals resolve ethical dilemmas predates experiences in graduate school. More recently, my interest in ethics was piqued as a result of first-hand experience as a graduate assistant. As I was preparing applications for human subjects research to be submitted to the IRB on behalf of the Graduate School at Ohio State and for The Carnegie Initiative on the Doctorate, I was struck by both the complexity and the significance of the responsibility researchers assume in relation to human subjects when administering even seemingly harmless protocols (Oakes, 2002) such as online surveys. During the IRB application process, I became aware of the discrepancies between how differently researchers, albeit working on the similar projects, view their particular responsibilities and respond to more uniform requirements for accountability.

There is a considerable body of anecdotal and empirical research identifying issues and challenges that qualitative researchers in particular have faced when dealing with IRB processes (Bruner, 2004; Gordon, 2003; Labott & Johnson, 2004; Lincoln & Tierney, 2004; Milne, 2005). While there are conflicting perspectives on the nature, structure, and functioning of IRBs represented in the literature, one explanation for these differences may be the result of the various ways IRB procedures and requirements have been implemented in institutions. Institutions receiving federal
funding\textsuperscript{10} are required to adhere to federal mandates. Another explanation might be the rapid growth and change in emphasis on research. Based upon a review of the literature related to the development and structures of IRBs in general, I study the particular situation of institutional review processes at Ohio State in order to offer a description of practices I have observed in a specific location.

\textbf{Acting Responsibly}

Sandra Harding has considered the science question in ways that may be helpful to social scientists engaging with issues that require categorizing their work as scientific (or not). In her overview of challenges “emerging in one form or another from recent analyses of science” (1991, p. 9), Harding points out there is an “influential tendency in conventional thought [that] there is only one standard for what counts as science, and that [standard] is provided by the natural sciences” (1991, p. 15). The questions Harding asks and the thinking she offers can be applied both to questions in this study, “What counts as ethical responsibility?” and also to questions being asked by qualitative researchers, “What counts as scientific research?”

In miming Spivak’s responsibility question and Harding’s science question to ask my own about ethical responsibility, I call attention to practices in Western research projects, which seem to privilege some ways of thinking about ethical responsibility in research while excluding other ways. The work that Harding has done developing the \textit{science question in feminism} and the theories she explicates contribute to a greater body of feminist literature addressing these issues. In my investigation of ethical

\textsuperscript{10} Institutions that do not receive support from federal agencies are not affected by sanctions for non-compliance in the same ways as institutions that do receive federal support.
responsibility in research, I become my primary research instrument and call upon Harding and other contemporary feminist epistemologists (Haraway, 1988; Scheman, 2001; Tanesini, 1999) to examine and uncover dynamics of ethical issues, constraints, and practices in research which recall questions similar to those asked by feminists about science.

The issues I address in this work coalesce around operations of power and authority, and mechanisms for monitoring accountability in relationship to researcher’s ethical responsibilities in the conduct and practices of research. Ethics are an integral part of responsibility in the conduct of research (Callahan, 2003; Kirsch, 1999; Peach, 1995; Solomon, 1995); however, the systems of ethics and moral codes that researchers follow are not visible in and of themselves. Acting responsibly and responsible conduct in research suggest observable behaviors or behaviors that researchers might describe as a way of demonstrating responsibility. Further, individual behaviors are more observable and describable than values (ethics) or codes of society (morality).

While I may be able to interpret ethical principles and morality from behaviors, responsibility in research conduct and practices become the doubled focus of investigation for my study. My theoretical questions attend to the behaviors and conduct of researchers, and my methodological questions address effects of behaviors and practices of institutional reviewers and regulatory officials. On the one hand, I am looking at ways that researchers interpret and follow federal regulations and requirements for the responsible conduct of research, and on the other, I look at how
institutional review processes create signs, shocks and effects\(^\text{11}\) on the practices of qualitative researchers.

**Generating Different Accounts**

This study contributes to current literature by bringing together a constellation of inter-related concepts. I investigate responsible practices in the face of current demands for accountability and objectivity at a moment in history when some theorists are challenging ideas such as “intelligent design” and feminists, especially, are questioning the notion of traditional science as a definitive way of knowing in research. The findings from this research could be useful to graduate students and faculty researchers who have an interest in considering the influence of institutional power and authority on researchers’ understandings of responsibility and accountability. Other researchers might find this work helpful when questioning the real or perceived boundaries between IRB and researchers, where, on the one hand, researchers are held accountable to IRBs for their actions, and, on the other, they are responsible to human subjects for their safety and welfare.

This ethnographic study, which originates in and is based upon observations and experiences, contributes to the literature of qualitative research studies that investigate epistemological questions and challenge traditional notions of science as an idealized way of knowing. The study has the potential to contribute to literatures offering examples of counter-hegemonic methods in practice, as the investigation of IRBs turns institutional review processes “inside out to expose its critical operations and interior
machinery” (Fuss, 1991, p. 1). Following the insights of Diana Fuss (1991), I transgress inside and outside borders to make visible the interior weakness of institutional review processes that depend upon exclusions for strength.

Visiting and Revisiting Research Sites

The study was multi-sited, iterative, and began in April 2004. The study includes data gathered from five project sites. The five projects representing primary research sites emerged in sequence, and initially, each of the projects appeared to have a beginning and an ending point. However, all of the projects have continued beyond those intended ending points. I have bundled the projects into one study that has an arbitrary stopping place in order to summarize the work thus far. If the research could be likened to a journey, the present moment in time represents more of a layover, than a destination. The itinerary for such a journey would begin with work on two surveys for the Carnegie Initiative on the Doctorate, continue with two visits to the Teaching Research Ethics (TRE) workshop and two summer assignments teaching in the Summer Research Opportunities Program (SROP). As I was preparing for the second SROP experience, which is reported in the Undergraduate Student Research Experience (USRE, see Appendix B), I was becoming a member of the IRB at the university where I am a graduate student.

IRB procedures require that members sign confidentiality agreements that prohibit them from discussing the IRB proceedings outside of meetings. This was a disappointment to my research, and I developed the faculty survey in order to have a way of bringing to light some of the faculty concerns I was learning about through the IRB service. The College of Education Faculty Survey (COEFS) appeared to have tidy
beginning and ending points, and that project is reported in a realist tale as though there had been a clear end point. In fact, I have been working on a needs assessment project related to ethics training for graduate students, and during summer 2007, I will look at data from the faculty portion of the needs assessment project in relation to the COEFS.

The most identifiable research sites for the position statement were the first and second meetings of the Qualitative Inquiry Congress. Less identifiable sites for the Qualitative Inquiry Position Statement (QIPS) project were on websites of social science organizations and federal regulatory offices, and at gatherings of qualitative researchers. The fifth project emerged out of one such gathering – a presentation by Joan Sieber that was held for researchers interested in issues related to empirical research on ethics and human subjects. Sieber announced a call for case studies to be presented at a conference in July 2006. Based on my experiences with the IRB at Ohio State and an informal network of feminist researchers, I proposed the case study I report as the Professional Development for Teachers Project (PDPT, see Appendix E).

Emerging Ethnographic Research Study

I describe my research as ethnographic. Features of the study contributing to this description include the emergence of research questions, the iterative nature of empirical projects, and the “becoming” of this researcher as the primary instrument for investigation. The dominant research question asks what it means to be responsible in the conduct of research with human subjects. As I traveled through research sites, visiting and revisiting the somewhat discrete projects, supporting research questions that were derived from the main question shifted. The focus of the empirical question moved from investigating what the concept of responsibility meant to asking how
responsibility could be demonstrated. In Chapter Four, where I discuss findings from the study, I restate the beginning research questions as they emerged later in the writing process. This refinement of research questions as the study progressed resulted in part from returning to research sites and from seeing the “lived experiences, daily activities, and social context of everyday life” (Buch & Staller, 2007, p. 187) from different perspectives and through lenses adjusted to reveal different insights on successive visits. I present original and refined research questions at the close of Chapter Four.

I invoke the concept of “becoming” to describe this study and myself as a research instrument. I intend for this notion of becoming to carry the research and this researcher across and beyond traditional boundaries. The ways I use the concept open up possibilities for “doing” the research differently and for “being” different as a researcher. As I have written about the study, the research and I become different in ways that are visible, not visible, and invisible. Writing about the study has been a necessary element of the becoming process, and in offering up this description of the process, I allow my neophyte understanding of Patti Lather’s suggestion that “the truth cannot be spoken directly” (2007, p. 40). Lather reports that in Troubling the Angels (1997), she and her co-investigator “address what it … means to know more than we are able to know and to write toward what we don’t understand’ (p. 40). In claiming that I am a becoming research instrument, I write and research toward what I can only partially understand.

This dissertation research examines gaps and discontinuities in human subjects research among federal regulations, institutional requirements, and practices of researchers as they interpret and apply standards for ethical conduct within their work.
Empirical aspects of the study trace effects of IRBs in an ethnographic study carried out over two years and across three subject positions. I was becoming the primary research instrument as I studied effects of institutional review processes. I performed the research as an investigator and graduate student in a research university, as a participant/observer and reviewer of research serving on an IRB, and as a policy writer.

Initially, as an educational researcher and IRB investigator, I studied the experiences of undergraduate students who are beginning research careers and learning about *Responsible Conduct in Research* (National Academy of Sciences, 1995). During the first phase of research, I participated in the IRB process as an investigator preparing IRB applications, amendments, renewals, and termination reports. Through this early work I became more aware of challenging relationships between IRBs and researchers, and I initiated a project that responds to calls for empirical research on IRB processes and procedures (Anthony, 2004; Breckler, 2005; Candilis, Lidz & Arnold 2006; Gunsalus et al., 2005).

The second phase of research involved participation as a reviewer serving on the Behavioral and Social Sciences panel of an IRB. Serving over an extended period of time as a proposal reviewer and observer of the review process informed my work by identifying and clarifying issues education researchers face in negotiating through institutional review processes. Another aspect of this work as a participant/observer (Haraway, 1988/1991) includes a survey of education faculty members. Findings from the survey contributed to the project by focusing attention on issues that are particularly salient for education researchers working with IRBs (Lincoln, 2004; Lincoln & Tierney, 2004).
There are two stages in the third and final phase of study. The first stage was based upon concerns expressed by qualitative researchers attending the First International Congress of Qualitative Inquiry (2005) and by faculty members responding to a survey administered in 2006. In response to issues identified by qualitative researchers and by survey respondents, a *Position Statement on Qualitative Research and IRBs* (Evans, 2006) was developed. This document articulates a problem statement, puts forward a draft of standards for practice, and proposes action plans for qualitative researchers. In the second stage of this third phase of research, I put to work my understanding of how IRBs carry out their work to devise strategies for qualitative researchers conducting research in educational settings. During the second stage, I developed a case study, *No Classroom Left Behind* (2006), which addresses issues of justice and equality in school-based research. My goal in conceptualizing and reporting the case study is to provide a model for accessing student data through the use of “unique identifiers” and to suggest a creative solution to current challenges for qualitative and educational researchers.

The case study focuses on conflicting ethical principles of justice (access to benefits of research), and respect for persons (the consent process). The researchers’ dilemma arises at the intersections of federal regulations expressed in the *No Child Left Behind* Act of 2001, the *Family Educational Rights and Privacy Act* (1997), *The Belmont Report* (1978) and current mandates for improvements in K-12 student performance. Many local IRBs require consent forms from parents before researchers are permitted to access student data or to measure student improvement through pre and post-test procedures. I proposed that researchers in education settings use school district
designated unique identifiers for reporting and coding student data. Thus, student data are not considered “human subject data” and can be brought into research findings without violating human subjects’ rights (Levine, 2003; Sieber, 1992).

The case study was reviewed at the First Annual JERHRE Conference. The subsequent case study report is grounded in earlier fieldwork and translates theoretical knowledge into action. The goal of both the focused project and the broader study is to demonstrate an empirically based model for initiating change in troublesome relationships between IRBs and qualitative researchers.

Organizing the Study

I organized the research study into a traditional five-chapter dissertation. The goal of presenting the research in this way is to render the study into a format that invites readers to move through the chapters and focus attention on the sections or parts that are of most interest. In addition to the five chapters, there are five appendices following the reference section. The appendices provide more detailed descriptions and accounts of the empirical projects, and each has been written as a stand-alone piece with a listing of references supporting the discrete report.

This chapter begins with a brief introductory statement and lays out the research problem. Next, I offer a theoretical discussion of the research questions. I touch on the methods used in the study and then provide rationale for how I generated my account of the research. I present an overview of research sites and summarize how I performed as the primary research instrument in this ethnographic study. Chapter Two presents a

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12 The case study is reported in Evans, Jane (2007). FERPA: No Child Left Behind. JERHRE, 2(1), 101-103.
literature review. Chapter Three includes a fuller discussion of methods used throughout the study. Data analyses can be found in Chapter Four, and the main body of the dissertation concludes in Chapter Five. The last chapter is organized around uncertainties, exclusions, and denials that emerged in the five projects and the study overall.
CHAPTER 2

REVIEW OF LITERATURE

This literature review addresses concepts of responsibility and accountability in human subjects research and focuses on what being responsible, or accountable, might mean in the context of research with human subjects. My goal in this chapter is to bring together in discussion and to blend current literatures that address the following three areas: (1) what being responsible and being accountable, or both, might mean in the context of human subjects regulations; (2) ways in which regulatory statements generated at the national level are currently interpreted at an institutional level; and (3) how the work of feminist theorists can be put to work to rethink and reframe issues of accountability and responsibility in human subjects research. The goals of the literature review are aimed at applying feminist standpoint theory to the work of finding ways to balance federal regulations and institutional requirements with ethical principles and to rethink notions of becoming more responsible in the conduct of research.

I begin by considering how the concepts, responsibility and accountability, are expressed and implied in national-level documents related to the conduct of human subjects research. Applicable federal regulations are specified in the US Code of Federal Regulations. In addition to codified regulations, writers for agencies, such as the National Research Council and the National Academy of Sciences’ Committee on
Science, Engineering, and Public Policy, (1994), the Office of Research Integrity (ORI), (Steneck, 2004), and the Responsible Conduct of Research Education Consortium (RCREC) discuss a program which the Office of Research Integrity (ORI) refers to as, Responsible Conduct of Research (RCR).

Following discussion of federal documents, I turn attention to policy documents and literature generated on an institutional level. At this local level in regard to human subjects research, institutions and organizations set policies and delineate procedural requirements for researchers by interpreting federal documents. Institutional Review Boards (IRBs), and an IRB accrediting organization, the Association for the Accreditation of Human Research Protection Programs (AAHRPP), set out the ways in which researchers may, and in some cases must, conduct their research in order to be considered responsible or accountable, or both. Literature that takes an interpretative approach to federal regulations also can result from the work of such groups as the Center for Advanced Study Project Steering Committee (Gunsalus et al. 2005, Improving the System for Protecting Human Subjects: Counteracting IRB “Mission Creep”) and the Congress of Qualitative Inquiry (Evans, 2006).

I conclude with a discussion of empirical and theoretical works that suggest different ways one might think about the notion of being responsible or accountable when carrying out research with human subjects in a postmodernist environment. In this section, I include works of Corlann Gee Bush, Sandra Harding, Donna Haraway, Naomi Scheman, and Gayatri Spivak. In this final portion of the literature review, I also apply the work of Deleuze and Guattari and Joan Sieber. These theorists, some of whom are postmodernist and others who are more traditional, are taken together in assemblage
and contribute to the review by speaking through their works and offering insights into how one might come to understand concepts of responsibility and accountability in research with human subjects on an individual level.

My purpose in synthesizing literatures associated with the concepts of responsibility and accountability from perspectives on three levels – national, institutional, and individual – is to support the empirical investigation of how researchers understand their responsibilities across those levels. In addition, I intend to reveal what it means for institutionally supported individuals to balance the tensions of regulations, requirements, and responsibilities on a path to becoming more ethically responsible and institutionally accountable in the conduct of human subjects research.

National Level: Understanding Federal Legislation and Documents

Congress passed the National Research Act (1974) and assigned to the Department of Health, Education, and Welfare\(^\text{13}\) (DHEW) the task of developing details for procedures, which ultimately became a part of the US Code of Federal Regulations (CFR). DHEW commissioned the *Belmont Report* (1978) to lay out ethical principles to guide how human subjects should be treated in research. These two national-level documents, The National Research Act and the *Belmont Report*, make a visible impact on human subjects regulations.

Traceable effects of these federal documents on institutions and individual researchers are transmitted through institutional policies that have been interpreted from

\(^{13}\) The United States Department of Health, Education, and Welfare existed between 1953 and 1979. IRBs are now overseen by the US Department of Health and Human Services.
federal regulations. Institutional requirements then have a direct effect on researchers. The traceable path of effects, from federal legislation to individual researchers, begins with the National Research Act. This Act identified basic principles, created a commission to undertake a comprehensive study of ethical and other implications in human subject research, and authorized regulations for the treatment of human subjects involved in research in the United States\textsuperscript{14}. The resulting federal regulatory scheme, controlling nearly all federally sponsored human subjects research, evolved into what is known as “The Common Rule.” Regulations implementing the Common Rule govern how IRBs are established and regulated and specify procedures for obtaining Federal Wide Assurances (FWAs) from institutions warranting their compliance\textsuperscript{15}.

In the \textit{Belmont Report}, the National Commission for Protection of Human Subjects of Biomedical and Behavioral Research (National Commission) recommended three guiding principles: respect for persons, beneficence, and justice. Respect for persons is described in terms of \textit{autonomy}. Researchers must acknowledge the rights of individuals to be informed and to make decisions for themselves. Further, persons who have diminished autonomy are to be protected additionally. The principle of beneficence addresses the well-being of individuals in relation to potential risks and harms of research. The intent of beneficence is that researchers not do harm and that they maximize benefits and minimize risks of research. Justice relates to fairness – who receives the benefits and who bears the burdens of research. Guidance in the \textit{Belmont}

\textsuperscript{14} Relevant parts of the Act were codified into Title 42 of the United States Code.

\textsuperscript{15} The central regulations are set forth in Title 45 of the Code of Federal Regulations. See 45 CFR Part 46, Subpart A.
*Report* leaves open questions of how these three principles should be balanced, although the National Commission explained in its 1978 report on IRBs: “The ethical conduct of research requires a balancing of society’s interest in protecting the rights of subjects and in developing knowledge that can benefit the subjects or society as a whole” (as cited in Coleman et al., 2005, p. 53).

The Office of Research Integrity (ORI) also offers guidance on ethical principles. The US Department of Health and Human Services (DHHS) assigns ORI the official task of dealing with scientific integrity and misconduct in research. As a part of that function, ORI provides online training in responsible conduct of research, a quarterly publication informing the public about current news from DHHS, and training conferences addressing scientific misconduct and integrity.

ORI’s publication, the *Introduction to the Responsible Conduct of Research* (ORI, 2004, p. 30) suggests that responsible researchers should make “moral judgments” about “right and wrong” when they design or review research projects. In contrast to the emphasis ORI places on making moral judgments about right and wrong, the *Belmont Report* calls attention to “balancing of society’s interest” with protecting subjects’ rights and “developing knowledge” for the benefit of both individual subjects and society. This disparity between federal documents can create tension for institutions and individuals when they are looking for direction on questions related to what responsibility means in practice, or how to bring ethical principles into research practices.
Ethical Questions: Making Moral Judgments about Right and Wrong

Critical ethical questions arise from the juxtaposition of the National Research Act and the Belmont Report, both of which originate at the federal level. Questions that researchers are asking and that drive my empirical project include: How can researchers and reviewers determine with certainty what is right and wrong for both individual subjects and society? What methods and standards could be used to ascertain such absolute truth? Where, or how, can “balance” be achieved?

Federal level documents indicate clearly that the ethical principles underlying institutional review processes and procedures continue to be based upon those set forth in the Belmont Report. However, the ways in which institutions and IRBs interpret those principles, derive standards for ethical conduct from them, and apply the principles in practice are changing. New policies are being developed to reflect changes in research practices, procedures, and protections. Examples of such changes can be seen in both biomedical and behavioral research. Recent developments in technology surrounding gene therapy trials provide an example from biomedical research, and new requirements for accountability in education evidenced in the No Child Left Behind (NCLB, 2002) legislation exemplify changes in behavioral research. In both biomedical and behavioral fields of study, researchers are confronted with ambiguous, complex, and changing requirements. On the one hand, researchers are encouraged to demonstrate ethical responsibility by making moral judgments about “right and wrong,” and on the other hand, they are not provided with much guidance about how to “balance” competing ethical principles.
Some researchers in the field of education, particularly those who study classroom teaching practices and student learning outcomes, report that their research involving human subjects is being constrained by increasing requirements for reviews of their research at the institutional level (Anthony, 2004; Breckler, 2005; Gunsalus et al. 2005; Kirsch, 1999; Rosnow et al., 1993; Townsend, 2006) and by demands for accountability at the national level. There is a considerable body of literature documenting the resulting tensions between IRBs and researchers. In many of these reports, researchers perceive that the tensions they experience are effects of changes in how the National Research Act, *No Child Left Behind* legislation, and the *Belmont Report* are being interpreted by IRBs. The tensions between researchers and IRBs at the institutional level may be due, in part, to ambiguous guidance that is available at the national level for how to conduct research in more ethically responsible ways. Guidance on how to be more accountable seems to be abundant, but researchers want to know what *responsibility* means, and how to demonstrate responsibility in the current environment that emphasizes accountability.

**Institutional Level: Interpreting Accountability and Responsibility**

The National Research Act requires assurances, in the form of FWAs, from entities conducting research involving human subjects if those entities also receive any type of federal funding. (This requirement applies to any federal funding received for any purpose by that entity.) One element of such an assurance is that the entity must have, or be affiliated with, an IRB that meets certain standards. The primary function of
IRBs is to protect the welfare and rights of human subjects involved in research. This function is carried out through reviews of biomedical and behavioral research. Another less-formalized function of IRBs is to interpret regulations of federal agencies and to develop policies for guidance at a local, or institutional, level.

*Interpreting Regulations: Tensions and Discontinuities*

How regulations are interpreted varies widely from IRB to IRB, and questions naturally arise about “Who is the IRB and who is making decisions for the IRB?” Regulations at the federal level are often interpreted and held out to be *requirements* for researchers in institutions governed by local IRBs. Misunderstandings can arise as a result of the latitude in, differences between, and procedures used by both local IRBs and federal regulatory entities. Thus, the operation of IRBs introduces discontinuities of the type described by Michel Foucault in *The Order of Things* (1966/1970).

In his writing, Foucault explains that by *discontinuity* he means “…a profound breach in the expanse of continuities… a radical event that is distributed across the entire visible surface of knowledge, and whose signs, shocks, and effects it is possible to follow step by step” (1966/1970, p. 217). Visible signs, shocks, and effects of discontinuities emanating from federal regulations can be seen at institutional and individual levels. The IRB operating as a functional body is both a sign of compliance with federal regulations at the institutional level and an effect of The National Research Act. Similarly, researcher submissions to IRBs for reviews of research protocols are signs of researchers’ compliance with, and recognition of, federal regulations and
institutional requirements for protection of human subjects. Shocks and effects of discontinuities become visible in the procedural problems researchers report having with IRB requirements and the complex ethical problems that researchers face in their work with human subjects.

Another way in which IRBs function is through interpreting federal regulations. IRBs work to help researchers appreciate that federal regulations and institutional requirements must work in concert. The IRB interprets, but cannot rewrite federal regulations. Primary roles of IRBs are to educate and train researchers, to interpret federal regulations, and to form policies based upon government regulations for institutions. These functions were visible in a message sent to the Ohio State University community from the Senior Vice President for Research, Robert McGrath. McGrath’s message announced new training requirements for researchers and others engaged in research processes.

**Collaborative IRB Training Initiative (CITI)**

In his July 2004 message, McGrath indicated that he had selected the Collaborative IRB Training Initiative (CITI) as “the core of the Institution’s new training effort.” Completion of the web-based training is signified by certification and is required for all members of the institutional community who engage in research with human subjects. CITI training is, therefore, required of OSU faculty, staff, and students

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16 Ohio State’s Federal Wide Assurance document includes a researcher training provision, the purpose of which is to “ensure the federal government that all faculty and staff who participate in research involving human subjects... are fully informed of current research ethics, best practices and regulatory requirements before they participate in human subjects research activities” (McGrath, 2004, ¶ 2).
before they are permitted to engage\textsuperscript{17} in research with human subjects or to serve as principal or co-investigators on research projects.

Obligations to complete training requirements and to comply with IRB decisions emanate from the particular relationship between the individual and the institution holding an FWA. Regardless of funding sources for research, individuals who are affiliated with Ohio State must act in accordance with FWA requirements. The decision to cover all research with human subjects, regardless of funding source, was made by McGrath in consultation with university legal officials and appropriate committees. McGrath serves as Ohio State’s primary signatory official on the agreement between the federal government and the university and bears ultimate responsibility for researchers’ and the university’s compliance with federal regulations.

As a part of its oversight function, the Ohio State University IRB maintains a record of certification dates for Ohio State researchers. Record keeping of this sort by the IRB is a requirement of the FWA agreement between the university and the federal government. Thus, while faculty members and other researchers may perceive this monitoring of their training compliance as being an accountability requirement of the IRB, the monitoring of training requirements is actually a stipulated element of the institution’s agreement with the federal government. It can also be seen as oversight of the institution by the federal government. The CITI training requirement is just one example of an oversight and accountability measure prescribed for human subject research.

\textsuperscript{17} Being “engaged” in research with human subjects has a specific meaning in the context of federal regulations. The New Federal Wide Assurance (2004) offers the following definition: “Under the Federal Policy (Common Rule) at Section 102(f) awardees and their collaborating institutions become "engaged" in human subject research whenever their employees or agents (i) intervene or interact with living individuals for research purposes; or (ii) obtain, release, or access individually identifiable private information for research purposes.”
protections by the federal government. There are numerous other measures that are visible and can be seen as effects of federal oversight at both institutional and individual researcher levels.

The CITI training modules are one type of “literature,” (or perhaps I should describe the modules as “documents”) having an educational training purpose. Additional examples of institutional level literature useful in interpreting federal regulations and offering guidance to researchers can be seen in policy documents that organizational entities, such as universities, write and publish to inform their constituents about requirements for human subjects research. Guidance materials produced by OSU’s Office of Responsible Research Practices (ORRP) are policy pieces of this type. These documents are available both on the ORRP website and also at the numerous training opportunities offered by this office.

Organizational and Institutional Policy Statements

I organize my discussion of institutional-level policy documents around the concepts of responsibility and accountability, focusing on the issues that either introduced the most significant impediments to research projects or those that affected researchers’ projects most frequently. I begin by considering how institutions and organizations interpret the concept of responsibility. I then examine how intermediate-level entities construe the notion of accountability.

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18 The Professional Development Program for Teachers (PDPT) case study provides an example of issues that were both significant impediments and frequently occurring. This research project was placed “on hold” for an extended period of time by local IRB administrators while the researchers worked through tensions between competing ethical principles and conflicting regulatory requirements. Appendix E includes a discussion of the case study and summarizes the resolution of issues.
What is “Responsible Conduct of Research”?

Responsible conduct of research is a complex concept that cannot be distilled into a universal list of standards for practice or norms for ethical behavior (Committee on Science, Engineering, and Public Policy, 1995; Frankel, 2004; Pascal, 2004). Nicholas Steneck, writing for the federal Office of Research Integrity (ORI) states: “In general terms, responsible conduct in research is simply good citizenship applied to professional life” (2004, p. xi). However, Steneck goes on to point out “the specifics of good citizenship in research can be a challenge to understand and put into practice” (p. xi). Indeed, understanding and putting into practice the specifics of good citizenship is a central issue for my research project. Regardless of whether institutions interpret “responsible conduct of research” as demonstrating “ethical responsibility” or “good citizenship,” a discontinuity, similar in effects to those described by Foucault (1966/1970), exists between stated ethical principles for decision-making and practical standards for conduct (Vanderpool, 2002).

The Responsible Conduct of Research Education Consortium (RCREC) was formed in 2001 as an association of institutions, organizations, and federal agencies to respond to the need for educational resources related to conduct and practices of research. The goal of RCREC was to reach beyond minimum standards or “baseline requirements.” This group describes responsibility as “the ongoing process of reconciling regulations, guidelines, standards, and ethics to promote integrity in the proposing, planning, conducting, reporting and reviewing of research” (RCREC, 2002). While the RCREC website offers a range of resources including links to descriptions of
Internet-based training courses, goals for instruction, and a specific home page for Human Subjects RCR training, the group neither defines responsibility, in terms of how researchers could demonstrate responsibility in their research practices, nor provides standards for what counts as responsible conduct.

In addition to tensions arising in and from documents published by ORI and RCREC, a report from within the Department of Health and Human Services (DHHS) points toward discontinuity between how researchers demonstrate responsible conduct and specific guidance on application of the Common Rule. A Report of the Equivalent Protections Working Group (Report of EPWG) was issued in 2003 to Bernard Schwetz, director of the Office for Human Research Protections (OHRP). The purpose of this report was to address concerns of DHHS about the increasing frequency of clinical trials being taken outside the US and into countries where the US was not overseeing protections for human subjects. The underlying concern of DHHS was to assess whether or not US researchers were demonstrating responsibility and were being held accountable to US standards when their work was beyond the reach of US regulations\(^\text{19}\).

The working group states in its report, “the responsibilities of investigators are not the main thrust of 45 CFR 46 [the Common Rule]” (2003, p. 10). The group in so saying includes investigators’ responsibilities along with IRB responsibilities. In the discussion, two primary duties are ascribed to investigators: (1) to “Protect against unnecessary or unjustified risk throughout the course of study,” and (2) to “Ensure

\(^{19}\) The working group’s report states that the Office of Inspector General for DHHS “recommended that the Office for Human research Protections advocate for the development of a voluntary accreditation system for human research subject protection programs, and exert leadership in developing strategies to ensure that adequate human subject protections are afforded for non-U.S. clinical trials regardless of the source of U.S. funding for the trials” (Report of EPWG, 2003, p. 4).
voluntary participation after adequate disclosure of information related to the study” (2003, p. 10). These investigator responsibilities are reoccurring sources of tension in researcher submissions to IRBs. Further, the tensions surrounding these responsibilities seem to be associated more often with how researchers account for their performance of duties, than with whether or not researchers actually accept responsibility for the duties.

In addition to identifying primary duties of researchers, the Report of EPWG (2003) importantly, points out, “The primary focus of the U.S. policy is the accountability of the research institution for the welfare and rights of human subjects” (2003, p. 18). The Report seems to distinguish between responsibility and accountability and to assign duties for accountability to institutions and for responsibility to researchers. Alignment of duties in this way suggests that institutions might measure, or assess, the extent of accountability they achieve through researchers’ reports and practices. This notion expands the question, “What is it, then, to be responsible?” to “What is it, then, to be both responsible and accountable”?

Researchers Harold Vanderpool (2002) and C.K. Gunsalus (2004), both of whom work within IRB systems, tackle additional issues they believe might be sources of tension. Vanderpool points out in his article, An Ethics Primer for IRBs, that there is a gap between the two most important documents related to research ethics: (1) the Common rule as expressed in The Code of Federal Regulations and (2) The Belmont Report. He writes:

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20 The “policy” to which they refer is the United States Agency for International Development (USAID) Equivalent Protections Policy. There are numerous parts to this policy, which addresses the equivalency of protections for human subjects in foreign countries and in the US.
Although they share [a] common goal, their means for accomplishing the goal of protecting research participants are exceedingly different. The problem over ethics occurs because the relationship between the means of protection in the CFR on the one hand and *Belmont* on the other is not mentioned or specified in either document. The CFR hardly mentions ethics, not to speak of the functions of ethics in protecting human research subjects. At the same time, *Belmont* details ethical principles and applications without specifying how they relate to interpreting and applying federal regulatory rules (2002, p. 3).

University of Illinois compliance officer, Gunsalus, expresses a concern that is similar to Vanderpool’s. “In too many cases, the focus is on form over ethical substance: counting what can be counted, rather than focusing instead on what counts” (2004, p. 369). It seems safe to say that many researchers who resist the increased monitoring may feel caught in this discontinuity between accounting and regulatory rules on the one hand and responsibility and “ethical substance” on the other.

*Being Accountable in Research*

Literature from the field of higher education suggests that in educational contexts, *accountability* is part of a broader reform movement (Ball, 2003; Burke, 2005; Towne et al., 2005). Stephen J. Ball, Director of the Education Policy Research Unit at the University of London, points out that in the United Kingdom (UK) systems of accountability “…bring into being unhelpful or indeed damaging practices, which nonetheless satisfy performance requirements” (2003, p.220). The US National Research Council’s publication, *Advancing Scientific Research in Education* (Towne,
Wise, & Winters, 2005) notes that in education there has been a shift toward accountability and specifically “evidence-based” research.

Reports and documents addressing responsible conduct in research reveal more about accountability measures than they do about what it means to be a responsible researcher. Discontinuities exist between accountability measures and responsible practices. Discontinuities begin with the noticeable absence of a definition for responsibility and extend into spaces where standards for accountability displace notions of responsibility.

Signs of discontinuity emerge from ambiguities about what responsible conduct in research entails. Shocks from discontinuity appear when national and institutional level documents focus on prescriptive forms for accountability measures and shift attention away from ethical substance and guidance about responsible conduct. Researchers who work to become responsible in their practices experience effects of the discontinuity when standards for accountability displace guidance for ethical substance and responsible conduct. The Report of EPWG captures the frustration that individual researchers report in regard to current documents and guidance.

The emphasis on regulatory compliance in the U.S. system is seen by some as excessive and contributing to the erosion of skillful judgment and appropriate discretion on the part of investigators and IRBs in determining the ethical acceptability of research with human subjects (2003, p. 16). Absences from federal and institutional level literatures and gaps in guidance they offer on what it means to be responsible and accountable warrant further study. I draw from
literatures addressing how individual researchers account for their responsibility practices to examine the signs, shocks, and effects of discontinuities and to cast light on these questions.

Individual Level: Accountability and Responsibility in Researcher Practices

This final portion of literature review takes up the challenge of understanding what being accountable or responsible, or both, might entail from the perspective of theorists on an individual level. I consider a recommendation from the editor of the Journal of Empirical Research on Human Research Ethics (JERHRE), Joan Sieber (2006). She suggests using empirical studies to reframe issues “so that neither science nor human subjects are placed in jeopardy” (p. 1). Sieber’s goal in reframing issues is to design research studies that not only will meet, but also will exceed institutional standards for accountability and achieve individual responsibility.

Signs, Shocks, and Effects of Accountability in Researcher Practices

According to Foucault (1966/1970), it is possible to trace discontinuities by following signs, shocks, and effects. If this is so, then discontinuities of accountability should become visible as signs, shocks, and effects in practices of researchers. In some situations, moves toward accountability can been seen when researchers wrestle with finding ways to follow guidance issued at both the federal and institutional levels. Signs of researchers struggling against the effects of accountability are evident in an article recently published in The New York Times. Patricia Cohen (2007) writes about “ethics

21 Sieber writes with Philip Rubin in the editorial from which this citation is taken (Rubin & Sieber, 2006 Vol.1, Issue 4, pp 1-4).
panels expanding their grip” and describes a scenario where a particular IRB shocks a researcher by its “demand [for] proof”\textsuperscript{22} of researcher compliance with regulations and requirements.

Cohen reports that a social science researcher\textsuperscript{23} was told recently by her IRB that she must prove she had \textit{not} violated federal regulations in her previous work. This amounts to a demand upon the researcher to \textit{prove a negative}, and such a demand provides a good example of institutional level pressure and the types of requirements researchers report as problematic and troubling. I see this type of IRB activity as a sign of discontinuity.

Responding to such demands from IRBs poses a threat to social science researchers. In the situation Cohen describes, the demand presents a sticking point\textsuperscript{24} for this particular researcher. A requirement for “proof” assumes a degree of certainty that does not make sense in social science research. In some studies and research projects, hypothesis testing\textsuperscript{25} is used to assess the probability of various outcomes or effects. However, even when probability is reported at the .01 level of significance, meaning that the probability of this finding happening by chance is less than one percent, the significance of this finding cannot be construed as an absolute certainty, or proof of a

\textsuperscript{22} In her discussion of ethics panels expanding their grip into fields of social science research, Patricia Cohen, writing for the \textit{New York Times} (February 27, 2007) notes, “The board [IRB panel] also demanded proof that previous research for a completed book did not use any archival material involving living people and banned her from doing any research.”

\textsuperscript{23} In this example, the researcher is a historian.

\textsuperscript{24} One of Joan Sieber’s strategies for resolving complex IRB/researcher issues is to identify and turn attention to “the sticking point” (personal conversation, July 28, 2006).

\textsuperscript{25} In hypothesis testing, the intent is to reject a hypothesis because the closest one can come to certainty is to reject an hypothesized statement.
particular outcome, in every situation\textsuperscript{26}. In Cohen’s example, the IRB demanded proof, and there is little chance that a researcher could provide absolute assurance of past compliance with current requirements.

Cohen discusses discontinuities between accountability requirements and social science researchers’ responsibility practices that result in some cases from adapting a more biomedical model for use in social science research. Sandra Harding offers a different approach to a similar issue in her work about effects of a traditional science model on social science research. After-shocks of traditional science, or science-as-usual (Harding, 1991b, p. 54), as Harding describes the problem, have an effect on the ways that social science research works against the direction currents are moving within frameworks of federal regulations and institutional requirements. The impetus for the Belmont Report and the National Research Act resulted from more traditional scientific endeavors that followed a biomedical model, and when social science projects such as the Tuskegee Syphilis Study, Tearoom Trade\textsuperscript{27} research (Sieber, 1992), and the Milgram Experiments (Coleman et al., 2005) came to light, the more traditional approach of a biomedical model was imported and used to frame requirements for accountability practices in behavioral and social science research.

If these same studies were to be conducted today in the current environment of IRB oversight, accountability for institutional requirements and federal regulations

\textsuperscript{26} This notion of proof or absolute certainty also carries with it the element of generalizability, which surfaces in the federal documents defining scientific research. This can be another sticking point for qualitative social science researchers.

\textsuperscript{27} Sieber (1992, p. 8) indicates that the stereotypical characterization of men who engaged in “impersonal sexual acts in public restrooms” was referred to as Tearoom Trade and was investigated by Laud Humphreys, a sociology doctoral candidate.
would be accomplished by conducting the studies “differently” (Sieber, 1992, p. 9). Sieber is a nationally recognized expert on “planning ethically responsible research.” She does not suggest in either her work or writing that social science projects cannot be conducted responsibly. Rather, she advocates for reframing issues through empirical work (Rubin & Sieber, 2006; Sieber, 2007) to achieve responsibility and accountability.

*Accountability and Responsibility: Theoretical Perspectives*

Calling for *proof of responsibility* in the performance of research is only one of the numerous and variously reported instances of signs, shocks, and effects of discontinuities between ethical responsibility and institutional accountability (Anthony, 2004; Breckler, 2005; Gunalsus et al. 2005; Kirsch, 1999; Rosnow et al., 1993; Townsend, 2006). Some of the literature informing my project suggests that demonstrating researcher *accountability* is not the same thing as, and does not stand in for 28 *responsibility*; however, proof of accountability seems to stand in for proof of responsibility, and both concepts appear in discussions of one or the other. The aim of ethical principles, as they are detailed in the *Belmont Report* goes beyond accountability, or compliance with stated requirements. According to philosopher and Dean in Residence at the Council of Graduate Schools, Paul Tate, the intention of the *Belmont Report* in specifying beneficence, autonomy, and justice is an appeal, or call, to the consciences of researchers. Tate (2004) advocates for moving beyond compliance (accountability) to conscience (responsibility). By recommending such a move, Tate

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28 Public policy writers Dubnick and Justice (2004, p. 5) suggest that accountability has the “capacity to stand in for” responsibility.
suggests that accountability is “not enough” and represents a partial, or perhaps a provisional, construction of responsibility.

Responsibility in trust relationships.

An essay by post-colonial critic and feminist Gayatri Spivak (1994) is helpful as a theoretical entry point because her work so clearly addresses the ambiguity and complexity of responsibility. Spivak shocks her reader in the first words of the essay when she states: “Responsibility annuls the call to which it seeks to respond” (1994, p. 19). With this statement, she points out that one’s sense of responsibility makes a demand that cannot be refused (“the call”), and at the same time, the demand removes the effect (“annuls”) of the provocative call. Spivak continues: “What is it, then, to be responsible to a changeful thought…?” “The changeful thought” in Spivak’s rhetorical question refers to the call that both makes and rescinds a demand. What it means to be responsible remains ambiguous, in the ambiguous sense of Simone de Beauvoir. In The Ethics of Ambiguity, de Beauvoir states: “To say that it [the notion of ambiguity] is ambiguous is to assert that its meaning is never fixed, that it must be constantly won” (1948/1976, p. 129).

Ambiguity is one aspect of responsibility noted by Spivak and de Beauvoir. Spivak raises additional questions in her shaping of possible connotations of responsibility. She states:

I can formalize responsibility in the following way: it is that all action is undertaken in response to a call (or something that seems to us to resemble a call) that cannot be grasped as such. Response here involves not only “respond
to” as in “give an answer to,” but also the related situations of “answering to,” as in being responsible for a name (this brings up the question of the relationship between being responsible for/to ourselves and for/to others (1994, p. 22).

By invoking one’s relationship with others in her explication of responsibility, Spivak gestures toward a duty for researchers who are always already in relationship with others in the conduct of research. Relationships, whether they are between researchers and others, or between researchers and the scientific community, are complex, ambiguous, and necessarily important to becoming responsible in the conduct of research.

Other theorists expand this idea and emphasize the importance of relationships and scientists’ responsibilities both to the scientific community and to others. In contrast to Spivak, who is informed by Marxism, deconstruction, and feminist theory and approaches responsibility from a post-colonial perspective, the committee of writers who authored *On Being a Scientist: Responsible Conduct in Research* (1995) addressed the issue of responsibility from the perspective of researchers in relation to the scientific community. They place a strikingly similar importance on relationships. In their call for greater attention to the development of ethical principles and awareness of responsibility in those who are becoming scientists, they state:

The level of trust that has characterized science and its relationship with society has contributed to a period of unparalleled scientific production. But this trust will endure only if the scientific community devotes itself to exemplifying and

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29 The committee of writers was comprised of representatives from the councils of the National Academy of Sciences, the National Academy of Engineering, and the Institute of Medicine. This group is known as the Committee on Science, Engineering, and Public Policy (COSEPUP).
transmitting the values associated with ethical scientific conduct… [S]cience has become so complex and so closely intertwined with society’s needs that a more formal introduction to research ethics and the responsibilities that these commitments imply is also needed…. *(Preface ¶ 1).*

The committee of writers for the National Academy of Sciences assumes that ethical conduct is a necessary part of relationships between scientists and society, and they suggest there is a need for a deliberate approach to becoming responsible scientists. Scientific researchers who recognize the complex and intertwined relationships between their practices and the needs of society are those who accept responsibility for their work and actions. In the words of Spivak, the scientific community must act upon “the problematic of responsibility, seen as an intermediary stage, caught between an ungraspable call and a setting-to-work” *(1994, p. 23).*

*Responsibility and accountability in relationship: Smooth and striated spaces.*

Spivak demonstrates in her writing the presence of both ambiguity and complexity in relationships of responsibility. In her essay, Spivak questions the relationship (which she derives from Derrida) between “being responsible for/to ourselves and for/to others” and “being answerable for” *(1994, p. 22).* I examine further the way that these concepts, accountability and responsibility, fold into an ambiguous sort of relationship. I question the nature of ambiguous and complex relationships between accountability and responsibility. How, or in what ways, might the two be
coming together but always apart? Is it possible that accountability (answerable for) is always present within the concept of responsibility (responsible for/to)?


Deleuze and Guattari explain that although the concepts, smooth and striated, initially appear to be opposites, the important difference between them is in the nature of the spaces.

Smooth and striated space—nomad space and sedentary space—…are not of the same nature…. [W]e must remind ourselves that the two spaces in fact exist only in mixture; smooth space is constantly being translated, transversed into a striated space; striated space is constantly being reversed, returned to a smooth space (1987, p. 474).

Deleuze and Guattari devote a chapter to describing models (technological, musical, maritime, mathematical, and physical) that illuminate how smooth and striated spaces are interdependently related.

I bring their work into the context of my study, and I apply their concepts to my analysis of accountability and responsibility as tools for thinking differently about concepts that flow throughout my investigation of responsible conduct of research. The
nature of smooth and striated spaces, and of responsibility and accountability, do not allow me to draw clean analogies. Similarities between their concepts and mine surface in the nature of the concepts and how they function. Deleuze and Guattari (1987) point out the constant mixing of smooth and striated spaces, and also the effects of assemblages of smoothness and striation, or how they function (Grosz, 1994) in mixture, rather than what each might mean if it were not in flow with the other. In the cases of Deleuze and Guattari’s concepts in their writing and of mine for this study, my point is that interdependent concepts are always in mixture and function in assemblages rather than as static and separable concepts.

In their later work, What is Philosophy? (1994), Deleuze and Guattari explain this type of relational functioning of concepts in the following way:

Every concept has an irregular contour defined by the sum of its components, which is why…we find the idea of the concept being a matter of articulation, of cutting and cross-cutting. The concept is a whole because it totalizes its components, but it is a fragmentary whole (1994, p. 15-16).

Smooth space is only smooth in that smoothness is more notable than the striation that is encroaching and striating what was formerly more smooth. Thinking of responsibility, accountability, and the assemblage of responsibility-accountability in this way engenders a consideration of relationships between components and a focus on multiplicities in relations. The idea I am developing is not directed toward reaching an end point where responsibility and accountability are separate and distinct concepts that interact or overlap in certain predictable ways; rather, I describe the ways in which
responsibility and accountability function, or commingle in a conceptual grid, within the context and conduct of research.

Responsibility and Accountability: Smooth and Striated Relations

I propose to use a flexible and transitory grid of smooth and striated spaces to analyze concepts of responsibility and accountability as they appear in practices and discourses of research. Although Deleuze and Guattari make a point of challenging all models, I am suggesting that the concept of smooth and striated spaces can be used as a grid to consider the conceptual space that Foucault refers to as conditions of possibility, or what I think of as the cultural, political and social milieu in which we live and think. The theoretical mapping I develop for my project places accountability in more striated space and responsibility in smooth space, while also noting that accountability and responsibility do not appear as a simple opposition, binary, or dichotomy.

The appeal of Deleuze and Guattari’s (1987) conceptual model for smooth and striated spaces comes in part from an effort to think in terms of both the multiplicities of difference within and between responsibilities and accountability and the often overlapping ways in which the two concepts appear in discourse. One example of the complex and nuanced uses of the terms accountability and responsibility from literature that aims to clarify and explain responsible research conduct is Steven Peckman’s

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30 Deleuze and Guattari develop the concept of smooth and striated spaces in A Thousand Plateaus (1987). Smooth space is nomad space “a space constructed by local operation involving changes in direction” (p. 478) and striated space is represented in their model as sedentary space, the space of properties where perceptions are based on measures and properties; “[T]he two spaces in fact exist only in mixture” (p. 474).

31 Amdur and Bankert (2002), editors of Institutional Review Board: Management and Function state in their Preface: “The purpose of this book is to produce an instructional manual that gives Institutional Review Board (IRB) members and administrators the information they need to run an efficient and
(2002) statement: “The responsibility of ensuring accountability or compliance for human research is often placed solely on the shoulders of the IRB and the IRB administrator” (Peckman, 2002, p. 19). In this statement, responsibility seems to be an undefined quality of both an institutional entity (the IRB) and an individual (the IRB administrator). Accountability seems to relate to the performance of duties by individuals and institutional entities to comply with federal research regulations for conduct in human research. The complexity of meaning suggests similarity, difference, and relationship between the concepts. In an effort to lay out how I use these concepts, I suggest rethinking and reframing the issues, or models, associated with researchers’ responsibilities and borrowing from the notions of variability and multiplicity of Deleuze and Guattari. “We must therefore envision a … number of models, which would be like various aspects of the two spaces [smooth - responsibility and striated - accountability] and the relations between them” (1987, p. 475).

Reframing “Responsible Conduct of Research”

In this final section of literature, I begin by focusing on Joan Sieber’s premise (Rubin & Sieber, 2006) that researchers reframe issues to balance ethical principles. I uncover the technique she uses from the example she provides, and I consider similarities between her approach and works of feminist theorists. I bear in mind Sieber’s strategy as I examine similar techniques recalled from the work of feminist theorists in venues other than IRB/research relationships. In Chapters Three and Four, I effective system of protecting human research subjects in compliance with federal research regulations” (p. xxvi).
adapt the insights of Sieber, along with the work of feminist theorists to enlighten my empirical project, which is designed to study how researchers might become responsible in research involving human subjects.

Sieber notes that researchers can begin by identifying sticking points in, and through, empirical research projects that do not find immediate acceptance with IRB review panels. In a recent editorial (Rubin & Sieber, 2006), Sieber names a sticking point mentioned on numerous occasions as a concern of both social science researchers and specifically educational researchers (AAUP, 2001; Gunsalus et al., 2005; Lincoln, 2004; Lincoln & Tierney, 2004;). Sieber identifies the sticking point as the “university faculty’s concern that review of minimal risk human subjects research encroaches on faculty autonomy to pursue their research interests” (Rubin & Sieber, 2006, p. 1).

Through this example Sieber demonstrates her strategy of reframing issues to resolve sticking points in relationships among federal regulations, IRB requirements, and researcher responsibilities. Sieber summarizes the frustration reported by the Association of University Professors (AAUP) as: “human research protection programs (HRPP) at many universities that seem to be more about regulating scholarly behavior than about protecting human subjects” (p. 1). She then posits: “While the complaint about infringement on the rights of some investigators is based in fact, we believe that empirical research can help to reframe the issue so that neither science nor human subjects are placed in jeopardy (Rubin & Sieber, 2006, p. 1). In effect, Rubin and Sieber recommend rethinking the issues and balancing science (in this case, the rights of faculty members to conduct research and publish their findings) and human subjects
protections (federal regulations, institutional requirements, and ethical principles). I refer to Sieber’s approach as *reframing issues*.

**Rethinking and Transforming “Responsible Conduct of Research”**

Sieber’s approach resonates with the earlier writing of Corlann Gee Bush in *Women and the Assessment of Technology: to Think, to Be; to Unthink, to Free*. In her essay, Bush argues for transforming inequitable relationships in technology and society by adopting a feminist thinking and unthinking of technology. She writes: “Feminist scholarship and feminist activism proceed not through a sterile, planar dialectic of thesis, antithesis, synthesis, but through a dynamic process of unthinking, rethinking, energizing, and transforming” (1983, p. 152). Bush’s prescription for transformation can be used as a framework to analyze relationships between the rights of researchers to study and publish and the protection of human subjects. Unthinking and rethinking practices of researchers through feminist theorists and philosophers of science responds both to Bush’s challenge of envisioning more equitable relationships in society and to Sieber’s recommendation to reframe issues.

I take the feminist framework set forth by Bush (1983) for transforming inequitable relationships in technology and society along with Sieber’s suggestion (Rubin and Sieber, 2006) for reframing issues related to the rights of individuals, federal regulations, and institutional requirements, and together these literatures light a path for me to follow.

**Rethinking Boundaries**

Donna Haraway models rethinking and reframing for readers with her cyborgian figure. In her *Cyborg Manifesto* (1985/1991), Haraway refers to socialist feminists as
“theorized and fabricated hybrids of machine and organism, in short, we are cyborgs” (p.150). The context she sets is of socialist feminists living in social relations during the late 20th century. She goes on to explain that we are engaged in a “border war” that is being carried out in “traditions of ‘Western’ science and politics” (p. 150) across constructed boundaries. In a later work, Situated Knowledges (1988/1991), her main arguments are “for situated and embodied knowledges and against various forms of unlocatable, and so irresponsible, knowledge claims” (p. 191). Haraway’s arguments and her discussions regarding different kinds of knowledge are important to all phases of my project.

Spivak’s critiques also are helpful in clarifying how I put to work Sieber’s and Bush’s strategies. By way of example, Spivak rethinks concepts of voice (1993/1996) and privilege (1988). She first poses a question that appears to have a simple answer. She asks: “Can the subaltern speak?” (Spivak, 1988). Then, she changes direction (using deconstructivist’s tools) to provoke readers into rethinking the notion of speaking. Spivak accomplishes this by calling attention to her readers’ privilege and by foregrounding the effects of a reader’s privilege on hearing, rather than on speaking. She confronts the issue of unlearning one’s own privilege and transports readers to theoretical spaces where they will begin thinking differently about the ways in which privilege affects the ability (or willingness) to hear (or to understand) when the “other” is “speaking.”

Sandra Harding’s work also has had a transformative effect on my project. The ways in which she discusses the notions of struggles and achievements (1991b) are
always already a part of thinking differently in my project. Harding’s analysis of critiques of science-as-usual (1991b, p. 54) opens up questions about the pursuit of responsible knowledge that had not been visible to me without her insights. Harding offers not only guidance on how I might think differently, but also a model for action. She “speaks,” and I am able to hear.

I conclude these examples of models with Harding’s description of the “complex and changing environment” where feminists and others might answer her call to action.

The joint action of these various and competing and interacting forces in the terrain in which feminism also operates—indeed, feminism is also part of all of these tendencies—will have consequences different from those one might imagine from the perspective of the feminist critiques alone….The necessity to struggle to advance their [“bands of men and women” who make up “the terrain] goals in the environment of everyone else’s equally determined efforts creates configurations different from those of individual groups marching alone. Similarly, feminist tendencies must struggle against, with, and within these other streams of contemporary intellectual, political, and social life (1991b, p. 9).

Conclusion

In this chapter, I have cited a few of the most visible, and perhaps recognizable, models for thinking differently that are drawn from the work of feminist theorists. These examples are included in order to demonstrate ways I might think differently about methods and analysis in my project. These examples of rethinking and reframing
highlight links between feminist reformulations of traditional approaches, and recent literature addressing ambiguous and complex issues related to what it means to be responsible in the conduct of human subjects research.

I extend these concepts of reframing and rethinking for my research project. In Chapter Three, I adopt feminist methods for investigating my research questions, and in Chapter Four, I borrow from feminist theorizing to analyze the interviews, observations, documents, and survey data that form the data corpus for multiple phases of empirical work.

Based upon this review of literature, I develop a course of action for the sections of work that follow. In Chapters Three and Four, the methods and tools I use shift from having a theoretical focus to highlighting a more practical perspective. I emphasize understanding how responsibility and accountability work together in practice “with competing and interacting forces.” In practice, achieving balance between responsibility and accountability in research will be most productive for this project.
CHAPTER 3

METHODOLOGICAL FRAMEWORK

This chapter describes the methodological approach taken to investigating questions of what is meant by the notion of “responsibility” in research, how ethical responsibility might be demonstrated by researchers in academic communities, and in what ways institutional review processes affect underlying ethical principles in the responsible conduct of research. There are three primary research questions; one is empirical, one methodological, and one theoretical. The first question addresses how “responsibility” is defined and interpreted by researchers and names practices of researchers they believe demonstrate “responsible” conduct in research, the second considers how an iterative approach to inquiry can be productive for rethinking complexities in a multi-sited ethnographic study, and the final question takes into account the first two questions to examine ethical principles supporting the concept of “responsible conduct in research.” As such, each of the three questions builds on and is related to the others, and reveals the emergent and relational nature of this research project.

Methods for data collection and analysis are drawn from a number of sources and combined in ways that support the primacy and complexity of relationships throughout the study. The triangulation of methods and sources provides researcher
accountability for multiple complexities of the study. The project is multi-sited and emergent, and the methods discussion reflects the resulting complexities and ambiguities. The discussion of methods in Chapter Three is organized around relationships between, and among: the theoretical framework; research perspectives, positions, and contexts; methods of data collection, analysis and interpretation; and considerations of validity throughout the project.

The methodological framework guiding this project is derived from approaches of feminist researchers upon whom I rely for their practices of interpretive analyses to make meaning of social and cultural phenomena. My methodological framework also draws upon the work of researchers who note the situatedness of knowledge, and the primacy of the contexts within which social and cultural phenomena operate. I follow the methodological theorizing of Sandra Harding, who points out “…there is no such thing as a problem without a person (or groups of them) who have this problem: a problem is always a problem for someone or other” (1987, p. 6). In taking a feminist standpoint, I rely upon a feminist lens and standpoint epistemologies to construct understandings of the actions, beliefs, and values of the participants, respondents, and actors whom I study within the contexts of academic research environments.

Theoretical Framework

The feminist standpoint I adopt for this study situates both the researcher and the “person (or groups of them) who have” a problem in positions of marginality (Harding, 1987, p. 6).

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32 By suggesting “interpretive analyses,” I do not intend the interpretation of peoples’ lives. Rather I follow the thinking of Sandra Harding who indicates that “Starting thought from marginal lives [intends] a causal, critical account of the regularities of the natural and social worlds and their underlying causal tendencies” (1992, ¶ 28).
1987), begins thinking from those marginal lives (Harding, 1992), and openly acknowledges the limited and partial perspective of any one researcher, person, or group of persons (Haraway, 1988/1991). The position I take for the doing of this research is that of an “outsider within” (Collins, 2004/1986). I do not claim that this point of view is the one or only from which this project could be achieved; however, a feminist perspective and standpoint epistemologies can lead to insights about the ways that accountability and responsibility operate as complex, powerful, and interrelated elements within social and political contexts for ethical research.

A number of feminist theorists (Benhabib, 1994; Harding, 2004a, 1992; Hartsock, 1983; Tanesini, 1999; and Tuana, 1996) explain origins and development of feminist standpoints. These writers agree that “the Marxian notion of a standpoint of the proletariat” (Tanesini, 1999, p. 139) provided the nidus for generation of a number of what are now different accounts of distinctly feminist standpoints. Some of these standpoints were grounded in assumptions claiming that the experiences of women provided a privileged and distinctive perspective. Patricia Hill Collins (1986/2004) theorizes a standpoint differently and bases her understanding on women’s marginal positions, rather than on the essential or universal nature of women’s positions. I extend feminist standpoints for my research by tracing a path through the work of Hartsock (1983) and Collins (1986) and then taking up theorizing of Sandra Harding, who describes a shift toward “becom[ing] marginal” (1991b, p. 289). From various positions that I normally occupy, I take a critically defined feminist perspective (from the
margins), and then shift to a standpoint and use grounded theory (Charmaz, 2001) to interpret experiences of researchers in regard to what it means to be ethically responsible and politically accountable in research. I refer to the position where I normally stand, and stand especially for this project, as an insider within.

Researcher Position, Perspective, and Standpoint

I describe my researcher positions as both an outsider within and an insider without. In so doing, I invoke the theorizing of critical feminist theorists, Patricia Hill Collins (1986), Donna Haraway (1991), bell hooks (1990), and Sandra Harding (1993) to explain how I work from three research positions in the margins and am at times both an outsider within and an insider without. Ultimately, my achievement of a feminist standpoint is based upon reflexivity and the positions I occupy, the perspectives I take, and the research projects I develop to “make visible a different, somewhat hidden phenomenon” (Harding, 2004, p. 8).

Positioning

There are two dimensions, subject location and political position, across which I work to carry out my study. On the one hand, in terms of subject location, I move among three positions in relation to the institutional review processes I investigate: an observer, a participant, and an actor. On the other hand, in regard to political position, I am at times an outsider within institutional processes, and at other times I operate as an insider without, one who might be seen as having some degree of expert knowledge.

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33 My statement indicating a shift from a “perspective” to a “standpoint” is based upon Harding’s writing in “What is Feminist Epistemology?” (1991, pp. 105-137).

34 Sandra Harding (1993) describes reflexivity as a self-critical process that involves rethinking one’s research, including its social and political questions and implications.
gained from studying inside the process, but also moves away from the center of process. The opportunity, or necessity, to move in and out of various positions along two dimensions is a function of the multi-layered and complex system of institutional review processes in the academic environment where I study.

Subject locations.

In the course of this study I took roles in three subject locations to investigate effects of political accountability on researchers’ understandings of ethical responsibility. My introduction to the domain of responsible conduct in research with human subjects arose in the course of work associated with my assistantship in the Graduate School and began from the observer position. While carrying out an assigned duty of reviewing a research proposal from the Carnegie Foundation that requested involvement of Ohio State graduate students and faculty as research participants in its project, the Carnegie Initiative on the Doctorate (CID), I began studying Institutional Review Board (IRB) processes. As I began learning about the complexity of institutional processes and policies in preparation for submitting an IRB application to the Behavioral and Social Sciences review panel, my subject position shifted between roles where I was both an observer and an actor. During the eventual administration of the graduate student survey by the Carnegie Foundation, I functioned as a human subject participant in research.

The final empirical phase of the study, Professional Development Program for Teachers (PDPT), instantiates a commingling of my subject locations and a more demonstrable shift in political positioning from outsider within to insider without.
My involvement with PDPT was initiated and activated through an informal network of feminist researchers. In the case of PDPT, graduate faculty members were conducting a research project that was federally funded and proposed research to be conducted with public school teachers. The graduate faculty members were pedagogy experts, but were relative novices in dealing with the increasingly complex institutional requirements for compliance with human subjects regulations. Importantly, these faculty members were relative outsiders to the nuanced ways that the institutional review processes and board were shifting in emphasis from responsibility to accountability. The researcher who negotiated my participation in PDPT had expert knowledge of both the graduate faculty members’ and my research, and she brought us together to bridge our proficiencies and extend our individual knowledges in collaboration. Through this process, I transverse three subject locations: observer, participant, and actor.

Political positions.

Critical and feminist theorist bell hooks explores the idea of marginal positions in her discussion of “the politics of location.” hooks refers to some subject positions as political and names both “the spaces where we begin the process of re-vision” (2004/1990, p. 153) and the places where one who takes a radical standpoint position struggles. My adaptation of the outsider within as a political position is informed by this theorizing of marginal positions, and also by the work of Patricia Hill Collins who discusses the “creative use of marginal positions” (2004/1986, p. 103). I extend their
concepts to include alternative positions that I identify as *outsider within* and *insider without*.

When I apply the theorizing of hooks, Collins, and María Lugones (1991, 1989) to my work and call these positions *political*, I point toward the “complex and ever shifting realms of power relations” (hooks, 2004/1990, p. 153) in institutional review processes and administration. I find the current social and political environments where institutional review processes challenge traditional practices of responsible conduct to demonstrate accountability in research to be an example of an ever shifting realm of power relations. In this study, when I operate within the realm of the IRB at Ohio State University, I am assigned the position of an *outsider within* in relation to the IRB. As I shift my position to working with other researchers, students, and administrators outside the IRB, I then become an *insider without* or traveler\(^3\) (Lugones, 1989) somewhere *in between* (Lugones, 1991).

*Troubling researcher locations and positions.*

I carry out this research project in an environment of institutional review that locates social science researchers as *outsiders*. Review procedures, forms, and requirements have been developed from a medical science model that defines research as systematic investigations contributing to generalizable knowledge. The structure and hierarchy of the IRB system originated in response to issues in medical research and continue to situate social scientists within a system of regulations that do not fit with

\(^3\) María Lugones writes: “The shift from being one person to being a different person is what I call ‘travel.’… one may be completely unaware of being different than one is in a different ‘world,’ and may not recognize that one is in a different ‘world.’ Even though the shift can be done willfully, it is not a matter of acting” (1989, p. 170).
their methods and goals. Both quantitative and qualitative researchers working in the 
social sciences have noted this lack of fit with social science research in general and 
with education research in particular (Breckler, 2005; Gunsalus et al, 2005; Sieber, 
2004; Townsend, 2006).

In addition to the problem faced by social scientists working within regulations 
and processes designed for medical research, I act as an outsider within on the IRB 
Behavioral and Social Sciences Panel. IRB administrators recruit panel members 
according to federal requirements specifying categories of participation. As a graduate 
student, I am categorized as an “affiliated non-scientist.” This designation indicates that 
I have a relationship with the university (affiliated), but have not earned a doctoral 
degree (non-scientist). Thus, while I am within the IRB organization, I am seen as an 
outsider to scientific research.

The outsider within position I occupy calls to mind the work of education 
researcher and methodologist Patti Lather, who describes her work as “a critical social 
science, a science designed to empower those involved to change as well as to 
understand the world” (1991, p. 4). Lather introduces the concept of “counter 
hegemonic knowledge, knowledge intended to challenge dominant meaning systems” 
(1991, p. 87). Making visible the need for changes in the ways that the IRB emphasizes 
compliance over education is one goal of my research, and a commitment to change 
drives me to “challenge dominant meaning systems” from the outsider within position.

When I travel to positions where there is more ambiguity about what it means to 
be an outsider or insider, I do so to create spaces for challenging the institutional and
federal systems of research regulation. From liminal spaces, I question current demands for accountability, and ask what it means to be ethically responsible in the conduct of research with human subjects. I take a position that is not-outside, not-inside, not-within, and is \textit{without}. In confronting the system of institutional review processes, I face up to the task of unlearning the privilege (Spivak, 1988) of being an affiliated non-scientist serving on the IRB.

\textit{Perspective}

The perspective I take for this research combines a feminist lens with various subject locations and political positions that I have described. In working from different locations and positions in five phases of the research project, I work against a “view from nowhere.” In so doing, I ascribe to Donna Haraway’s (1988/1991) notion of situated knowledges and acknowledge that as a researcher, I am always located \textit{somewhere} and have a limited and partial perspective.

Joan Hartman and Ellen Messer-Davidow define a perspective as, “the function of relatively positioning a knower and a subject of inquiry,” and they point out “The knower’s perspective is determined by her values, ideas, and feelings, and these in turn are produced by her location in society” (1991, p. 37). A number of other feminist theorists have made similar distinctions. Critical feminists suggest that one’s position in respect to others (Lugones, 1991) and how one relates to others (Lorde, 1984), make differences in how the world is viewed (hooks, 1990/2000). hooks further notes that individual women’s perspectives can vary as a result of differences in their lived experiences. “This lived experience may shape our consciousness in such a way that our
world view differs from those who have a degree of privilege (however relative within
the existing system)” (hooks, 2000, p. 16).

These critical feminists, bell hooks, Audre Lorde, and María Lugones, refer to
the privileged positions of white feminists, and I borrow from their theorizing to
consider my position serving on the IRB’s Behavioral and Social Sciences review panel
member as a privileged position. In both instances, privilege signifies being in some
ways part of a dominant system. Thus when I work against the administration of
institutional review processes, from either within or without, and move toward
peripheral boundaries of systems of domination, I strive to unlearn privilege.

Feminist perspective.

Sandra Harding (1986, 1987, 1991a, 1991b) and other social scientists have
written about the potential for generating knowledge through feminist methodology and
find Harding’s argument that “commitments to antiauthoritarian, antielitist,
participatory, and emancipatory values and projects… increase the objectivity of
science” (1987, p. 27) particularly compelling, and I based my decision to adopt a
feminist perspective on the rationale she describes. My methodological goal in taking a
feminist point of view has been to generate research questions of import to women and
other outsiders from a counter-hegemonic perspective, to carry out data collection and
analysis that recognizes the experiences of women and Others (whose experiences are
systematically devalued and underrepresented), to introduce a fresh perspective
(Millman & Kanter, 1975/1986) on the effects of accountability on responsibility in
research, and to advocate for change in the current practices and procedures of institutional review processes.

Feminist Standpoint – A Methodological Guide

Over the last twenty years, Sandra Harding has written about her conceptualization of a feminist standpoint, origins of the theory, sites of controversy, and central themes. During that time period, she has refined her theorizing in response to the critiques from other scientists; however, basic tenets remain the same. In a recent article, A Socially Relevant Philosophy of Science? Resources from Standpoint Theory’s Controversiality (2004b), Harding outlines central themes of standpoint theory, and it is these in some form that I take up and follow as a methodological guide (2004a) in my project.

Features of a feminist standpoint.

There are three methodological features (Harding, 1987) that are consistently emphasized as being fundamental to a feminist standpoint. First, the feminist work of knowledge production begins from “particular, culturally specific, women’s experiences, lives, or activities (or ‘labor’)—and, for some, from the diverse emerging discourses of their day” (2004b, p. 29). Secondly, the goal of feminist standpoint projects is “studying up,” or “focusing explanations on dominant social institutions and their ideologies” (p. 30). Thirdly, such projects “could not occur without political struggles” (2004b, p. 30) and are aimed more at “the creation of groups’ consciousness than about shifts in the consciousness of individuals” (p. 32). Throughout Harding’s discussions, there is a common thread suggesting that reaching the level of a feminist
standpoint is an actual achievement, rather than a methodological claim or statement of purpose.

Achieving a feminist standpoint.

In her *Feminist Standpoint Theory Reader* (2004a, p. 12), Harding writes: “a main objective of standpoint theory and research is precisely to map the conceptual practices through which particular institutions, such as disciplines, serve oppressive forms of power.” In a more recent article, Harding and Kathryn Nordberg (2005) delineate elements of feminist research methodologies that they believe are important to knowledge production and to engendering “socially engaged research—that is, research that holds itself ethically and politically accountable for its social consequences” (Harding & Nordberg, 2005, p. 2010). These statements resonate with the goals of my research, and I propose to apply the methodological tools of a feminist standpoint in my research investigating the effects of institutional accountability requirements on responsible practices in the conduct of research with human subjects.

A primary goal of Harding’s research (1991b) is to “re-think the gap between what we want and the way the world is” (Lyon & Conway, 1995, ¶ 2). The terms I interpret in this study are responsibility and accountability. My goal is to rethink what I perceive to be a gap between performing research responsibly (what we want) and being sufficiently accountable in research (the way the world is).

Research Questions

This project responds to calls for greater accountability in research by challenging assumptions suggesting that prescribing and emphasizing performance-
based standards for accountability in research procedures and practices will lead
necessarily to increased demonstrations of responsibility by researchers in the conduct
of research with human subjects. From a feminist standpoint, I investigated three broad
research questions through multiple phases of interrelated empirical projects. The
research questions address empirical, methodological, and theoretical issues that arise in
the experiences of social science researchers and other outsiders, focus on dominant
social institutions and their ideologies, and advocate for change.

This research was and is emergent. I call attention to the changing and evolving
nature of the research in order to help readers understand the visible effects of shifts that
occasionally threaten to rupture the flow of the study. As examples of the emergent, or
emergency, nature of some of the work, I note how I began reading federal documents
as literature, and came to see some of those documents as data. As such, literature
became data. During the research process, my initial questions evolved as I probed for
deeper insights. From time to time, issues I first saw as being related to ethical
responsibility became caught on the hooks of accountability. I responded to these and
other challenges by learning to see these changes as productive for the research.

The research questions I state here represent my initial constructions of ways to
partition the primary question addressing what it means to be responsible in the conduct
of research with human subjects.

Empirical Question: What does “responsibility” mean to university students, faculty,
and administrators in the context of research involving human subjects?
**Methodological Question:** How can an iterative approach to inquiry engender rethinking of complexities in multi-sited qualitative research?

**Theoretical Question:** Can balancing ethical principles in the performance of research achieve responsibility and accountability in practice?

**Research Methods**

This research study was multi-sited and emergent by design. Five projects, which are described chronologically and more discretely in following sections, were performed as overlapping and interrelated phases of empirical research. Each *project* contributes to the *study* through triangulation of sources, methods, and "lessons learned." Each project is related to the others in that the earlier projects were formative in developing the successive ones. The phases of data collection and analysis overlap in an iterative way. As lessons were learned, insights from those lessons were applied to earlier phases of the work. This process of repeating earlier steps and returning to earlier stages required becoming reflexive and was a critical part of the rethinking process. The discussion of methods in this chapter takes a summative approach and stitches together the individual reports into a rhizome-like recounting of methods that were used throughout the study. This chapter concludes with a brief discussion of where this work rests temporarily.

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In her discussion of what it means to be reflexive in research, Patti Lather describes such a process, and she states: “...by “reflexive”, I mean those stories which bring the teller of the tale back into the narrative, embodied, desiring, invested in a variety of often contradictory privileges and struggles” (1991, p. 87).
Research Sites, Agents, Methods, and Context

For purposes of this discussion of methods, there were five sites for data collection. The data corpus is a composite that is anchored in and relates to all of the sites. While each grouping of sites with agents is distinguishable from the others, the pairings always already maintain relationships between the data and its agents\textsuperscript{37}. Thus, data gathered during the faculty survey provide a somewhat discrete portion of the data corpus and are in some ways distinct from data gathered in the undergraduate student research experience project. Data analysis and interpretation from all the generating agents are brought together in creation of situated knowledges (Haraway, 1988/1991) for the overall study. This theoretical approach has been taken in order to work against practices in the sciences\textsuperscript{38} of abstracting knowledge from experience (Haraway, 1988/1991; Hubbard, 1995) and to work toward a more grown up attitude toward science (Lather, 2004).

Agents who contributed data for this research study were situated in five locations. Included in these groupings of participants are: administrative personnel (from both the Carnegie Foundation and Ohio State University) working on the Carnegie Initiative on the Doctorate, and administrative personnel from Ohio State’s IRB office (CIDS), undergraduate students participating in a summer research program (USRE), faculty members in the College of Education at Ohio State University

\textsuperscript{37} Donna Haraway states: “Situated knowledges require that the object of knowledge be pictured as an actor and agent, not a screen or a ground or a resource, never finally as slave to the master that closes off the dialectic in social and human sciences” 1988/1991, p. 198).

\textsuperscript{38} Ruth Hubbard (1995, p. 228) notes that she uses “the conventional short-hand of calling the natural sciences ‘the sciences,’ because that is what most people call them.” This distinction is similar to that made by Sandra Harding when she discusses “science as usual.” I have the work of both writers in mind when I refer to “practices in the sciences”.

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(COEFS), qualitative researchers attending the First and Second International Congresses on Qualitative Research (QIPS), and teachers and administrators involved in a professional development program for teachers of mathematics (PDPT).

Data Corpus

The data corpus for the study is arbitrarily described according to discrete projects. This recounting includes 178 agents who contributed in constructing knowledge for the work overall. These research participants are enumerated in relation to primary research sites and their originating relationships (for this research) with institutional review processes. The primary data and methods (documents, observations, interviews, and surveys for analysis) are summarized to capture a broad picture of the data corpus.

- CIDS – Data summary: research notes generated and recorded between April 2004 and December 2005; copies of email messages and communications between Carnegie Foundation researchers (n=4), OSU Graduate School administrators (n=4), and Ohio State’s institutional review board personnel (n=3); historical documents from Ohio State’s Graduate School; two surveys with recruitment scripts and IRB application forms. Researcher position: Outsider.

- USRE – Data summary: reflective writings from undergraduate students (n=32 in 2005), research notes recorded during ethics workshops, observations of undergraduate students carried out in group discussions and unstructured interviews (n=76) during 2005 and 2006 summer workshop programs, and
undergraduate student responses (n=44) to evaluation surveys administered in July 2006. **Researcher position:** Outsider moving toward insider

- **COEFS – Data summary:** responses to survey instrument administered to COE faculty members (n=62) in January and February 2006. **Researcher position:** Outsider within in relation to faculty members and Insider without in relation to the IRB.

- **QIPS – Data summary:** transcription of notes from qualitative researchers’ (n=24) group discussions on the topic, Wrestling with IRBs, recorded during the *First* (and the *Second*) *International Congresses of Qualitative Inquiry* (May 2005 and 2006); unstructured interviews with qualitative researchers from Australia, Canada, Denmark, and the United States. **Researcher position:** Outsider within and insider without.

- **PDPT – Data summary:** research notes generated during a period extending from April 2006 through August 2006, research notes from informal information gathering conversations with PDPT investigators and key personnel (n=5), documents, unstructured interviews, and observations from a July 2006 conference in Oakland California where PDPT was presented as a case study, and IRB related documents posted on Ohio State’s web site. **Researcher position:** Insider without.

The broader context for this study unified participating agents, who represented students, faculty and administrators, in an academic community of researchers. The
participants had experiences associated with institutional review processes in academic environments and worked with, or were concerned about, human subjects. Work on the individual projects was divided into chronological stages for purposes of this discussion; however, the data corpus, when viewed as a whole, developed over a twenty-eight month period of engagement in the field.

Data Analysis and Interpretation Procedures

Procedures for analyzing the body of data assembled for this research began with a coding process that focused on major themes and used both a priori and grounded analytics. Themes, such as responsibility and accountability, emerged during the early stages of document analysis and remained central to the analysis. Literature from fields outside education was helpful in identifying additional themes, especially in regard to seeing what remained hidden from view in institutional review processes. For example, mentoring was a recurrent theme in the undergraduate student phase, and this particular theme did not appear in coding data that was generated from IRB administrators. Similarly, advising was a coding feature for the faculty survey data and did not appear from the students’ perspective. Aspects of mentoring and advising could be relevant to students, faculty, and administrators; however, from some perspectives these topics did not surface in the data.

Data were also coded by research site-agent associations. This a priori approach was helpful as projects developed in the study and as the coding task became more complex. Combining focused analytics with grounded analytics was helpful as a way to attend to the notion of what might have been excluded from the data. The coding
scheme I adopted during the first phase while working with data from the undergraduate research study was particularly well suited to Adele Clarke’s situational mapping. She recommends this technique for its potential to “elucidat[e] complexities—the key elements and conditions that characterize the situation of concern in the research project broadly conceived” (2003, p. 553). Clarke’s method emphasizes the relational aspects of data and is conducive to analysis from a feminist perspective. The relational maps suggested by Clarke were helpful in identifying relationships within the data as well as in analysis of what had been excluded from the data. Clarke refers to these omissions from data\(^{39}\) and analyses as “empty spaces and silences” (2005, p. 76).

Feminist philosopher Lorraine Code also argues for attending to exclusions from data and for actively listening to muted voices (1995b). Code notes that in decontextualized research, exclusions can “disappear in the analytic process” (1995a, p. 18). Code, then, advocates for “situated” knowing and contextualized research citing Haraway’s charge to feminists to “become answerable for what we learn how to see” (Haraway, 1988/1991, p. 190). Code adds her voice to Haraway’s statement writing: “To be thus accountable, feminists have to see what is systematically and systemically screened from view by the most basic assumptions about how people know the world; and they have to understand the power structures that effect these erasures” (Code, 1995a, p. 23).

Interpreting the data frequently led back to additional analyses, rather than toward drawing conclusions or making claims; seemingly, both the analysis and interpretation processes engendered more questions than answers. In some ways, the

\(^{39}\) Adele Clarke explains the sites of silence as “What seems present but unarticulated” (2003, p. 561).
empirical research revealed complexities and ambiguities of both responsibility and accountability as assemblages of multiplicities, and these tensions were not fully resolved. To a certain extent, the lengthy time period of investigation worked against any resolution of this and other issues. I found that just as participants were changing over time\textsuperscript{40}, the institutional review process was changing as well. The changing over time was never more apparent than in the case of the IRB Behavioral and Social Sciences review panel. Following a meeting, one panel member shared that he felt as though every time he returned for a meeting, the panel and decision making processes had changed.

During stages of preliminary and tentative writing, I created a summary of “lessons learned” for each of the projects individually. Those lessons from the projects were then useful in grounding and feeding the later projects. This strategy of reviewing processes, actions, and their meanings throughout the writing process follows the suggestions of Kathy Charmaz (2001). She explains the logic of grounded theory and states that these strategies were developed from the work of Anselm Strauss (1916-1996) who “…adopted both the pragmatic philosophical tradition with its emphasis on studying process, action and meaning …” (Charmaz, 2001, p. 336).

As Charmaz explains grounded theory, the distinguishing characteristics of this method include: (1) simultaneous involvement in data collection and analysis phases; (2) creation of analytic codes and categories\textsuperscript{41} developed from data, not from

\textsuperscript{40} A small number of students participated in the USRE research during both 2005 and 2006.

\textsuperscript{41} “Categories” can be more dangerous than helpful. Charmaz points out that, for her, “Categories reflect the interactions between observer and observed.” She also notes that she is writing about “conceptual
preconceived hypotheses; (3) the development of middle-range theories to explain behaviors and processes; (4) memo-making, that is, writing analytic notes to explicate and fill out categories, the crucial intermediate step between coding data and writing first drafts of papers; (5) theoretical sampling, that is, sampling for theory construction, not for representativeness of a given population, to check and refine the analyst’s emerging conceptual categories; and (6) delay of the literature review (Charmaz, 2001, p. 336).

Charmaz’s explanation of grounded theory emphasizes the importance of interactivity throughout the data analysis process. She specifically mentions that analysis is not static and recommends: “looking at action in relation to meaning” in order to understand meaning better. “I assume that the interaction between the researcher and the researched produces the data” (Charmaz, 2001, p. 339). As I understand Charmaz’s strategies, interactivity between elements of the research process and emergence of theory from “layers of meaning” contribute to an iterative process of analysis that can stimulate a more thoughtful and responsible study.

Initially, I was uncomfortable with Charmaz’s suggestion of “filling out categories.” However, her explanation of “conceptual categories” as “points of departure” was helpful and also seems to cohere with Patti Lather’s writing about “categorical schemes” as “provisional constructions” in that both writers move categorizing in more productive directions. In her discussion of “postmodern writing strategies,” Lather (1991, pp. 84-85) states: “Conceiving useful categorical schemes as

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categories,” and that concepts are used “as points of departure to look at data, to listen to interviewees and to think analytically about the data” (2001, p. 337).
provisional constructions rather than as systematic formulations, focus shifts to how
data escape, exceed and complicate rather than how to impose a specific direction of
meaning on the unfolding of the narrative.” I take from this explanation that while
systematic category assignment might be viewed as a more familiar way of scientific
writing, the approach to categories suggested by Charmaz (2001) and Lather (1991)
opens up possibilities for becoming “part of a movement that is reinscribing science
‘otherwise’, reshaping it away from a ‘one best way’ approach to the generation and
legitimation of knowledge about the world” (Lather, 1991, p. 3).

Throughout this study, I have worked to develop “provisional constructions” for
the relational concepts of accountability and responsibility. Behaviors and actions of the
people and processes operating in the context of research are theorized as not entirely
separable, but existing in mixture (Deleuze & Guattari, 1987). Reflexive and middle
range questions I posed included: “How does responsibility function in the multiplicity
of relationships existing within research practices”; “Where are the sites of silence and
blind imitations in the institutional review process?” “In what ways is responsibility
related to other concepts such as accountability”; and “What practices lead to faculty,
administrators and graduate students becoming responsible and/or accountable in the
conduct of their research?”

Validity Practices

Researcher reflexivity was an essential tool (and sometimes weapon) that was
used to support the trustworthiness of data and the selection of validity practices
throughout the study. The ways in which reflexivity was put to work in different
instances depended upon the particulars of the different phases of research. Examples of differences in the self-critical practices can be drawn from a comparison of methods in the faculty survey phase and the professional development for teachers phase. In the case of the former, survey invitations, instructions, and items were submitted to other COE faculty members for comments and feedback before they were administered to all COE faculty members. For the latter phase, I proposed the issues in a case study for discussion at a national conference of professional researchers and received suggestions of strategies and resources for analyzing issues related to this phase of research. In both situations, the counsel and analysis of other researchers was formative to developing validity for the projects.

This example combines elements of critical reflexivity with member checking, and peer review (Glesne, 1999) as practices supporting trustworthiness of data. Triangulation of sources, theories, and methods also encourages validity and contributes to “establishing data trustworthiness” (Lather, 1986/2003, p. 191) in the study. The triangulation of data collection methods was discussed earlier; however, it is worth noting additionally that triangulation of data sources and theories in the study contribute to validity practices. Data sources include historical and current documents, literature from a number of academic fields, and participants who contributed as agents and were engaged purposefully for their diverse perspectives. Although the primary theories at work in this study are associated with “feminist” researchers, differences between and among the theories I apply provide more than one way of looking at data. The diversity

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42 I have chosen these two phases for comparison because they involved participants with similar perspectives.
in theoretical approaches is exemplified by the way in which I bring together the work of Gayatri Spivak with that of Sandra Harding. While Spivak is noted for her work with critical theory and post-colonialism, Harding is closely allied with standpoint theory and the philosophy of science.

According to Corrine Glesne (1999, p. 32), “prolonged engagement and persistent observation” address validity issues as well. My engagement with this research seems quite prolonged, with the project having begun in April 2004, and only threatening to reach a temporary suspension in March 2007. I continue to observe processes and agents involved with IRBs, and those observations have been persistent as I have attended and participated in more than 25 IRB meetings at this point. My term serving as an IRB panel member does not end until September 2007, and by that time I anticipate having developed provisional constructions as starting places for future projects. Realistically speaking, my engagement with the IRB process will continue for as long as I am part of an academic community and performing research.

There is another feature of this research that I believe contributes to its validity, and that is the nature of investigating such a research topic as responsible conduct in research. First, this topic sets up the researcher as some sort of expert on a contested topic, and as a result, expectations for demonstrating high standards of responsibility weigh heavily on this type of project. Secondly, the research is designed to challenge dominant systems, and this sort of investigation seems to me to invite, if not to beg for, criticism from those within the dominant system, as well as from others who are challenging systems in other ways.
Across the study, the concept of responsibility is a unifying thread drawn throughout the methods and practices. The selection and use of methods were guided by individual standards of responsibility; however, as a self-critical researcher, I cannot ignore that while standards for responsibility are individual and ambiguous, there are widely accepted normative standards for accountability. Although individual projects were designed and carried out in ways that hold the findings to those normative standards for accountability, there remains a silent call to demonstrate an even higher standard for responsibility.

My understanding of how responsibility and accountability operate together in the performance of research suggests that on the one hand, responsibility represents ways in which the researcher cares for the interests of others, or answers that sometimes-silent and inward call from human subjects participating in the research and also from human subjects who are potential participants\textsuperscript{43}. On the other hand, accountability stands in for responsibility when empirical evidence of responsibility is expected or required by those who undoubtedly will challenge this research and its provisional constructions, or both. In effect, I face similar challenges in claiming validity for the project to those faced by my participants when they claim responsibility in the conduct of research with human subjects.

Summary

This chapter reviews the methods, practices, and theories that underlie the research study. Greater detail on these issues is laid out in the sections addressing the individual projects. Similarly, lessons learned from the discrete projects are included in

\textsuperscript{43} Potential participants are those who might benefit from the project at some future point in time.
the individualized sections, and analysis and interpretation of data from the study are discussed in the following chapter in a summative fashion.
CHAPTER 4

ANALYZING DATA

Dominant themes emerging from this research have been movements and tensions in and across: 1) relationships, 2) places and contexts, and 3) time. Movements and tensions in and across relationships refer to the emergence of networks of connectedness among individuals, identities, participants, historians, researchers, and the situated knowledges these actors embody. The context for the study always has been ethics in human subjects research, and the site a large midwestern university. Three research questions guided data gathering, and data collection reached across the US through multiple sites. Introductory research questions guided the emergence and development of new or different questions (becoming research questions), contexts for investigation, and tensions or issues. The passing of time punctuated five discrete projects and created a historical path through the study overall.

Data for this study consists of: documents in the forms of publications, reflective writings, field notes, and training materials; informal interviews; survey instruments and responses; and observations\textsuperscript{44} of institutional review processes. As situated learnings came to light for each project, research questions were refined and provisional projects emerged. Project reports present analyzed data, and record “lessons learned” from study

\textsuperscript{44}“Observations” in this study focused on processes and procedures, rather than on human subjects.
experiences. Lessons learned and supporting data from the discrete projects reveal the situated and embodied knowledges (Haraway, 1988/1991) reported in this chapter.

Approaching Data

A traditional approach to discussing these data would be to provide a comprehensive descriptive account of the people and relationships, places and contexts, and time periods and data collection points that contributed to the study. This approach offers a path to “…becom[ing] answerable for what [I] learn how to see” (Haraway, 1988/1991, p. 190) in the real world. The telling of realist tales for the five discrete projects follows similar paths beginning with data collection, progressing through data analysis, and summarizing with lessons learned from the projects.

Donna Haraway (1988/1991) proposes a feminist approach that leads to more responsible knowledge claims. She asserts that situating knowledge and “establishing the capacity to see from the peripheries and the depths” (p.191), or viewing from partial perspectives, yields a better account of the world. “Irresponsible means unable to be called into account.” In terms of this study investigating ethics in research, being accountable for data and being responsible for knowledge claims mean being answerable for accounts of the data and becoming responsible for rendering an analysis that sees from partial perspectives. The five discrete projects represent accounts from perspectives of administrators (CIDS), undergraduate students (USRE), faculty members (COEFS), qualitative researchers (QIPS), and teacher educators (PDPT).

Haraway’s approach can be assimilated along with the direction advocated by C.K. Gunsalus, compliance officer at the University of Illinois and lead author of the

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45 Reports for the discrete projects are included in Appendixes A through E.
“Mission Creep” *Illinois Whitepaper* (2005). Gunsalus’s work is useful in this data analysis because she has experience and expertise working both within and against institutional review systems. In her critique of IRB systems, Gunsalus counsels focusing more on what counts, that is “ethical substance,” than on what can be counted. When she makes reference to “what can be counted,” Gunsalus troubles effects of regulatory formalities (2004).

In the context of my study, regulatory formalities surfaced in details that were visible in institutional accountability measures. Questions that investigators reported receiving from IRB administrators reflected effects and potential shocks. Examples researchers cited include requests for details of procedures and clarifications about participant numbers and sample sizes. IRB pre-screeners ask such questions as: “Have adequate subject numbers been entered on application forms?” or, “Have telephone interviewers (data gatherers) in Manila completed CITI training?” These are kinds of things that can be “counted” and have the effect of shocks on research projects, as well as on investigators. Requests for additional information in pre-screening processes represent shocks to researchers because incomplete or ambiguous information is a part of that which “can be counted.” Errors and omissions have the potential to cause suspension of the application process before reviews of ethical substance have started. This chapter traces signs, shocks, and effects that surfaced during data gathering, analysis, and rendering of lessons learned.

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46 Gunsalus (2004, p. 372) notes that Albert Einstein is credited with having said: “Not everything that can be counted counts and not everything that counts can be counted.”

47 Throughout this discussion, I provide examples from the five projects. The examples I cite are not inclusive, and I do not attempt to lay out a detailed recounting of each project in this chapter.
The epistemological pathways proposed by Haraway engender analyses that avoid strict binaries and dichotomies. Concepts of accountability and responsibility are primary codes for analysis throughout the study and do not necessarily represent “two poles of a tempting dichotomy” (Haraway, 1988/1991, p.183) on the question of ethics; rather, accountability and responsibility are always already revealed as existing in mutually dependent mixtures. The blending of these concepts is evident in the five empirical projects that comprise the full study.

The recounting of a data analysis story in this chapter provides a highlighted view of each of the discrete projects. The story is organized along the lines of subject positions and locates the data as situated and embodied knowledge. This chapter also traces examples of discontinuities that became visible over the course of two years. The chapter concludes with revised research questions.

Phasing the Study

This study troubling the notion of “responsible conduct in research” and asking what responsibility might mean to university students, faculty, and administrators who engage in research with human subjects was proposed as a three-phase study. Time periods and subject positions demarcate recursive phases of investigation. The empirical work was initiated to trace effects of IRBs over the course of two years. While investigating signs, interpreting shocks, and uncovering effects of institutional review processes, I moved through three subject positions in the research: (1) graduate assistant/investigator in a research university; (2) participant/observer and reviewer of
research; and (3) policy analyst and writer. Each of these positions represents a differently partial and limited perspective.

*Phase One: Graduate Assistant/Investigator*

The first phase of study developed from an assignment associated with my assistantship in the Graduate School. The Carnegie Initiative on the Doctorate Surveys (CIDS) provides an example of subject positions taken up during Phase One. This project began when the Graduate Dean asked that I review a proposal from the Carnegie Foundation for the Advancement of Teaching (Carnegie Foundation). In that proposal, the Carnegie Foundation requested participation of Ohio State faculty members and students from six graduate programs. My activities focused on working with Carnegie Foundation scholars to implement surveys that had been designed to gather information about doctoral education experiences in six graduate programs across 44 universities.

In 2004, the Carnegie Foundation was sponsoring a multi-year action research project in response to concerns about doctoral education in the 21st century (Walker, 2004). My involvement with the CIDS project, which began in April 2004, progressed with an IRB application that was approved in April 2005, and concluded with an IRB termination report in March 2006. Primary actors involved in the processes included researchers and administrators from the Carnegie Foundation, the Graduate School at OSU, and Ohio State’s Office of Responsible Research Practices (ORRP).

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48 A calendar year elapsed between the time that the project began and the time when an IRB application to participate in the research was approved. This lengthy period of time and the tensions that caused the delay represented a sign of the discontinuities that came to light in dealing with ethical issues in this particular endeavor. In April 2005, the local IRB was not familiar with the style of participatory action research that was proposed by the Carnegie Foundation.
My role in the CIDS was twofold. I researched IRB policies and procedures for the Graduate Dean, who served as the primary investigator on the project. In this role my subject position was that of “investigator.” At the same time I was carrying out research tasks for the Graduate School, I was also functioning as a “graduate assistant.” In the latter role, I communicated through email and telephone conversations with Carnegie Foundation scholars and prepared IRB application forms for the Graduate School and the Carnegie Foundation.

The first phase of study involved two roles that together I name as one subject position. I also suggest that the co-dependent roles of “graduate assistant/investigator” represent a perverse identity. The notion of a “perverse identity” is one I borrow from feminist philosopher Naomi Scheman (1991, p. 196) to describe ambiguous movement between two, or more, mutually dependent roles. Scheman claims: “Those with perverse identities (perhaps everyone, but certainly every feminist and other radical academic) can have no easy answers to what counts as acting responsibly; we have no straight paths to follow.”

During analysis of the day, it became evident that these two simultaneously operating roles were reenacted in each of the projects. There was a phase-one-phase that included adopting the perverse identity of graduate assistant/investigator, (but not a perverse capacity\(^{49}\) as Haraway uses the term) each time a discrete project emerged.

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\(^{49}\) Haraway refers to the “perverse capacity” (1988/1991, p. 188) of human eyes “to distance the knowing subject from everybody and everything in the interests of unfettered power.”
Phase Two: Participant/Observer and Reviewer of Research

My activities as a participant/observer and reviewer of research were designed to ground later projects in the study and to provide empirical experiences in research. Both of these goals were realized. Phase Two of the study is ongoing and involves my participation as a protocol reviewer serving on the Behavioral and Social Sciences panel of an IRB at a midwestern research university. The extended period of time spent reviewing proposals and observing how human subjects review processes facilitate research has informed the study by drawing my attention to frequently recurring issues education researchers, and others, face in negotiating through institutional review processes. The College of Education Faculty Survey (COEFS) generated additional data (some of which was used as a triangulating source) to the second phase of research, where my role was that of “participant/observer.”

A number of issues were mentioned in responses from the faculty survey that had also been identified in educational research literature (AAUP, 2001; Lincoln, 2004; Lincoln & Tierney, 2004). Thus, survey responses contributed to the study by highlighting, confirming, and disconfirming particular issues that concerned education researchers working with IRBs.

Primary issues identified by faculty members (44%) who completed the survey included the following:

• Faculty members expressed concern regarding and asked for more information about how ethical principles were being interpreted and applied by the IRB.

I attended 30 Behavioral and Social Sciences Review Panel meetings between August 2005 and March 2007. My role was noted in minutes of the meetings as: “Non-scientist, Affiliated.”
• Faculty members also raised questions about how IRBs set and implement policies that affect all researchers within the university.

• Respondents had the impression that ORRP administrators and IRB panel members did not have a good understanding of research conducted in educational contexts.

• One faculty member applied the principle of autonomy (respect for persons) to the IRB and wrote: “The design of the procedures and the way they have been implemented show a lack of respect for the needs and culture of the faculty and students of this College.”

• Faculty members believed that research in educational contexts is inherently less dangerous than is human subjects research in biomedical contexts, and therefore, they perceived that risk/benefit analyses were over emphasized in application and review processes.

The primary purpose of the second phase of study was to investigate IRB processes and procedures from different perspectives. Data from the faculty survey were particularly useful because respondents seemed to have answered questions with thoughtfulness and candor. Responses from the COEFS were helpful also in that they identified issues that needed to be investigated further.

As was the case in the first phase of research, in this phase, there was a blending of my researcher subject positions with multiple roles being enacted simultaneously and recursively. Although I performed (or was identified) as a graduate student in both
projects, I identified a discontinuity in how faculty members responded to my activities in the two aspects of this phase of research. There were a number of responses to the COEFS suggesting that faculty members appreciated that someone was looking into institutional review processes. In contrast to this affirmation, my participation on the IRB raised questions and suspicion about my research goals.

There may have been more suspicion associated with the IRB service because in some cases faculty, students, and administrators who do not serve on the IRB have the impression that panel members must be faculty members. In fact, the composition of the panels is set out in federal guidelines, and there is a requirement that a “non-scientist” be present during each meeting. While the moniker, “non-scientist,” seems in some ways to suggest a person with less or inferior training, in fact, the non-scientist is intended to represent the perspective of human subjects who are not primarily researchers. Thus, a non-scientist brings lived experiences (and embodied and situated knowledge) to the review process.

The lessons learned from conducting the survey of faculty members, submitting IRB forms, and participating in IRB procedures as a panelist were valuable resources as I moved to the third phase of the study.

Phase Three: Policy Writer – A Modest Witness

There were two stages in the third and final phase of my study. For both stages I translated theory into practice reviewing current and suggesting new policies. I refer to this work as “policy writer.” The first stage was based upon concerns expressed by two

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51 This phenomenon was revealed in informal conversations that took place away from campus. Specifically, faculty members asked questions about my goals while I was attending the AERA meeting in San Francisco.
groups of researchers: qualitative researchers attending the First International Congress of Qualitative Inquiry (QIPS); and College of Education faculty members at Ohio State who responded to a grounded survey. In Stage One, I drafted the *Position Statement on Qualitative Research and IRBs* (Evans, 2006). This document articulates a problem statement, puts forward a draft of standards for practice, and proposes action plans for qualitative researchers.

For the second stage, I developed a case study that featured issues raised by researchers who were developing a program of professional development for teachers. This project was informed by strategies I considered while studying IRB processes. The case study associated with the PDPT project addresses issues of justice and equality in school-based research, and attempts to achieve a responsible balance between competing ethical principles.

While putting to work an understanding of how IRBs carry out their work in order to uncover techniques that would be productive for qualitative researchers conducting research in educational environments, I shifted from performing as an *outsider within* to acting as an *insider without*. My researcher position shifted from *outsider within* to *insider without* for both stages of this phase in the research; however, the move was more difficult in the second stage than in the first. The move in my work with the PDPT project was an awkward one because I approached becoming “engaged” in the PDPT research project. I was constantly aware of my position and was (re)negotiating my stance as a policy analyst and writer as opposed to being a researcher involved with human subjects.
My move from outsider-to-insider in the second stage assumes that the IRB is at the “center” and that marginal spaces (away from that center) are spaces where researchers who do not “belong” in some way might be permitted to approach and to interact with the IRB. I cannot not think about Donna Haraway’s refiguration of the modest witness in relation to my researcher positions in this third phase of study. Haraway takes the modest witness figure from an historical account of the experimental way of life in the seventeenth century (Shapin & Schaffer, 1985) and develops a more modern figure, which she then uses as a trope in her discussions of technoscience, feminism, and what counts as reliable knowledge in the world. I refigure her figure to conceptualize my movements in Phase Three of my study.

In her work, *Modest Witness* (1997/2004) Haraway theorizes about “public space” in the scientific environment that surrounds the story of Robert Boyle’s demonstration of the air pump. Haraway notes that Boyle operated in “a most peculiar ‘public space,’ with elaborate constraints on who legitimately occupied it” (p. 225). She goes on to cite Steven Shapin and Simon Schaffer’s (1985) account of Boyle’s demonstration for an analysis of “public space” – that space where experimental procedures were put out for public viewing in the seventeenth century. Shapin and Schaffer write: “What in fact resulted was, so to speak, a public space with restricted access” (Shapin & Schaffer, 1985:336 as cited in Haraway, 1997/2004, p. 225).

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52 Haraway explains how she uses the term “figure.” “A figure collects up the people; a figure embodies shared meanings in stories that inhabit their audiences” (1997/2004, p. 223). Each time I (re)read Haraway’s article, I think differently about the notion of modest witnessing. The many possible (re)readings of her work make this trope and others quite useful when thinking about movement between subject positions.
I think of the policy work and the presentation of the case study in terms of modest witnessing because IRBs operate in a similarly peculiar type of public space. IRB meetings are open meetings, but they are held under a claim of restricted space. Panel members are required to sign confidentiality agreements that function in such a way as to claim restricted access to the proceedings of meetings. As an example of this, any knowledge of IRB procedures that I, or any other panel member, might have gained as a result of participation on review panels feels dangerously restricted, or even secretive. The confidentiality requirement and claims of restriction created tension and discontinuity for an insider without.

Modest Witnessing and Situating Knowledges

In both Modest Witness (1997/2004) and Situated Knowledges (1988/1991), Haraway argues convincingly against the kind of objectivity that splits subjects from objects and removes inquiry from contexts of investigation. She advocates for “a doctrine of embodied objectivity that accommodates paradoxical and critical feminist science projects; feminist objectivity means quite simply situated knowledges” (1988/1991, p. 188). Haraway’s explanation of situated knowledges and embodied

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53 Position Statement on Qualitative Research and IRBs (Evans, 2006) is included in Appendix C.
54 In Ohio, the Open Meetings Act “is based on the principle that citizens must be able to observe the operations of their representative government” (Yellow Book, 2006, p. 37). The Yellow Book (2006) discusses statutes and case law related to open meetings of public bodies. “[T]he Open Meetings Act is intended to require public bodies to take official action and to conduct deliberations upon official business in open meetings” (2006, p. 37). Based upon definitions and provisions set out in the Yellow Book, I posit that IRB meetings are gatherings of “public bodies” whose business generally is conducted in public.
55 Fundamental principles of the public’s right to know the operations of its governmental agencies strongly suggest that the meetings and written proceedings of the IRB are indeed open.
56 A copy of the confidentiality agreement I signed for IRB service is located in Appendix F. This appendix also includes other IRB documents such as my letter of appointment to the Behavioral and Social Sciences panel. In the same appendix are copies of IRB approval forms for the research projects.
Objectivity are valuable in my work as ways to think about emerging knowledges. My study was intentionally conceptualized to “…generate its problematics from the perspective of women’s experiences” (Harding, 1987, p. 7) and “…to start from [others’] lives to ask research questions, develop theoretical concepts, design research, collect data, and interpret findings” (Harding, 1991, p. 268). These starting points for inquiry are where knowledge is “situated,” and “embodied” in this study.

Naomi Scheman gestures toward a similar theoretical path when she points out that research questions do not exist in a vacuum (Scheman, 1991). Neither do signs, nor shocks, nor effects of discontinuities exist in a vacuum (although they may “appear” only as empty spaces or exclusions). Responses to the faculty survey (COEFS) and reflective writings and field notes from the undergraduate student research workshops (USRE) provide examples of signs, shocks, and effects from discontinuities that master and novice researchers claim to have experienced. The USRE project is discussed here as a way of uncovering effects that were revealed in the study.

As an educational researcher and IRB investigator, I studied the experiences of undergraduate students who were beginning research careers and learning about Responsible Conduct in Research (National Academy of Sciences, 1995). I participated in the IRB process as an investigator preparing IRB applications, amendments, renewals, and termination reports. In this chronologically-early project I began to see how novice researchers experience tensions in their dealings with the IRB.
Investigating Signs, Interpreting Shocks, Uncovering Effects

The primary research purpose of the USRE project was to gain insight into how novice researchers understand their responsibilities in research. There was also a teaching purpose, which was to discuss ethical issues that arise in scientific contexts. Eighty-eight undergraduate students who had been selected for the Summer Research Opportunities Program (SROP) were invited to participate in my project. Four data collection methods were used across six data collection points over the course of two summers. Appendix B reports details of this project.

A preliminary sign that students did not automatically assume they could trust the IRB process, or perhaps the research as it was presented, was evident in their close scrutiny of the consent forms that were required for the project. During the first summer, approximately 75 percent of eligible students voluntarily signed the consent forms. (There was no difference in either requirements or procedures for the students based upon whether or not they agreed to participate in the research aspect of the project and signed consent forms.) Qualitative researchers reported similar effects of the consent process. The consent form and the explanation of possible, though seemingly minimal risks predicted for the project discouraged participation in the research. Other researchers have suggested that the consent form is too rigid and seems “foreign” to potential participants. In the case of the USRE project, I did not probe for a reason; I simply noted that the consent process created an effect. The discontinuity in these instances exists between intents of the process (establishing trust and honoring
autonomy – ethical responsibility) and effects of the consent form and explanation (demonstrating institutional accountability).

Another sign of discontinuity related to the online CITI training requirement. All students participating in this summer research program were required by the SROP program director to access and complete the online CITI training course. Some students were frustrated in their attempts to access the training. An education coordinator of the IRB was contacted who resolved the issues on a case-by-case basis; however, the students reported that the additional steps in contacting an administrator were time consuming and felt like a poor use of limited available time. SROP students invest their summers in learning about research, and the CITI training did not make a favorable impression on the students. Both the difficulties in accessing the course and the overly simplified content were signs to some of the students that this type of ethics training was not relevant to their research or studies. Overall, students reported that they did not see much value in the training.

Tracing Discontinuities

“Time” was a beginning code for analyzing data from the projects. Students complained about deadlines, faculty resented the 365-day approval limitation, administrators were frustrated by waiting for responses, and a few graduate students claimed that their graduations were delayed by as much as three quarters while they waited for approval of their research protocols. Interpreting and finding effects of “lost time” did not appear until farther along in the analysis process.
Philosopher Lorraine Code and qualitative researcher Adele Clarke suggest analyzing “exclusions” from the data (Code, 1995a) and “empty spaces and silences” in the data (Clarke, 2005). Secondary effects of time appeared in recoding processes as exclusions, or as empty spaces. When data from the study were examined for exclusions, there were signs that discontinuities were being generated by the ways in which IRBs interpret federal timing regulations, track researcher compliance across time, and protect the time of IRB panel members.

These discontinuities related to time are especially complex and difficult to present for discussion. The study’s central argument is for understanding the meaning of responsibility. Time-related effects are more associated with accountability than with responsibility. The complex nature of defining or describing responsibility without a focus on accountability ruptures the logic of traditional arguments. No straight path toward understanding responsibility without focusing on accountability appears. Likewise, this discussion of signs, shocks, or effects of discontinuities relating to time centers attention on accountability, exclusions, and empty spaces.

In discussions of problems that individuals face when dealing with IRB processes and procedures, the length of time required for IRB review of protocols is mentioned frequently. Researchers report that in some instances funding from external sources has been withdrawn while waiting for approvals, or that on a number of occasions graduate students have had to postpone graduation, or that from faculty

57 Haraway refers to “coding of the world” and notes that codes are “not still.” Clarke (2005) also discusses “recoding,” but for practical reasons.

58 Empirical data are drawn from responses to the faculty survey, COEFS, from field notes recorded during discussions with qualitative researchers attending the Qi2005 session, Wrestling with IRBs QIPS, and from literature and field notes that informed work surrounding the PDPT project.
members’ perspective the length of time required to complete IRB application forms is unreasonable. Such discussions often lead to conclusions that IRBs are focusing on unimportant details, or the panels are over-burdened by paperwork, or that if submission processes were put online, the system would be more efficient. It seems unlikely either that IRB processes and procedures will become more responsive to these time-related concerns from researchers, or that greater efficiency would resolve the tensions related to time issues.

Measures, in the sense of counting things or accounting for activities, that have been institutionalized locate the power for moving, holding, or stopping research with the IRB. The same measures situate the onus for accounting with researchers. Controlling the flow of protocols through the IRB system allows institutional administrators to account for and document the activities of researchers. As researchers interact with the system through submissions and responses in performance of these duties, researchers create accountability data about their activities. These data compliantly provided by individual researchers provide useful measurements to the institution. The IRB can, and may\(^{59}\), report these measurements in accounting for their activities and demonstrating their compliance to accrediting organizations (such as AAHRPP) and to federal level oversight offices.

The PDPT project serves as a rich example of how time-related discontinuities can affect researchers and their research projects. Principal investigators (PIs) for the

\(^{59}\) None of the researchers have reported, no administrator has mentioned, and the literature does not mention whether or not the IRB obtains consent from researchers to use these personally identifiable data in their reports. Suggesting that IRBs should obtain permission from researchers to use these data in published reports would probably be a “shock” to IRB administrators.
PDPT project received a grant from the Ohio Department of Education (DOE) to implement a program of professional development for teachers that was designed to improve student performance on standardized tests of achievement. The PIs submitted an application to the Behavioral and Social Sciences review panel of the IRB so that they would be permitted to include a research component to their study and publish preliminary findings from the first year of the project, a pilot study. The IRB panel did not receive the PIs’ application and the project did not appear for review for six months. When the panel initially reviewed the application, it was not approved. A number of revisions to the study design were required before the application was accepted and approval was granted for the research project. As a result of this delay, a year’s worth of data were “lost” to the research component of the project.

The PIs on this project reported feeling that their research was being constrained and their efforts were being thwarted by the IRB system’s protracted approval process. When the time approached for the PIs to initiate the renewal procedure for the pilot study and to submit a new application for the second year of research, the PIs were concerned that the time-consuming experience they had the year before would be repeated. In fact, the PIs discovered that the application processes they faced in the second year were more challenging than those they had experienced in the first year. In order to develop a better understanding of what was required for the

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60 The first year of the project was a pilot study. The PIs anticipated requesting approval for additional research elements, such as student test scores, during the second year.
61 Regulations allowed the PIs to implement the professional development program before IRB approval was granted; however, research aspects of the project could not be commenced before IRB approval was received. The effect of this discontinuity was that any activities involving human subjects that were carried out before IRB approval was granted could not be included in publications, or scientific reports of the research.
second year, the PIs discussed their research within a network of feminist researchers. Through the feminist network, the PI who was taking the lead in commerce with the IRB made contact with me. At the same time, I was developing a case study for presentation at the JERHRE conference in July 2006, and PIs for the PDPT project agreed to having their research discussed in this arena.

One of my goals in conceptualizing and reporting the case study was to provide a model for accessing student data through the use of school district assigned “unique identifiers” and to suggest a creative solution to one of the challenges facing qualitative and educational researchers. The case study focused on conflicting ethical principles of justice (access to benefits of research), and respect for persons (the consent process). This is a conflict that often surfaces in education research. The researchers’ dilemma arises at the intersections of federal regulations expressed in the *No Child Left Behind Act* (2001), the *Family Educational Rights and Privacy Act* (1997), *The Belmont Report* (1978) and current mandates for improvements in K-12 student performance.

Many local IRBs require consent forms from parents before researchers are permitted to access individual data or to measure student improvement through pre and post-test procedures. I proposed that education researchers use school district

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62 Suzanne Damarin, who practices within a network of feminist researchers, facilitated the contact between Diana Erchick, a PI on the PDPT project, and Jane Evans. Suzanne and Diana participated in my research by providing member checks, a validity practice. As such, their participation in my study, and my participation in the PDPT project exclude the possibility of defining any of us as “human subject participants” in any of the others’ research projects. We witness modestly.

63 In *Modest Witness* (1997/2004, p. 223), Haraway refers to “the communicative commerce of technoscience.” She explains in a footnote: “Commerce is a variant of conversation, communication, intercourse, passage. As any good economist will tell you, commerce is a procreative act” (p. 246).

64 In a conversation with IRB administrators, I shared my plans for submitting the case study.

65 The case study report is included in Appendix E of this work. The case study will be published in a forthcoming issue of the *Journal of Empirical Research on Human Research Ethics*. 

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designated unique identifiers for reporting and coding student data. Thus, student data are neither identified as, nor considered to be, “human subject data” and can be brought into research findings by teachers participating in the professional development program without violating human subjects’ rights (Levine, 2003; Sieber, 1992).

The notion of thinking of student data, as not-human subject data, rather than as human subject data, called for another shift in thinking by PDPT researchers. Considering students as not-human in any regard was a distinction that seemed to go against guiding principles for qualitative methods and research, which emphasize in depth knowing of research participants in their natural settings. Thinking of student data as not-human subject data is not the same as thinking of students as not human. Although the distinction is a narrow one, the procedure was necessitated by federal, state, and institutional regulations. In addition to working against fundamental qualitative research principles, rethinking students as not-human in any sense conflicts with understandings of the autonomy of individuals – an ethical principle featured in both the Belmont Report and CITI training.

Qualitative researchers have mentioned such conflicts among ethical principles, and some researchers have gone so far as to suggest that IRB processes displace their sense of individual ethics in research. A concern is that in balancing ethical principles, IRB processes are served at the expense of human subjects and the researcher’s individual ethical principles. For PDPT researchers, the ethical principles in conflict

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67 A COE researcher made a statement that suggested this issue on the faculty survey.
were autonomy, or respect for persons, and justice, or equal access to the benefits of research for all.\textsuperscript{68}

The consent process and defining who were to be human subject participants in this project seemed to be the primary sticking points in the IRB approval process. If students were human subjects, permission forms would be required from the parents of all the participating students. This was particularly problematic. The schools where the research was to be conducted had been selected for the project by the state, which was funding the project. The schools had been selected for the low performance of students. Although the researchers had made attempts to secure permission forms from all parents during the first year of the project, response rates overall and to repeated reminders had been so low, that scientific validity for the project was in jeopardy.

Researchers observed that schools in which parental consent is difficult to obtain are among those that have the greatest number of students at risk and the most to gain from inventive programs such as PDPT. Low response rates to requests for consent forms effectively impede research and result in these students and classrooms being left behind. Without parental permission to access individual student records, the IRB generally does not allow researchers to share findings with the education community or to contribute to scientific knowledge. In the case of the PDPT, the lack of parental permissions was discouraging the research. This would have meant that the benefits of research would be denied to students and classrooms at the greatest risk of failing. Thus,

\textsuperscript{68} If the researchers were required to have parental permission forms, their research could more easily be carried out in schools where performance on achievement tests was high.
the lack of consents could lead to the injustice of inequitable access to and distribution of benefits.

*Interactions of Policies*

Although PDPT researchers reworked their proposal in light of students not being human subject participants in the research, and permission forms not being requested from parents, there were other obstacles in the way of IRB approval for the project. If parental permissions were not obtained – for the non-human subject student data – then the IRB wanted some form of permission from the schools for use of these data. Policies that were in conflict were federal, state, and institutional.

*No Child Left Behind* (2001), a federal law, and state mandates set improvement standards for K-12 student performance. State-funded projects supporting implementation of innovative programs to raise test scores require reporting and demonstrating improvement in students’ test results. Student performance records are available to school teachers and administrators for evaluation of programs; however, the *Family Education Rights and Privacy Act*, which is also referred to as the Buckley Amendment (1974), requires that researchers using identifiable student data obtain parental permission to access students’ educational records. At all levels, federal, state, and institutional, issues turned on the possible identify-ability of student data.

Further modifications were required in the design of the PDPT in order to assure the project’s compliance with requirements. The researchers needed to clarify that data from student records would be de-identified by authorized school personnel before

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69 A panel of experts reviewed the PDPT case study at a national conference. The experts uniformly agreed that the MCP research proposal met the federal standards for protections of human subjects (JERHRE Conference, 28 July, 2006. Oakland, CA).
these data were shared for the research project. (De-identification of the data by authorized personnel and its subsequent delivery to researchers do not require parental permission.) Thus, my analysis of IRB policies and requirements indicated that researchers would need to create a data sharing arrangement with authorized holders of the data to satisfy institutional requirements of the IRB overseeing the research. Once the data had been de-identified by authorized personnel according to accepted practices, students would no longer be considered human subject participants by the IRB, and the use of such de-identified data would not be in violation of The Buckley Amendment.

In response to a communication from the IRB that the PDPT research had been placed “on hold,” the researchers and I worked together to create a data use memorandum (DUM). The researchers proposed to send the DUM to the school principals who could act as signatory officials for their schools. The proposed plan was that school employees, who had legitimate access to the data through FERPA, would de-identify the student data and provide it to the researchers as measurements of teachers’ performance.

Understanding the IRB requirements for the DUM was troubling because no template or guidelines are available on the IRB’s web site of resources. Legal officials for the university reviewed the DUM and found it to be acceptable. A template for such a document would be a helpful addition to available guidance documents.

Analysis of the PDPT project, the surrounding literature, and the reported case study illustrate points in the commerce with IRBs where the IRB retains power for controlling the flow of research. Pre-screening for completeness of the application and
setting the agenda for panel reviews are important steps that occur early in review processes. Incomplete applications, or those with insufficient detail (as that is assessed by pre-screeners), can delay subsequent scheduling. Determining what makes an application “complete,” and to certain extent deciding what is a sufficient level of detail are skills that researchers may be able to develop through study and practice. In addition, IRB administrators answer questions through email and on the telephone in response to inquiries. Predicting how, or when, a particular application will be placed on the agenda for review is a less-understood area. IRB meeting dates are posted online and are accessible to researchers; however, the scheduling process depends on numerous other factors such as how many applications are ready for review. Setting the agenda is not a predictable process for those who work outside the IRB administrative arena.

When pre-screeners place a “hold” on a research protocol, this can be a shock to the researcher. In the case of the PDPT project, the principal investigators’ experiences from a year earlier suggested to them that the “hold” might extend for an indefinite period of time. In fact, a new policy was adopted by the IRB that allows the researcher to request that the hold be removed within a period of two weeks. It is unclear how often researchers invoke this policy. Data collection and analysis were resumed when IRB approval was in place for another year of the PDPT project. Lessons learned through the project focused on redefining relationships between researchers and the IRB in order to bridge the gap that exists between IRBs and academic researchers.
The report for the PDPT project summarized the major challenges PDPT researchers faced in gaining approval for their project. The tensions experienced by the researchers that resulted from the complexities of the research project, from relationships between the IRB and the researchers, and from interactions of conflicting principles are highlighted in the fuller report. Additional tensions embedded in the process relate to relationships between the researchers’ ethical responsibility, as individuals, and the requirements of the institution for accountability of IRB administrators and panelists. Issues related to discontinuities between individual responsibility and institutional accountability are more the focus of the study overall.

Learning Lessons

In Laurel Richardson’s discussion of taking responsibility for the ways we speak about, how we name, and what we write about things we learn in the postmodern world, she includes the notion of “wording the world into existence” (Richardson, 2004). That idea now comes to mind in regard to my study. Richardson’s poststructuralist challenge to “grand theory,” her explanation of postmodernity, and her explanation of assumptions supporting the social construction of knowledge created an opening that invited work from marginal spaces such as those where insiders without work.

Concepts that are central to human subjects research appear more open to changeful thinking from outsider within and insider without positions. Responsibility and accountability are always already in mixture. Accountability and responsibility do not mark the ends of a linear accountability-responsibility continuum. Unfortunately, there is no word to represent the way these concepts works together in smooth and
striated flows. I respond to this void and to Richardson’s invitation to “word the world” differently, by suggesting a new configuration to stand in for an accountability-responsibility mixture. Recounsability represents (in a poststructuralist fashion) the way that accountability and responsibility become visible and coexist in relation with each other.

This study, where working from outsider within and insider without subject positions are productive strategies, calls for a postmodern shift toward thinking and acting differently and toward “becoming”70. Goals of the study (re)emerge and expand beyond understanding the meaning of responsibility to challenging the use of the concept as a normative standard in dominant meaning systems of institutional review processes. Acknowledging that accountability stands in for responsibility in institutional practices achieves a minimal level of understanding and short changes the notion of ethically responsible conduct.

I redefine the research questions and identify “becoming” research questions as a way of further demonstrating the iterative and emergent nature of the study. In the becoming questions, I extend the challenge of responsibility. I propose a move from understanding what it means to be responsible in the conduct of research to achieving more responsible (or recounsable) methods and practices71 in the conduct of research with human subjects.

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70 Rosi Braidotti discusses the concept of “becoming” and cites the works of Luce Irigaray and Gilles Deleuze. I use the concept to suggest a Deleuzian becoming: the “multiple and constant process of transformation, a flux of multiple becomings” (Braidotti, 1994, p. 113).

71 At the same time I suggest blending words and concepts, I also challenge this idea and question whether or not such a move is nothing more than being “trapped by two poles of a tempting dichotomy.”
Revising Questions

Three research questions guided the design of five discrete projects. From these projects, the study emerged with redefined research questions. The central question for the study was an empirical question one, which then provided the conceptual and methodological frameworks for lessons learned in the course of the projects and the study overall. Initial research questions are presented along with the becoming versions of these questions as an introduction to implications from the study overall. Becoming research questions that became visible through studying these data are both provisional constructions and also lines of flight\textsuperscript{72} for future projects.

*Empirical Question:* What does “responsibility” mean to university students, faculty, and administrators in the context of research involving human subjects?

*Becoming Empirical Question:* In what ways, other than through demonstrations of accountability, can responsibility in the conduct of research with human subjects be practiced?

*Methodological Question:* How can an iterative approach to inquiry engender rethinking of complexities in multi-sited qualitative research?

*Becoming Methodological Question:* How can an iterative approach to inquiry and meta ethnographic reporting of research in multi-sited qualitative studies be productive and intelligible?

\textsuperscript{72} Deleuze and Guattari (1987) describe the developmental relationship between rhizomes and lines of flight in their discussion of rhizomes. They write: “There is a rupture in the rhizome whenever segmentary lines explode into a line of flight, but the line of flight is part of the rhizome. These lines always tie back to one another. That is why one can never posit a dualism or a dichotomy, even in the rudimentary form of the good and the bad” (p. 9).
Theoretical Question: Can balancing ethical principles in the performance of research achieve responsibility and accountability in practice?

Becoming Theoretical Question: If multiple bodies – federal regulations (the Belmont Report), IRB requirements, and researcher practices – convey and carry the notion of ethical responsibility, is it possible to set a standard for responsible conduct? Or is it possible only to approximate a beginning point, a line of flight, which in the case of IRBs may be where accountability begins?
CHAPTER 5

REVIEW OF THE STUDY

This work investigating concepts of ethical responsibility in research explores ways that researchers understand notions of being responsible and of demonstrating responsibility in their work involving human subjects. Five empirical projects inform the study and examine practices and procedures of academic researchers who respond to institutional requirements and federal regulations for responsible conduct in research. Empirical projects and the study overall are related across three levels (individual, institutional, and federal).

The study entered the discourses of institutional review procedures (IRBs) and federal regulatory documents (RCR) through literatures describing “what might be” and “what is” regarding individuals’ ethical responsibilities. “What might be” is embodied in ethical principles. “What is” is embodied in researchers’ practices, institutional requirements, and federal regulations; “what is” is revealed through observations and reports of researchers’ practices and institutional interpretations of federal regulations. Bringing these together is a complex and uncertain process.

The *Belmont Report* outlines ethical principles—autonomy, beneficence, and justice—that guided the development of federal regulations for responsible conduct. Institutional policies and procedures establish requirements for researcher conduct and
set standards for researcher accountability in practice. Individual researchers working in institutional settings, such as universities, demonstrate their understandings of responsibility through practices and conduct that meet standards for accountability. Yet, gaps exist between how researchers and institutions interpret standards for accountability and responsibility, and discontinuities surface at intersections of institutional requirements with individual researchers’ understandings of accountability and responsibility in practice.

In 2005 when the study was conceptualized, we focused on topics related to ethics in research. That focus was narrowed in order to set a course for empirical work. The aim of including empirical projects was to understand how various groups of researchers in academic settings (such as universities) were responding to increased attention to “responsible conduct in research,” institutional review processes, and responsibility’s sparring partners, accountability and assessment, in higher education.

The study emerged through a series of five empirical projects. Each of the five projects explores how researchers understand the concept of responsibility in research. I designed the projects to involve groups of participants who experience research activities from different perspectives. The first group of researchers, those who participated in the Carnegie Initiative on the Doctorate surveys (CIDS) were mainly administrators; the second (USRE) were undergraduate students, the third (COEFS) were faculty members in a college, the fourth (QIPS) were qualitative researchers, and the fifth (PDPT) project dealt with experiences of principal investigators on a state-funded project.
Goals of the projects were related to one another in that they all addressed the primary research question and topic: “What is it, then, to be responsible?” As projects were planned, the focus of preliminary research questions narrowed. Thus, the variations in research questions trace a path through the research. As the research progressed, questions were refined. The strategy of reformulating research questions was used as a way of responding to uncertainties that arose as the projects were conducted. The study concludes with newly formulated research questions, becoming research questions. I refer to the last iteration of questions as “becoming research questions” as a way of acknowledging the continuing necessity to unthink concepts of accountability and responsibility and to rethink initial research questions.

Uncertainties surfaced throughout the study. As new interpretations of federal requirements came to light, new policies developed in the university. As relationships changed among actors in the study, ways of proceeding through IRB processes also changed. As projects were added, the study expanded to include perspectives of different groups of researchers. The length of time I spent in the field grew from 18 months to more than two years. Uncertainties became an unanticipated theme in the research. What began as a search for some type of certainty about ethical responsibility became a quest for grasping assemblage of uncertainties.

In this final chapter, I consider implications of uncertainties, or the displacement of certainties, that arose from the study. The chapter follows a path through the five projects that appears to be a path of uncertainties — signs, shocks and effects of discontinuities congregating in spaces surrounding IRB policies. Following the
discussion of uncertainties, I note the growth of phenomena, another important theme in
the research. I wrap up the discussion with a recounting of exclusions and denials that
affected the research and prevented the closing of gaps between “what might be” and
“what is.” The concluding section of this chapter suggests implications of the study that
could be useful to other researchers.

Displacements of Certainties

In his work *The Quest for Certainty*, American philosopher John Dewey (1859-
1952) discussed relationships between truth and knowledge, and “the sharp division
between theory and practice” (1929/1988, p. 5). He observed that the quest for certainty
is always “an effort to transcend belief” (p. 21) and that “…the ultimate ground of the
quest for cognitive certainty is the need for security in the results of action” (p. 32).
Dewey’s ideas in this part of the Gifford Lectures resonate with current emphases on,
and recent debates about scientifically based research in education (Lather, 2004;
Towne, Wise & Winters, 2004). In some ways my research study enters into similarly
contested areas\(^7\) of education research.

The approach I took in the hope of achieving some degree of certainty to
investigate my theoretical hunches was to design and carry out empirical projects that
were intended to lead to an unfolding of valid and trustworthy assertions at the
conclusion of the study. However, the projects and my retelling of these tales are based

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\(^7\) Stephen Toulmin explains in his introduction to the record text of Dewey’s lectures that with these
lectures, Dewey makes “a major contribution to the historical debate about human knowledge and
practice” (1988, p. viii). I am not suggesting that my arguments are the same as Dewey’s, only that at a
fundamental level, I am taking up questions that bring together investigations of intersections between
knowledge and practices.
in realist experiences of the research, and therefore reflect uncertainties, rather than the
certainties I had hoped to achieve at some idealized conclusion.

Dewey noted that in Greek traditions of philosophy, “the ideal of certainty” was
“superior to belief.” Dewey argued that the devaluing of experience as a way of
knowing, or as a basis for knowledge, followed the same tradition. He then contrasted
the “…rational sciences which dealt with eternal and universal objects and which
therefore were possessed of necessary truth” (p. 22) with the observational (or
empirical) sciences which were not. Dewey concluded if one were on a quest for an
“ideal of certainty,” the observational sciences could not provide such a truth or
knowledge.

In this study, I did not follow traditions of Greek philosophy didactically. I
acknowledge that I cannot “know truth with certainty” about responsibility. Further, I
would not have claimed to know with certainty – if I had used experimental methods. In
this work, uncertain knowing is more responsible knowing.

Highlighting Uncertainties in the Study

In this section, I point out uncertainties that came to light in five empirical
projects. I take the projects in chronological order and summarize one instance where
uncertainty displaced certainty in lessons learned from that project. The themes I
mention appeared on more than one occasion. I highlight topics in the projects as a way
of providing examples and as a way of tracing a path of uncertainties and uncertain
connections in the study.

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74 The basis for this traditional claim was that the observational sciences could not be “known by
experimental methods” (p. 22).
In the conclusion of Appendix A, primary lessons learned from the CIDS project are summarized. Three lessons addressed methodological aspects of the project, and one lesson was more theoretical. The dominant lesson of the project related to the shifting ground that underlies institutional review processes.

Uncertainties in the CIDS project came to light when my role in the project shifted from administrative assistant to investigator. The shift depended on how I was situated in relation to administrators and the IRB process. Interpretations of regulations and requirements changed depending on which institution (Ohio State or the Carnegie Foundation) was considered the primary researcher and on whether or not the institution had a Federal Wide Assurance (FWA). Carnegie Foundation researchers and administrators interpreted federal regulations for human subjects differently from the way that Ohio State researchers and administrators interpreted regulations and requirements. Some individuals working on the project changed assignments, and others left the project for a variety of reasons (e.g. the IRB coordinator, the Dean of the Graduate School, and Carnegie Foundation researchers). The shifting of administrators’ roles, assignments, and duties gave the impression of more flux than was expected in what appeared to be a highly legalistic system.

Multiplicities of interacting changes complicated the research and appeared as shifting flows throughout the project. The most definitive moment, if not the only, of certainty in the CIDS project came with termination of the project in April 2006.

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75 My position as an outsider within is explained in Chapter 3.
Undergraduate Student Research Experiences (USRE) – Embodiment of Ethical Principles

In response to a growing sense of uncertainty about “where” ethical principles were theoretically located in institutional review processes, I examined the Teaching Research Ethics Workshop (TRE), a program offering ethics training for researchers. This was a first step in preparing to teach an ethics course to underrepresented minority undergraduate students. The “ethical theory” track of discussions brought out connections between ethical principles and individual ethical decision-making. Connections between ethical principles and institutional accountability systems were not so evident.

Ethical principles seem to be embodied in subjects, rather than being located in documents, standards for practice, or institutional requirements. This idea gives rise to Rosi Braidotti’s discussion of “embodiment of the subject.” She writes that according to Deleuze, “The embodied subject is a term in a process of intersecting forces (affects), spatiotemporal variables that are characterized by their mobility, changeability, and transitory nature” (1994, p. 163). The possibility of ethical principles being embodied in various subjects, in ways similar to how knowledges are situated (Haraway, 1988/1991), became an uncertainty that was explored in the USRE project.

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76 TRE workshops are held annually at Indiana University in conjunction with the Poynter Center for the Study of Ethics and American Institutions.
77 In the section, “Rhizomatic Thinking” of Toward a New Nomadism (1994, p. 163) Braidotti analyzes works of Deleuze. I refer to her interpretation of Deleuze’s notion of embodiment of the subject.
College of Education Faculty Survey (COEFS) – Effects on Research

Forty four percent of faculty members (n=62) in the College of Education responded to an anonymous online survey asking for their opinions on a number of issues related to effects of CITI training and the Office of Responsible Research Practices (ORRP). The primary rationale for exploring perceptions on these issues was to evaluate if CITI training was helping faculty members understand the federal regulations and institutional requirements for responsible conduct in research. A secondary purpose was to explore perceived effects of CITI training and ORRP on faculty members’ research projects.

An assumption of this project was that faculty members in a college of education would be able to evaluate the required training they were receiving. This seemed like a reasonable assumption. Findings from the survey were not conclusive. Respondents questioned policies and procedures of the IRB. Further, open responses to survey items indicated that there was more than a little uncertainty about effects of the IRB system on researchers. Examples of responses from which this inference was made included the following statements: “ORRP has thwarted my research efforts. The rules seem to change regularly, and as a result, the process seems completely overwhelming;” “We are very careful to use terminology that ORRP won’t misconstrue even though the terminology means something different in our research;” and “I believe ethics should be emphasized, but current procedures foreground legal issues and federal regulations, which may theoretically be undergirded by ethics, but these undergirdings have lost all meaning in this process.”
Faculty members’ responses revealed their uncertainties about IRB policies – how policies are developed; how policies are enforced; and who bears responsibility for making policy decisions. Their reports of experiencing multiplicities of unexpected changes in rules and policies led faculty members to perceive the IRB as an unknowable system. The project that followed the COEFS was an exercise in policy study and analysis. This next investigation developed in response to questions and concerns posed by respondents to the faculty survey.

*Qualitative Inquiry Policy Statement (QIPS) – Emergence of Policies*

Researchers attending the First International Congress of Qualitative Inquiry in 2005 raised questions about a perceived gap between their understandings of what it means to conduct ethically responsible research and their empirical experiences with IRBs. The *Position Statement on Qualitative Research and IRBs* (2006) responded to those concerns.

The position statement was structured around three sections, and its purpose was to suggest ways that qualitative researchers might situate themselves in relation to IRBs. The first section, a problem statement, addresses concerns of participants from the 2005 Congress session, *Wrestling with IRBs*. Proposed “Standards for the Practices of Qualitative Researchers” are enumerated in the second section. The final section lays out “Action Plans” and suggests strategies for working at the local and national levels on issues raised by qualitative researchers in regard to institutional review processes.

The position statement project troubles the notion of IRBs operating primarily to protect the interests of human subjects participating in research. Some researchers hold
the belief that IRBs operate primarily to protect the interests of institutions. There is also concern that institutional accountability may be overshadowing, if not eclipsing, ethical responsibility in research.

The draft of a position statement was presented to qualitative researchers in a number of ways at the Congress. Copies were posted on the Congress website along with meeting information; copies of the draft were distributed to Congress attendees in their information packets; the draft was discussed in the *Ethics and Human Subjects Research* workshop; Patti Lather introduced the draft statement during the opening session of the Congress; and finally, the draft was offered for adoption in the closing session of the 2006 Congress.

The proposal received mixed reviews. There was, however, extensive discussion of the draft throughout the meeting. Some participants felt that the document was overly focused on “IRBs” and a United States perspective. Those attendees suggested that more time be taken to broaden the scope of the document to deal more expressly with entities such as “ethics committees” that operate in Australia and REBs (research ethics boards) in Canada. Another impediment to adoption of the draft that surfaced related to the lack of formalized procedures for the newly formed International Congress of Qualitative Inquiry. *Not* adopting the position statement seemed to make a statement about uncertainties related to the newly formed organization’s procedures as well as to this group of researchers’ uncertainty about IRB procedures and policies.
Questions about how institutions develop policies, who has access to policies, and who makes policy decisions continued to generate uncertainty for the study. The final project, PDPT, approached policy issues from a different angle. This project looked at IRB issues from the perspective of principal investigators.

The PDPT project responded to tensions between researchers and IRB policies and procedures. The purpose of the project was to move the principal investigators into a different type of relationship with the IRB – one that would be less adversarial and more productive. The goal of the project was to balance ethical principles with institutional requirements and federal regulations and in so doing to find a way for the researchers to meet standards of ethical responsibility and institutional accountability.

Because of the lengthy and difficult IRB review process for the pilot study in their first year of research, the principal investigators were uncertain about how to prepare an IRB application for the second year of research. Their concerns in regard to the IRB application process included: (1) understanding application questions and providing acceptable responses; (2) the length of time approval processes could take; (3) unpredictable outcomes of a pre-screener’s and IRB administrator’s decisions; (4) unknown policies and procedures of the institutional review process.

The case study developed for presentation and review at a national conference helped sort out a number of the complex issues operating in this project. The opinions of national experts about ways to negotiate through IRB processes were useful. In spite of applying these strategies, problems surfaced for the project. IRB administrators
notified the principal investigators that a “hold” had been placed on their research. Principal investigators were informed that they needed to provide a “data use agreement” in order to use certain types of data for the research component of the project. The IRB had no specifications, template, or guidance about how to create, such an agreement. In this instance, IRB requirements reflected uncertainties all the way down.

Growth of Phenomena

Discontinuities and uncertainties are factors that have been revealed in the study as affecting the IRB system. Effects of these factors have been interpreted as making the system overly complex and troublesome. Another factor exposed as complicating institutional processes in general, and the IRB system in particular, is the growth of multiple phenomena. Phenomena include: increased attention to ethics in practice at the individual level (Miller, 2005; Zylinska, 2005), proliferation of policy reforms at the federal level (Ball, 2003; McDermott, 2007), escalating dominance of assessment and accountability systems at the institutional level (Shulman, 2007; Spellings, 2006), and incursion of accountability into the concept of responsibility. All of these factors contribute to discontinuities in and uncertainties of understanding what it means to be responsible in research.

The Association for Accreditation of Human Research Protection Programs (AAHRPP) is a recent addition to the hierarchy\(^78\) of accountability mechanisms. The organization offers programs of accreditation to “academic institutions, independent

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\(^{78}\) AAHRPP positions itself between federal regulations and institutional requirements. Thus, accreditation would add a level to the federal-local/institutional-individual three-level scheme.
institutional review boards (IRBs), contract research organizations (CROs), and U.S. and international medical centers” (AAHRPP Advance, 2007, p. 1). According to its newsletter, AAHRPP “is steadily extending its reach — and its higher standards — throughout the research enterprise, shaping research practices” (2007, p.1).

Effects of AAHRPP’s purported extended reach and higher standards have not yet been realized at Ohio State. On the one hand, there could be positive effects such as guidance for the local IRB on how to be less intrusive and more effective. AAHRPP might be able to assist institutions in focusing more on ethical substance and less on what can be counted. On the other hand, an additional level of standardizing procedures could have the opposite effect. In the foreseeable future, there may be greater emphasis placed on institutional compliance with higher standards and less attention given to individual researchers’ concerns about ethical responsibility.

A sign of growth at the local level can be interpreted from Ohio State University’s Office of Research Five-Year Business Plan. The Plan states that for the 2005 fiscal year (FY), ORRP worked with 4,693 “active protocols” (2006, p. 22). The office predicts that for FY 2011, there will be 10,853 “active protocols.” The average growth in active protocols projected over the next six years is 15.2 percent per year. The report includes historical information indicating that over the last 5 years (FY 01 through FY 05) “The number of human subject protocols has increased by 150%” (2006, p. 23). Over the same retrospective five-year period, the number of “Policy Boards” decreased from 2 to 1.

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79 This report is available from http://oaa.osu.edu/irp/support_units_fy07/OR%205%20Year%20Plan%20Final%20031506.doc
The perception of growth that researchers perceive seems to be justified. When active protocols are reported as a measure of growth, the IRB system has been growing in terms of “what can be counted.” An omission from the Plan is a similar reporting of the number of complaints from principal investigators. The Plan does report in a narrative format that researchers are “vocally objecting to institutional review board (IRB) review timelines, to IRB policies and procedures, and to IRB decisions” (2006, p. 24). The Plan speculates that the new, and longer, reporting forms are the source of much of the “faculty investigators’” dissatisfactions. However, the Plan notes, “the objective of the new form is to minimize the number of protocols that are retuned to PIs because the IRB lacks sufficient information to complete its evaluations” (p. 24). And in regard to objections about the length of time taken in review of protocols, the Plan cites faculty members’ “continuing” lack of volunteers to serve on panels as a constraint on IRB performance.

In my two years serving on the IRB, I have experienced certain aspects of the IRB system as unknowable. One example relates to the reporting of “what can be counted.” I contacted an IRB administrator and requested updated values for the actual number of “active protocols” in 2006. The administrator with whom I spoke indicated that the information I had requested was not that office’s (the IRB’s) to give. Since I know an updated report exists, I can only conclude this information is unknowable.80

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80 The Office of Research includes the actual number of active protocols for FY06 in its proposed budget request. That document is posted on a University Senate (pass-word protected) website that is accessible to members of the Senate’s Fiscal Committee. I serve on the subcommittee that reviews budgets and have access to the most recent report; however, I believed that it would be more responsible to request the information from the office that accounts for active protocols. I was told that the actual number of active protocols is not available from the IRB.
Exclusions and Denials

Not being allowed to have information about the number of active protocols for 2006 confuses me more than it limits this study. In fact, the denial is useful in that the necessity to exclude these data from the study exposes a systemic lack of transparency with the IRB system. A similar phenomenon has been in the local news recently. Columbus journalists have been challenging the public’s right to see “public” records. Writers for *The Columbus Dispatch* (Rowland et al., 2007, April 22) allude to secrecy in their article pointing out that digital communication devices make it easier for public officials to transact public business privately and to protect records of those transactions from the public’s view. The *Dispatch* writers propose that the issues they discuss “revolve around new technology,” and they suggest that policies have not caught up with technology. In the case of the IRB, it is hard to speculate about what has not caught up with what – so many “whats” are invisible. In this closing section, I call attention to the types of exclusions and denials that veil some aspects of the IRB system.

The categorization scheme I adopt to make visible exclusions and denials takes into account intentional and unintentional omissions as well as purposeful and inadvertent restrictions. I frame this discussion in terms of how researchers (and excluded others) experience institutional review processes in academic communities. I approach issues from a feminist standpoint and situate issues within the experiences of participants for consistency with the theoretical framework. In this exploration of issues, I neither attempt nor intend to ascribe intentions to the actors, processes, or procedures
effecting the omissions and restrictions I mention. The reader is free to make her own inferences from this discussion.

**Exclusions**

I examine exclusions from the study in two ways and categorize them as omissions and restrictions. Things that are “missing” from the study are exclusions in the sense of *omissions* – information or data that have simply not been included (Code; Clarke). *Restrictions* refer to the kinds of things that have been “systematically” excluded. Examples of systematic exclusions might be protected information, confidential documents, or names of participants.

One example of a type of omission is missing reflective writing papers; some SROP students chose not to submit required papers. An example of a systematic restriction is comments not recorded on the faculty survey. In some cases, the survey software truncated responses because they exceeded the character limit. In the instances I suggest of an omission and a restriction, the exclusions result in potential weaknesses to the data corpus; in neither case did I intend to withhold data or to create secrets. Rather, these examples reveal issues of access that challenged the collection and analysis of data in the study.

A more complex type of exclusion reveals both an omission and a systematic restriction. This is the scenario of an interview that I chose not to conduct. IRB administrators were aware of the nature and goals of this study. The IRB applications submitted for the CIDS, the USRE, and the COEFS projects included research proposals. I asked one of the IRB administrators if she would be willing to be
interviewed for this study, and she generously agreed. I chose not to interview her because I did not see a way that I could, and I did not want to, make her anonymous in reporting the study. I respect this person and the job that she does; however, it would not have been responsible to guarantee anonymity that I knew I could not protect.

Other instances of exclusion occurred that resulted in what appear to be hidden data or perpetuated secrets – I refer to these instances as obscurances. The categorization of IRB panel members as “scientists” or “non-scientists,” as “affiliated” or “not-affiliated,” or as “voting members” or “alternates” provides examples of systematic restrictions operating as obscurances. Assigning the label of “non-scientist” to persons who work within a scientific context places those persons in a compromised position. This practice is systematically excludes certain people. Similarly, labeling some people as “not affiliated” within a specific context, such as the IRB at a university, automatically disqualifies them as having a stake in the proceedings of the group. I serve on an IRB panel that can dis-privilege some people on three accounts by categorizing them as “not-affiliated” “non-scientist” “alternates.”

The works of a number of feminist theorists informing my work assert that the process of categorizing by gender creates systematic exclusions or restrictions (De Beauvoir, 1970; Frye, 1992; Keller, 1985; Piercy, 1991; Woolf, 1942/1979). Some theorists address systematic categorizing and excluding of women – from science in particular (Harding, 1986, 1991; Haraway, 1997; Keller, 1992). Donna Haraway’s uses her figuration of the modest witness to “trouble identifications and certainties” (1997,

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81 Obscurances are occurrences that obscure, or are equivocal or ambiguous. Such occurrences are not clearly understandable.
I invite Haraway’s figure into my study to trouble the identifications and certainties that operate in the exclusionary and restrictive categorization scheme of IRB processes I witnessed⁸².

Haraway explains, “My modest witness cannot ever be simply oppositional. Rather, s/he is suspicious, implicated, knowing, ignorant, and hopeful” (1997, p. 3). She locates the modest witness in the context of technoscience, and reveals that s/he “lurks” (as both, or alternately, a spy and/or a scout) on the Net (1997). Haraway’s modest witness functions in the environment of technoscience while mine situates me in the context of institutional review processes broadly, and IRBs in particular.

My modest witness incubates, more than “lurks”, and watches, more than witnesses, from the largely invisible category of non-scientist, affiliated, voting member (sometimes, and sometimes not) on the IRB. From this position, I observe exclusions and restrictions in the IRB processes. An example of an exclusion/restriction that occurs frequently is that of a visiting investigator. Visitors to open meetings wait in hallways until they are summoned to enter the IRB meeting space (at a pre-appointed time) to offer thoughts and statements about their research projects. These visitors come to the meetings in anticipation, or on the occasion, of problems with their protocols. Graduate students are another category of functionally invisible actors in the IRB process, and it is they who generate, or at least receive credit for, many problems.

⁸² I use the term, witness, to describe how I experienced being a member of the IRB. I intend for this usage to trouble what it means for a graduate student to be a member of this particular institutional group.
Denials

Next, I turn to denials. Some exclusions lead to denials, and on occasion denials lead to the appearance of secrets. I include protected information, such as the information about performance indicators for ORRP, which is password-protected, in the category of denials. In this example, the number of new protocols the Behavioral and Social Sciences review panel received for 2006 is information to which I could not gain access. In some regards performance indicators are “public” information that is undisclosed and thus “private” information.

Denials also include data that was protected by a confidentiality agreement IRB panel members sign before participating in the review process. As a modest witness, I trouble the use of confidentiality agreements between panel members and review panels. In fact, minutes are maintained for IRB meetings that reveal the results of voting, absences from the room of panel members, and outcomes of reviews. Since panel members are agents in these decision-making processes, a more appropriate document for actors to sign would be a consent form. Members would give their consent to IRB administrators to include their “data” in the minutes of meetings and to record their activities while they are engaged in the research process.

The work of Adrienne Rich, *On Lies, Secrets and Silences* (1979), is helpful in understanding how researchers might experience withheld information. Rich posits that when women are complicit with lies told or when the truth is withheld or distorted, “secrets” result. She theorizes lies as weapons of powerless people, and she suggests there is a “kind of power that can be obtained through lying” (1979, p. 447). By
maintaining silence about the lies we tell (and the lies we are told), we are complicit in a process that undermines truthfulness and honor. She points out, “Facts we needed have been withheld from us” (p. 446). I extend her analysis to understand how information that is withheld or denied by the IRB can lead to the perception of secrets – whether or not the information is indeed being held as a secret. The perception of a secret also can be a weapon of the powerful.

Along a similar trajectory, Marge Piercy’s (1991) character, Nili, observes a relationship between access to information and power. Nili says, “The ability to access information is power…. We have always considered getting knowledge part of being human” (as cited in Haraway, 1997, p. 1). Piercy’s observation, “getting knowledge [is] part of being human” is on point for my discussion related to the treatment of human subjects in research. The IRB purports to hold in the highest regard principles of autonomy, justice, and beneficence. However, as one faculty member pointed out in her response to the COEFS survey, she felt the IRB violated her autonomy. She stated: “The design of the procedures and the way they have been implemented show a lack of respect for the needs and culture of the faculty and students of this College.”

Evelyn Fox Keller (1992) discusses secrets in a different context. She writes about discovering secrets of life, death, and nature. Her work is also productive as a way of unthinking how researchers experience the perception of secrets in the context of IRB administrators, processes, and procedures. Participants in the SROP and COEFS projects mentioned their discovery of changing procedures and the discontinuity that unexpected changes brought to them. In the CIDS project, the disappearance of an
administrator upon whom we had come to rely seemed to be shrouded in secrecy as no explanation was provided for his seemingly sudden disappearance. In this high ambiguity context, the absence of information about his whereabouts triggered the informal graduate student network of communications to rumor that the administrator had been relieved of his position for ignoring (or for hiding) IRB applications in his desk.

Keller writes: “Well-kept secrets…pose a predictable challenge to those who are not privy. Secrets function to articulate a boundary: an interior not visible to outsiders, the demarcation of a separate domain, a sphere of autonomous power” (1990/1992, p.40). Keller’s insights about secrets in science and nature apply equally well to how denials for requests for information seem to function as a way of excluding outsiders from IRB processes.

Reflections on Modest Witnessing and IRBs

My modest witness “mutates” throughout the course of this research – shifting her subject position to swerve around obstacles; she moves about taking different perspectives on questions of responsibility-in-the-making; she generates a distinctive account of what responsibility looks like in the conduct of research with human subjects.

My modest witness works to perform research responsibly, and like Haraway’s figure she is “alert.” In this final stage of the study, my modest witness is especially alert to danger and risk – the danger of claiming a view from nowhere and the risk of drawing conclusions that might be used against researchers. In The Ethics of

83 Haraway (2004, p. 5) “argue[s] for mutated modest witnesses who can be more alert….”
Ethnography (2001), Elizabeth Murphy and Robert Dingwall point out a risk that resonates with this modest witness. “Ethnographic studies typically increase knowledge of the adaptive behaviours that actors use to accommodate to structural and institutional pressures. By uncovering such behaviours, ethnographers offer tools for those with power to control or manipulate those without” (2001, p. 341).

This study describes a complex arrangement of power and knowledge that plays out in the relationships between researchers, their participants, and institutional review processes. Ethical principles outlined in the Belmont Report provide theoretical guidance for researchers; however, researchers need to translate those principles into practice. Current emphases on “what counts” in practice have the effect of overshadowing ethical substance in human subjects research. Regulations and requirements focus on how to be accountable at the expense of offering guidance on how to be responsible. A culture of compliance and secrecy, “what is,” overwhelms a culture of conscience – what “might be.” IRBs maintain a system with too many exclusions and denials and too few inclusions and affirmations.

The IRB processes I observed operate as “public spaces with restricted access” (Haraway, 1997, p. 25). And the IRB process situates some panel members like seventeenth century modest witnesses whom Thomas Hobbes (1588-1679) critiqued as being “part of private, or even secret, and not civil, public space” (as cited in Haraway, 1997, p. 25). “‘Public space’ for the experimental way of life had to be rigorously defined; not everyone could come in, and not everyone could testify credibly” (p. 25).
Similarly, IRB space is rigorously defined; not everyone can come in, and not everyone can testify credibly.

Rethinking Gaps between *What Might Be* and *What Is*

Sandra Harding’s work was at the outset, and continues to be, catalytic for my research. Her proposal to apply feminist standpoint theories to epistemological projects and her claim that “a problem is always a problem for someone or other” (1987, p. 6) transformed the ways I thought about relationships between qualitative researchers and IRBs. Harding’s achievements, particularly her working of the gaps between notions of subjectivity and objectivity, revealed ways to rethink the tensions I observed between “what might be” and “what is” in relations between researchers and IRBs.

I framed my observations of tensions between researchers’ and IRBs as *signs, shocks, and effects* of IRBs on researchers. I discussed what appeared to be gaps as *discontinuities*. And I noted *ambiguities, uncertainties, and exclusions* I perceived as contributing to continuing tensions between researchers and IRBs. These notions of signs, shocks, and effects, discontinuities, and uncertainties and exclusions suggest some of my concerns with “what is” from my engagement with responsible conduct in research. I have not yet pulled together in this writing the strategies I found to be most productive in the work of rethinking gaps and moving toward “what might be,” and I will attempt to that in this final section.

I begin by noting that this type of research demands an extended period of fieldwork. Empirical work was formative in developing an understanding of the present moment in relations among researchers, the concept of ethical responsibility, and
institutional review processes. The five empirical projects have taken more than two years to carry out, and I now know I have only scratched the surface of the work that might well be done. I observed that changes are taking place in IRB procedures much of the time. Learning to see change as a constant and as contributing to tensions in the research took more time than anticipated. Initially, I did not understand the depth of Simone de Beauvoir’s (1948) pronouncement that with ambiguities meaning must be constantly won. In the case of IRBs, I found that researchers’ interpretations of what might count as ethically responsible conduct in research also must be constantly won.

Rethinking institutional requirements in terms of “what might be” demands not only time, but also an extended engagement with federal regulations. Researchers perceive changes as coming from IRBs and institutional administrators. My observation of changes suggests that the federal regulations themselves offer a better starting place for proposing more workable interpretations of the regulations to IRBs. The successful rethinking of the PDPT project demonstrates my point. The work of IRBs has increased over the last few years, and IRB administrators do not have the time, or as in the case of teacher educators, the expertise to develop creative solutions to particular researchers’ dilemmas.

The federal regulations are densely written and are embedded in the complexities of IRB procedures. In many instances, federal regulations create the very problems that researchers face. Surprisingly, in some of these contentious situations, federal regulations hold the answers to the same problems they create. I found that reading and rereading federal regulations, thinking and rethinking the IRB
interpretations, and then wording and rewording applications to the IRB worked as a strategy for approaching “what might be.”

Complexities of the federal regulations and institutional requirements contributed to researchers’ perceptions of IRBs as unknowable. Teacher educators indicated that they would prefer to be told “what to do,” rather than being told “what not to do.” This preferences came through in the COEFS and PDPT projects. I heard similar requests for more guidance, or for step-by-step approaches, on ways to resolve difficult IRB issues at the Congresses for international qualitative researchers. Perhaps there is something about the way or the type of guidance that IRBs provide that contributes to the complexity of federal regulations and institutional requirements.

The approach I found to be the most helpful combines the recommendations of Corlann Gee Bush (1983) and Joan Sieber (2004). From Bush, I took the notion of simplifying by naming the complexity. Following simplification and identification of issues, such as competing ethical principles or conflicts between ethical principles and institutional requirements, I applied Sieber’s recommendation of locating “sticking points.” Sieber acknowledges that there may not be “one best way” to plan ethically responsible research. Rather, she suggests finding balance among competing elements.

Sieber’s notion of balancing ethical principles calls to mind Bush’s discussion of technology and equity. In the conclusion to her discussion of feminist assessments of technology, Bush points out that technology is an equity issue. I understand the IRB system as an equity issue. Bush’s insights about how to assess implications of technologies are useful in rethinking relationships between individual ethical
responsibilities and IRB requirements. I conclude my research by applying Bush’s 
argument for equity in technology to my discussion of complexities in the responsible 
conduct of research.

[The IRB] is, therefore, an equity issue. [The IRB] has everything to do with 
who benefits and who suffers, whose opportunities increase and whose decrease, 
who creates and who accommodates. If women are to transform or “re-valence” 
[IRBs], we must develop ways to assess the equity implications of [IRB] 
development and develop strategies for changing social relationships as well as 
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This recounting of circumstances and conditions leading up to Ohio State University’s (OSU’s) participation in the Carnegie Initiative on the Doctorate (CID) project describes a retrospective case study. The primary research question for this project asked whether or not the Graduate School at Ohio State should participate in a multi-year action research project sponsored by the Carnegie Foundation for the Advancement of Teaching (Carnegie Foundation). Broader research questions emerged from conceptual fieldwork surrounding the investigation of the primary research question and led to development of the dissertation research, *A Study of Responsible Conduct in Research: Complexities All the Way Down.*

Participation in the Carnegie Initiative on the Doctorate (CID)

The CID project was designed by the Carnegie Foundation in response to concerns about doctoral education in the 21st century (Walker, 2004). Work on the CID project began in the OSU Graduate School in April 2004, progressed with an Institutional Review Board (IRB) application that was approved in April 2005, and concluded with an IRB termination report in March 2006. Primary actors involved in the processes included researchers and administrators from the Carnegie Foundation, the Graduate School at Ohio State, and OSU’s Office of Responsible Research Practices (ORRP).

The context within which the CID project took place included 44 universities across the United States and the Carnegie Foundation, which is located in California. On Ohio State’s campus, CID activities were coordinated in the Graduate School and
were carried out in six programs. Program activities began on campus in October 2003 with acceptance into the project of doctoral programs in chemistry, education, English, history, mathematics, and neurosciences. Over a two-year period, administrators in the Graduate School who were working on the Carnegie Initiative on the Doctorate Surveys\(^{84}\) (CIDS) project relied upon document analysis for data gathering, informal interviews and conversations for construction of understandings, and IRB applications and guidance documents for learning how to conduct ethically responsible research across institutional boundaries.

The CIDS project developed as a social process, and the context where this work unfolded, in the Graduate School at OSU, and the relationships of the particular individuals working in the Graduate School at that point in time were important elements in the social process. Between April 2004 and March 2006, the appropriate circumstances\(^{85}\) existed for this work to happen and for conditions “to be right and to go right” (Austin, 1962/1975, p. 14) for participation in the Carnegie Foundation’s project.

Critical theorist, J.L. Austin’s claim that words in certain situations can ‘do things’ is salient. Throughout the CIDS project, utterances were used in the performative sense, that is, to perform actions (Austin, 1962/1975). Austin’s work on performative utterances provides a theoretical framework for “surveying the invisible depths of ethical space” (Austin, 1962/1975, p. 10) and an analysis of the CIDS project.

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\(^{84}\) I draw a distinction between the Carnegie Foundation’s project, the CID, and the research project in Ohio State’s Graduate School, the CIDS. The CIDS project relates to participation in surveys that had been designed by the Carnegie Foundation. The surveys were only one aspect of the Carnegie Foundation’s project.

\(^{85}\) Austin stated in his Lectures at Harvard in 1955: “Speaking generally, it is always necessary that the circumstances in which the words are uttered should be in some way, or ways, appropriate, and it is very commonly necessary that either the speaker himself or other persons should also perform certain other actions, whether ‘physical’ or ‘mental’ actions or even events of uttering further words” (1962/1975, p.8).
Human Subjects Research Across Institutions

In April 2004, two requests came into the Graduate School at OSU. Considerations of how to respond to these inquiries required understanding issues related to research involving human subjects. Both requests were for research projects in educational contexts and were related to outcomes of doctoral education. Both proposed the participation of current or former graduate students, and both used qualitative designs. The “PhDs: Five Years Out” (FYO) study requested participation of former OSU graduate students and was conducted by researchers from The Center for Innovation and Research in Graduate Education (CIRGE) at the University of Washington. The second project, the CID, addressed a question posed by the Carnegie Foundation, ‘What is the purpose of doctoral education?’ (Walker, 2004, p. 238).

These requests were followed in July 2004 by a message from the Senior Vice President for Research at OSU announcing the most-recently signed Federalwide Assurance (FWA) and a “New Human Subjects Protection Education Program” (McGrath, 2004). The FWA explains the relationship between OSU and the federal government and highlights the importance of “federal rules, regulations and policies regarding the ethical use of human subject volunteers in research” (McGrath, 2004, ¶ 2).

PhDs: Five Years Out (FYO)

The purpose of the FYO study was to collect86 and analyze empirical data on career and family paths in order to learn about educational outcomes, career trajectories,

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86 Data collection for the FYO study concluded in February 2006. Seventy-one alumni from OSU enrolled as human subjects in the study.
and ways that Ph.D. recipients in six social science fields were using their doctoral
degrees (CIRGE, n.d.). The Director for CIRGE, Maresi Nerad, requested from the
Graduate School access to contact information and records of doctoral degrees granted
in the fields of anthropology, communication, geography, history, political science, and
sociology. Nerad proposed to extend her earlier work on PhD career paths (Nerad,
Aanerud & Cerny, 2004) with the FYO project by administering a national web-based
survey to respondents who received their doctorates from OSU and other institutions
between July 1, 1995 and June 30, 1999.

Following correspondence with CIRGE staff members, a decision was reached
in the Graduate School at OSU that an IRB application would be required before
supplying the requested contact information to researchers working on the FYO project.
Administrators in the Graduate School who were considering the FYO project did not
have prior experience with preparing IRB applications for research across institutional
boundaries. The FYO project manager from CIRGE was familiar with IRB procedures
at the University of Washington, and she shared the application that had been submitted
to and approved by that institution’s IRB.

Two issues surfaced as primary during preparation of the Graduate School’s
IRB application for the FYO study. The dean of the Graduate School, as principal
investigator at OSU, and her staff, which included this writer, needed to design
procedures for protecting the confidentiality of demographic data about Ohio State
alumni. Providing data of the sort requested by Nerad necessitated an examination of
the Family Education Rights and Privacy Act (FERPA), which requires that researchers
accessing identifiable student data obtain parental permission to access student
educational records. The second issue that emerged related to setting up a collaborative arrangement between Ohio State and the University of Washington for the protection of human subjects from one institution participating in research at another. This latter issue troubled fundamental questions such as: “What is research?” and “When and how does one become engaged in human subjects research?”

Carnegie Initiative on the Doctorate

The CID project was conceptualized by senior scholars at the Carnegie Foundation and funded by Atlantic Philanthropies. George Walker, program director, indicated that the purpose of the CID project was to invigorate and energize Ph.D. education. Walker believes that the purpose of Ph.D. education is to train “stewards of the discipline.” He further defines “stewards of the discipline” as those who will generate new knowledge, conserve history and foundational ideas, and transform knowledge for its use by others (Walker, 2004).

Initial invitations to participate in the Carnegie Foundation research were issued, and programs in those disciplines throughout the United States applied to be included. Walker stated that criteria for acceptance included “having a critical mass of students and faculty who are willing to think deeply about the foundations of their graduate programs” (2004, p. 241). Additionally, the CID staff indicated that all programs were chosen based upon their past success, reputation, and plans for self-reflection and study of their own programs. The CID staff proposed to work with representatives of the 84 selected programs located on 44 campuses. In addition to these 84 partner programs

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87 The CID examined programs in six disciplines: chemistry, education, English, history, mathematics, and neurosciences.
there were also *allied* programs that were designated to participate in a more limited sense.

Funding from Atlantic Philanthropies for the CID covered the Carnegie Foundation administrative staff and the activities that these decision-makers generated. Examples of CID-generated activities were the commissioned essays published on the CID website and summer sessions convened in Palo Alto, California for representatives of the partner programs. All expenses for two representatives from each participating partner program were paid while they were attending convened sessions in California. The purpose of the meetings was to bring representatives together, for “bonding,” sharing of ideas, and data gathering by the CID.

There were three elements of the CID program: conceptual analysis; experimentation; and evaluation and dissemination. At the convenings and through activities on university campuses, the CID proposed:

- In-depth study of current programs with consideration of how current procedures aligned with desired outcomes
- Proposals of new departmental procedures
- Implementation of initiatives
- Assessment and distribution of findings from experimental efforts.

Ohio State was the only institution to have representatives from all six eligible programs participating. The CID attached some importance to this fact, and recommended that some form of coordinating effort be organized on the OSU campus for the six programs. The Dean of the Graduate School and her staff, thus, become involved in the project. Coordinating CID activities involved reviewing budgets for
participating programs, arranging for on-campus meetings, and serving as a gathering point for questions.

Funding from OSU for the on-campus activities was modest, and yearly budget proposals were handled through the Graduate School. In July 2004, the Graduate School became aware that CID researchers were soliciting participation in a graduate student survey through representatives of the six OSU programs and were preparing to administer a web-based survey to students.

When Carnegie Foundation scholars working on the CID project sent a request for graduate student contact information to the six programs at OSU, a graduate student in the Department of History questioned the Graduate School about whether or not IRB approval would be required before he, or his department, shared email addresses with Carnegie Foundation investigators. Administrators from the Graduate School contacted ORRP for guidance and were directed to the ORRP web site for resources on when and how to prepare IRB applications. The ORRP web site provided information in FAQs: Human Subjects. This document explained that researchers must determine “whether a proposed activity involves ‘research’ and, if so, whether the research involves ‘human subjects’” (ORRP, 2006, ¶3). The primary questions that arose in the course of determining whether or not the CID graduate student survey would be defined as human subjects research, were similar to questions encountered while working on the FYO project: “What is research?” and “When and how does one become engaged in human subjects research?”
Similarities and Differences Between Projects

Concerns that dominated conversations at the Graduate School about the CID proposal were similar to, but more extensive than, issues with the FYO study. The projects were similar in that both proposed data collection through web-based surveys of graduate students from OSU and obligated researchers to maintain confidentiality of student records. The projects seemed to be requesting collaboration from OSU, although the FYO would only require a one-time sharing of information. The two projects were both presented as qualitative research, and, if they were research as opposed to internal evaluation projects, both would require applications to and approval from OSU’s IRB.

The CID project differed from the FYO project in a number of important ways that raised additional questions about whether or not the Graduate School dean would agree to authorize participation in the CID graduate student survey. Unlike the FYO where the research was covered by the University of Washington’s FWA and federally approved IRB, the CID research was generated by an organization, the Carnegie Foundation, that did not receive federal funding and had neither an IRB conforming to federal regulations nor an FWA. As a result, the CID project was not expressly conceptualized in accordance with federal regulations for oversight of human subjects research. This difference between the sponsoring institutions — CIRGE had an authorized IRB, but the Carnegie Foundation did not — made a difference when the time came to prepare IRB applications for the projects.

Researchers from CIRGE at the University of Washington shared their IRB application for an approved qualitative research project with the Graduate School at
OSU. In effect, administrators at OSU were able to learn from both the shared application and also from researchers who had prepared the application. The CIRGE application provided a model of an ethically responsible qualitative research project for the Graduate School staff and for OSU’s IRB. One instance when this was particularly helpful was in preparing the risk/benefit assessment for the project. When Graduate School administrators prepared the FYO application, they were able to use the risk/benefit analysis included with the CIRGE application to assess the risks and benefits for OSU alumni.

Other differences between the projects related to overall research designs, the degree of involvement proposed for participants, and the compatibility of research projects with quantitatively based models for institutional research. Assessments of risks and benefits for the two IRB applications reflected these differences. In some ways, creating the IRB application for the FYO study prepared OSU staff for the more complicated task of writing the CID application.

*Requirements for Human Subjects Research at OSU*

When Robert McGrath, Senior Vice President for Research at OSU, announced the most recent signing of OSU’s FWA, he also indicated that all OSU faculty, staff, and students involved in human subjects research activities would be required to complete an ethics training and certification process. McGrath’s rationale for initiating the training requirement cited OSU’s obligation to abide by agreements between the federal government and the university as they are specified in the FWA.

While the FWA is an agreement between the university and the federal government, effects of the agreement extend beyond oversight of activities within
institutional boundaries and include activities conducted by and with OSU affiliated personnel. Thus, recruitment of alumni as human subjects for the FYO study, and recruitment of graduate students as human subjects for the CID were research activities of the sort referred to in the university’s FWA and McGrath’s message.

*Federalwide Assurance.*

The Office for Human Research Protections (OHRP), which is administered by the United States Department of Health and Human Services, approved the FWA agreement between OSU and the federal government. The agreement is for a term of three years and stipulates that human subjects research conducted at OSU “may not be initiated … until the research is reviewed by one of the institutional review boards designated on the FWA” (FWA, 2004, ¶ 3). OSU’s FWA also includes a researcher training provision, the purpose of which is to “ensure the federal government that all faculty and staff who participate in research involving human subjects… are fully informed of current research ethics, best practices and regulatory requirements before they participate in human subjects research activities” (McGrath, 2004, ¶ 2). As McGrath indicated in his July 2004 announcement, Collaborative IRB Training Initiative (CITI) was selected as “the core of the institution’s new training effort.” Further, completion of the web-based training, signified by certification, was required by December 2004 for all members of the institutional community who were engaged in research with human subjects.
Collaborative IRB Training Initiative.

CITI training was, therefore, required of faculty, staff and students at OSU before they were permitted to engage\textsuperscript{88} in research with human subjects or to serve as principal or co-investigators on research projects. (Obligations to complete training requirements and compliance with IRB decisions emanate from the relationship between the individual and the institution holding the FWA. Regardless of funding sources for research, individuals who are affiliated with OSU must comply with the FWA requirements.) As a part of its oversight function, the IRB maintains a record of certification dates for OSU researchers. Record keeping of this sort by the IRB is also a requirement of the FWA. Thus, while faculty, staff and students may perceive this monitoring of their training compliance as being oversight by the IRB, the monitoring of training requirements is, in fact, an essential element of the institution’s agreement with the federal government and can also be seen as oversight of OSU by the federal government.

The multiply-layered management of human subject protections can be challenging to understand for researchers who do not have experience with such a system of oversight. Researchers at the University of Washington working on the FYO study were accustomed to working within the constraints of an FWA. Researchers at the Carnegie Foundation were not. The Carnegie Foundation did not receive federal funding and was not required to have an FWA. While the Carnegie Foundation had an

\textsuperscript{88} Being “engaged” in research with human subjects has a specific meaning in the context of federal regulations. The most recent FWA (2006) offers the following definition: “Under the Federal Policy (Common Rule) at Section 102(f) awardees and their collaborating institutions become "engaged" in human subject research whenever their employees or agents (i) intervene or interact with living individuals for research purposes; or (ii) obtain, release, or access individually identifiable private information for research purposes.”
internal institutional review panel, that panel was not constituted according to federal regulations. As a result, administrators in the ORRP at OSU did not recognize the Carnegie Foundation’s review process as sufficient for protection of OSU graduate students as human subjects, and, importantly, the Carnegie Foundation researchers were not familiar with FWAs, IRB procedures, or CITI training. The combination of these conditions affected the Carnegie Foundation project and contributed to complicating the review process.

*Code of Federal Regulations (Regulations).*

Records that IRBs are required to maintain are specified in the Regulations at 45 CFR 46.115. The regulations specify that institutions maintain the following: records related to documentation of IRB activities, copies of communications between the IRB and investigators, information (by name) and listing of “IRB members,” and written procedures of the IRB. FWA documents indicating requirements of the agreement between OSU as an institution and the government’s granting organization, the US Department of Health and Human Services, OHRP, state:

OHRP strongly recommends that the Institution and the designated IRB(s) establish educational training and oversight mechanisms…to ensure that research investigators…maintain continuing knowledge of, and comply with, relevant ethical principles, relevant Federal regulations, OHRP guidance, other applicable guidance, state and local laws, and institutional policies for the protection of human subjects…and complete appropriate institutional educational training before conducting human subject research (FWA, 2002, A.12).
Summarizing the impact of these requirements reveals that the IRB at OSU is responsible to OHRP for overseeing training of researchers and for keeping records of researchers’ compliance with training requirements. McGrath indicated that completion of CITI training fulfills this requirement, and the certification process provides the necessary documentation of compliance.

Engagement in Human Subjects Research

Similar to the way in which ‘educational training’ has a specific meaning within the context of an FWA, there are additional key terms that appear in federal and institutional regulations and documents. How those terms are defined and understood makes a difference in how the regulations are applied. Two important terms are ‘research,’ and ‘engagement.’ If the CID and FYO projects were not defined as research activities, the Graduate School would not be required to complete IRB applications for each. Thus, administrators in the Graduate School first needed to determine whether or not supplying contact information for graduate students and alumni constituted “research.” Constructed understandings of these key terms and others were informed by literature review, document analysis and informal interviews.

Defining ‘Research’

The Regulations define ‘research’ in 45 CFR 46.102(d). This is one of 10 definitions provided in the regulations.

Research means 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. For example, some demonstration and service programs may include research activities.

In the case of the FYO project, Nerad had already determined that her project, as she was conducting it at the University of Washington, met the definition of research. The CID project could not be defined as research so easily.

The major difficulty in deciding if the CID project constituted research rested on whether or not the project was “designed to develop or contribute to generalizable knowledge.” This issue surfaces frequently in discussions of qualitative research. In fact, George Walker suggested that based upon his training as a theoretical physicist, he would not define the project as research (personal communication, December 2004). The distinction Walker made may have been based upon differences in how ‘generalizability’ was understood. ‘Generalizability’ can be interpreted differently in qualitative research from the way the same word is interpreted in the context of quantitative methods, and quantitative and qualitative researchers could have different goals in terms of generalizability for the knowledge they plan to contribute.

Generalizability in Research

Researchers working with quantitative methods generally cite random sampling as justification for generalization of findings. This is especially the case in true experimental designs which rely heavily on quantitative techniques and begin with a testable hypothesis. In the case of the CID, there did not appear to be either a testable hypothesis or evidence of a random sample. What did this mean then about generalizability of findings? Carnegie Foundation researchers were looking for best practices in programs and planned to disseminate information about those practices.
One goal of the CID project was to make the learning from programs participating as partners accessible to other programs, disciplines, and institutions. Further, the Carnegie Foundation scholars referred to their project as ‘action research.’ The CID project seemed to reflect an emergent research design and to fit somewhere between that which is generalizable knowledge and that which is not intended to be generalizable. It seemed as though partner programs had been selected by the Carnegie Foundation to participate in the CID for their capacity to generate and demonstrate rich details about Ph.D. education, and not because the programs were representative along particular dimensions.

The CID project took more of a case study approach than a quantitative approach to research. Michael Patton (1987) describes different approaches to research in a research textbook, and he refers to this type of inquiry as ‘naturalistic.’ He points out that in qualitative case studies people or programs are studied in their natural environments, and there is not an attempt to create a true experiment or to manipulate variables. Stake also describes naturalistic inquiry as taking people in their natural settings (as cited in Worthen, Sanders & Fitzpatrick, 1987).

In response to how one might generalize from this type of research or evaluation, Patton suggests that ‘lessons learned,’ reported as findings, are a way to have others benefit from naturalistic inquiry. He believes that the rich detail and description of the cases allows others to find applications for those lessons in their own experiences. In fact, Lee Shulman, President of the Carnegie Foundation, highlighted the importance of sharing ‘lessons learned’ (2004, ¶ 17) among universities, disciplines and programs. Carnegie Foundation scholars may have been using the case study approach in the CID project to generate ‘lessons learned.’
The question of generalizability also arose in consideration of whether the research conducted by the Carnegie Foundation was research per se or evaluation. When Patton (1987) writes about “evaluation” as naturalistic inquiry, he is referring to a unique type of research that has a particular application and does not aim to generalize about findings.

Generalizability of findings was another difference between research and evaluation identified by OSU’s IRB. When IRB panelists were evaluating whether or not human subject approval would be required for a project in 2004, they configured evaluation as a type of research that did not involve generalizable findings and therefore did not require review by a full IRB panel. J. Michael Oakes, writing in Evaluation Review, suggests that basing a decision about whether or not a protocol should be reviewed by the IRB on this distinction might be inaccurate (Oakes, 2002).

Oakes indicates that IRBs are increasingly burdened by projects to review and guidelines to interpret, without knowing exactly where the line between evaluation and research falls, or on what basis to make the decision. In July 2004, decisions may have been made based on whether or not a researcher called his project evaluation or research, and that may have led to some confusion. Merely characterizing one’s project as evaluation could be a way of circumventing the IRB review process. Joan Sieber, editor of the Journal of Empirical Research on Human Research Ethics, pointed out a similar case of misnomers in her April 2006 visit to OSU. She indicated that following the decision to exclude oral history projects from IRB review, some researchers took advantage of this situation and called everything they were doing ‘oral history.’
The Carnegie Foundation scholars in the CID project demonstrated confusion about how to characterize their research and methods according to OSU’s IRB definitions. This is understandable given that definitions and requirements differ across contexts. The Carnegie Foundation staff did not feel that it was necessary to obtain IRB approval for the CID activity before contacting students to respond to their survey. Their intention was to report best practices and to report those as lessons learned from the project. While the IRB review process might have operated to prevent universities, programs, graduate schools, and students from participating in an activity that was not clearly defined, lessons learned from such a project would have been lost as a result of the complexities of IRB review requirements and processes.

‘Engagement’ as Performative Language

‘Engagement’ was a key term in conceptualizing the Graduate School’s possible research relationships with CIRGE and with the Carnegie Foundation. In the context of both the CID and FYO studies, “When and how does one become engaged in research?” was a fundamental question. Understanding what the term ‘engagement’ means and the actions it implies in the context of human subjects research were essential to determining how the Graduate School would proceed with the FYO and CID requests for graduate student contact information.

The Regulations refer to ‘engagement’ of institutions in 45 CFR 46.103. In this section, the Regulations lay out the requirements for compliance and refer to institutions being ‘engaged’ in research.

Each institution engaged in research which is covered by this policy and which is conducted or supported by a federal department or agency shall provide
written assurance satisfactory to the department or agency head that it will comply with the requirements set forth in this policy.

Engagement\textsuperscript{89}, when used in the Regulations or within the context of human subjects research and institutional requirements, functions as ‘a performative’. Austin explains how performative utterances operate and states: “The name [a performative] is derived, of course, from ‘perform’, the usual verb with the noun ‘action’: it indicates that the issuing of the utterance is the performing of an action—it is not normally thought of as just saying something” (1962/1975, pp. 6-7). Extending Austin’s theory of performative utterances to written statements, such as within the context of federal regulations and institutional requirements, determining that one is engaged in research is not merely a description or statement of what is happening, and it is not thought of as just saying something. Determining that one is ‘engaged’ in research sets in motion a chain of institutional review procedures, and resembles what Austin refers to as “the different case in which by saying something we do something” (p. 91).

In Austin’s discussion of three types of speech acts, locutionary, illocutionary, and prelocutionary, he explains the concept of prelocutionary acts. “[T]he prelocutionary act always includes some consequences, as when we say ‘By doing $x$ I was doing $y$’” (1962/1975, p. 107). Austin clarifies how sentences or utterances can be said to be performing prelocutionary acts: “what we bring about or achieve by saying something, such as convincing, persuading, deterring, and even, say, surprising or

\textsuperscript{89} The Department of Health and Human Services defined engagement in a January 1999 memo that is available on the Internet. “An institution becomes "engaged" in human subjects research when its employees or agents\textsuperscript{1} (i) intervene or interact with living individuals for research purposes; or (ii) obtain individually identifiable private information for research purposes [45 CFR 46.102(d),(f)].” Retrieved July 9, 2006 from: http://www.hhs.gov/ohrp/humansubjects/assurance/engage.htm
misleading” (p. 109). Adopting the concept of a prelocutionary performative act and applying the concept to what federal regulations for human subjects research intend to achieve with the meaning of ‘engagement’, then, instantiates Austin’s point that prelocutionary acts can produce effects.

Austin’s theory of performative utterances provides a schema for understanding how the Graduate School came to be engaged in research with the CID project. The course of action set in motion by Graduate School administrators’ determination that OSU would engage in research through providing contact information for graduate students required as a consequence that an IRB application be submitted for the CID research project.

IRB Review of the CID Project

A meeting of Graduate School staff members, the director of the ORRP, and OSU attorneys was arranged in November 2004. A determination was made during that meeting that if the Graduate School decided to participate in any of the CID surveys90, the overall CID project would need to be reviewed by a full IRB panel. Staff members were directed to the ORRP web site for guidance on how to complete the appropriate IRB applications. ORRP administrators did not indicate which application would be required, although they did point out that before applications were submitted, staff members, including the Graduate School Dean would need to complete CITI training. This decision to submit an IRB application initiated an informal study of IRB policies and procedures by this writer who was working as a graduate assistant in the Graduate

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90 Carnegie Foundation researchers indicated in telephone conversations that there were also planning to launch a survey of faculty members in partner programs.
Document analysis, conversations with researchers, and a focused literature review informed the investigation of IRBs and later became the spark for additional fieldwork related to the dissertation study.

**Risk/Benefit Analysis**

Identification and assessment of the risks and benefits of proposed research projects is an essential element in IRB review processes. As Sieber explains: “Risk/benefit assessment weighs the risks, or costs, of the research to subjects and to society, against its benefits” (1992, p. 76). A primary duty of IRB panel members is assessing risks and benefits of research protocols. According to OHRP’s *IRB Guidebook*, “both the probability and magnitude of possible harm may vary from minimal to significant” (OHRP, 2003, p. 284). The Regulations define minimal risk in 45 CFR 46.103(i).

A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily life or during routine physical or psychological examinations or tests.

The Graduate School researchers initiated an assessment of risks and benefits for the CID project in August 2004. In preparation for a meeting with the University Provost, key issues, facts and chronology, and salient definitions were laid out and summarized. Issues identified for the meeting included the following questions. “Do the proposed activities constitute research as defined in 45 CFR 46.102(d)?” If so, “Does

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91 The August meeting was arranged in response to an announcement by the University that Lee Schulman, President of the Carnegie Foundation, would be OSU’s summer quarter commencement speaker.
the research involve human subjects as defined in 45 CFR 46.102(f)?” “Is the Institution engaged in research as defined in 45 CFR 46.102(d) and (f)?” “Has another authorized IRB approved the project as in defined in 45 CFR 46.103?”

Administrators in the Graduate School believed the greatest potential risks of the CID project were to students and faculty, and those risks were mainly related to possible breaches in confidentiality. The instance of a survey administrator from the Carnegie Foundation suggesting the possibility of notifying a program about the comments made by a student in that program provides an example of the type of risks that concerned Graduate School administrators. Students were promised anonymity and confidentiality and to breach that agreement in order to report dissatisfaction with a faculty member or a program would be inappropriate. The survey administrator’s suggestion revealed both that identifiable information was being collected and stored about respondents (anonymity) and also that the confidential information submitted on surveys might not be kept in confidence. The good intentions of the survey administrator to help resolve a student issue did not mitigate sufficiently the potential risks.

Additional potential risk to faculty members existed in that students were called upon to provide information about faculty that could be misinterpreted. One item on the survey instrument asked students to rate their level of agreement with the following statement: “My advisor clearly keeps my personal and professional interests in mind.” This question is ambiguous and calls upon students to speculate about what faculty members might be thinking about their students.
It seemed that benefits to the Carnegie Foundation were greater than the benefits to academic communities or to the students completing the surveys. Risks to the Carnegie Foundation as a result of the survey project were not identified. In summary, the risk/benefit assessment suggested that the group at greatest risk, the students, would have the least to gain, and the group with the most to gain, the Carnegie Foundation, would carry the lightest burden of risk.

CID Surveys

The web-based CID survey that was distributed to graduate students in June 2004 was not submitted for IRB approval before it was administered. Administrators in the Graduate School learned of the survey through the students and faculty in the participating programs at OSU. The policy of the IRB at OSU is not to review proposals for research that have been started before applications have been submitted. Therefore, an IRB application for the survey of graduate students could not be submitted retroactively. While data had been collected from OSU graduate students in the first administration of the survey, those data were removed from the data set and not reported in early findings from the Carnegie Foundation.

CID researchers proposed a survey of faculty members from participating programs in September 2004. The Graduate School staff members worked with the Carnegie Foundation and with OSU’s IRB to submit an application for approval so that faculty members could participate and data from OSU faculty could be included in findings. When IRB approval for the faculty survey was granted, CID researchers proposed a re-survey of graduate students from OSU. An application was submitted for the re-survey, and this also was approved.
OSU’s Behavioral and Social Sciences IRB panel approved the CID survey protocols for 365 days calendar days. Before those approvals were due to expire, IRB administrators notified the principal investigator that either renewal applications or termination reports would be due before the approvals actually expired. Termination reports were filed for both protocols in March 2006.

Lessons Learned

Methodological and theoretical lessons emerged from work on the CID project. Early learnings related to the ways in which IRB processes operate within, between, and across institutional boundaries. IRB policies and procedures functioned to protect students, faculty, and the institutions at various points and in different ways. Variations in protection differed in accordance with which individuals or group were conceptualized as participating in human subjects research. When “protections” for one group were perceived as an impediment to the research project of another group, the protecting entity, which was the IRB in most cases, was viewed as the barrier to research. In such cases, closer examination of the research project might reveal that there might have been an imbalance between risks and benefits for human subject participants.

Tracing effects of institutional review processes overall on qualitative research was another lesson that came to light during work on both the CIRGE and CID projects. An effect that can be seen in early communications between Carnegie Foundation researchers and Graduate School administrators suggests that there is an underlying mismatch between IRB application processes and qualitative research designs. In some regards, researchers and administrators seemed to be speaking two different languages –
one a language more familiar to qualitative researchers and the other a language more familiar to quantitative research. IRB policies and procedures have arisen from a quantitative approach to medical research, and understanding intents and requirements of policies and procedures often requires translation of the ways that IRB policies and procedures “speak” and “respond” to researchers.

Since July 2004, I have observed an increased emphasis on research compliance at the institutional level. While research compliance covers activities that are broader in scope than human subjects issues, attention paid strictly to compliance with human subjects requirements has been noticeable. CITI Training, in particular, generates considerable criticism – as much for what it does do as for what it does not. Some faculty, staff, and students search for the most expedient way to complete the training, some complain about the way in which the CITI training seems to reduce ethical principles to a check list, and some resist completing the training altogether. Regardless of the intrinsic value of completing the web-based training, CITI training and McGrath’s announcement of the requirement to complete the training have generated conversation about human subjects issues in research. There has been an effect that was not achieved prior to July 2004 in behavioral and social sciences with other training programs such as the Responsible Conduct in Research (RCR) training program92.

Theoretical lessons continue to emerge about the power of words to create effects. In summarizing his lecture series, Austin acknowledges “the notion of the purity of performatives” will not survive in a transition to a “theory of speech-acts”

92 RCR training is supported by the US Department of Health and Human Services’ Office of Research Integrity. Information about training is available from http://ori.dhhs.gov/education/
(1962/1975, p. 150). Austin creates five categories of performatives and does not make claims of causation between words and their effects. Neither will I claim to link the words of institutional and federal policies purely with the effects I have observed. I will claim that I observed effects of words and surrounding policies that were performed in July 2004 by OSU’s Senior Vice President for Research. “[T]he issuing of the utterance is the performing of an action” (Austin, 1962/1975, p. 6). The effects of these performative utterances warrant further investigation and become the guiding force for exploring boundaries in the broader study.
LIST OF REFERENCES


APPENDIX B

UNDERGRADUATE STUDENT RESEARCH EXPERIENCES
The Undergraduate Student Research Experiences (USRE) project explores effects on novice researchers of changes to institutional review processes in academic settings and considers ways in which these researchers engage with institutional and individual responsibilities in research. This project involved a series of ethics in research workshops for undergraduate students at Ohio State University during the summers of 2005 and 2006. This writing describes the data collection methods used, presents an overview of data gathered, and summarizes the primary lessons learned during two iterations of the workshops. Three dominant themes are identified from this work that inform the larger study, *A Study of Responsible Conduct in Research: Complexities All the Way Down*, examining relationships between institutional review processes and ethics in research.

Ethical standards supporting institutional review procedures for human subjects research are based in principles that are outlined in the *Belmont Report*, and those standards have not changed substantively since they were written in 1978. However, the ways in which Institutional Review Boards (IRBs) interpret those standards in the review of human subjects research projects have changed over time. The meanings of terms such as “engagement,” “research,” and “human subjects” have changed along with interpretations of standards, and these terms are now defined in federal regulations. Some researchers in the education research community perceive the shifting meanings
to be an effect of increased federal regulations on research and others consider recent changes to be signs of a greater emphasis on accountability in education.

Policy changes to institutional review requirements for human subjects research have created a need for more explicit approaches to training researchers to understand the approval mechanisms and application processes required for research proposal reviews (McGrath, 2004). Web-based training programs have been developed to meet the needs of institutions and to train research investigators in the specialized area of human subjects research. Responsible Conduct in Research (RCR) and the Collaborative IRB Training Initiative (CITI) programs are two examples of online training that are available to members of the academic community at Ohio State through the Office of Responsible Research Practices (ORRP). These offerings provide important introductions to broad issues involved in the responsible conduct of research.

An empirical project with teaching and research goals was initiated during the summer of 2005 and extended through the summer of 2006. The teaching aim of this work was to introduce novice researchers to notions of ethics in research and engagement of human subjects in research. The research goal of the project was to investigate how undergraduate students begin to understand the concept of “responsibility” in their research. This project is part of a larger study investigating understandings of, and relationships between, accountability and responsibility in ethical conduct in research. The larger research study examines a perceived gap between federal and institutional requirements for human subjects research and
practices of researchers as they interpret and apply standards for ethical conduct within their work.

Empirical Research Project Design

The USRE project was the second in a series of empirical projects that took shape from perspectives of differently situated researchers. Five individual projects informing the study contribute to an exploration of how researchers representing different perspectives understand notions of responsibility in their research. Perspectives of researchers vary according to the contexts where researchers are situated, the roles of participants in research endeavors, the approaches taken to investigations, and methods used for data collection.

Research Context

Ohio State University hosts a Summer Research Opportunities Program (SROP) that was developed in 1985 by graduate deans representing the Committee on Institutional Cooperation (CIC). The program offers mentored research opportunities in a variety of disciplines to talented underrepresented minority students. The SROP program helps prepare these undergraduates for graduate and professional school experiences by involving students in scholarly activities, offering weekly professional development workshops, and guiding them through professional conference presentation experiences. In the spring of 2005, Jean Girves, who brought the SROP program to Ohio State, requested that the Graduate School at Ohio State provide a training workshop to address ethical issues in research for the Summer 2005 class of
SROP students. In response to Girves’s request, an introductory workshop on responsible conduct in research (the USRE project) was initiated.

Research Participants

Participants in this research project were students enrolled in SROP at Ohio State University during two summers. There were 41 SROP students at Ohio State in 2005, and of these students, 31 voluntarily consented to participate in the research. Forty-seven SROP students were enrolled during the second summer and 43 of these voluntarily consented to participate in the research. All students enrolled in the SROP program were part of the ethics workshops, and 74 students were human subject participants in this research.

Case Study Approach

Through an ethnographic collective case study approach, the USRE research project contributes to the fuller study by investigating ways that certain members of a defined population of undergraduate students, in this case SROP students, understand the concept and practices of ethical responsibility in the conduct of research at OSU. Methodologically speaking, this facet of the study is predominately qualitative and paradigmatically postpositivist, in that it draws from a range of methods (document analysis, observations, informal interviews, and surveys) and acknowledges that there are no universal truths or grand narratives to legitimize researchers’ claims of capturing some verifiable reality of the lived experiences of participants (Lather, 1991; 93)

93 I use Guba’s (1990, as cited in Denzin and Lincoln, 2000, p. 9) explanation of postpositivism, which states in part, “...the postpositivists argue that reality can never be fully apprehended, only approximated.” Denzin and Lincoln, further indicate: “Emphasis is placed on the discovery and verification of theories.
Reporting of these data relies upon “the postmodern period of experimental ethnographic writing” (Denzin & Lincoln, 2000, p. 17) to make sense of lessons learned from the experiences of SROP students who shared their thinking, writings, and activities for inclusion in the study.

Instructional content for the workshops was drawn from sources that included RCR training and CITI course materials and case studies adapted from Teaching Research Ethics Workshops (TRE) at Indiana University. SROP students had access to web-based materials and were asked to read from the course materials of their choice. RCR and CITI training provide course completion certificates, and students were asked to turn in completion certificates during the final workshop session.

**IRB Approval of Research**

An IRB application for exempt research was submitted to Ohio State University’s IRB. Approval was granted under Category 1, “Research conducted in established or commonly accepted educational settings, involving normal educational practices” and under Category 2, which provides for “Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior)” (ORRP, 2005). ORRP administrators determined that the research did not involve greater than minimal risk to human subjects. Participants in this study were guaranteed confidentiality and anonymity. All of the participants were over the age of 18 years.
Research Question

What are characteristic attitudes, values, and language regarding researcher responsibility of SROP students who are participating in mentored research activities and intermittently learning about responsible conduct and practices in their research through the ethics workshop series?

USRE – Summer 2005

This section describes the methods used and data collected during the first ethics training workshop series.

Data Collection Methods

The data corpus for the first workshop series includes a research journal of notes from observations and quasi-interviews and students’ reflective writings. Research journal entries were made by this writer to record group discussion questions, assigned writing topics, and the coding system of pseudonyms developed to protect the confidentiality of students’ identities. Although a number of student comments contributed to findings and were recorded during group discussions, the most useful data were generated through students’ writings.

Student Discussions

During group discussions, students talked about ways in which the concepts of responsibility and accountability are woven together and the meanings of the concepts may overlap. Students mentioned such things as: “the two [accountability and responsibility] go hand in hand;” “I think that to be responsible, you must be

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94 I use the term quasi-interview to refer to the data generated through question and answer sessions at formal presentations and students’ responses to questions posed during group discussions.
accountable for your action;” and “a responsible person would be accountable for their actions and in research there is no difference.” One student added another dimension to this discussion by proposing that he perceived tension between the two concepts. This student brought out complexities and uncertainties he perceived in his suggestion that the concepts could conflict with one another. “Being accountable to [another] person might not be responsible to yourself.”

Student Writings

The overall theme for student writing assignments addressed what being responsible in research entails for an SROP student. Some students described ethical issues in mentoring relationships, and others wrote about concerns related to authorship. A number of students reported ways in which they demonstrated accountability or responsibility in research, and a few writers drew distinctions between the ways they demonstrated responsibility and accountability in research.

SROP student writings revealed that these students watched their mentors and were guided by mentoring relationships in their thinking about responsibility and accountability in research. Students seemed to view themselves as beginners and were looking for direction about how to conduct themselves as researchers. One student who worked on a social science project for the summer indicated in her response to the prompt asking students to consider responsibility and accountability in their particular summer assignments that she viewed herself as a novice learner in relation to her mentor whom she identified as an expert. “I never do anything without permission… Whenever you find out that you are responsible for something, then you should be
ready to be held accountable for whatever results.” Although this student stated in her writing: “There is no difference between being responsible and being accountable,” she distinguished between conditions of being responsible and being held accountable.

Another student’s writing repeated a theme of responsiveness that a number of students included in their construction of responsibility, and in addition, she captured the notion of engaging actively in research. “Responsibility is consciousness in action; it is an active force. Accountability is reactive.” This student teased apart a distinction she founds between responsibility and accountability. In her writing, she suggested that responsibility requires a conscious choice to actively engage with ethical issues.

Actions and practices students cited as demonstrating responsibility or accountability included the following: “Knowing the science of what I am doing,” “Studying on my own time,” “Presenting my research correctly to avoid misinterpretations by readers,” “Sharing new information,” “Running the lab and carrying out experiments while my mentor and the grad students are away,” “Getting along with others in the lab,” “Being accurate,” “Using proper citations in research,” and “Asking for permission.”

Observations of Student Behaviors

Student behavior was observed and recorded in three areas: the consent process, including consent form signing; CITI training completion and certification; and writing and submission of reflection papers. Of the 41 students enrolled in the SROP class of 2005 students, 32 returned signed consent forms; three submitted a CITI training certificate; and 17 presented reflection papers.
SROP program graduate assistants required students’ attendance at the workshop series; however, attendance was not enforced. On a number of occasions, students notified the graduate assistants that they would not be able to attend a group discussion. Explanations for missed sessions that were reported generally related to scheduling conflicts, and in most instances, conflicts for students were between individual laboratory work schedules and group ethics training attendance.

USRE – Summer 2006

The ethics in research workshop series was repeated during Summer 2006 with a new group of SROP students. The question, “What does it mean to be responsible in research?” was taken up for a second time with undergraduate students participating in the SROP program through a three-session workshop series organized around RCR and CITI online training resources. These training options were selected for a second time because they offer structured frameworks and starting places for thinking about questions of ethics and responsibility in research.

A weakness of the workshop series identified following Summer 2005 was a lack of engagement of students with available resources and the workshop series. A goal for Summer 2006 was to respond to this weakness and to address the students’ needs by designing activities to connect students’ issues with discussion topics and resource materials. The revised approach allowed ethical principles and salient themes to emerge from students’ comments and writings.
Engagement of Students

Engaging students in discussions about responsible conduct in research and encouraging them to access on-line training materials and resources related to ethical practices and conduct in research were emphasized during the Summer 2006 SROP workshop series. Two data collection points were used to assess students’ engagement and to survey their areas of interest. Primary sources of information were responses to a written prompt asking each student to identify an instance or scenario that she or he perceived to present an ethical issue or conflict. The 39 students participating in the research identified 42 scenarios involving ethical issues. A second data source was the workshop series evaluation survey completed by 26 students during the final meeting.

Identifying and categorizing ethical issues students identified.

Asking students to provide instances of ethical issues within the context of their research served as a way of learning what issues were relevant for these particular students. Based upon the student’s responses, group discussions were planned to heighten students’ awareness of these sorts of ethical issues. The prompt asking for identification of ethical issues arising in research was open to interpretation by students. Students responded anonymously by submitting questions or comments or both. Students’ responses were coded along two dimensions. The first coding was an interpretation of the ethical principle(s) a student’s comment reflected. The second coding indicated whether or not the student’s concern was addressed in the web-based resources available to students (the RCR materials or one of the two tracks for the CITI training course).
In the first coding of identified issues, autonomy (respect for persons), beneficence, and justice were the fundamental ethical principles used for categorization. There were 29 student responses sorted according to these theoretical themes. Eighteen issues were grouped as being related to respect for persons; four issues addressed the principle of beneficence, or “maximiz[ing] possible benefits and minimiz[ing] possible harms” (Belmont, 1978); and nine issues represented concerns about justice, or equal treatment of human subjects in research. This categorical scheme was followed in order to connect students’ issues with ethical principles from the *Belmont Report*, which serves as the basis for federal regulations and institutional requirements regarding research involving human subjects.

Additional codes were created to represent issues students raised that did not fit within the ethical principle categorization scheme. Some student comments addressed institutional review processes and procedures. This was the case with the following question: “If a participant feels uncomfortable and makes a complaint, what is the process taken to find out whether there was an ethical issue involved?” This response was categorized as “research.” Other comments related to how students understand the concept of “science” and research within a scientific context. These comments also were not coded according to underlying ethical principles. Instead, these were categorized as “science.” Examples of responses categorized as “science” were: “Is it still research if you review other people’s writing and just write a paper supporting their arguments?” and “How do you test software that people’s lives depend on, such as software for radiation machines or military defense systems?” Two student responses
did not fit into either schema and seemed to be too broad in scope to code for analysis in this focused study.

*bRelationship between ethical issues and training materials.*

Preparations for group discussions were aimed at making the sessions relevant to students. With that goal in mind, issues identified by students were starting points for conversation, and discussions were guided to demonstrate connections between issues and ethical principles. One comment posed by a student provides an example of how this process was instantiated. The student wrote, “Ethical issue: A student organization planning to play a ‘Capture the Immigrant’ game on campus on the oval.” During discussions with each of the four groups of SROP students, this comment was presented as a starting point for conversation. Some participants in the first group thought that this was a harmless game when played among friends. A participant in another group was troubled by the idea, but wondered how this situation related to anyone’s research.

Asking about how people with different points of view might understand such a game shaped the discussion. Students discovered that in their groups not everyone perceived the situation in the same way. When students were reminded of the three ethical principles, autonomy, beneficence, and justice, they identified without prompting, that a game such as “Capture the Immigrant,’ played on a university campus, and sponsored by a university affiliated student group would not be respectful of persons. Students seemed to agree that autonomy was a fundamental ethical issue. While autonomy was a primary issue in this scenario, issues of beneficence and justice also came into play. This situation provided a strong example of the ways that ethical
issues are complex and do not have easy answers. Sorting out ethical issues often requires a balancing of not only principles, but also perspectives.

Both RCR and CITI training materials deal with the notion of balancing ethical principles. However, these web-based resources predominately offer suggestions of how principles should be applied in single-principle situations related to human subjects research. Responses of SROP students, who may or may not see themselves as involved in human subjects research, suggested that the students were recognizing that how people are treated in social contexts (in and by the university, and on campus) presents ethical issues for both science and research.

Student Opinion Survey

Student attitudes and perceptions related to the workshop series were evaluated through an opinion survey. Specific goals of the evaluation survey were to gain information about what students were taking away from the ethics training offered during Summer 2006 and to inform the planning of ethics training for SROP students in Summer 2007. A pencil and paper instrument was administered to 26 students at the conclusion of the third session. A copy of the survey instrument is included with this report.

Students who completed the survey represented research projects in disciplines that were distributed across six colleges: Engineering (7), Social Work (1), Social and Behavioral Sciences (5), Humanities (5), Arts (1), Food, Agricultural, and Environmental Sciences (1), and School of Allied Medical Professions (1). Five

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95 Ten students were excused from attending the third session because this group was scheduled to attend an ethics lecture that was offered within their discipline. Thus, the “n” was smaller for the survey than for the ethical issues data collection.
students did not indicate the college with which they were associated. This distribution of disciplines was somewhat representative of Summer 2006 participation in SROP by college, with the exception that responses from students assigned to Math and Physical Sciences and biological sciences were not identifiable by colleges in survey responses.

Survey questions focused on knowledge of research ethics students had gained from the training resources and effects of that training, RCR or CITI, on their thinking. Survey items also addressed perceived effects of institutional review processes (the IRB) on research, and how students think about ethical responsibility in their research. Fifty percent of the students (n = 13) indicated they felt they had a better understanding of human research subjects’ protections following completion of either RCR or CITI training. Of those students who responded to questions asking whether or not the web-based training had an effect on how they thought about their research, responses were evenly split with nine students indicating they perceived an effect of the training and nine indicating there had not been an effect. Similarly, students’ responses to the question asking whether or not the IRB had an effect on the way they thought about their research indicated that nine felt the IRB had an effect, and nine felt that it did not have an effect.

Student responses to these “effects” questions were then looked at together. Nine students answered both questions in either the affirmative or negative. The other nine students indicated that either the training or the IRB had an effect on how they thought about their research, but not both. There were no evident patterns in the student
response data overall, although students who identified the College of Engineering as their discipline, had the highest rate of non-responses to these questions about effects.

Specific survey questions designed to inform planning of ethics training for future SROP students asked (1) where students recalled learning about issues of ethics in research and (2) how they had first learned that there are ethical requirements (e.g. Institutional Review Boards) for human subjects research at universities. Fifty-four percent of students (n=14) who recalled where they had heard about what they identified as ethical issues in research included the SROP program among those places. (Other choices were: on the Internet, in the news, in academic course settings, or from family and friends.) When asked how they learned about institutional review processes related to ethics, 38 percent of students (n=10) listed aspects of the SROP program. (Responses included in the category, “aspects of the SROP program,” were: “mentors,” “SROP,” and “CITI.”)

*Observations of Student Behaviors*

For students enrolled in the SROP class of 2006, observations of student behaviors that were recorded included signed consent forms, identification of ethical issues writing, completion certificates for either RCR or CITI training, or responses to the final student survey. Of these records, consent forms and RCR or CITI training completion certificates were viewed as measures of engagement. From students in the second year of ethics training, percentages of students engaged were higher on both measures; 83 percent of students returned signed consent forms, and 43 percent
submitted completion certificates. (In 2005, seventy-eight percent signed consent forms and 7 percent submitted completion certificates.)

Students also demonstrated engagement with the workshop series by identifying ethical issues and by completing the final survey instrument. Eighty-nine percent of the students described issues they perceived as having ethical implications, and 70 percent of students responded to the final evaluation survey. (In 2005, forty-one percent of the students wrote reflection papers.)

Lessons Learned

The primary research purpose of the USRE project was to gain insight into how novice researchers understand their responsibilities in research, and both methodological and thematic lessons emerged from the project. I report methodological lessons first, and then turn to the three major themes that inform the lessons learned.

Methodological Lessons

Four data collection methods were used over the course of two summers, and data generated from each method contribute in some way to the project overall. Although the research question calls for a more qualitative approach to data analysis, quantitative and qualitative methods were used together to cast light onto how undergraduate students understand the notion of ethically responsible research.

Quantitative measures were used as broad indicators of students’ perceptions, beliefs, and activities. For example, frequency counts were used to describe the numbers of students who completed certain tasks (e.g. RCR or CITI training completed, consent forms signed, and assignments submitted) and to support the observation that a
greater percentage of students participated either in more ways or on more occasions during the second workshop series than did in the first. Frequency counts also were used to describe the distribution of student responses on a number of the opinion survey items. In response to being asked if and, if so, where students recalled learning about ethical requirements for research, 73% named their mentors and advisors, academic courses, or the SROP program. Data generated from this survey item seems to support the notion that undergraduate students learn to think about ethical requirements for research in academic settings more than in non-academic environments.

Open and unique responses students recorded in written documents and group discussions yielded rich qualitative data and more nuanced insight into the question of students’ perceptions, beliefs, and activities related to responsible conduct in research. The reflective writing assignments students submitted during the Summer 2005 workshop series were particularly useful in identifying recurrent themes. Students’ writings that described aspects of mentoring relationships and also those writings that addressed accountability and responsibility were helpful in understanding how students learn and think about responsibility in research.

**Thematic Lessons**

Three thematic areas surfaced in students’ writing and discussions during the workshops. These thematic areas are important to this project as well as to the broader study. Engagement, mentoring, and responsibility are introduced here as concepts that occurred frequently in this study with undergraduate students who were novice
researchers. These three themes generated questions for future lines of flight and for other facets of the overall study.

Engagement.

In various ways, students asked: “What counts as engagement?” On the one hand, engagement can be seen as a sort of threshold for responsibility in practices of research (DHHS, 1999), and on the other, engagement also seems to be a fluid aspect of mentoring relationships. SROP students appropriately asked many questions about activities that were required for successful completion of the SROP program as well as the workshop series. A number of students’ writings about mentoring relationships and understandings of what it means to be responsible in research mentioned issues of engagement, and students’ reports of their behaviors demonstrated some level of understanding about the complex nature of conceptual engagement. Students did not, however, describe explicitly what various levels of engagement would entail.

The idea of engagement in learning also arises in the literature related to situated learning, or “legitimate peripheral participation” (Lave and Wenger, 1991). Lave and Wenger describe engagement in learning in terms of a developing social relationship. “Viewing learning as legitimate peripheral participation means that learning is not merely a condition for membership, but is itself an evolving form of membership” (p. 53). In the context of this study, individual students participating in the workshop were involved in mentored learning processes aimed at encouraging their individual development from novice researchers to more expert levels, and the students were also participating within a social learning environment. Therefore, engaging individual
students in learning about responsibility in research was always part of a larger and socially relational process; “…learning, thinking and knowing are relations among people in activity in, with, and arising from the socially and culturally structured world” (Lave & Wenger, 1991, p.51).

*Mentoring.*

The mentoring relationship is an essential element of the SROP student experience. Students are assigned to mentors within the disciplines they have chosen as areas of interest. One of the purposes of having designated mentors for students is to encourage learning about the culture of research and to facilitate networking among students and faculty (Girves, Zepeda & Gwathmey, 2005).

The theorizing of American philosopher Hubert Dreyfus is helpful in understanding the key role that SROP mentors play in their mentees’ learning experiences. He lays out changes that take place in apprenticeship relationships as apprentices move from the “novice” stage to “mastery” in his work *On the Internet* (2001). Dreyfus states:

Even where the subject matter is purely theoretical, apprenticeship is necessary. Thus, in the sciences, post-doctoral students work in the laboratory of a successful scientist to learn how their disembodied, theoretical understanding can be brought to bear on the real world (p. 44).

Mentoring relationships include aspects of Lave and Wenger’s (1991) and Dreyfus’s (2001) notions of learning in social contexts. In the SROP program, students are encouraged to experience the research cultures in different areas before choosing a
graduate or professional program, and the mentoring relationships work toward this end. Students’ writings about their mentors in reflection papers during the summer of 2005 demonstrated that mentoring relationships were as important in practice as they are in theory. In 2006, students were not asked specifically about their mentors; however, when given the opportunity of an open response format on the final survey, students cited their mentors as a way they had learned about ethical requirements in research.

Responsibility.

Responsibility in research and how different constituencies in the university environment understand the concept of responsibility is a primary theme for the overall study. In this situated project, the primary focus is to take into account the perspective of novice researchers, how they understand their responsibilities, and what they say responsibility looks like to them. One of the things these students seemed to be saying was that they identified complexity and ambiguity⁹⁶ in the concept of responsibility.

Some students addressed the complexity and their uncertainty about the concept of responsibility by anchoring their writing in descriptions of how responsibility looked different from, or similar to, accountability. “Accountability is owning problems and successes, making right and wrong choices.” Other students dealt with the issue of what responsibility looked like by writing about aspects of responsibility or accountability. “Responsibility is consciousness reflected in action; it is an active force. Accountability

⁹⁶ “Ambiguity” is used in this writing to indicate the meaning of responsibility is always partial. In The Ethics of Ambiguity, Simone de Beauvoir refers to ambiguity as “troubling aspects of a too complex situation” (1948, p. 8), and she states: “to say that [existence] is ambiguous is to assert that its meaning is never fixed, that it must be constantly won” (p. 129).
is reactive.” A number of students included in their statements about what was entailed in being responsible a suggestion that responsible actions would be accompanied by empirical evidence. For example, students said that they demonstrated responsibility by: “meeting due dates,” “completing a two-hour IRB tutorial,” or “double checking data entry.”

Reflections

To my way of thinking, some of the examples students gave as descriptions or explanations of responsibility lean more toward how I think about accountability. Specifically, the fulfilling of an obligation seems more like accountability than responsibility. Thus, when being accountable for particular actions is allowed to stand in for being responsible, I find the ambiguity of responsibility to be an example of what Simone de Beauvoir refers to as “troubling aspects of a too complex situation” (1948, p. 8). It seems that an emphasis on accountability adds to ambiguities of responsibility by obscuring underlying ethical principles and values and at the same time detracts from the complexity of responsibility by providing easier answers to “what counts as being responsible.”

The participation of undergraduate students in the USRE project was an important first step toward developing an understanding of the complexities of responsibility in research. The larger study builds on these perspectives of novice researchers by taking up similar questions with more experienced researchers. A report on a survey of faculty members in the College of Education follows this study and provides another valuable perspective from the university community.
SURVEY INSTRUMENT

Your responses to this evaluation survey will be used to improve the Responsible Conduct in Research workshop series that will be offered to SROP students in the future. The survey is anonymous and your responses will not be associated with your name or your mentors’ names. Please answer the questions to the best of your knowledge.

In responding to the following questions, please think about your experiences with the CITI Training Course, or RCR Training and in SROP during the summer 2006.

1. To which college have you been assigned for summer research?

2. Which track(s) of the CITI or RCR training course did you complete?
   - Behavioral and Social Sciences
   - Biomedical

3. Please indicate your level of agreement with the following statement.
   Following completion of the CITI or RCR course, I have a clearer understanding of human research subjects’ protection.
   - Strongly Disagree
   - Disagree
   - Undecided
   - Agree
   - Strongly Agree

4. Has the CITI or the RCR training had an effect on how you think about your research?
   - Yes
   - No

   If “yes,” please describe.
5. Where do you recall learning about issues of ethics in research? Please check all that apply.

- ☐ Internet
- ☐ Radio/Television
- ☐ Newspaper/Journals
- ☐ Coursework or classes in school
- ☐ Conversation with friends or family
- ☐ SROP

6. Did you participate in the submission of an Institutional Review Board (IRB) application related to your research project this summer?

- ☐ Yes
- ☐ No

If “no,” have you seen the IRB application that was submitted for your research?

- ☐ Yes
- ☐ No

7. How did you first learn that there are ethical requirements (e.g. Institutional Review Boards) for research at universities?

8. Please briefly describe experiences you have had with an Institutional Review Board (IRB) at Ohio State.

9. Has the Institutional Review Board (IRB) had an effect on how you think about your research?

- ☐ Yes
- ☐ No

If “yes,” please describe the effects.
10. Please share any additional comments you would like to make about CITI or RCR training and Institutional Review Board (IRB) requirements and processes. (e.g. Which training lesson was most interesting or useful to you?)

Thank you for your time and for your responses to these questions.
LIST OF REFERENCES


APPENDIX C

COLLEGE OF EDUCATION FACULTY SURVEY
The College of Education Faculty Survey (COEFS) project investigates the perceptions and opinions of faculty members at Ohio State University regarding institutional requirements for research involving human subjects. Recent changes in federal guidelines require new training on ethical principles. Updated procedures for approval of human subjects research have raised questions about effects of current institutional review processes on the research and teaching of faculty in the College of Education (COE). The purpose of the faculty survey was to examine whether or not faculty members perceived effects of those changes on their research. The main goals of this project are: 1) to explore the perceptions, beliefs, and attitudes of COE faculty members concerning principles, policies, and procedures related to human subjects research; and 2) to trace possible effects of recently enacted requirements for institutional accountability and ethical responsibility through faculty reports of their experiences.

This work builds on a dissertation study that explores the concept of ethical responsibility in research. The recounting of faculty perceptions and opinions in this facet of the research contributes to the larger project by considering the ways a group of participants within the academic community perceive effects of policy changes in their research. The primary goal of the larger study is to understand how various members of an academic community understand the notion of “responsible conduct in research.”

This report begins by laying out the most salient federal and institutional requirements that guide responsible conduct in research involving human subjects. The
context and rationale for the survey are described, and a discussion of the survey administration and data collection follows. Major themes and issues that emerged from the study are summarized as “lessons learned,” and the report concludes with reflections of this writer that together with the lessons learned inform subsequent aspects of the larger research project.

Federal and Institutional Requirements for Human Subjects Research

In July 2004, Robert McGrath, Senior Vice President for Research at Ohio State University announced “new requirements for human subjects research.” The new requirements were necessitated by federal mandates and have led members of the education research community to question the effects of these changes on their research. Some faculty members have suggested that new policies and procedures have created a gap between individual responsibilities for ethical research and institutional accountability for federal requirements.

Recently enacted federal mandates for institutional accountability require individual researchers to demonstrate responsibility in the conduct of human subjects research by complying with prescriptive procedures that narrowly define normative ethical practices. McGrath’s announcement signaled not only a change in institutional requirements, but also an increase in oversight of research. An example of such a change in requirements experienced by faculty was the addition of training and certification processes for research involving human subjects. Monitoring of training
certifications by the Institutional Review Board (IRB) is an example of increased oversight and adds to requirements for accountability.

Federal Policies

Congress passed the National Research Act (1974) and assigned to the Department of Health, Education, and Welfare\(^7\) (DHEW) the task of developing details for procedures, which ultimately became a part of the US Code of Federal Regulations (CFR). DHEW commissioned the *Belmont Report* to lay out ethical principles to guide how human subjects will be treated in research. These two national-level documents have a visible impact on human subjects regulations.

Agreements between institutions and the government that are related to human subjects research are known as Federal Wide Assurances (FWAs). The most recently approved FWA between the Office for Human Research Protections\(^8\) (OHRP) and Ohio State has a term of three years and stipulates that human subjects research conducted at Ohio State “may not be initiated … until the research is reviewed by one of the institutional review boards designated on the FWA” (Federal Wide Assurance document, 2004, ¶ 3). Ohio State’s FWA also includes a researcher training provision, the purpose of which is to “ensure the federal government that all faculty and staff who participate in research involving human subjects… are fully informed about current research ethics, best practices and regulatory requirements before they participate in human subjects research activities” (McGrath, 2004, ¶ 2).

\(^7\) The United States Department of Health, Education, and Welfare existed between 1953 and 1979. IRBs are now overseen by the US Department of Health and Human Services.

Institutional Requirements

McGrath indicated in his July 2004 announcement that he had selected the Collaborative IRB Training Initiative (CITI) as “the core of the Institution’s new training effort.” Completion of the web-based training is signified by certification and is required for all members of the institutional community who engage in research with human subjects. CITI training is, therefore, required of COE faculty, staff, and students before they are permitted to become engaged in research with human subjects or to serve as principal or co-investigators on research projects.

Obligations to complete training requirements and to comply with IRB decisions emanate from the particular relationship between the individual and the institution holding the FWA. Regardless of funding sources for research, individuals who are affiliated with Ohio State must comply with FWA requirements. The decision to cover all research with human subjects (not just that research receiving federal funding) was made by administrative officials of the university in consultation with Vice President McGrath, who serves as Ohio State’s primary signatory official.

As a part of its oversight function, the IRB maintains a record of CITI training certification dates for Ohio State researchers. Record keeping of this sort by the IRB is a requirement of the FWA between the university and the federal government. Thus, while faculty may perceive this monitoring of their training compliance as being an accountability requirement of the IRB, the monitoring of training requirements is

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99 Being “engaged” in research with human subjects has a specific meaning in the context of federal regulations. The New Federal Wide Assurance (2004) offers the following definition: “Under the Federal Policy (Common Rule) at Section 102(f) awardees and their collaborating institutions become "engaged" in human subject research whenever their employees or agents (i) intervene or interact with living individuals for research purposes; or (ii) obtain, release, or access individually identifiable private information for research purposes.”
actually a stipulated element of the institution’s agreement with the federal government and can also be seen as oversight of the institution by the federal government. The CITI training requirement is only one example of the multiple layers of oversight and accountability prescribed for human subject protections by the federal government.

Other examples of federal oversight include the records that IRBs are required to maintain. Requirements are specified in the Code of Federal Regulations at 45 CFR 46.115 and include: those related to documentation of IRB activities; copies of communications between the IRB and investigators; information (by name) and listing of “IRB members,” which denotes panelists; and written procedures of the IRB. “Written procedures” include requirements and procedures for educational training of researchers. FWA documents indicating requirements of the agreement between Ohio State, as an institution, and the government’s granting organization, OHRP, state:

OHRP strongly recommends that the Institution and the designated IRB(s) establish educational training and oversight mechanisms…to ensure that research investigators…maintain continuing knowledge of, and comply with, relevant ethical principles, relevant Federal regulations, OHRP guidance, other applicable guidance, state and local laws, and institutional policies for the protection of human subjects…and complete appropriate institutional educational training before conducting human subject research (FWA, 2002, A.12).

Summarizing the impact of these requirements reveals that the IRB at OSU is responsible to OHRP for overseeing training of researchers and for keeping records of researchers’ compliance with training requirements. McGrath has indicated that
completion of CITI training fulfills this requirement, and the certification process provides documentation of compliance. In this climate of required compliance, researchers’ accountability for fulfilling the training requirement and the records of such certifications appear to stand in for a demonstration of institutional responsibility in the conduct of research with human subjects.

Research Context and Rationale

When the COE faculty survey was administered, there were 140 members of the graduate faculty. This faculty supervises the research and teaching of graduate students working on both master’s and doctoral level degrees. Faculty members also conduct funded and non-funded research projects of their own.

According to the college’s mission statement, faculty members take as a core value “research and teaching that impacts and influences our global society in meaningful ways.” Further, the college’s vision is “to be in the forefront of efforts to extend and improve teaching, learning, health, leisure, and the overall quality of life for...constituents in the United States of America and abroad” (COE, n.d.). Most of the teaching and a considerable part of the research, which faculty members perform, involve human subjects.

Based upon anecdotal reports and literature in the field of education suggesting that faculty members were being affected by the new requirements for human subjects research, this project was directed toward asking faculty members to identify potential effects on their research and the research of their graduate student advisees. The survey asked faculty members to report experiences that they perceived to be effects associated
with new training on ethical responsibility, the CITI training. In addition, faculty members were asked to share their beliefs about effects on their research stemming from the Office of Responsible Research Practices (ORRP), which determines and oversees institutional procedures and individual requirements in human and animal subjects research.

CITI Training

CITI training was chosen as the focus of the COE faculty survey because this training represents a point where the majority of faculty members have engaged with institutional review processes. The training is available to members of the university community through an institutional subscription with the CITI Program. CITI training is offered in an online format for Social and Behavioral Science researchers as a course of 11 modules. CITI Program administrators developed the modules in 2000, and they maintain the web-based course.

Following completion of CITI training modules, participants are provided with a Voluntary Course Evaluation Survey, which may be indicative of users’ satisfaction with the training program. It is difficult to determine if, or whether, faculty member’s perceptions (positive, negative, or somewhere in between) of CITI training are engendered by ethical principles, federal requirements, by IRB processes and procedures, or by the training process and content. The anonymous evaluation survey includes 29 items; of these items there are 28 that offer multiple options for responses through drop down menus and check boxes. The last item on the instrument asks for

100 A demonstration of CITI training can be accessed through the following web site: https://www.citiprogram.org/demointro.asp?intDemoID=26293
“suggestions to make the course a better learning experience” (CITI, 2005, Course Survey Item #29).

The consent form for the survey indicates that findings from the survey are part of “a research project to assess learner attitudes about the CITI course,” and that Paul Braunschweiger, one of two developers of the CITI Program, serves as principal investigator for this research. In a report to OHRP, Braunschweiger indicated that greater than 90% of survey respondents believed they had learned or understood something regarding human subjects protections from the course that they had not known before completing the course (Braunschweiger, 2005, Slide # 32).

Survey Administration and Data Collection

The goal of this survey was to gather empirical data from COE faculty members about effects on their behavior, which they perceived to be associated with recent changes to institutional review policies and procedures at Ohio State. Questions in the survey focused on faculty members’ experiences with CITI training, the ORRP, and the IRB. Survey items asked for recollections about faculty members’ perceptions, attitudes, and behaviors. The primary research question was: What are the perceptions of faculty members about the usefulness of CITI training in regard to the course’s and ORRP’s effects on their knowledge base and behavior in the conduct of research with human subjects?

IRB Approval of Project

An application for exemption from full IRB panel review was submitted on December 2, 2005, and the research was determined to be exempt on December 7, 2005.

101 Text of the COE faculty survey is appended to this report.
(Project No. 2005EO656). The ORRP reviewer requested a clarification in language of the survey instrument addressing how respondents might withdraw from the research. That was the only modification made to the protocol; no procedural changes were made.

**Survey Administration**

The web-based survey was administered during winter 2006 to 140 members of the COE graduate faculty. A graduate research associate assisted in the survey process by placing the instrument online with WebSurveyor® software. The Associate Dean for Research in the College of Education, sent messages to faculty members encouraging their participation in the project. The survey was launched on January 11, one reminder message was sent on January 22, and the survey was closed on February 8, 2006. Response rate to the anonymous survey was 44% (n=62). Following administration of the survey, responses were downloaded, without IP addresses, and the data were stored electronically in “csv” files.

**Distribution of Survey Responses**

Respondents were asked to respond to an eleven-item instrument that included the following response formats: check boxes, for answers to “yes,” “no,” and “unsure” questions; ten point Likert-type scales for responses to statements about usefulness of specific modules from CITI training; and open response boxes for explanatory statements about perceived effects of CITI training, and ORRP procedures. The final item on the instrument asked for any additional comments that faculty members wanted to record. Discussion of all the data generated by the survey is beyond the scope of this report. This writing focuses on responses to the items asking about perceived effects of
CITI training and ORRP procedures and policies, and salient comments offered in the final item.

The survey asked faculty members to indicate within a range of values the number of IRB applications for which each of them had served as an investigator. This particular item was interpreted as being indicative of a level of experience with IRB procedures. “Minimum numbers of applications submitted” were reported as approximate levels of experiences. Table C.1 illustrates the distribution of survey responses arranged by the minimum number of “expedited” and “full review” IRB applications together, or initial applications, faculty members reported they had submitted.

<table>
<thead>
<tr>
<th>Applications submitted</th>
<th>Survey responses</th>
<th>CITI Effects reports</th>
<th>ORRP Effects reports</th>
<th>Additional Comments reports</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>11</td>
<td>4</td>
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<td>3</td>
</tr>
<tr>
<td>Total</td>
<td>62</td>
<td>19</td>
<td>32</td>
<td>32</td>
</tr>
</tbody>
</table>

Table C.1: Distribution of faculty responses by minimum number of IRB applications submitted.

102 The range offered was “0,” “1-2,” “3-4,” “5-6,” and “7 or more.”

103 This calculation excludes “exempt” applications, which require a less extensive and different application form. Exempt applications are generally used for the most minimal risk level of research and are not reviewed by IRB panels. IRB administrators review exempt applications.
Respondents were also asked to indicate the number of “continuing review” applications that they had submitted as investigators. Those numbers of continuing review applications have not been analyzed and are not reported at this time. The format and requirements for a continuing review application are different from initial applications.

Table C.1 shows that faculty members who had a range of experience with submitting IRB applications offered opinions about effects of the CITI training requirements and ORRP procedures. Table C.1 also reveals that respondents to the survey were concentrated in the range of having submitted a minimum of zero to two IRB applications, with almost one third of respondents overall (32%) reporting having submitted one application. Another observation based upon the distribution of responses illustrated in Table 1 is that there were more reports of perceived effects associated with ORRP, than with CITI training. The data in Table C.1 suggests that the majority of survey responses were recorded from faculty members who had submitted between zero and two applications to the IRB.

Effects

Items on the survey focused on perceptions about CITI training and ORRP. Respondents were queried about the usefulness of various modules in CITI training, perceived effects of CITI training and ORRP procedures on faculty members’ research or the research of their graduate students. In order to capture the level of experience that faculty members had with CITI training and ORRP, a question was posed asking for reports of the numbers of applications submitted to the IRB. Reporting all of the data
from the survey is beyond the scope of this writing, which is limited to an examination of experience levels and “effects” reports.

This initial reporting of data combines the minimum number of applications submitted to the IRB with reports of perceived effects. This writer, then, interprets the reported effects as having been either “intended” or “unintended.” Other methods of interpretation might yield a different sort of findings; however, looking at effects in this manner allows the opinions of survey respondents, rather than of this writer, to be highlighted.

 Effects of CITI Training

The CITI training course was developed as an educational tool to inform researchers about the ethical principles that ground the guidelines for currently accepted practices and procedures in the responsible conduct of research involving human subjects. For researchers at Ohio State, CITI training was designated as the way for faculty, staff, and students engaged in research involving human subjects to demonstrate their understanding of ethical principles. Thus, researchers demonstrate their understanding through the certification process that is required and monitored by ORRP. Those researchers who choose not to complete the CITI training are not permitted to conduct research with human subjects. Further, ORRP can regulate privileges for researchers based upon their compliance with ORRP regulations.

The hypothesized regulation of privilege is based upon this writer’s observations of IRB processes and procedures and is only partially supported by data from the faculty survey where nineteen respondents indicated that they perceived effects on their
research from the CITI training. Seventeen respondents offered comments in explanation of perceived effects. The majority of those comments (n=15) were coded as “intended effects” of the training. One participant wrote: CITI training “clarified the principles of human subjects research…[and] the information…offered a reminder of the importance of human subjects protection and the procedures of the IRB.” This participant noted effects related to both ethical principles and regulatory procedures. Other participants perceived effects that were coded as increased awareness of, or heightened sensitivity to, either principles or procedures or both.

There were two responses that did not fit this pattern of intended effects. These two responses stated differently a similar unintended effect. One participant captured the essence of both respondents’ concerns. “I find myself making methodological decisions based on IRB approval rather than sound research practices and appropriate data sources.” In this example, it seems that striving for “IRB approval” has overshadowed, or perhaps replaced, ethical principles as a goal of methodological decision-making. Although informing researchers’ choices of methodological decisions might be considered an intended effect of CITI training, demonstrating ways to select methods based on predicted IRB approval rather than on ethical and research principles is probably not an intended effect of CITI training.

Effects of Office of Responsible Research Practices

The “Welcome” message for ORRP highlights three primary functions for this office. These are: assisting faculty, staff, and students in conducting research with human and animal research; providing educational resources for the university
community in responsible conduct in research; and supporting the institutional committees that review applications for human and animal subjects research (ORRP, 2006). One faculty member responding to this study’s survey stated, “ORRP procedures have helped me clarify OSU’s expectations.” This researcher cited what would seem to be an intended effect of ORRP’s aims of assisting, educational programming, and support.

Another researcher did not dispute ORRP’s intentions and wrote, “I know these people mean well…but the effect of their work has really stymied me.” Other respondents offered specific aspects of ORRP review processes that they perceived to have affected their research. Comments identified the following issues: overall difficulty “gain[ing] approval;” not understanding the rationale for changes in policies; a perceived bias toward the medical model for research; and feeling the need to change research designs, questions, and or methods. The most frequently noted effect that faculty members perceived ORRP to have on their research was related to the time that review processes take.

There were also comments that credited ORRP with enhancing protections for human subjects. A faculty member wrote: “[I am] paying more attention (on a regular basis) to the subjects of my research in terms of their ‘rights’ and my responsibility to inform them of their rights.” However, the majority of comments from faculty members who reported that they perceived effects of ORRP on their research suggest that faculty members are not finding ORRP’s assistance to be especially helpful.
Additional Comments

Participants who offered comments on the final survey question, “Please share any additional comments you would like to make about CITI training, ORRP procedures, and conducting research with human subjects,” identified a number of additional issues that are noted here. These issues were not categorized according to the earlier scheme of “intended” and “unintended” effects. Rather, these comments contributed to a developing list of responsibility and accountability issues for further investigation. The following categories were used: CITI – Training materials, access, and usefulness; IRB – Interpretation and application of federal and local policies; ORRP – Institutional requirements, policies, and procedures.

- CITI – Training materials, access, and usefulness:
  - Access is difficult for non-OSU personnel.
  - Training provides an “inadequate substitute for true learning.”
  - Materials include redundant information and contain “information that research professionals should already know.”
  - “Faculty should be required to take this every other year, to keep informed and in-tune to what is responsible research.”

- IRB – Interpretation and application of federal and local policies:
  - Panel reviews are biased toward quantitative research.
  - Administrative and academic calendars are different. This creates a time constraint during breaks when some graduate students and faculty may not be on campus.
  - Flow of information between the IRB and investigators and graduate student co-investigators is inconsistent.
  - Review panels appear to lack an understanding of research in educational contexts.
“IRB approval is unpredictable.”

- ORRP – Institutional requirements, policies, and procedures:
  - How are policies set and communicated to members of the research community?
  - Who decides how much of “research” is covered by IRB review?
  - Current procedures foreground legal issues and federal regulations, “ethics have lost all meaning in this process.”
  - Procedures should distinguish between social science research and medical research.
  - The website has very helpful templates. There should be “outreach for faculty about such resources!”

Lessons Learned

The primary purpose of this project was to inform a larger study investigating the concept of ethical responsibility in the conduct of research at universities. Prior projects carried out by this researcher, one related to the Carnegie Initiative on the Doctorate surveys and another focused on undergraduate students attending a summer research program, explored perceptions of administrators and students on similar issues. Extending the project to include the opinions of faculty members adds an important dimension to the dissertation study overall.

The survey instrument was developed in order to get a sense of how faculty members on Ohio State’s campus understand the relationship between individual ethical responsibility in research and the institutional requirements, policies, and procedures for reviews of research. Dominant messages that emerged from data gathered in the survey
Ethical Principles

The CITI training program was developed and has been designated as the training for faculty staff and students at Ohio State who are involved in research with human subjects. When COE faculty members were surveyed about usefulness of the training, in terms of whether or not the training had an effect on their research, there was a range of responses.

Overall, respondents indicated that the training had the intended effect, in that it provided helpful background and general information. Respondents were not as positive about how the training helped them, as education researchers specifically, in understanding the ways that ethical principles are interpreted and applied by IRBs. More than anything else, respondents seemed to be saying that they already were familiar with the ethical principles discussed in the CITI training, autonomy, beneficence, and justice; they wanted more information about how those principles are being interpreted and applied by the IRB on a local level.

IRB Procedures

IRB procedures are covered rather broadly in the CITI training. The program was developed for use in a wide variety of social and behavioral science contexts, and does not set out to address any one context in particular. Perhaps as a result of the broad aims, usefulness of the training in a field such as education research is less evident.
Data from the survey suggested that some COE faculty members have the impression that research in educational contexts is not well understood by ORRP administrators or IRB panelists. One respondent suggested that the nature of educational research, and qualitative research designs in particular, make application of IRB procedures more problematic for qualitative researchers than for quantitative. Another respondent proposed that IRB procedures might actually be biased toward quantitative studies. A number of study participants indicated that the way in which IRB processes are structured does not fit well with research in education contexts. Finally, one faculty member applied the principle of autonomy (respect for persons) to actions of the IRB in stating: “The design of the procedures and the way they have been implemented show a lack of respect for the needs and culture of the faculty and students of this College.”

Federal and Local Policies

The IRB procedures that a number of faculty members report as being problematic are directly related to federal and local policies. Issues that were raised in the “additional comments” section of the survey suggest that there are unanswered questions about how policies are formed, interpreted, and implemented. Specifically, COE faculty members had questions about how policies are initiated, and how researchers are notified of changes in policies. One respondent offered the following example: “The way we learned about the need for continuing review was that a demand for reapplication showed up in the mail with no prior warning and no rationale.”

Another concern that surfaced was the “level of enforcement” for local policies and procedures, and yet another concern was that requirements of local procedures “go
far beyond what is necessary and reasonable for protection.” Overall, faculty members
acknowledged the importance of protecting the rights of human subjects in research.
However, numerous respondents pointed out that educational contexts are inherently
less dangerous for human subjects than are biomedical research contexts, and it seems
that the protections for human subjects are based upon the risks associated with
biomedical research. One of the survey participants who addressed the minimal risk
level for education research stated: “Observing classrooms does not in any way
endanger [human subjects].” Some faculty members seemed to be suggesting that
applying regulations and policies to qualitative researchers, or to social science projects,
in the same way that regulations and policies are applied to quantitative researchers, or
to biomedical projects, signaled a lack of flexibility on the part of those who set
policies.

Questions about “Who is making policy decisions?” “On what basis?” and
“What will the effects be?” remain unanswered. Faculty can only respond and react to
policy decisions when they are not participating in the decision making about policies –
they cannot have a voice in the policy development process. The survey data would
suggest that the COE faculty might have valuable input to offer to those who are part of
the decision process.

104 These questions are framed in the way that Corky Bush (1983) asks questions about technology in
Women and the Assessment of Technology: to Think, to Be: to Unthink, to Free. She asks “Who is making
technological decisions?, on what basis?, what will the effects be?” (p. 156). The intent of miming Bush’s
questions is to suggest that these are important questions to be asking in regard to policies in the context
of this research.
Reflections

Perceptions that respondents shared in this survey are examples of the entanglement of responsibility and accountability that are addressed more fully in the larger study. On the one hand, the procedures which faculty members describe as “frustrating,” “unreasonable,” “biased,” “punitive,” “inconsistent,” and “unpredictable,” reveal reactions to institutional requirements for accountability. On the other, respondents’ endorsement of ethical principles demonstrates a commitment to individual responsibility in human subjects research.

The project of first disentangling what counts for accountability from purposeful intentions for responsibility and then finding a way to weave the two together more smoothly is a goal of this research study. As COE faculty members described their experiences with CITI training and ORRP, it seemed that they had the impression that accountability was being privileged over responsibility, or as one respondent said, “I believe ethics should be emphasized, but current procedures foreground legal issues and federal regulations, which may theoretically be undergirded by ethics, but these undergirding ethics have lost all meaning in this process.”

Ethics may or may not have lost meaning as this respondent suggests. Another possibility would be that ethics have become obscured by the current emphasis on accountability procedures. In any case, finding a balance between individual responsibility and institutional accountability emerges as the challenge of the larger study.
CITI Training Opinion Survey

This survey is part of my dissertation research in which I am studying several aspects of responsible conduct in research. I would like to know the opinions of faculty members in the College of Education in regard to the Collaborative IRB Training Initiative (CITI) training and institutional review procedures carried out at OSU by the Office of Responsible Research Practices (ORRP). This survey has been reviewed by Ohio State’s Institutional Review Board (IRB) and qualifies as “exempt” research.

Procedure: This is an on-line anonymous survey. After you have read this informed consent text, you can proceed directly to the on-line questionnaire. Clicking on the “submit” button will be understood to represent your consent to participate in the survey. If you would prefer not to participate, you may close the browser window and delete my message.

It will take 5 – 10 minutes to complete the survey.
Your responses will be stored in a database, but will not be linked to your name or any other unique identifier. That means that your responses will be anonymized.

Risks and Benefits: Completion of the survey carries no known or foreseeable risks. Because neither your name nor any other unique identifier is linked to your responses, no one will be able to discover your individual answers or whether or not you completed the survey.

You will not benefit personally from completion of this survey, although your participation may lead to a better understanding of how CITI training and institutional review processes affect the research of faculty and students in the College of Education.

Confidentiality: Your participation in this survey will generate no personally identifiable data or document. Upon submission of your survey answers, the data will be unlinked from any unique identifiers, such as your IP address.

Right to Withdraw: Your participation in the survey is voluntary; you have the right to withdraw at any point or to skip any questions you want to omit.

Other Pertinent Information: You may print a copy of this consent page. The principal investigator, Suzanne Damarin (damarin.1@osu.edu), or the co-investigator, Jane Evans (evans.676@osu.edu) will answer any questions you may have about the study.

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact Ms. Sandra Meadows in the Office of Responsible Research Practices at 1-800-678-6251.
Introduction:

On July 27, 2004, Senior Vice President for Research, Robert McGrath, announced to the OSU community the first of a number of revisions to university policies related to research with human subjects. In accordance with the university’s new Federal Wide Assurance, all faculty, staff, and students participating in human subjects research activities are required to complete a web-based training program, which is referred to as CITI training. The purpose of having a training requirement is to assist members of the research community in conducting research responsibly and to inform researchers of their duties and obligations to human subjects in research. The Institutional Review Board (IRB) monitors compliance with training requirements, and makes an effort to coordinate training materials with institutional procedures for the IRB applications and approval processes.

Collaborative IRB Training Initiative (CITI) Program:

Please consider your experiences with the CITI training course in responding to the following questions:

1. Have you completed the CITI training course?
   
   - [ ] Yes
   - [ ] No

   If you answered “yes” to question #1 please proceed to question # 3.

2. Why have you not completed the training?
   
   - [ ] I don’t know about CITI Program
   - [ ] I was not able to log on to the course web site
   - [ ] I have not yet had time to complete the training
   - [ ] The training is not required for me
   - [ ] I completed another training course in place of CITI
   - [ ] Other

3. Please rate your level of agreement with the following statement:
   Following completion of the CITI course, do you have a clearer understanding of human research subjects’ protection?

   (Likert-type scale ranging from 1 to 10 where 1 indicates strong disagreement and 10 indicates strong agreement.)
4. Please consider the following required modules within CITI training and respond with your opinions about usefulness and importance of the modules in the following categories: **Useful** in terms of your work, **Important** for development of knowledge base about responsible research conduct, **Neither** useful nor important, **Do not recall** this module. (Please check all that apply.)

<table>
<thead>
<tr>
<th>Useful</th>
<th>Important</th>
<th>Neither</th>
<th>Do not recall</th>
</tr>
</thead>
<tbody>
<tr>
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<td>History and Ethical Principles</td>
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<td>Basic IRB Regulations and Review Processes</td>
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<td>Records-Based Research</td>
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<td>Genetic Research in Human Populations</td>
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<td>Research with Protected Populations – An Overview</td>
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<td>Research Involving Pregnant Women and Fetuses in Utero</td>
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<td>Research with Culturally or Medically Vulnerable Groups</td>
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<td>HIPPA and Human Subjects Research</td>
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<tr>
<td>Ohio State University</td>
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</tbody>
</table>

5. Has CITI training affected your research in some way?
   - Ø Yes
   - Ø Unsure
   - Ø No

5a. If you are “unsure” or responded, “yes,” what have been possible effects of CITI training on your research?
The Office of Responsible Research Practices (ORRP) at Ohio State:

ORRP maintains a website (http://orrp.osu.edu/) with information about institutional review procedures, links to submission forms, announcements about workshops and forums, and suggestions for additional resources. The next questions ask you to base your responses on your experiences with these institutional review processes at OSU.

6. Including research conducted by your advisees, how many times in 2005 have you made the following types of submissions to an institutional review panel at OSU? (Please use the pull-down counters to indicate a range for the number of submissions of each type.)

   Application(s) for exempt review ______
   Application(s) for expedited or full review ______
   Application(s) for continuing review ______

7. Have ORRP procedures affected on your research in some way?

   ○ Yes
   ○ Unsure
   ○ No

   7a. If you are “unsure” or responded, “yes,” what have been possible effects of ORRP procedures on your research?

8. Overall, how satisfied are you with CITI training as a way of informing faculty in the College of Education about responsible conduct in research with human subjects?

   (Likert-type scale ranging from 1 to 10 where 1 indicates weakest level of satisfaction and 10 indicates the highest level of satisfaction.)

9. Overall, how satisfied are you with ORRP’s website as a way of informing faculty in the College of Education about responsible conduct in research with human subjects?

   (Likert-type scale ranging from 1 to 10 where 1 indicates weakest level of satisfaction and 10 indicates the highest level of satisfaction.)
10. Overall, how satisfied are you with your own level of knowledge and understanding about the IRB process?

(Likert-type scale ranging from 1 to 10 where 1 indicates weakest level of satisfaction and 10 indicates the highest level of satisfaction.)

11. Please share any additional comments you would like to make about CITI training, ORRP procedures, and conducting research with human subjects.

Thank you for your time and responses to these questions.
LIST OF REFERENCES


APPENDIX D

QUALITATIVE RESEARCHERS WRESTLING WITH POLICIES:

QUALITATIVE INQUIRY POSITION STATEMENT
The goal of this project was to develop a discussion draft for a policy statement for researchers who have expressed concerns about effects of institutional review processes on academic research. Researchers attending the First International Congress of Qualitative Inquiry (Congress) raised issues about a perceived gap between their understandings of what it means to conduct ethically responsible research and their empirical experiences with Institutional Review Boards (IRBs). A position statement was drafted in response to these issues and was presented at the second meeting of the Congress in 2006. This writing summarizes the development and presentation of the position statement draft.

Leaders in the field of education research called for a policy statement to clarify positions of qualitative researchers relation to IRB policies and requirements. These researchers claimed that IRBs had increased scrutiny of qualitative research methods in the face of its recent emphases on positivist approaches to research. The purposes of this review are to provide background for the drafted position statement, to put forth the draft for further discussion, and to consider what lessons can be learned from the process overall.

The position statement is structured around three sections, and its purpose is to suggest ways that qualitative researchers might situate themselves in relation to IRBs.

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105 Denzin and Lincoln define *qualitative research* as: “a situated activity that locates the observer in the world. It consists of a set of interpretive, material practices that make the world visible…Qualitative researchers study things in their natural settings, attempting to make sense of, or to interpret, phenomena in terms of the meanings people bring to them” (Denzin & Lincoln, 2003, pp. 4-5).
The first section, a problem statement, addresses concerns of an international group of researchers who attended the 2005 Congress session, *Wrestling with IRBs*. Proposed “Standards for the Practices of Qualitative Researchers” are enumerated in the second section. The final section lays out “Action Plans” and suggests strategies for working at the local and national levels on issues in qualitative research related to institutional review processes.

This project exploring policy issues contributes to a larger study that troubles the notion of IRBs operating primarily to protect the interests of human subjects participating in research. Tensions between institutional review procedures and the concept of ethically responsible research are the focus of the larger study. Some researchers hold the belief that IRBs operate primarily to protect the interests of institutions. There is also concern that institutional accountability may be overshadowing, if not eclipsing, ethical responsibility in research.

The work of other researchers was instrumental in identifying tensions and initiating calls for a policy statement. The work of those other researchers led to drafting of the position statement. This report begins with a brief summary of issues that have been raised by researchers in regard to IRB procedures. The report then focuses on the three components of the draft. Finally, lessons learned in this study are summarized, and questions for further study are considered.

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106 A copy of the drafted position statement with its annotated bibliography is included with this report and immediately precedes the list of references for this document, Appendix D.
Tensions between IRBs and Researchers

Qualitative researchers who gathered at the First International Congress for Qualitative Research in May 2005, discussed ethics in qualitative research and strategies for dealing with recent emphases on accountability for ethically responsible research. IRB procedures seem to demand a demonstration of responsibility that looks more like accountability than it looks like ethical responsibility. A question that emerges in this climate of accountability is: “How does one demonstrate responsibility?” This is one issue that creates tension between IRBs and researchers.

There is a considerable body of literature addressing tensions between institutional review boards and researchers who submit applications to those boards for approvals of research protocols. Many researchers analyze and discuss IRB procedures in light of ethical standards and offer anecdotal evidence for the ways that IRBs can operate to constrain researchers (Anthony, 2004; Breckler, 2005; Gunsalus et al. 2005; Kirsch, 1999; Rosnow et al., 1993; Townsend, 2006). Some of these writers have focused their reports on strategies for dealing with IRB-related issues, and these works were most useful in the development of action plans for the position statement draft (Bach, 2005; Candilis, Lidz & Arnold, 2006; Gunsalus et al., 2005; Lincoln & Tierney, 2004; Sieber, 2004).

Strategies for Working with IRBs

The work that has brought the most visibility to IRB issues, and thus to strategies for action, is the University of Illinois white paper (Gunsalus et al., 2005). Highlights from the white paper are summarized in a Science editorial where the white
paper authors define “mission creep” as misdirection of the IRB system. “Our IRB system is endangered by excessive paperwork and expanding obligations to oversee work that poses little risk to subjects. The result is that we have simultaneous overregulation and underprotection” (Gunsalus et al, 2006, p. 1441). The argument made in the Illinois white paper for refocusing efforts on “core issues” is convincing. The level of visibility that this one work has achieved has brought increased attention to the problems with IRBs in general and the tensions between researchers and IRBs more specifically.

Themes of overregulation, underprotection, and constraints on social science models of research and proposals are discussed by a number of other researchers, some who attended the Congress and some who did not. Yvonna Lincoln, who served as a co-leader for the roundtable session that called for a policy statement draft, has written two articles that offer insight into the issues faced by qualitative researchers. One of Lincoln’s articles interprets IRB procedures as limiting academic freedom (Lincoln, 2004). In another work (Lincoln & Tierney, 2004), Lincoln suggests strategies for dealing with IRB issues. Lincoln advocates for researchers becoming involved in the work of IRBs at the local level in order to “help to educate [IRB] board members who may be less than well informed about new theoretical formulations of research and inquiry” (Lincoln & Tierney, 2004, p. 232). Lincoln further recommends that researchers communicate “…with IRB members, defend the research that they or their students are undertaking, and seek to educate IRBs more broadly concerning issues of level of risk and potential direct benefits” (p. 233).
The perspective of another social science researcher, Joan Sieber, is valuable for her “creative problem solving” approach. She is a nationally recognized expert on the topic of research ethics and IRBs (Sieber, 1992, 2006). She supports the work of researchers who engage with IRB processes and, toward that end, Sieber has launched an international journal, the *Journal of Empirical Research on Human Research Ethics* (JERHRE), which aims “to identify and promote meritorious research and collaboration that will enhance ethical problem solving in human research” (2006, p. 5). She suggests “On discovering the most ethical way to proceed, [researchers] need to look to the federal regulations of human research to discover how to document their decision and justify it within that somewhat flexible regulatory structure” (2004, p. 297).

The strategies recommended by these writers were formative in the preparation of actions plans for qualitative researchers looking to improve their relations with IRB panels and procedures. Researchers recommend (a) refocusing on core issues (Gunsalus et al., 2005), (b) becoming involved with IRBs (Lincoln & Tierney, 2004), and (c) returning to federal regulations to document ethical decisions (Sieber, 2004). These recommendations were incorporated into the *Action Plans* for qualitative researchers, as they seem to offer new ways of thinking about how researchers can demonstrate responsibility in human subjects research.

*Unthinking and Rethinking Relationships between IRBs and Researchers*

There are numerous other works that are useful in understanding issues social science researchers face when dealing with IRBs. Those that are cited in this discussion
of background are mentioned here because they offer strategies for “unthinking”\textsuperscript{107} the ways that IRBs operate and for “rethinking of new relationships” (Bush, 1983) between IRBs and social science researchers.

\textit{Issues of Standards}

Questions of whether organizations for qualitative researchers should, or should not, have standards were discussed in other sessions at the Congress in 2006, and that discussion is beyond the scope of this study. However, standards were drafted for the position statement because analysis of policy documents from other groups that have formalized productive approaches to dealing with IRB issues seemed to include standards with their policy statements. In some organizations, standards are offered as a way of justifying the ethical stances of researchers in those groups. For example, the Oral History Association posts on its web site\textsuperscript{108} principles and standards to “ensure such work is done responsibly” (Townsend, 2006, p. 9). A case could be made that such guidelines demonstrate responsibility by researchers who are members of the Oral History Association and use oral history methods in their work\textsuperscript{109}.

\textbf{Statement of the Problem}

Discussions within the community of qualitative researchers at the 2005 Congress revealed and recent literature confirms that there is a widely shared belief that performance monitoring of qualitative research by IRBs constrains the teaching and

\textsuperscript{107} In Corlann Bush’s article, \textit{Women and the Assessment of Technology: to Think, to Be; to Unthink, to Free} (1983), she suggests that unthinking frees the mind to form new relationships. I adopt this feminist perspective as a way of proposing that unthinking and rethinking assumptions about IRBs is a productive place to begin an assessment of, or to form a new relationship with, IRBs.

\textsuperscript{108} Available at \url{http://omega.dickinson.edu/oha/pub_eg.html#Principles%20and%20Standards}

\textsuperscript{109} It is worth noting that Sieber discussed the current situation of oral historians during her July 2006 conference. She suggested that historians had taken their strategy to an extreme and were calling all of their work “oral history” in order to avoid the IRB process.
practices of qualitative inquiry as well as the academic freedoms of qualitative researchers. A primary concern is the lack of fit between self-delineated standards of qualitative research and IRB procedures, which seem to be grounded in a narrow model of science.

Recognizing the interdependent duties of qualitative researchers, institutions, and IRBs to share responsibility for the protection of human subjects, some researchers attending the Congress, which represents a diverse array of researchers and research methodologies, engaged in the work of developing a position statement. The purposes of the position statement were: 1) taking ownership for protection of human subjects by a proactive articulation of standards that better fit qualitative research practices, and 2) organizing discussion within and against IRB procedures to counteract mission creep at both local and the federal levels.

Standards for the Practices of Qualitative Inquiry

Standards for qualitative researcher practices were adapted from standards suggested by The Association for the Accreditation of Human Research Protection Programs (AAHRPP), a voluntary accrediting body for institutional review boards. On its web site, AAHRPP posts a list of suggested standards for practice. The AAHRPP standards were modified for this project in order to achieve a better fit with the positions held by qualitative researchers. In addition, the research ethics work of qualitative theorists such as Clifford Christians (2003), Gesa Kirsch (1999), Maurice Punch (1994), and Edith Wyschogrod (2000) was helpful in formulating a starting point for possible standards.
Presentation of Position Statement Draft

The draft was presented to qualitative researchers in a number of venues. Copies were posted on the Congress web site along with meeting information; copies of the draft were distributed to Congress attendees in their information packets; the draft was discussed in the *Ethics and Human Subjects Research* workshop on May 4, 2006; Patti Lather introduced the draft during the opening session of the Congress; and finally, the draft was offered for adoption in the closing session of the 2006 Congress.

The proposal received mixed reviews. There was, however, extensive discussion of the draft throughout the meeting. Some participants felt that the document was overly focused on “IRBs” and a United States perspective. Those attendees suggested that more time be taken to broaden the scope of the document to deal more expressly with differently named entities such as “ethics committees” that operate in Australia and REBs (research ethics boards) in Canada. Another barrier to adoption of the draft related to the lack of formalized procedures for the newly formed organization itself.

Not adopting the position statement seemed to make more of a statement about the developing nature of organizational procedures than adoption would have made about acceptance of the position statement. Postings on the web site for the third conference to be held in May 2007 do not mention an emphasis on ethics in research, ethics committees, REBs or IRBs.

Lessons Learned

This report describes a process of developing and presenting a position statement for qualitative researchers working with and against IRBs. While the

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qualitative researchers attending the 2006 Congress did not adopt the position statement, the lessons that emerged in the process were instructional for the dissertation study that addresses issues of ethics in research.

Political considerations clouded the presentation of the position statement to a certain extent. In one sense this was unfortunate, and in another, this was helpful. The way that political issues took command of the proposed adoption process was not entirely unexpected, and demonstrates the entwining of politics with ethics (Christians, 2003). The open forum for discussion of the position statement was an important aspect of the process, and is an aspect that seems to be absent with development of IRB policies. The outcome of the position statement shows the importance of listening to divergent view points and holding public forums for such discussions.

Another lesson can be gleaned from the visibility of the Illinois white paper. Attention to this one document seems to be based in part on the presentation style of the first author, C.K. Gunsalus. She speaks with authority and captures audiences. I have observed her presentations on three separate occasions and have tried to discern what it is about her speaking that makes her memorable. Her delivery is entertaining, her arguments fit well with the issues she discusses, and she has a command of the subject knowledge.

Reflections

them — including the perverse ones — to generate new ways of seeing the world makes a necessary contribution to such an epistemology” (1991, p. 113). Gunsalus uses her identity as a lawyer and researcher and her social location as an experienced compliance officer at the University of Illinois to see the IRB world differently. She translates her ideas into action plans that encourage others to participate in change processes.

Although Sieber’s presentation style, identity, and social locations are quite different from those of Gunsalus, she too uses her identity and social location to see the IRB world differently. The ways in which these two differently strong, yet similarly effective women work for change and find new ways of seeing the world are important to consider for the contribution they make to reframing IRB issues and focusing attention on ethics in research.

Questions for Further Study

Little information was uncovered about how IRB policies are formed. This was a concern of education researchers at Ohio State, and the group of qualitative researchers that gathered in 2005 raised a similar issue. The latter group questioned the risk level that is assigned to social science research proposals. It seems likely that IRBs have policies that assist panel members determine risk levels for different types of research. This leads to a number of questions. Who is setting those policies and on what basis? What are the effects of policies and do policies differ based upon the types of research (biomedical or social science, quantitative or qualitative) proposed? These questions would be worth addressing in the dissertation study project.
Position Statement on Qualitative Research and IRBs

“Qualitative research is a situated activity that locates the observer in the world. It consists of a set of interpretive, material practices that make the world visible...Qualitative researchers study things in their natural settings, attempting to make sense of, or to interpret, phenomena in terms of the meanings people bring to them” (Denzin & Lincoln, 2003, pp. 4-5).

Problem Statement

Discussions within the community of qualitative researchers at the First International Congress of Qualitative Inquiry (2005) revealed and recent literature confirms there is a widely shared belief that performance monitoring of qualitative research by Institutional Review Boards constrains both the teaching and practices of qualitative inquiry as well as the academic freedoms of qualitative researchers. Our primary concern is the lack of fit between self-delineated standards of qualitative research and IRB procedures grounded in a narrow model of science.

Recognizing the interdependent duties of qualitative researchers (faculty, administrators, and students), institutions, and Institutional Review Boards to share responsibility for the protection of human subjects, the Congress of Qualitative Inquiry, which represents a diverse array of researchers and research methodologies, has engaged in the work of developing a position statement for the purposes of: 1). Taking ownership for protection of human subjects by a proactive articulation of standards that better fit qualitative research practices, and 2). Organizing discussion within and against IRB procedures to counteract mission creep at both local and the federal levels.

Standards for the Practices of Qualitative Inquiry

The Association for the Accreditation of Human Research Protection Programs (AAHRPP) is a voluntary accrediting body for institutional review boards. The following standards for practice have been adapted from the AAHRPP standards for investigators toward a better fit with qualitative inquiry and draw upon previous work of qualitative theorists (Christians, 2003; Kirsch, 1999; Punch, 1994; Wyschogrod, 2000).

Qualitative researchers uphold the following standards in the conduct of research involving human subjects:

1) Consider, identify, and resolve conflicts of interest that might affect research participants, researchers, institutions, and research outcomes.
2) Understand and use valid study designs for qualitative inquiry that respect the rights of individuals and protect the well being of research participants.
3) Apply standards of minimal risk as set forth in the Common Rule for the protection of human subjects in the conduct and practice of research.
4) Involve and recruit participants according to best practices for weighing risks to individuals and benefits to society.
5) Document their plans in study proposals for fulfilling responsibilities to research, institutions, sponsors, and participants.
6) Respect participants’ autonomy and the voluntary nature of participation and document the informed consent processes that are foundational to qualitative inquiry.
7) Provide for and encourage communication with participants and respond to respondents’ requests for information, withdrawal, or modifications to consent agreements in a timely and appropriate manner.
8) Design and conduct qualitative studies in compliance with federal and local institutional requirements for the protection of human subjects in research.
**Action Plans**

1) Operationalize academic and ethical standards for qualitatively based research.
2) Conduct empirical evaluation studies at local level of current IRB practices to inform future discussions and action plans.
3) Volunteer to serve on IRB panels. Attend IRB open meetings. Observe review processes in order to take ownership of procedures and requirements and counteract mission creep.
4) Develop a *Best Practices Compendium* (Gunsalus et al., 2005) to provide guidance to IRBs reviewing qualitative research.
5) Work at the federal level with Office for Human Research Protections (OHRP). The case of oral history is instructive.
6) Coordinate with other academic groups who value and practice qualitative methods e.g. American Historical Association, American Sociological Association, Consortium of Social Science Associations.
Annotated Bibliography

Association for the Accreditation of Human Research Protection Programs, Inc. categorizes standards for accreditation of organizations into five domains. Standards for Investigators and for Participant Outreach were reviewed in the preparation of this policy statement. The Consortium of Social Science Organizations (COSSA) is one of the founding members of AAHRPP.

Anthony, Robert (2004, October). Consistency of ethics review. Forum: Qualitative social review, 6(1), Art. 5. Author calls for accountability of REBs (IRBs) in reviews of research protocols. Anthony claims that qualitative research “…must overcome…obstacles that are not shared by their counterparts in other disciplines” (¶ 2). Arnold cites the “dual role” played by faculty members who conduct and teach action research as the cause of this injustice.

Stephen Breckler, Executive Director of the Science Directorate of the American Psychological Association calls for “empirical research” on the problems social scientists perceive, claiming that there is “little reliable data on the extent or origin of the problem.” Breckler states that when IRBs “work as intended, IRBs help researchers” protect human subjects, and toward that end, he recommends that social scientists “take ownership of IRBs.”


In light of recent policy initiatives, which “might result in inappropriate, ineffectual, and harmful modifications to the IRB decision-making process” (p.1), these authors recommend empirical investigation of how IRBs make decisions and point out that “…individuals [on IRBs] approach decisions with a variety of presumptions and biases.” They further recommend application of the “Janis and Mann model” (1977) based on social-cognitive theories for decision making.


“COSSA is an advocacy organization supported by more than 100 professional associations, scientific societies, universities and research institutions. COSSA stands alone in representing the full range of social scientists.”


Defines “mission creep” and has generated considerable conversation around issue of IRB performance monitoring. Recommends empirical research to inform policies.
Journal that "publishes empirical research and reviews of empirical literature on human research ethics. Empirical knowledge translates ethical principles into procedures appropriate to specific cultures, contexts, and research topics."


United States Department of Health and Human Services website covering federal regulations and requirements for institutional review boards.


Secretary’s Advisory Committee on Human Research Protections (SACHRP). Retrieved April 20, 2006 from http://www.hhs.gov/ohrp/sachrp/
The subcommittee charged with review and interpretation of 45 CFR 46 posts recommendations on this website clarifying OHRP requirements and guidelines.


Latest update on oral history situation.

LIST OF REFERENCES


This report of the Professional Development Project for Teachers (PDPT) has a two-fold purpose. The first is to render an account of activities related to this project that took place in collaboration with researchers implementing the Math Coaches Project. The second is to begin unthinking\textsuperscript{111} relationships between academic researchers and IRBs. The recounting takes a case study approach. The rethinking of relationships revisits explorations of my suggestion for recounsability in research.

Together the recounting and rethinking purposes contribute to a primary goal of the dissertation study. My goal is to reformulate notions of institutional accountability and individual responsibility into more productive relationship. Achieving the purposes and goal of the project depends upon rethinking ways in which researchers interact with federal regulations, institutional requirements, and individual responsibilities for conducting research with human subjects.


\textsuperscript{111} Corlann Bush gives examples of “unthinking” in \textit{Women and the Assessment of Technology}. In her article, she discusses unthinking traditions and rethinking new relationships. She suggests that in a feminist critique, one analyzes assumptions and “unthink[s] them, making them simpler by naming their complexity” (1983, p. 153).
rereflection; Code’s reflections on responsibility to practice “reflexive rereadings and
critical re-visionings even of one’s own best insights” (1994, p. 2); Haraway’s
encouragement to cross boundaries, her insistence on the situatedness of knowledge,
and her suggestion of holding necessary concepts together; Harding’s discussion of
“whose ‘problems’ get to count as scientific ones” (2004, p. 32) and her idea,
foundational to standpoint theories, that scholarly projects must begin asking questions,
collecting data, and interpreting findings from others’ lives (1991, p. 268). In summary,
I discuss PDPT as an unthinking of complexities of IRBs and a rethinking of new types
of relationships between IRBs and researchers.

In some ways, these theorists describe strategies and techniques that I borrow to
formulate my notion of recounsability – an individualized and situated working together
of accountability and responsibility. Methodologically, I work against assumptions
about responsibility and accountability in this counter-hegemonic work. The nature of
my engagement with this task and the text (Lather, 1991) centers on a “most cherished
assumption” – responsibility to the Other in research. In the context of PDPT, there
are both institutional and individual “others.” I respond to Lather’s call for transcending
limits by rethinking the framework for and conceptualization of the Math Coaches
Project. In so doing, I mix a realist tale with a reflexive account and intentionally create

112 Patti Lather cites Gayatri Spivak’s (1989) argument for “examining the limits of what we cannot think
without, our most cherished assumptions” (Lather, 1991, p. 5).
Awareness of Complexity

Tensions exist between institutional review processes related to human subjects research and researchers in academic communities. Examples of discontinuities, uncertainties, and complexities can be seen in other aspects this study. The earlier projects focus on administrators from a research university working with the Carnegie Initiative on the Doctorate surveys (CIDS); undergraduate students participating in summer research projects (USRE); faculty members practicing, supervising, and teaching education research (COEFS); and a group of researchers at an international conference discussing how institutional review processes interface with ethics in research (QIPS). Reports of these projects identify effects of the tensions created by ways that Institutional Review Board (IRB) policies challenge understandings of ethical principles. In this part of the work, I describe an education research project that faces off against tensions and creates new relationships in an ethical space — allowing the researchers to perform their research to meet standards of both ethical responsibility and institutional accountability.

Describing PDPT through a Case Study Approach

The PDPT case study presented here illustrates ways that education researchers worked through tensions between requirements for institutional accountability and standards of individual ethical responsibility by rethinking relationships between institutional requirements and individual responsibilities. This report places PDPT within the context of human subjects research, describes the case study, identifies effects of conflicting issues, and names complexities of the tensions experienced by
researchers. The process of identifying the human subjects in this project (the teachers rather than the grade-school students) allows the researchers to balance ethical principles and institutional policies and to relieve the stresses that threatened to bind researchers in untenable relationships with IRBs.

_Human Subjects Research in an Educational Setting_

Faculty members in colleges of education who engage in teaching, research, and service are involved with human subjects. The students whom faculty members advise, the populations they investigate, and the activities they perform require interactions and relationships with human subjects. In the case of faculty members in colleges of education, research and teaching activities are always already imbued with service aspects. Education researchers focus their attention and energy on improving learning opportunities through combinations of teaching, research, and service activities that sometimes overlap and challenge boundaries among those three areas.

Evaluations of how well faculty members balance their responsibilities for teaching, research, and service are often included in assessments of faculty performance. Tensions erupt when institutional policies require faculty members to tear apart these areas of responsibility in their work and to define sharply: “What is service?, What is teaching?, and What is research?” At least one College of Education (COE) faculty member conducting research in community schools asserts that institutional review policies are creating this kind of tension when IRB policies specify increasingly stringent requirements for human subjects research. Privileging one area of
responsibility, such as accountability to institutional requirements for research, above teaching and service disrupts a balance that many faculty members strive to achieve.

In response to a January 2006 COE survey investigating perceived effects of institutional review policies and procedures, one faculty member offered the following observation in regard to the effects of institutional review practices and procedures:

The ORRP [Office of Responsible Research Practices] process has made research incredibly frustrating. … ORRP seems to have NO sense of doing research with children or in schools. … The people who review do not seem to understand the types of research being done in COE – we certainly need some COE intervention in this ORRP process.

This statement reveals a tension that educators doing research with children or in schools seem to be experiencing. Faculty members who designed a research project aimed at implementing a program of professional development for teachers expressed the same sentiment. These researchers believed they could improve student learning in mathematics by developing an intervention for math teachers in elementary schools.

The IRB application process for PDPT frames the discussion of this study and demonstrates the complexity of tensions between researchers and IRBs. Tensions existed primarily among the ethical principles of autonomy, beneficence, and justice, and within and between the policies and procedures of institutional review processes.

Situating the Project within a Context

This case study takes up issues of ethical responsibility and institutional accountability that emerged in a number of ways during the IRB application process.
The primary research question related to the case study was: What approach to human subjects research in PDPT would best serve the needs of grade school children studying mathematics, the researchers who designed and would implement the project, and the IRB charged by the university to “…ensure the safety and welfare of those individuals who participate in research”\textsuperscript{113}?

\textit{Overview of the Project}

Researchers affiliated with a midwestern university received state funding to implement and evaluate a professional development program for teachers in 34 state-identified low performing schools. The purpose of this program is to improve mathematics instruction in elementary schools. Researchers hypothesize that job-embedded professional development for teachers will increase mathematics content knowledge of students and teachers. Implementation and evaluation elements of the program do not require parental permission for teachers to access student records. However, the sharing of findings by researchers and communicating findings with the education community and society necessitate consideration of when, or if, the elementary students are human subjects in research for the purposes of the program.

Different aspects of the professional development program were reviewed by the IRB during the 2005-2006 academic year. The first application was initiated in August 2005. IRB approval for the project was deferred initially, and approval was granted in April 2006. The IRB panel primarily objected to the lack of clarity between activities

\textsuperscript{113} This charge is delivered to members of IRB panels in appointment letters. The Senior Vice President for Research makes appointments to the panels, and members indicate their acceptance by signing and returning a confidentiality agreement and a copy of the appointment letter.
that would take place for evaluation of teaching and curriculum and other activities that appeared to be proposed solely for research.

Parsing and defining which activities are used for evaluation of a program and which activities and procedures are included for “research” is one of the complexities of completing an IRB application. Evaluation activities conducted as part of the customary curriculum are generally determined to be exempt from IRB processes. Activities carried out for research purposes require IRB approval and consent from all identifiable human subject participants.

PDPT called for evaluation and research activities to be carried out simultaneously. The IRB determined that parental permission was required for the more than 3,000 elementary students who were considered to be human subject participants in the research. (Permission from the students’ teachers participating in the program and letters of support from the corresponding schools had been proposed and included in the original application.)

Research elements of the program were added to procedures in the 2006 IRB application. The professional development pilot study originally included both evaluation and research activities, and the researchers were concerned that months might pass again between submission and approval for their IRB application. As researchers were not permitted to begin data collection before approval was granted, the investigators were concerned about a potential delay for the project, and they wanted to begin data collection for the research component in September 2006.
Complexities All the Way Down

Issues that the researchers considered in preparing and developing strategies for how to approach the IRB application process in 2006 included: (1) understanding application questions and providing acceptable responses; (2) the length of time approval processes could take; (3) unpredictable outcomes of a pre-screener’s and IRB administrator’s decisions; (4) unknown policies and procedures of the institutional review process. All of these issues can arise during the pre-screening process, and these issues also interact with more theoretical questions of ethical responsibility and institutional accountability.

Delays in beginning their research that resulted from the difficulty of obtaining IRB approval in 2005 caused the investigators to rethink IRB processes and their relationship with administrators representing the IRB. The researchers’ goal in rethinking their relationship with the IRB was to create new ways of seeing, and of being seen by, the IRB world.114

Preparing for the Pre-screening Process

Researchers who work with IRB panels115 or follow decisions made by panels have a sense that IRB forms sometimes request information in an indirect way and then require rather explicit responses. In some cases, this situation can lead to inadequate responses on applications, and in other cases, uncertainties related to responses on the application can lead to time delays for review and approval processes. A hypothetical

115 I have served on the Behavioral and Social Sciences IRB panel as an “affiliated non-scientist.” I have attended 30 panel meetings. On some occasions, I served as a voting member of the panel and participated in decision-making. On other occasions, I attended panel meetings as an observer of the IRB process. On all occasions, I had access to the documents that were being reviewed by the panel.
example of such a scenario can be demonstrated with the template for participant
consent, which asks for “Duration.” The question asks for duration, and the
accompanying instructions for researchers specify: “expected duration of the subject’s
participation;” however acceptable and thorough responses require mentioning the
total time required from participants, broken down by interactions. Thus, a response of
“two years” would be inadequate. Similarly a response such as: “This research is
scheduled to conclude by June 30, 2009” would also lack sufficient detail. An
acceptable response to the duration question would say something along the lines of:
“Participants will spend 40 minutes contributing to this research on three occasions
during the first six months, and there will be no interaction required during the second
year.”

During pre-screening processes, researchers sometimes learn about the existence
of policies and procedures that are not spelled out in guidance documents posted on the
Office of Responsible Research Practices (ORRP) web site. This is a case in point for
the unannounced, or perhaps merely unpublished, role of pre-screeners in review
processes. I return to the scenario of a “duration” question and extend that example to
consider what is likely to happen subsequently or how delays might occur. IRB
administrative pre-screeners generally note inadequate responses before assigning the
application to an IRB panel for review. Further, pre-screeners determine whether or not
an application will be forwarded to the panel for review, if the researcher will be

116 Consent form instructions are available online at http://orrp.osu.edu/humansubjects/consent.cfm

117 There are other required elements for this portion of the consent form. Those are covered more clearly
in the instructions and do not seem to generate problems for researchers.
contacted and asked to clarify an inadequate response, and if the application will be placed “on hold.” Thus, effects of pre-screeners’ decisions can make critical differences in how the review process proceeds. Pre-screening processes can identify inadequacies in applications that cause delays for unspecified periods of time.\(^\text{118}\)

**Complexities of the Project**

Researchers faced a number of challenges in gaining IRB approval for the project. An early issue was the complexity of the research design. Another test for the project came, as researchers were required to rethink the balance of ethical issues. The most exigent task was recognizing and working through interactions among federal, state, and institutional policies.

There were multiple complexities in the project that surfaced in 2006, as they had in 2005. The research design used a mixed methods approach, combining qualitative and quantitative procedures to investigate questions in a social science setting. In addition, participation of human subjects in different capacities (those who contribute data, those who have access to data, those who collect data, and those whom the data describe) complicated the research. Finally, the researchers had obligations to at least three agencies overseeing this research project (e.g. Institutional agencies through the IRB and researchers’ academic units for CITI training and contributions to generalizable knowledge; State agencies for funding and reporting of findings in compliance with a grant; Federal agencies for compliance with human subjects

\(^{118}\) Long delays in the IRB approval process and a lack of understanding about how processes move forward were among the concerns of COE faculty members who responded to the grounded survey about effects of the Office of Responsible Research Practices in January 2006.
regulations required through the institution’s FWA). Although these aspects are inter-related in practice, they are treated separately here for the sake of analysis.

*Complex Research Design*

Based upon their 2005 experiences with submitting an IRB application for the pilot study, researchers decided to separate the teaching and evaluation components of the professional development program. They thought that doing this would make the project more understandable to IRB reviewers. Data collected about teachers and qualitative observations of their teaching were part of the research component, Quantitative measures of their students’ achievement were collected as data for evaluation of the project.

The research protocol indicated that the coaches who were providing an intervention for the teachers would also carry out qualitative observations of the teachers. If the research were to be carried out in this way, the coaches would be “engaged in the research,” and would need to complete the university’s CITI training requirement. Teachers would be human subjects in the research and would need to sign consent forms, even though information about the teachers would be reported in the research without personally identifiable information.

Teachers, who evaluate students with quantitative measures of achievement as a normal part of the curriculum, would *not* be engaged in the project as researchers. The teachers would still be considered human subject participants in the research. The purpose of student evaluations is not a part of the research project; students’ test scores by classroom would be used as indicators of teacher performance. The result is that
students would at no time be individually identifiable in research reports. Data from
students’ test scores would be reported in aggregate (by classrooms of teachers). As
such, student performance would be identifiable only as composite scores from a
particular school. (This is also how the state reports performance on standardized tests
of achievement.) Because the students do not perform activities expressly for the
research, and because they are not individually identifiable, the students are not human
subjects in the research.

Clarifications to the research design, such as the example with teacher and
students, had the effect of simplifying the research design. In turn, the simplification of
that complex issue worked positively toward IRB approval for the project. In this
example, breaking down the elements of participation helps explain “who will be doing
what” and “on what occasion.” The same scenario with students and teachers can
demonstrate how consent issues were examined and conceptualized differently in the
2006 application for the project, from how the researchers had written the application in
2005.

Coaches, teachers, and students were categorized in order to achieve a “better
fit” with expectations of IRB pre-screeners and to make the research more intelligible to
IRB reviewers. This process of categorization does not fit as well with qualitative
approaches to research. However, IRB procedures necessitated that the researchers
rethink their research design in order to develop new ways of thinking about the
relationships between the qualitative research aspects of the project and the human
subjects who contributed human (and not-human) subject data for the project.

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Balancing Ethical Principles

The notion of thinking of student data, as not-human subject data, rather than as human subject data, called for another shift in thinking by the researchers on the project. Considering students as not-human in any regard was a distinction that seemed to go against guiding principles for qualitative methods and research, which emphasize in-depth knowing of research participants in their natural settings (Patton, 1987). Thinking of student data as not-human subject data is not the same as thinking of students as not human. Although the distinction is a narrow one, the change was necessitated to bring the research into conformity with federal, state, and institutional regulations and requirements. In addition to working against fundamental qualitative research principles, rethinking students as not-human in any sense works against assumptions about the autonomy of individuals – an ethical principle highlighted in the Belmont Report and CITI training.

Qualitative researchers have mentioned such conflicts between ethical principles, and some researchers have gone so far as to suggest that IRB processes displace their personal sense of ethics in research. One concern is that in balancing ethical principles, IRB processes are served at the expense of human subjects and the researcher’s individual ethical principles. For PDPT researchers, the conflicting ethical principles were autonomy (respect for persons) and justice (equal access to the benefits of research for all.)

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119 A COE researcher made a statement that suggested this issue on the faculty survey.
120 During the pilot study, the researchers observed that they were getting a very low return rate on parent consent forms. If the researchers had been required to supply parental permission forms for students’ test scores in 2006, the research would have produced biased results and the scientific validity of the project
The consent process and definition of “human subjects participant” for this project seemed to be the primary sticking points in the IRB process. If students were human subjects, permission forms would be required from the parents of all the participating students. This was particularly problematic. The schools where the research was to be conducted had been selected for the project by the state, which was funding the project. The schools had been selected intentionally for the low performance of students. Although the researchers had made attempts to secure permission forms from all parents during a pilot study for the project, the response had been so low, that scientific validity for the project was in jeopardy.

Researchers observed that schools in which parental consent is difficult to obtain are among those that have the greatest number of students “at risk” and the most to gain from inventive programs such as the program of professional development for teachers. Low response rates to requests for consent forms effectively impede research and result in these students and classrooms being left behind. Without parental permission to access individual student records, the IRB generally does not allow researchers to share findings with the education community or to contribute to scientific knowledge. In the case of this project, the lack of parental permissions was discouraging the research. This would have meant that the benefits of research would be denied to students and classrooms at the greatest risk of failing. Thus, the lack of consents could lead to the injustice of inequitable access to and distribution of benefits.

would have been compromised. One solution to this problem would be to conduct research only in schools where return rates on consent forms are higher. The higher return rates are often achieved in schools where student performance on achievement tests is also higher.
**Interactions of Policies**

Although researchers involved in PDPT reworked their proposal in light of students not being human subject participants in the research, and permission forms not being requested from parents, there were other obstacles in the way of IRB approval for the project.\(^{121}\) If parental permissions were not obtained – for the non-human subject student data – then the IRB wanted some other form of permission from the schools for use of these data. At this stage in the project, the conflicting policies, once again, were federal, state, and institutional.

*No Child Left Behind* (2002), a federal law, and state mandates set improvement standards for K-12 student performance. State-funded projects supporting implementation of innovative programs to raise test scores require reporting and demonstrating improvement in students’ test results. Student performance records are available to schoolteachers and to administrators for evaluation of programs. However, the Family Education Rights and Privacy Act (FERPA) requires that researchers using identifiable student data obtain parental permission to access students’ education records. Issues turned on the possible identify-ability of student data at all – levels, federal, state, and institutional.

Additional clarifications and modifications were required in order to assure the project’s compliance with local IRB requirements. The researchers needed to specify that data from student records would be de-identified by authorized school personnel before these data were shared for the research project. (De-identification of the data by

\(^{121}\) A panel of experts reviewed the PDPT case study at a national conference. The experts uniformly agreed that the research proposal met the federal standards for protections of human subjects (*JERHRE Conference, Oakland, California, July 28, 2006*).
authorized personnel and its subsequent delivery to researchers do not require parental permission.) Thus, researchers would need to create a data sharing arrangement with authorized holders of the data to satisfy requirements of the local IRB overseeing the research. Once the data had been de-identified by authorized personnel, students would no longer be considered human subject participants by the IRB, and the use of such de-identified data would not be in violation of FERPA.

In response to a communication from the IRB that the research had been placed “on hold,” the investigators in collaboration with this writer created a Data Use Memorandum (DUM). The researchers proposed to send the DUM to the school principals who could act as signatory officials for their schools. The proposed plan was now that school employees, who had legitimate access to the data through FERPA, would de-identify the student data and provide it to the researchers as indicators of teachers’ performance.

Understanding the IRB requirement for the DUM was troubling because no template or guidance for such an arrangement are available on the IRB web site. Subsequent to submission of the DUM, legal counsel for the institution reviewed the document and found it to be acceptable. The researchers wondered why policy analysts who had requested the agreement had not intervened and provided a model, a template, or guidance for the preparation of such a document.

Individual Responsibility and Institutional Accountability

This report summarizes the major challenges PDPT researchers faced in gaining approval for their project. The tensions experienced by the researchers that resulted
from the complexities of the research project, from relationships between the IRB and the researchers, and from interactions of conflicting principles are highlighted. There were additional tensions embedded in the process that related to relationships between the researchers’ ethical responsibility, as individuals, and the requirements of the institution for accountability of IRB administrators and panelists.

Researchers are expected to demonstrate responsibility for human subject participants by presenting their research for IRB approval. How this responsibility might be demonstrated, or performed, is not entirely clear. Guidance on ethical issues is available through the required ethics training course, CITI training; however, the information provided in CITI training is not specific to any one university, and the project illustrates how IRBs and nationally recognized experts differ in their interpretations and requirements. Administrative IRB offices do offer additional training opportunities specific to their institutions. But researchers observe that detailed instructions in the additional offerings generally tell research what not to do, rather than telling them what to do.\(^\text{122}\) For PDPT researchers, the lack of guidance on preparation of the DUM was one such instance of being given direction about what not to do, rather than what to do.

IRB panel members might offer some guidance for researchers, if these panelists were not constrained by confidentiality documents. Panel members are accountable to the institution and to the institution’s signatory officials, although there is variability in their levels of expertise. It seems likely that the more experienced participants in IRB

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\(^{122}\) From personal observation of the process, I note that IRB panel members do not understand their responsibilities as including advising researchers on how “to do” their research.
processes contribute to the training of less experienced panel members and administrators. In addition, when panel members sign acceptance letters for appointments, they agree to complete additional training, to participate in continuing education, and to understand and apply the principles of the *Belmont Report* and the federal regulations related to the protection of human research subjects.

Training aimed at helping academic researchers understand what to do would be useful and could contribute to improving relationships between academic researchers and IRBs. PDPT researchers have taken an important first step in developing a new type of relationship with their IRB, and the sharing of their experiences could be instructional for other education researchers.

**Reflexivity, Rethinking, and Recounsability**

In this writing, I describe an individual and situated working together of accountability and responsibility that begins to address the emerging concept of recounsability in research. At the outset, I suggested elements of a reformulation of responsibility and accountability based upon the works of feminist theorists. I included Bush’s unthinking of traditions (and/or assumptions) and rethinking new relationships; Code’s reflexivity and re-visioning of one’s own work; Haraway’s crossing of boundaries, situatedness of knowledge, and holding together of concepts; and Harding’s starting points for asking questions.

In one sense, the theorists I follow have given direction for how one might proceed in a recounsable way; in another sense, none of them has mapped out what “to
do.” This seems to be the case because of the necessarily individualized nature of recounnsability. If there were a list of prescriptive procedures, a map so to speak, one would be following a path to accountability, and not to responsibility. The best suggestion I have to offer would be to take direction from feminist standpoints and feminist theorists.

Naomi Scheman pointed out much of what I have found to be the situation in my research; there are “no easy answers to what counts as acting responsibly; we have no straight paths to follow” (1991, p.224). I would add to her observation, that pathways to responsibility and recounnsability are highly individualized; there are no normative standards to follow.
THE RELATIONSHIP BETWEEN THE MATHEMATICS COACHING PROGRAM (MCP) AND STUDENT ACHIEVEMENT

DATA USE MEMORANDUM

This Memorandum is made and entered into by Diana Erchick, Ph.D., on behalf of and as Principal Investigator for the research entitled The Relationship Between the Mathematics Coaching Program (MCP) and Student Achievement to be performed at The Ohio State University (“OSU”), and the ____________ School (the "School"), within the ____________ School District (the “District”). The purpose of this research is to report on a professional development program aimed at assisting existing and accomplished teachers of mathematics at the School in the assessment, evaluation and enhancement of their teaching skills. The MCP is in receipt of a Letter of Support from the District and/or the School giving its/their agreement to the research intended by and the performance of the MCP. The teachers, rather than students of the School, are the subjects of all research in the MCP. The purpose of this Memorandum is to define and limit the use of human subject research data (the “data”) in the performance of the MCP.

The data will be de-identified scores recorded for elementary students in the School on Ohio standardized tests of academic performance in mathematics. These data have been collected through established testing procedures of the Ohio Department of Education (the “Department”). The data will be communicated to the MCP by the District and the School without any information from which the identity of any particular student can in any way be ascertained. All data received by the MCP shall be used it solely for the MCP project. Enabling links ("crosswalks") between student identities and student identifiers will not be communicated to or shared with investigators or researchers.

In the unanticipated event that any information is received by the researchers or the MCP from the Department, the District, the School or otherwise that appears in any manner to facilitate the identification of any individual student or students, the Principal Investigator will immediately notify the School that students might potentially be
individually identified from the suspect portion of the data and no research use whatsoever shall be made of that suspect data. The MCP will not attempt to re-identify students or re-link the data to students.

The MCP shall at all times handle and use the data in a manner consistent with: the accepted standards of responsible academic research; the applicable oversight of the OSU Institutional Review Board; the applicable provisions of the Family Educational Rights and Privacy Act and the regulations thereunder; and applicable provisions of the Ohio Revised Code ("ORC") and the Ohio Administrative Code. The applicability of ORC §§ 3301.0714 and 3319.321 is specifically acknowledged.

This Memorandum was executed on and is effective from the dates set forth opposite the appropriate and authorized signatures immediately below.

Date: ______________________, 2006

Diana Erchick, Ph.D.
Professor, Ohio State University

Date: ______________________, 2006

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Principal

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School
LIST OF REFERENCES


