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The Institutional Review Board (IRB) and Faculty: Does the IRB Challenge Faculty Professionalism in the Social Sciences?

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Abstract

Institutional Review Boards (IRB) were instituted to protect the rights of research participants and due to past (and at times egregious) practices committed in the name of research. We question whether the IRB is currently overstepping its bounds into the domain of the researcher. We illustrate possible ways in which the IRB subtly and not so subtly challenge faculty professionalism and limit faculty research independence, highlighting some instances in which qualitative research topics bump up against boards that mistrust or misunderstand the nature of qualitative research. Using case study vignettes from five universities, our concerns focused on mission creep and potentially legitimating censorship. Areas of mission creep can include institutional reputation, methodological design, and chilling/legal language verses accessible language. In addition we consider multisite studies and when committees focus too much on form rather than content.

Keywords

HumanSubjects, IRB, Institutional Review Board, Ethics, Academic Freedom, FacultyProfessionalism, Qualitative Research

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The Institutional Review Board (IRB) and Faculty: Does the IRB Challenge Faculty Professionalism in the Social Sciences?

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Institutional Review Boards (IRB) were instituted to protect the rights of research participants and due to past (and at times egregious) practices committed in the name of research. We question whether the IRB is currently overstepping its bounds into the domain of the researcher. We illustrate possible ways in which the IRB subtly and not so subtly challenge faculty professionalism and limit faculty research independence, highlighting some instances in which qualitative research topics bump up against boards that mistrust or misunderstand the nature of qualitative research. Using case study vignettes from five universities, our concerns focused on mission creep and potentially legitimating censorship. Areas of mission creep can include institutional reputation, methodological design, and chilling/legal language verses accessible language. In addition we consider multisite studies and when committees focus too much on form rather than content. Keywords: Human Subjects, IRB, Institutional Review Board, Ethics, Academic Freedom, Faculty Professionalism, Qualitative Research

On February 25, 2011, Associate Professor Jin Li sued Brown University for excluding her from using data that Li collected over a three-year period which she believed was under Institutional Review Board (IRB) approval (Jin Li v. Brown University in Providence in the State of Rhode Island and Providence Plantations, 2011). Li sued Brown on five counts, including overreach of the IRB authority, failure to have minority representation on the board, and lack of due process in appealing their decision. Li's main complaint was that the institution was "barring her from using her own data because she paid her human research subjects different amounts of money based on their economic status," (Barrett, 2011) which was a change from the original IRB proposal. She made the change because it was costing participants more than the original amount to participate. With this decision, Li used the kind of emergent mindset that typifies qualitative researchers in the field--"an openness to contingency, shifting slightly in order to respond to participants needs" (Leisey, 2008, pp. 422-423). However, changes require an additional review by the IRB, and Li did not seek such approval. Ultimately, Li and Brown University reached an out-of-court settlement and requested a case dismissal. Li did violate the human subjects' policies of the institution because of her disparate compensation, yet the consequences seemed disproportionately severe.

While the Li case is a dramatic and somewhat complicated example, this examination leads us to question whether IRBs may be slowly and quietly limiting faculty research and applying a single standard to a diverse body of research. It appears there is often only one standard penalty for all IRB violations: the researcher cannot use the data. Some violations

need greater penalty and others a lesser penalty. Further for our purposes, the Li case illustrates the power imbalance between the researcher and the Review Board. Li felt the need to engage the courts in order to reach a satisfactory resolution. The intent of this paper is to demonstrate ways that IRBs can be overly intrusive in faculty research and challenge research faculty professionalism. In raising these issues, we ask the reader to consider whether these are disturbing patterns or a few rogue IRBs.

One of the university's most important commodities is its reputation. Therefore, care should be taken to guard the high ideals for which a university stands. Research ethics is a serious responsibility, and the Institutional Review Board's (IRB) role is to protect and minimize risk to human subjects. Yet, what are the boundaries of that role, and is the IRB responsible for broader institutional ethics, institutional reputation, and/or ethical issues that arise for researchers in the field that are not a part of the original IRB (Blee & Currier, 2011)? A brief review of the history of the abuse of human subjects (Lemonick & Goldstein, 2002; Schrag, 2010) makes it apparent some form of peer oversight is absolutely necessary. For example, since 1951 Henrietta Lacks' cancer cells have been used in thousands of research studies without her or her family's knowledge. In an unprecedented agreement reached in the summer of 2013, the National Institutes of Health and the Lacks family established a plan to protect the family's genetic privacy and for future oversight of use of the cells in research (Vergano, 2013).

When has the IRB overstepped its bounds into the domain of researchers' academic freedom and ethics? It is important to understand at some level, the IRB is us, the faculty. United States IRB boards are comprised of a faculty peer review committee along with full time staff and/or legal counsel. If faculty panels are reviewing one another's research, why is the approval process sometimes adversarial? Should not collegiality prevail?

Some may rightly argue for a critical challenge of the IRB bureaucracy or a complete overhaul (Hammersley, 2009); here we focus more on corrections to the system. Hammersley (2009) makes an interesting argument that the ethics committee, Britain's version of the IRB, is less qualified to make ethical judgments than the researcher in the field in qualitative research. Blee and Currier (2001) point out that in qualitative research "ethics are involved at every stage of research" (p. 404) and not just before the research begins. Hammersley asserts that not all possible circumstances can be anticipated and context is necessary for ethical decision making, therefore the ethics committee is to engage in periodic ongoing review, yet the committee still knows less about the research context than the researcher. Hammersley also provides an excellent framework for understanding the ethical issues, therefore those are not reviewed here.

Context

The foundation for the current regulation is the Nuremberg Code developed for dealing with the Nazis' human medical experiments. Subsequently, highly publicized violations of human subjects such as the Stanford prison experiment, which did not make enough provision for voluntary participation, and the Tuskegee Study of Untreated Syphilis in the Negro Male, wherein participants were denied available treatment also illustrate abuses of human subjects (Lemonick & Goldstein, 2002; Schrag, 2010). These violations led to the creation of the ethical principles in the Belmont Report. In, 1979, the Belmont Report established the guiding principles of respect for persons, beneficence, and justice (Health & Human Services, n.d.) that direct current university IRB practices. However, new findings of irresponsible behavior have the courts, governments, and universities re-examining their IRB policies and the researchers in the United States (US) and elsewhere. For example, in November 2010, the Obama administration instructed the President's Commission for the Study of Bioethical Issues

(PCSBI, 2011) to reexamine the current IRB rules, particularly focusing on international research participants after it was made public that the United States Public Health Service financially supported research in the 1940s that infected Guatemalans with sexually transmitted diseases without their consent (PCSBI, 2011).

The US Federal Policy for the Protection of Human Subjects, known informally as the Common Rule, (HHS, 2010) is utilized by multiple federal agencies and guides current practice. The Common Rule was initially published in 1981 and is currently under review. In keeping with the principles of respect for persons, beneficence, and justice, the Common Rule's defined mission of the IRB is to: (a) minimize unnecessary risks to human subjects by using sound research design and existing data when possible; (b) ensure that the risks are proportional to the benefits gained; (c) safeguard the selection of subjects so it is equitable, paying special attention to vulnerable populations; (d) ensure informed consent is sought and appropriately documented; and (e) monitor data security and protection of the privacy of research participants (HHS). Since 1981, university IRB staff have progressively professionalized including training, national conferences, and certification (PRIMR, 2013). This professionalization has moved the IRB office from being fully volunteer faculty to a more staff influenced process, and as McAreavey and Muir (2011) suggest from research ethic to research governance and risk management. The framing of research ethics as risk management may be especially problematic for qualitative researchers who are often trained to view research as a partnership with their participants--indeed even calling participants "subjects" is uncomfortable for many qualitative researchers concerned about power in relationships.

In 2011 there was an invitation for public comment for revision to the Common Rule in the US (HHS, 2011); possible changes would include all research regardless of funding source and include international research under IRB. The recommendations also suggest simplifying review of low-risk studies in order to allow more focus on higher-risk studies, streamlining review of multi-site studies, and improving informed consent. There were also recommendations for data security and data collection to enhance oversight. There were more than 1,000 comments submitted including a white paper from 22 research societies (AERA, 2013). The American Association of University Professors' (AAUP, 2013) report on the IRB and academic freedom recommended expanding the exempt categories to include research on autonomous adults if the study methodology imposes no more than minimal risk of harm. The National Research Council (2014) went slightly further and wanted removal of the restriction for excused research to "competent adults." Moreover, the AAUP argue the 1995 change to give the IRB committee control of determining whether a study is exempt from committee review should be reversed and cite the request for comment's statement that this IRB review has slowed research without adding significant protection. They point out that a faculty member is no more likely to knowingly avoid a needed review than deliberately not follow an IRB approved protocol. Finally, the AAUP recommends the IRB appeals body be the faculty committee that reviews violations of academic freedom and suggest there are other campus experts better able to advise researchers on data security than the IRB. The President's Commission's (PCSBI, 2011) recommendations in 2011 include streamlining approval for low-risk cases, public access to research study summaries, and making the ethical underpinnings of the regulations explicit. The NRC also emphasized streamlining approval for low-risk studies, utilizing an excused category, removing ambiguity regarding reasonable risk, reuse of data without requiring new informed consent, single IRB approval for multisite studies, and greater flexibility in the form of informed consent.

Considering the level of interest, one would expect substantial research has been conducted on IRB review to guide these changes, yet there is limited empirical research (AAUP, 2013; PCSBI, 2011; Schrag, 2010). Schrag (2010) has reviewed the development and process of the IRB and emphasizes the mismatch between his own discipline of history and

IRB review policies. Traditionally historical research was not subject to IRB review. Schrag's (2010) and Oaks (2002) make clear that the medical model was exported across disciplines with little input from non-medical researchers and may be particularly ill-fitting for qualitative research.

Lincoln and Tierney (2004) and Oaks (2002) argue that IRBs are often ineffective in handling qualitative research methodology. Some of the arguments that qualitative researchers have made to illustrate why IRBs are ineffective with qualitative research methodologies include: lack of understanding about qualitative research (Johnson, 2008; Macdonald & Carneval, 2008; Swauger, 2009) and the position of power that the researched have (Leisey, 2008; Swauger, 2009), the awkward application of biomedical research to humanistic research (Leisey, 2008; Macdonald & Carneval, 2008), ethical decisions are not a one-time event but rather an ongoing process (Blee & Currier, 2011; Leisey, 2008), and ethical decision making within qualitative research is deeper and more robust than IRB processes (Blee & Currier, 2011). Review boards, based on a medical model, can lack the philosophical understanding of qualitative research and therefore unnecessarily hinder research that lacks the clear boundaries between the so-called objective researcher and the subject. However, the federal code for IRB memberships states, "The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members ... to promote respect for its advice and counsel ..." (HHS, 2010, n.p.).

The majority of research is in the gray area between having no risk and obviously too dangerous, therefore faculty peer review is appropriate. The only way to completely avoid risk is to not do research. Tierney and Corwin (2007) argue that colleague review best protects academic freedom and avoids the de-professionalization associated with excessive administrative oversight. Some qualitative researchers think that they should be exempt for IRB processes because qualitative research does not look like the kind of studies that IRBs define as research or fits the review model (de Sola Pool, 1980; Hammersley, 2009) while others argue that we should be asking different questions of qualitative research (Macdonald & Carnevale, 2007).

We would like to add to this conversation in the education research community about the challenge to faculty professionalism and research freedom from the administrative nature of human subjects review. Where is the line between the oversight of the IRB panel and the academic freedom for faculty members to research what they wish based on their professional ethics and expertise? Who owns the final ethical responsibility? Is it the individual researcher or the IRB panel? In this paper, we will use case examples to illustrate the ways in which the IRB can subtly (and not so subtly) challenge faculty professionalism. By doing so, we certainly do not wish to undermine the importance of limiting risks to human subjects or dismiss the researcher's responsibility to behave ethically, but rather we point out problems that can arise when IRBs pedantically limit faculty independence.

Methods

Case study vignettes from the researchers' experiences provide the examples in this case. This process builds on the growing body of case evidence of the tension between the researcher and IRB (McAreavey & Muir, 2011; Oaks, 2002; Pritchard, 2002; Tierney & Corwin, 2007). In many ways this paper could be viewed as a multi-site case study in that the experiences are bounded by a system--higher education, and it uses multiple sources of information--the authors, their conversations with others, paperwork from institutional review boards at multiple institutions (Creswell, 2007). However this paper is also a form of autoethnography--albeit a collective autoethnography. Autoethnography "make(s) the researcher's own experience as a topic of investigation in its own right" (Ellis & Bochner,

2000, p. 743). Autoethnography requires reflection over time to set aside one's own biases and see the situation more clearly.

The following findings and discussions are the result of our experiences (cases) as both graduate students and faculty members over multiple years and across seven different institutions in which we have conducted research, or served as the Principal Investigator (PI) for our graduate students conducting research. In the process of our discussions about our experiences with IRBs, we challenged one another to "stop ranting" and instead focus on a deeper cultural understanding and meaning of how the IRB both functions in and limits the academy.

Data Sources

Combined we, the authors have twelve years of tenure-line experience. Authors are a faculty member and an academic administrator at research universities and a faculty member at a mid-size state system university. One of our research team has published both quantitative and qualitative research studies. While philosophically qualitative and critical, she believes quantitative and qualitative methods can provide knowledge. She believes all research is impacted by our values and choices whether deciding which variables to include in the model, making choices to recode quantitative variables, or discerning meaning from interview transcripts. Qualitatively she has conducted interviews and focus groups, and quantitatively she has most frequently used regressions: logistic regression, OLS, and HLM.

The second of the team has worked on both quantitative and qualitative research studies and teaches a research course that explores both types of research. She defines herself as a qualitative researcher interested in constructivist inquiry and critical theory. She has been involved in a range of qualitative research projects which include interviews, focus groups, and autoethnography. She has also used arts focused reporting of results.

The third team member has also done both quantitative and qualitative analyses as part of her responsibilities as the director of a student support program at a large research university. As a practitioner whose outlook has been informed by feminist and literary theory, she is particularly interested in examining how women experience higher education. She recognizes the need for collecting not only numeric data as part of her ongoing assessment of program efficacy but also the words from the participants themselves as a means of more fully understanding the educational context in which students, faculty and staff are operating.

Data Collection

These case reflections were not our only encounters with IRB committees. Across our time in academia, we submitted an estimated 29-30 IRB proposals, most with minimal or no revision before approval. These cases are selected to illustrate the issues, yet none of the concerns were isolated to a single campus and should not be seen as only outliers. Finally, in the vein of autoethnography, we do not consider the important perspectives of the research participants, funding agencies, or Review Panel members and staff--the stories contained here are ours, and such and as the authors of the paper, we did not seek IRB approval to write up our experiences intuiting that we by virtue of telling our stories have granted consent. We did not collect any data for this manuscript. In considering the ethics of writing our stories and thereby uncovering what may be misapplications of power by IRB administrators, it reminds us of Richardson (2000), when she writes, "For the most part, I have found no ethical problem in publishing stories that reflect the abuse of power by administrators; I consider the damage done by them far greater than any discomfort my stories might cause them" (p. 932). In addition, pseudonyms are provided in case vignettes and the fact that these vignettes were

collected across several institutions, many years and by three researchers, we have little worry that anyone could be exposed. In looking at our cases, we challenged one another to focus on a deeper cultural understanding and meaning of how the IRB both positively functions in and limits the academy.

IRB Issues

We begin our conversation with illustrations followed by discussion of the issues raised. Our concerns focused on mission creep and potentially legitimating censorship. Areas of mission creep can include institutional reputation, methodological design, and chilling language/legal language verses accessible language. In addition, we consider multisite studies and when staff focus on form rather than substance.

Mission Creep and Institutional Reputation

Andrea wanted to measure the benefits of fitness experiences on students' health for her dissertation. She designed a quasi-experimental study to test the health benefits of a physical education course, and the course instructor at the local college was happy to support the research. The fitness assessments were extensive, but six of the seven measures were a regular part of the course requirements, therefore the additional burden would have been a ten-minute survey. The research university IRB committee approved the dissertation study contingent on approval of the research site, a nearby college that offered the course. The nearby college denied her access, citing the burden to students. However, a member of the institution's committee shared with Andrea that the focus of the research committee's discussion was the potential of the research findings reflecting negatively on the college. Consequently, the university rescinded the conditional approval until Andrea was able to secure an alternate research site at another college. The burden to students was greater at the new site because the health assessments were not a regular part of the new course.

Preventing risk to human subjects is an extremely important task; however, in the prior example, the determination of approval may not have been a matter of protecting human subjects. In Andrea's situation, the neighboring college committee overtly discussed institutional reputation as a reason for denial, a rationale outside the purview of the IRB committee. The university IRB unquestioningly deferred to the college research sites' IRBs. This practice appears to be relatively common as we have seen at least five universities who require approval by the research site if it is another educational institution. Employees at the research site were neither engaged in human subject's research nor in need of protection through committee oversight. Therefore, many would argue their review was unnecessary. Alternatively, these research site institutions argued that they had a responsibility to protect the students and staff in their community.

The results of research (positive or negative to the institution's reputation) and the subject to be researched are not the purview of the IRB. The IRB's job in maintaining an institutional reputation is to assure ethical research in relation to human subjects' treatment, not to determine what is researched. Therefore, research findings that could potentially reflect negatively on the institution cannot, independently constitute a legitimate reason to deny IRB approval. Lincoln and Tierney (2004) provide several case examples of institutions that did not want their names associated with particular research. Yet, there are many historical examples of institutions that supported controversial research that make our current example of censorship seem highly discouraging. Imagine the void in our understanding of human sexuality if Indiana University had been afraid of the impact of Alfred Kinsey's research on the university's brand image.

It is good for the collegial relationships between institutions to steward those relationships by informing one another that a researcher will be collecting data at the neighboring institution. It is also reasonable for both institutions to have their own review panel for the protection of their researchers. However, it is less clear how collegiality has much to do with the ethical obligation to protect human subjects, and the university IRB gave their power to the college IRB in this example.

Further, it was not an isolated event where a committee initially determined a study was appropriate, but subsequently rescinded approval because of the research site committee. These instances lead us to ask: If we do not challenge such censorship in easy cases, how will we protect academic freedom when it is hard? If both committees do their primary job without mission creep, theoretically this would not happen.

Methodological Design and Mission Creep

Sam, who is an assistant professor, met with an IRB staff member. New to this university's procedures, Sam wanted to make sure the paperwork would sail through the process. While talking, the staff member told Sam to use a quantitative survey in lieu of the qualitative design submitted for approval. It took two firm rejections by Sam for the staff member to back down--one a simple no and the second an assertion of a faculty member's authority to decide research methodology. The staff member's subsequent nonverbal communication showed frustration that the advice on methodology was being ignored.

IRBs should not prioritize one type of methodology over another, yet as Lincoln and Tierney (2004) point out, review boards are less experienced in working with qualitative research. Johnson (2008) reported similar frustration with the IRB process. Johnson, with her dissertation advisor, appeared before the IRB committee to answer questions about her research to seek approval. While questioned, Johnson found herself defending qualitative methodology to quantitative panel members. While there was a qualitative researcher on the panel, Johnson wondered why this researcher as a qualitative representative did not defend Johnson. Later Johnson learned that the researcher did not come to Johnson's defense because of the political nature of the panel and the panelist's broader objectives. While panels are required to have qualitative scholars, and Johnson's did, it was still dominated by a quantitative model. Macdonald and Carnevale (2008) go further and suggest IRB panels see qualitative research as a handmaiden of quantitative research and found the review process to be inappropriate. Unlike quantitative studies, in qualitative research explanation is sufficient justification for a study. However, in their example the review panel applied standards of beneficence and rigor that suggested explanation was an inadequate justification to conduct the research. Macdonald and Carnevale also reported that IRB panels tend to approach qualitative researchers as guilty until proven innocent rather than vice versa. The staff member in Sam's example and others have been empowered to believe it is their role to address research design beyond assuring that the design minimizes the risk and burden to human participants. While the advice is often more subtle than in Sam's case, all researchers including staff and faculty panelists have philosophical preferences for particular research methodologies, yet it is not their role to control methodology. We empathize with staff and panelists' frustration when they see a study that could be improved, but the power differential in the approval process makes questions of the methodology coercive. Perhaps a better approach might be approval with optional recommendations (McAreevey & Muir, 2011).

Further illustrating the tension between qualitative researchers and IRB processes was the experience of Swauger (2009). In getting approval for her study from the research site director, she wanted to offer back to the site a report of the findings that would benefit their programming. This desire for reciprocity with research participants is philosophically

important to some qualitative researchers including Swauger. Yet, the IRB would not approve the release for fear of violating the participating girls' confidentiality.

Chilling Language/Legal Language and Mission Creep

The default text for the verbal informed consent statement at one university reads, "The U.S. Department of Health and Human Services (DHHS) and/or the Food and Drug Administration (FDA) may request to review and obtain copies of your records. Your records may also be reviewed for audit purposes by authorized University or other agents who will be bound by the same provisions of confidentiality."

Similarly, at another university the template for the information sheet when consent is not required reads, "Information about you will be kept confidential to the extent permitted or required by law. People who have access to your information include the Principal Investigator and research study personnel. Representatives of regulatory agencies such as the Office of Human Research Protections (OHRP) or (if FDA regulated) the Food and Drug Administration (FDA) and entities such as the [institution] University Human Subjects Protection Program may access your records to make sure the study is being run correctly and that information is collected properly." According to the university web site, the researcher is expected to use this language even though a waiver of consent or waiver of documentation of consent is approved.

Imposing chilling language can be problematic for researchers. At the first university, there was no information on the IRB's website that this text was optional. After a call to the staff, it was clarified that the federal notice is only required when the research is federally funded. However, the second line about "for audit purposes" is to be included on all informed consent statements without regard to funding source. When asked why, the response included reference to a "random selection of studies for a quality assurance review" which they distinguished from a "for-cause audit." The review would be about the quality of "compliance with federal regulations on human subjects' protection" with the addition of the statement, "It will be used as an educational process for the PI." There was no reference to learning by IRB staff or committee members. The purpose of the audit may be to review both researchers and Review Board, but that was not the way this staff member explained it.

Our concern is that chilling language is being subtly or blatantly imposed. Can you imagine an undocumented immigrant, sex worker, or juvenile delinquent participating when they know a branch of the federal government or some unknown administrator can demand their transcripts? The federal language is removable in some cases; however, the default text remains chilling. Equally important, the language sets an inappropriate tone for the interview; official language can be the reverse of establishing rapport.

Furthermore, while legal language is precise, it contradicts the informed consent principle. The informed consent principle recommends all written text be accessible to the least educated research participants. In addition to having a chilling effect, the approved text above does not keep the language at an appropriate reading level. We try to ascribe to the advice that consent statements should never be over an 8th grade reading level and often needs to be lower because one cannot assume the reading level of the participants. The shift toward the specialty language of the legal profession is, by definition, a shift away from common use language and readability. An attempt to simplify the recommended language was met with why questions from staff rather than a review of whether the new text met the standard of informed consent. Christopher, Foti, Roy-Bujnowski, and Appelbaum (2007) found about one third of patients in mental health clinical trials had not graduated from high school, yet in four separate assessments of consent statements, the reading grade levels ranged from grade 12 to 14.5. They also found as subjects' risks increased, the readability scores also increased. We believe informed consent is being lost in risk management.

The IRB process of informed consent can also be at odds with the philosophical and methodological approaches of qualitative research. Often studies are emergent and researcher interaction with participants is ongoing, while IRBs see data collection as a defined incident. Swauger (2009) wanted to interview low-income girls' about their perceptions of their future. The IRB's framing of children as a vulnerable group was problematic to her view as a feminist qualitative researcher who saw them as self-determining agents. Further, because IRB committee's required adult consent on behalf of young people, girls, who lived in a foster home had no one to sign consent, were not allowed in the study. One young woman wanted to participate, and the IRB process marginalized her among the girls for her foster home status.

Multisite Studies and the Imbalance of Power

Ken accepted an Associate Professor position at a new university two years into a three-year collaborative study. His research had been covered under the IRB committee of his prior university, the study site. Ken submitted an IRB application at his new university because he was still collecting data. However, the second university required different language in the consent statement. There was no change in methods or procedures. For the sake of expedience, Ken made the changes, but the result was about half the research participants were interviewed under the original consent statement while the others received the adjusted statement.

At another university, virtually identical research projects were to be conducted at two different research sites. While the two IRB applications were not identical because they were written by different members of the research team, they both included language that stated if a sufficient sample of teachers from the school participated in the survey; the school would be given its aggregated results for use as their state evaluation report. The research team saw the studies as parallel with the same survey instrument, distributed the same way, and identical "compensation processes," yet the process that was approved in the first application was denied in the second because it was deemed coercive.

These scenarios illustrate two separate points. Two separate committees may have different policies or the same panel may come to different conclusions depending on which staff member reads of application. This issue is much more problematic in clinical trials with at least a half dozen different IRB panels (Joffe, 2012), but multiple sites are also common in education research. There is little evidence that the multiple reviews by independent panels add to the protection of human subjects at an appreciable level to the effort of the researcher completing multiple unique applications. One of the recommended changes to the Common Rule is to remove this redundancy.

The second issue is the imbalance in power and culture of fear in the process. While IRB committees were envisioned to be a panel of peers, the relationship between the individual faculty researcher and the primary contact IRB staff is often not one of collaborative peers. Two issues surround this relationship. First, at some institutions, the individual faculty member usually deals more with the staff than with the actual faculty panel. Second, power primarily resides on the side of the IRB staff in any discussion. The panel can deny the study with little or no appeal process at most institutions. In the second example where the similar studies resulted in different outcomes, the research team chose not to point out the inconsistency to the staff for fear of loss of the first approval. While there are appeals that could rectify this power imbalance, some faculty members who are eager to begin research wish to avoid the delays of extra review and therefore acquiesce. In some instances the IRB committee has unquestioned authority, and there is not a viable appeal process, as was alleged in the *Li v. Brown University* (2011) case.

Form Rather than Substance

A doctoral student was reprimanded for copying one sentence from the approved informed consent document into the approved recruitment letter at the request of the research site director. As a result, participants were given information about the study earlier as a result of the change, increasing their opportunity to be fully informed. While an IRB amendment was technically required, the text was approved in the consent statement so the amendment was not filed. When a cautious research participant called the IRB office to confirm that the study was legitimate, the language change came to light. The professor as principal investigator and the doctoral student were summoned for an emergency meeting and were reprimanded by IRB staff with threats that the doctoral student would not be able to use the data. The intentionally humbling nature of the interchange seemed disproportionate to the mistake. In the spirit of the ethical principle, participants were given greater consent rather than less in the researcher's actions.

Both our experience and prior published work (Clinical Trials Administrator, 2010) suggest that review boards or staff can focus on minor issues while ignoring important risk issues. We have had proposals sent back multiple times for revision about font size and formatting of the consent statement but never for the content or form of interview questions. The doctoral student example was probably exacerbated by an overzealous staff member, but the lack of distinction between major and minor issues is more pervasive. The proposed revisions to the Common Rule suggest less oversight of low risk studies allowing greater oversight of high-risk studies, which may improve this situation if implemented.

In addition, IRB committees seem to have greater concerns surrounding students' work. Review Boards have required paperwork from students that is not required of faculty. If an IRB can determine all they need for a professor's study from the standard forms, the requirement for inclusion of the student's dissertation abstract, for example, seems redundant. Considering a four-member faculty dissertation committee has approved the dissertation research, perhaps a student's proposal should need less review from the IRB. Further, for a student trying to do a study in one semester for a class project, small delays can completely derail an assignment or future publication. To be sure, approval is not needed for a class project, but if faculty want to use class assignments to mentor students in the publishing process, delays can be extremely challenging.

We, like many other researchers (Johnson, 2008, Leisey, 2008; Lincoln & Tierney, 2004, Oakes, 2002; Swauger, 2009), have experienced frustrations from working with the IRB and feel called to write about such hindrances. Like these authors, a majority of the vignettes we have shared stemmed from a lack of understanding of qualitative research by the IRB; however, unlike these authors some of our experiences stem from quantitative projects. Like these authors, we as researchers attempted to be diligent in our ethical considerations, and at these points of frustration we were often made to complete extra steps that felt unimportant due to the fact that our studies did not fit the one size fits all mentality of many IRBs.

Balancing Protection of the Institution with Encouraging Faculty Research: Recommendations

Is this restrictive relationship between faculty and the IRB necessary? Pushing research design preferences and imposing chilling language or legal language may be inevitable mission creep. It is the nature of committees to expand their power, and it is the natural inclination for researchers to make the research design the best possible. While qualitative researchers have asserted their place to some extent and while some of the concerns of Lincoln and Tierney in 2004 may have been addressed, this growing oversight represents many of the same concerns

and ongoing censorship of qualitative and quantitative research disguised in new language (i.e. quality assurance). Again, we affirm the importance of peer review for ensuring that no human subject is harmed, and we do not fully align ourselves with those who argue for the illegitimacy of the Review Board (de Sola Pool, 1980; Hammersley, 2009). However, boards that review qualitative research should have experience with it, as required. We also believe a type of oversight more fitting to qualitative researchers could be envisioned. As researchers we all could have benefited from an ethical discussion group when issues in our research have arisen—perhaps groups like this could be a viable alternative. As faculty, we strive to build our individual reputations through doing good research; we also hope that the ethical research we do adds to our institution's reputation. As such, we feel that the dialogue between researcher and review board need not be contentious. Rather than simply being contrarians, we offer a few suggestions for consideration.

First and foremost, we believe the faculty committee members must take ownership of the review process or academic researchers must handle contact between the committee and researchers. We recommend consideration of the parallel processes of the tenure and promotion committee. Staff handles factual questions (what goes in the file), but staff refer junior faculty to the committee or department chair for questions about deliberations or advice on which manuscripts to put in the file. It may be naïve or arrogant to think faculty are more trustworthy overseers than administrators, yet it is still the most collegial alternative. Administrators or staff, who do not research and are not rewarded for researching, may find it more difficult to identify with researcher interests, and the current structure sets up an imbalance of power. Further outsourcing of the review process to external companies removes local control and incentivizes approval in order to maintain the financial contract (House Committee on Energy and Commerce, 2009)¹.¹ Institution administrators can also be tempted by large research grant dollars to approve studies, but faculty members who have little direct reward may be best able to handle this pressure. Additionally, utilizing external companies sets up a structure of a distant agency that must be managed by faculty rather than a collegial process, a process more akin to our relationship with the Internal Revenue Service than with the Promotion and Tenure committee.

Further, contextualizing the experience locally is important. At one university, the faculty members from each college who sit on the panel review proposals from their colleagues before the proposals are submitted. This collegial process could be less adversarial and theoretically utilizes the most qualified review board member. This policy will mean more volunteer time from board members; however, it is easier to discuss the concerns face-to-face with a colleague in one's discipline than respond to an office across campus via e-mail that includes warning language that the researcher is forbidden to begin subject recruitment before the questions are resolved.

Third, universities should conduct annual evaluations of staff and policies. A quality assurance review of the IRB office rather than only of approved projects could help to highlight inconsistencies, mission drift, and perceived artificial barriers. While there is an external accrediting agency (Association for the Accreditation of Human Research Protection Programs) for IRBs, we are unfamiliar with any review that asks faculty for their evaluation of the IRB staff. If all administrators must be reviewed annually, this lack of faculty feedback illustrates the institutional position on the value of faculty opinion in this regard. This form of

¹ In a U.S. Government Accountability Office sting operation, one of three for profit companies approved an intentionally flawed study with only minor edits. It was determined this one company had approved virtually all of 300 submitted proposals. The other two companies denied the study and the company, Coastal IRB, has subsequently closed. It should be noted, there are no oversight standards over what is required to be an IRB business beyond market demand. In the interest of full disclosure, it should also be noted that no institutional not-for-profit IRBs were tested in the sting.

evaluations would also help balance the power relationships between researchers and IRB staff. Evaluations could consider whether qualitative researchers are less satisfied or experience more challenge to their protocols.

Issues with IRB deserve national attention, and research should be done to identify “best practices” for IRB offices, so that we may learn from institutions that excel at balancing the needs of all parties within the IRB process. Hammersley (2009) suggests that social science research could be better aligned on the ethics of the journalism profession rather than the medical model. The stakes are much higher in medical research than much of social science research. The President’s Commission report also recommends this type of research. Research on IRB committees that would require IRB committee approval is in itself an interesting dynamic.

Several recommendations of the President’s Commission align well with our findings and we endorse those recommendations. Calibrating the level and intensity of review activities to the level of risk is important. This consideration allows the IRB committees greater time to focus on those studies that need the greatest oversight. Continuing review for low-risk studies appears unnecessarily time-consuming for all involved.

The President’s Commission report and recommended changes to the Common Rule appear to have some strong insights that we endorse, but they will not address all the concerns we have raised here. The mission drift we observe has not been a focus of their work. We need to remove the growing link between institutional reputation and IRB approval. When concerns about institutional reputation go beyond human subjects, this mission drift must be forcefully challenged. Moreover, outside entities should not have the authority to suppress academic research. When researchers are collaborating across institutions, multiple full proposal reviews seems burdensome or at least inefficient.

Committee review of actual transcript data is troubling when there have been no concerns raised. Blanket informed consent statements that include committee third party review can suppress research quality and integrity, yet the IRB quality reviews would only include a subsample of research studies. The risks exceed the benefits.

Finally, we have raised more questions than provided answers here, but we are concerned about the erosion of faculty independence and wanted to raise the warning flag and reignite a discussion. Risk management is not necessarily the same thing as research ethics (McAreavey & Muir, 2011), and faculty must own the responsibility for their own ethical research. If faculty members believe they have dealt with their research ethics by IRB approval, they may fail to be conscious of ethical practice once in the field, and ethics becomes a one-time event (McAreavey & Muir, 2011). Considering the intimate nature of qualitative field research, ongoing ethical diligence is imperative. Hammerley points out that the ethics committee operates prospectively, deciding whether the action is unethical before it is committed. This form of preemptive regulation is rare in professional roles.

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