

Social Work Researchers and the Institutional Review Board

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Abstract

The death penalty is a controversial social issue in our society. Few other issues engender such debate or stir such emotions. Although the percentage of people who support capital punishment has decreased in recent decades, the majority of Americans still support it. The National Association of Social Workers, however, staunchly opposes the death penalty. This study examined the differences in death penalty attitudes between social work and non- social work undergraduate majors at a large public university. Far fewer social work students supported capital punishment as compared to students in other majors. Additionally, the results indicated that social work majors significantly differ from other students in the reasons for supporting/opposing capital punishment.

Keyterms: Ethics; Social work research; Institutional Review Board.

Introduction

University-based social work researchers must submit a human subjects' application to the Institutional Review Board (IRB) when their projects meet the definition of research as specified by the federal regulations. The IRB process aims to strengthen the research ethics and to assure that study participants are not exploited. The federal human subjects' regulations, also known as the Common Rule, define research as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge" (Department of Health and Human Services, et al., 2001, §46.102).

The Belmont Report (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1979) articulated the guiding ethical principles that inform the Common Rule. These ethical principles are Respect for Persons, Beneficence, and Justice. These three principles were written in the abstract to provide a conceptual framework for ethical analysis and to allow for local interpretation of the principles (Jonsen, 2001). While the Belmont *Journal of Social Work Values and Ethics*, Fall, 2005, Volume 2, Number 2 -page 29

Report's primary intent was to create an analytical framework, the Common Rule's intent was to articulate what are the rules, key definitions used within these rules, and the functioning and composition of the IRB review committee.

The Common Rule specifies criteria for three different levels of ethical review: exemption, minimal risk and full review. An exempt project must meet one of six criteria listed within the regulations, e.g., *Educational Research Conducted in Educational Settings*. Studies eligible for minimal review are those in which risk is assessed to be no greater than what can be expected in daily life. Full review is required for a study where risks include potential damage to the physical or psychological health, reputation, or economic welfare of a subject. As an example, this research study required full review. Risks to reputation and economic welfare were considered the primary concerns, as the study potentially could reveal a lack of compliance with the human subjects' regulations.

The IRB committee must include at least five reviewers. Committee composition is further outlined in the Common Rule. As an example, the Common Rule states, "each IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution" (Department of Health and Human Services, et al., 2001, §46.107). The overall intent is to create a diverse and knowledgeable review committee.

The authority of the IRB includes approval, approval with contingencies, deferral, or no-approval of research proposals; continuing review; observing, monitoring, and auditing of research projects; and suspension or termination of approval. The charge of the IRB is to assess research proposals across the Belmont Report's three ethical principles. This includes a careful examination of the informed consent process, a risk/benefit analysis, and determination as to whether there is a fair distribution of burdens and benefits.

As the review process differs across universities, researchers should familiarize themselves with local IRB practices and the Common Rule. To more fully understand the regulations, it is also strongly recommended that researchers gain an understanding of the historical context and critiques of the regulations. Numerous articles and texts within the bioethics literature, for example, provide a historical overview of the regulations and describe the challenges with a regulatory system that has largely developed in response to ethical violations (e.g., Advisory

Committee on Human Radiation Experiments, 1996; Kahn, J., Mastroianni, A., & Sugarman, J., 1998; Moreno, J., Caplan, A., & Wolpe, P., 1998).

Relevance to Social Work Field

The IRB review process has not been explored systematically in the social work literature. Murray, Donovan, Kail and Medvene (1980) reviewed the social work literature and found no references to how the ethical guidelines affected social workers. These authors also reported that the 1980 version of the *NASW Code of Ethics* failed to make “specific reference to formal procedures either for obtaining informed consent or for institutional review” (Murray et al., p. 26). Of note, the revised 1996 NASW code continues to assume a less stringent position implying that the IRB “should be” consulted, rather than stating consultation as a requirement. Additionally, Murray et al. interviewed twelve social work researchers and found that, in general, there was a desire to strengthen the professional code of ethics rather than increase “governmental intrusion.”

Grigsby and Roof (1993) also found inadequate attention to ethics within social work research texts published after 1975. They reviewed nine texts and found that only a third of the texts explicitly mentioned participant rights. Implications include the potential for “impediments to the generation of high-quality social work research that involves human subjects, in that researchers may be less attuned to the pitfalls for research that is not sensitive to ethical issues” (p. 459). Current research texts indicate a shift toward greater attention to ethics through an inclusion of a historical overview of the human subjects’ regulations, a discussion of the IRB purpose and function, and information regarding informed consent requirements (e.g., Rubin and Babbie, 2001; Grinnell, 2001).

Several social work journal articles provide more specific calls for action within the social work community. Blaskett (1998), for example, advocates for social workers to have a stronger voice in the promotion of ethical research, seeing the benefit of applying social work skills to the ethical review process. Similarly, Massat and Lundy (1997) recommend infusing the current ethical principles, as specified by the human subjects’ regulations, with empowerment principles.

There is a need for increased attention within social work to the human subjects review process. There is no recent empirical data on how social work researchers perceive the benefits and challenges with the IRB, nor is there discussion on how researchers can be supported through the review process. A need for this information was further reinforced through the authors’

experiences offering support to social work researchers in the completion of IRB applications. The authors noted that applicants frequently voiced confusion and/or frustration with the IRB process. The current study was designed to explore social work researchers' perceptions of and experiences with the IRB. The compilation of experiences and challenges encountered in the review process will help to create a preliminary set of recommendations for Schools of Social Work and IRBs aimed at enhancing the human subjects review process.

Methods

The study sample included twenty social work researchers who submitted a research proposal that required a minimal risk or full review. Exemption applications were excluded, because anecdotal evidence suggested that the minimal risk and full review process present greater challenges than the more streamlined exemption process.

The participants included 7 graduate students, 6 staff, and 7 faculty researchers. Researchers used a wide range of designs, including ethnographies, clinical trials, epidemiological studies, and participatory action research. The researchers' data sources included interviews and survey results, as well as secondary data sets. The estimated number of submissions per researcher ranged from 1 to 15, with an average of 4. The majority of applications (89%) required full review. Student researchers overall submitted the smallest number of applications. Of note, the results do not specify whether researchers are student, staff, or faculty. Contrary to what we expected, the researcher's position did not result in significant differences.

Participants chose whether to be interviewed or to complete a written survey. Ninety-five percent of the participants completed the interview. The written survey contained the same questions as the interview guide. The questions included 1) what are your perceptions of the review process; and 2) how can the School of Social Work and/or IRB offer increased support to applicants? The interviews lasted approximately 45 minutes and were audiotaped with the participants' permission. The audiotapes were transcribed verbatim. The authors coded the transcripts independently and compared and discussed their tentative coding schemes. Themes were identified using the constant comparative method (Lincoln and Guba, 1985).

Participants also provided their correspondence between themselves and the IRB regarding the status of their application. When participants had submitted more than one application to the IRB, they selected which application to include in the study. A content analysis of the written

correspondences was completed across the following two areas: 1) the types of changes required, or questions posed by the IRB and 2) how the researcher responded to the IRB's feedback.

As this study is exploratory and included researchers affiliated with one university, the findings and recommendations represent an important first step in understanding potential challenges and recommendations to facilitate the IRB process. Social work researchers are encouraged to critically reflect upon which recommendations are most appropriate, given the specifics of their social work program and university culture. This paper concludes with recommendations for future studies, including the suggestion to broaden the study sample to include social work researchers affiliated with various institutions.

Results

Study results were categorized into three broad areas: 1) perceptions of the review process, 2) areas of IRB feedback, and 3) assessment of practical support and recommendations. For the remainder of this paper, the term "researcher" will be used instead of "study participant."

Perceptions of the review process

Perceived purpose of the IRB

Researchers described the IRB's primary purpose as the protection of study participants from harm and the assurance of ethical research. Protection includes researchers safeguarding confidentiality and presenting participants with an informed consent that relays key information, including the voluntary nature of the study.

Several of the researchers also considered the IRB purpose to extend beyond study participant protection, to include consideration of the general public and the legal protection of the investigative team and the University. For several of the researchers, protection of the University made sense, yet they were wary it potentially took precedence. As one researcher shared, "I would like to think the purpose of the IRB was to actually look at the research that we are doing [but] in practice I really have felt like they are more in the business of protecting the university."

While most of the researchers agreed that the purpose included the protection of study participants, questions were raised with how "research" was defined by the regulations. A researcher voiced frustration with the operating assumptions underlying the regulations, stating that research funded by federal grants is considered the norm. As a result, two problems were identified. First, the underlying assumptions of the definition create a "gray zone" for program

evaluation, which may not meet the regulation's definition of research. Without an approval, the dissemination of evaluation findings may be restricted. Secondly, unethical practices that are not labeled as "research" might occur without the benefit of the regulatory protections. This researcher commented, "I can do anything to anybody here at the University as long as I don't call it research."

Perceived value of the IRB

All the participants saw the value of the IRB process in theory. The process can strengthen the conceptualization of the project, as it not only forces applicants to carefully explain the design but also provides applicants with feedback. For example, one researcher described an iterative process in which the IRB "would problem solve and toss some of those questions back at us," which led to a more thorough design.

The process also can counter the tendency for researchers to think predominantly in terms of benefits, and instead encourages researchers to think carefully about the potential harms and how to minimize these. As one researcher stated, the IRB is positioned well to "closely examine the protections for the subjects...and to look for potential problems with the procedures, to find our blind spots." The notion of finding "blind spots" was voiced by another researcher who equated the IRB's approval as an assurance that the research team was "not blindly fooling ourselves that these things will work or won't hurt people." Others voiced concern that without an independent review there is a risk of intentional or inadvertent harm to study participants.

Other researchers voiced mixed feelings about the process. For some it seems burdensome yet also is understandable given the historical violations. One researcher's comment exemplifies this conflicted feeling, "When I look at it from my own point of view, I think of it as a big headache, but when I am ... thinking about it from a point of view of participants or how things ought to happen, I think of it as extremely important."

For others, the stated purpose of the IRB was valued, but the actual process did not necessarily strengthen the ethics. The actual value of the IRB review may depend upon whether the committee understands the research proposal, which requires that the proposal is conceptualized well and/or that the review committee is familiar with the proposed methodology. The value may be undermined, however, if researchers complete their applications with an emphasis on gaining approval rather than critically examining the ethics. As one researcher shared,

“More seasoned researchers know how to word IRB applications so they could pass muster for the review board, but that doesn’t necessarily reflect the content of their research.”

Perceptions of the IRB application process

The application provides a structure to strengthen research ethics; for example, completion of the application can help minimize problems with coercion. A researcher described the application as a means “to crystallize what is the purpose of the study, what are the benefits, and what are the risks...it also helps us think through what the supportive measures are we need.” “Supportive measures” include having trained professionals on staff or strategies to assure data security. The application was also equated to a final checklist, which helps assure a clear presentation of the information.

In completing the application, several researchers reported that the anticipation of IRB feedback also strengthens ethics. For example, one researcher described omitting sensitive questions when she could not justify these questions given the project’s stated purpose. Another researcher shared that the application “sharpens your awareness of the rational process of seeking an exception ...When you know that this kind of question is coming at you and you have to think through ‘just how are we going to be responsive to that special vulnerability,’ you’re likely to be a more competent researcher.”

For others, ethical issues were considered prior to submission and consequently the application did not strengthen the ethics. A researcher described how ethics were considered at the time of the grant submission, and that the application was just a means to tell the “tale” to the IRB. For others, ethical issues were covered within the social work curriculum, and therefore researchers tend to be “pretty well-versed in the ethics of the situation by the time we get to the IRB process.” Other comments suggested that the application fails to effectively highlight all the relevant ethical issues and for one researcher it seems to create a sense of paranoia since it “takes it to extremes where you are asked to think of every contingency,” which in theory might be a good idea, but “in practice ends up taking a lot of energy.”

Areas of feedback

As part of the review, researchers receive written IRB feedback on their human subjects’ application that may include questions of clarification or required revisions. The feedback is oftentimes quite lengthy, which one researcher described as “shocking.” The IRB feedback was

assessed in terms of 1) its perceived impact on the research project, 2) whether it was perceived as negotiable or mandatory, and 3) whether the IRB raised recurring questions or concerns.

Recommendations that strengthened

IRB feedback at times clarified consent forms and reduced potential risks to study participants. One researcher described the feedback process as having to “spell out in our consent form where audiotapes would be stored and how the identifiable data would be kept and destroyed by a certain date. It helped us create a protocol about what are we going to do.” Other examples of valuable feedback included recommendations to develop community resource lists for study participants, and feedback on interview questions to reduce the potential risk to study participants. IRB feedback also helped researchers understand and apply the human subjects’ regulations, such as how to ethically proceed with a passive consent process.

Recommendations that did not strengthen

Many researchers did not think the IRB feedback strengthened the research. For some, this was because the application process acted as a checklist and the ethical issues were identified prior to feedback, and for others the feedback seemed more about semantics or details. This type of feedback potentially hindered the research progress yet was not viewed as weakening the study. Comments regarding feedback that did not strengthen the design focused primarily on issues with the consent form.

At times, the requirements for informed consent appear “unwieldy.” One researcher shared that her initial consent seemed more readily understandable than the revised form. The IRB required a level of detail and formality that may have decreased the likelihood that study participants would actually read and retain the information. Similarly, another researcher commented that while the level of detail required made the consent form “more exact,” it also made it “more onerous to read,” which is particularly problematic for study participants with limited reading skills.

The language requirements did not always seem to strengthen the ethics. For one researcher, the revisions to the consent form were “just a lot about conforming to the established acceptable language.” For others, the language requirements were perceived as disconcerting or even inappropriate. Examples of this include:

- A requirement to use the term “subject” rather than “study participant,” which created a “power relationship” that was “philosophically at odds with how we try to interact with people.”
- A recommendation to reduce the consent form’s reading level, in essence requesting a “dummying down effect.”
- A requirement to translate a consent form, even though the study participants were unlikely to be literate in their native language.

Responding to IRB feedback

After identifying feedback that did not strengthen the design, researchers were asked whether they incorporated these changes. Some researchers sensed that certain changes were negotiable while others were mandatory.

Negotiable

Primarily experienced researchers, defined as having submitted at least three applications to the IRB, saw recommendations as negotiable. One researcher stated that investigators should not unquestioningly incorporate IRB feedback if it potentially weakens the ethics. This researcher cited an example in which the IRB recommended the consent form include a statement about repercussions to future insurance. The researcher felt that while the risk existed, the prominence of a statement would suggest that participants decline STD screens in order to avoid future problems securing health insurance. Morally and ethically, the researcher opposed this suggestion and negotiated with the committee for an acceptable approach. Another researcher provided an example of how she successfully negotiated an informed consent format by explaining “if the format is not something that people are going to read and understand accurately, in fact that is deterring our ability to fully inform participants.”

Mandatory

Some researchers complied with the requested IRB changes even when they questioned whether the feedback actually strengthened research ethics. The language and tone of the written IRB feedback contributed to an assumption that the feedback was mandatory or at least required if approval was to occur in a timely fashion. In some instances, researchers questioned the ethical rationale for certain requirements, yet they realized state or federal regulations required these changes. This issue arose mainly in the context of requirements for research with prisoners.

Within the response to why changes were made, several researchers used either an analogy that conveyed a sense of the IRB's power or battle metaphors. These included:

- “The sense I have is that this is a body that can completely hold up your research or not. They could hold it hostage for months, so unless it's something that I really feel is worth bickering over, and it would have to be fairly significant for me to want to bicker over it, I would just answer the question. Pick your fights, pick your battles.”
- “I guess there is this sort of aura of combat...that this is an adversarial relationship and I think that I suffer from some of those assumptions myself, but in fact when I have asked people for help, they have been very helpful.”
- “It feels quite often that the IRB is this sort of god to which we must bow if we're going to be allowed to do what we want to do.”

Analysis of IRB written feedback

A content analysis of the written IRB feedback was conducted to assess the repeated concerns or questions raised by the IRB. Additionally, researchers rated the frequency of IRB feedback they received in eight topics, which were chosen by the authors based on their experiences in helping researchers with the IRB process. These topics included: informed consent language, content, and format; recruitment approaches; confidentiality; anonymity; sampling concerns; and scientific merit.

Content analysis of written IRB feedback

Nineteen of the researchers provided a copy of their IRB feedback and their responses to the IRB. One researcher did not provide feedback, as her co-investigator was also interviewed and submitted the information. There were six categories within the structure of the IRB feedback form. Analysis entailed tabulating the number of IRB comments that fell within each of these categories. Across the 19 feedback forms, there were 255 comments. The categories and their frequency were as follows: “additional information” (n=139), “revisions in the consent form” (n=92), “revisions in the recruitment advertisement” (n=9), “revisions in the initial contact letter” (n=7), “revisions in the telephone script” (n=6), and “revisions in the eligibility screen” (n=2). The majority of the “additional information” items asked the researcher to clarify or confirm. The revision items primarily asked the researcher to add or modify. In all instances, the researchers complied with the IRB feedback by either making the required modifications or providing clarification. Below is a detailed description of the two largest categories.

Additional analysis was done on the two larger categories, “additional information” and “revisions in the consent form.” The authors independently coded these two categories to identify

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sub-categories. The five most frequently cited areas within “additional information” were study procedures (n= 59), data management (n= 30), discrepancies within the application materials (n= 9), submission of finalized materials (n= 8), and submission of letters of cooperation (n= 7). Many of these IRB comments requested clarification or confirmation, followed by the requirement to revise the consent form accordingly. The following tables provide greater detail on the three most frequently cited topics within the study procedures and data management sub-categories.

Table I. Most frequent feedback issues regarding study procedures (n=59)

Issue	Example questions or concerns
Recruitment (n=16)	Who will approach participants and how, content of the recruitment texts
Survey/interview procedures (n=16)	Content issues, specifics of administration
Sampling (n=9)	Eligibility criteria, selection process

Table II. Most frequent feedback issues regarding data management (n=30)

Issue	Example questions or concerns
Confidentiality (n=18)	Use of study codes, certificates of confidentiality, data security provisions
Audio-tape plans (n=7)	Who has access to tapes, transcription plans, use of tapes
Record extraction (n=4)	What information will be extracted, who will access records, consent of participants

The second most frequent topic of IRB feedback was revisions to the consent form. These comments addressed issues of content, language, format, and the process of obtaining consent. Revisions to the content were the most frequent areas of feedback. These comments included the need to: 1) specify how long the data would be maintained in identifiable form, 2) include sample questions, 3) clarify risks and/or benefits, 4) seek permission to extract data from personal records, 5) specify the audio-taping plan, 6) provide greater detail on study procedures, and 7) state participation is voluntary. The IRB raised each of these areas of feedback with at least five of the nineteen researchers.

Feedback to a lesser extent addressed issues of consent formatting and language. The most common formatting topic was to adhere to the standardized format, which included using the *Journal of Social Work Values and Ethics*, Fall, 2005, Volume 2, Number 2 -page 39

appropriate font size. In terms of language related comments, these focused on reading level, translation, and grammatical suggestions. In several instances, the IRB included verbatim suggestions for how to revise the consent form. For example, whole paragraphs were re-written using shorter sentences and lay language. Feedback also focused upon the informed consent process, explaining the requirements for written consent for certain projects or suggesting a waiver of consent for other projects.

Researchers' self-report of IRB feedback

Overall, researchers identified informed consent language and content as the areas receiving the most feedback. Changes to the language involved reducing the reading level and translation requirements, while changes to the content involved inclusion of the most sensitive study questions or statements about the study's risks. Recruitment scripts and concerns with confidentiality were the next most frequent areas of feedback.

Researchers reported less feedback regarding informed consent formatting, concerns with anonymity, and scientific and sampling issues. Explanations for the lower feedback rates in these areas included the availability of informed consent templates, few anonymous studies, and the IRB's tendency to focus on ethical rather than scientific issues. Additionally, several researchers attributed the low rates of feedback from learning through past experiences. For example, through previous submissions researchers learned how to write a consent form to meet IRB standards.

Researchers also generated a list of "other" areas of IRB feedback. These included the need to correct inconsistencies across application materials, submit additional materials, and specify strategies to respond to child abuse as well as domestic violence. These areas of feedback were perceived as strengthening the ethical design.

Comparison of researchers' self-reports and the IRB written feedback

The content analysis identified recurring areas of feedback that were not included in researchers' self-reports. For example, researchers would benefit from additional information regarding how to effectively describe study procedures and strategies to increase data management security. Both the researchers' self-reports and the IRB written feedback identified the consent form (especially content) as a recurring area for IRB feedback. It should be noted, however, that not all the feedback on informed consent was perceived as strengthening ethics.

Assessment of practical support and recommendations

IRB

Respondents were asked what type of IRB resources would be helpful, which could include resources already offered or resources that should be offered. The primary themes that emerged from the data were 1) opportunities to dialogue with IRB staff, 2) revised human subject applications, 3) computer-based suggestions, 3) posting of sample forms and checklists on the human subjects' division Web site, and 4) trainings and workshops.

Repeatedly, researchers acknowledged that the IRB staff is extremely busy. To increase accessibility to a knowledgeable IRB staff, Universities need to allocate greater resources, including funding for increased staffing and staff training opportunities.

Opportunities to dialogue

Many of the researchers discussed how written communication with the IRB is less desirable than a phone call or face-to-face meeting. Verbal communication allows for dialogue in which the researcher and the IRB can discuss concerns and strategies to strengthen a proposal. One researcher described a positive experience resulting from a phone conversation with the IRB.

“It made it [so]...it wasn't some anonymous committee somewhere sitting in judgment...she actually framed each of the concerns in a way that made me understand that it wasn't this onerous hurdle, but the objective was to make me think about the implications of my research.”

Consultation prior to the IRB application submission was another point when dialogue could improve the thoroughness and quality of applications. As one researcher stated, “I would rather do this in a way they'll approve versus disapprove because it saves me time.” While consultation may help, this researcher recognized that it does not guarantee IRB approval. Effectiveness of consultation may depend upon the IRB's familiarity with the range of social work research approaches. For example, one researcher requested access to IRB staff who are knowledgeable about when an evaluation project requires IRB review.

Another suggestion was to involve principal investigators during the IRB review. This initially would be more time-consuming for both the researcher and the review committee but may clarify issues within the application and ultimately reduce the amount of feedback. Overall dialogue was considered a means to reduce the written feedback, to create a greater sense of collegiality, and to avoid seeing the process as adversarial.

Revised human subjects' applications

As stands IRB applications may seem confusing or inapplicable to the range of social work methodologies. A challenge exists when a single application is expected to adequately account for the specifics of every project. One researcher suggested developing a separate application for social-behavioral research to enhance the relevancy of the questions. Several qualitative researchers also requested that the application not assume the experimental design as the norm, and thereby account for research approaches in which data collection is not a “one shot quick interview or survey.” Comments about the application from other qualitative researchers included “it was awkward to try and fit my explanation of my methodological process” and “filling something out where you feel like a square peg fitting into a round hole gives the whole thing a flavor that isn’t very helpful.”

Additional recommendations to strengthen the application included inserting an orienting paragraph and clarifying terms. Particularly for first time applicants, it may help to include an orienting paragraph that describes the ethical considerations behind the application questions. As stands, applicants may not fully consider the ethical intent and therefore view the application as a bureaucratic necessity. In terms of clarification of terms, applicants may have varied interpretations of what constitutes a benefit or a risk. For example, one person may consider a “benefit” to be payment, while another may think in more global terms. Another area requiring greater clarity is how to differentiate between the three levels of research review (exempt, minimal risk, full review).

Computer-based suggestions

A mechanism for researchers to access information online regarding the status of their application would help researchers know whether their application was received and when it is scheduled for review. Currently, a researcher described how it is “a mystery as to when the committee was going to see [the application].” A question was also raised whether the IRB could compute the maximum waiting time based upon historical and seasonal trends. Posting an approximate turnaround time would help researchers plan their timelines. A researcher acknowledged that an estimated timeline depends not only on the IRB’s workload, but also on the quality of submissions, as a poorly conceptualized project will require extensive revisions. Another computer-based suggestion was to distribute electronic newsletters that provide “up to the minute

updates” on regulatory changes and relevant topics. One suggestion, either for a newsletter or as part of the IRB’s Web site, was to post a statement outlining what researchers might expect after their application is reviewed, and a description of the researcher’s rights and responsibilities, including steps researchers can take if they disagree with the IRB’s feedback.

Posting of sample forms and checklists

Researchers advocated for the posting of sample application responses and materials. One researcher suggested “sample consent forms, sample scripts, sample review packets of completed applications from A to Z in various disciplines.” Posting checklists (e.g., on the required content for newspaper advertisements) also could help researchers submit materials that are in compliance. Following a checklist also may help eliminate the sense of “being judged.” Several researchers described this sense of “being judged” particularly when communication with the IRB relied upon written correspondence and lacked personal contact. For example, a researcher commented that “there’s a certain ‘gotcha’ feeling...it sets up a really unfortunate dynamic where people feel like they’re being found out and judged to be not ethical.”

Training and workshops

Several researchers found the mandatory NIH trainings helpful to understanding the historical factors behind the regulations. Other suggestions included offering trainings on a regular basis (e.g., quarterly) and on different topics. This would allow researchers to choose when training is most needed and which topics are relevant to their research. Suggestions for workshops included “how to apply” and sessions geared specifically to particular ethical concerns such as research involving youth.

The IRB could also sponsor workshops that promote an exchange with the researchers, allowing for discussion of the regulations and review process. Ideally this exchange would be mutually beneficial for both the IRB and researchers. For example, a dialogue between the IRB and qualitative researchers could help clarify or identify strategies to address the areas in which there potentially is quantitative bias. A researcher also shared that an orientation would help to “take a little bit of the mystery and anonymity out of the process,” as workshops provide opportunities to meet the IRB staff.

Schools of Social Work resources

Researchers identified consultation and mentorship as two key strategies to provide support with the human subject's process.

Consultation

Consultation within the School of Social Work was the most frequent recommendation. Whereas consultation with the IRB was also desired, several researchers felt in-house consultation would be equally if not more effective as an in-house consultant would be more aware of the range of social work research approaches.

Researchers generated a list of supportive tasks for an in-house consultant.

- Organize an orientation to the process, integrating an overview of the ethical rationale for the process with the actual required procedures.
- Create a flow chart of the review process, including the steps to be taken within the school and the IRB.
- Ensure that communication flows effectively between the school and the IRB.
- Coordinate with the IRB to assure access to templates (e.g., of consent forms) relevant to the wide range of methodologies used in social work.
- Create a file with sample application material, including IRB written feedback and researchers' responses.
- Be accessible and supportive, extending services to include social work researchers who are connected to the University system and working in the field.
- Review applications prior to submission to the IRB.
- Refer applicants to researchers experienced with the review process and who use similar methodologies or examine similar substantive areas.
- Collaborate with the IRB to develop Web-based tutorials on research ethics and the human subjects review process.

Mentors

Schools of Social Work could also benefit from a formalized system of mentorship between experienced and new social work researchers. Mentors could provide assistance with such aspects as the review process timeline and how to think through issues of risks and benefits. One researcher suggested developing a "system that links student research projects with people who have done similar work providing a systematic way for people to talk about IRB applications, what's expected, and how to think about ethical issues." The value of a mentor, however, may depend upon whether the mentor has "some real experience, the time to communicate, and some examples."

Discussion

The ultimate purpose of this study was to identify recommendations to support social work researchers with the IRB process. Contrary to what we had expected, there were not significant differences according to whether the respondent was a student, staff, or faculty researcher. Instead, differences emerged primarily by the type of methodology used, for example, program evaluation or qualitative research.

Recommendations that emerged from the interview responses included steps that require action or consideration by the University, the IRB, the School of Social Work, and the human subjects' applicant. These recommendations address the major themes that surfaced within the interviews. These themes include the challenges associated with 1) impersonal written feedback, and a lack of opportunity for verbal communication with the IRB, 2) the perception that the review process is not fully relevant to the range of social work research approaches, and 3) areas of confusion regarding regulatory or review process requirements.

The University and the IRB

Many of the recommendations require that the University provide adequate resources to the IRB. As one researcher urged, "I beseech the central administration to give the human subjects office more resources because the long waits and the inaccessibility of knowledgeable people are really my only complaints."

Recommendations for the IRB included 1) increase opportunities for verbal communication, 2) provide a succinct overview of the entire process, 3) examine the application and review process for research assumptions that may not be applicable to all social work research, 4) provide sample materials and training relevant to different research approaches and topics, and 5) provide additional information to address the recurring questions or concerns raised in the written feedback. These suggestions include aspects that IRBs may already do, as well as aspects that researchers would like to see.

Schools of Social Work

Schools of Social Work can support researchers by providing sufficient resources for a consultant who could act as the "point person" for human subjects' applicants. The consultant can provide guidance, refer applicants to experienced researchers, and serve as the liaison to the IRB. As a liaison, the consultant can keep the school informed of regulatory changes and foster a

positive relationship between the IRB and the school. Beyond increasing collegiality, Grigsby and Roof (1993) purport that a relationship with the IRB can “help researchers to improve research proposals, so that IRB approval can be easily obtained and so that the rights of research subjects will be maintained” (p. 460). A formalized mentoring system could also support the consultant.

Based upon our experiences offering support to social work researchers, we suggest the consultant and the applicant meet in person when the applicant has questions. If the applicant is submitting for the first time, the consultant could provide an overview of the process, including the purpose of the review and how the process flows. After listening to the applicant describe his or her proposed research, the consultant could help assess the level of review that may be required, highlight the ethical concerns, and suggest strategies to minimize these concerns. The consultant should encourage the applicant to contact the IRB if there are additional concerns and help counter any adversarial perceptions of the IRB. To facilitate the consultant’s job with student research projects, the faculty supervisor should first provide an overview of research ethics and the IRB process, as well as guidance with ethical and scientific design.

As Gibelman and Gelman (2001) suggest, the school might also consider how research ethics are presented within the curriculum. While one researcher felt that research classes covered ethics, others voiced a desire to learn more about ethical issues in general as well as specific to different methodologies. An increased understanding of the ethical principles that inform the human subjects process could help decrease the resistance to the IRB process. Recommendations to infuse ethics into the curriculum included inviting IRB staff or experienced social work researchers to present to research classes. Researchers should also be encouraged to read their professional code of ethics, as well as the Belmont Report.

5.3 Human subjects’ applicant

Human subjects’ applicants must be accountable and provide the IRB a clear description of the purpose and procedures of their studies. This includes describing the study population and explaining whether the benefits outweigh the risks. If risks exist, researchers should outline the measures they will take to minimize risks and explain why the study is important (Kitson et al., 1996). To facilitate the human subjects, review process, applicants also should be aware of and exercise their right to contact the IRB to ask questions or seek advice. Applicants are also encouraged to volunteer as IRB reviewers and contribute their skills and knowledge to the process.

Future Directions

The recommendations reflect the experiences and perceptions of twenty social work researchers with one IRB at a large university that conducts a high volume of research. Recommendations for future studies include comparing experiences across universities, as well as including the perspectives of IRB staff and reviewers. More specifically, future studies should include study participants from social work programs where there is a range in the volume of research conducted. Another suggestion is to compare experiences by whether or not a researcher's IRB has a dedicated social-behavioral research review committee. Whereas additional research on this topic is needed, the study findings and recommendations ideally will generate discussion among social workers and their IRBs on how to facilitate the review process. The recommendations can provide guidance for these discussions with the ultimate aim of strengthening the review process and contributing to the ethical conduct of research.

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