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ARTICLE

Qualitative Inquiry and the IRB

Protection at all Costs?

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ABSTRACT
Implications of Institutional Review Board (IRB) decisions, especially for qualitative inquirers, may be that already marginalized voices continue to go unvoiced. Using a constructivist inquiry as a case study, this article examines IRB assessment of risk for interpretive qualitative research.

KEY WORDS:

Institutional Review Board

IRB

protection

qualitative inquiry

qualitative research

research risk

sampling

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QUALITATIVE INQUIRY AND THE IRB: PROTECTION AT ALL COSTS?

The Common Rule, Department of Health and Human Services (DHHS) Title 45 Code of U.S. Federal Regulations (CFR) § 46.111 Criteria for IRB Approval of Research, the federal policy for protection of human subjects, was accepted by most US Universities in 1991 (White, 2007), making Institutional Review Board (IRB) approval a legal requirement before beginning any research project involving participants in the USA. It is based on underlying assumptions inherent to the biomedical model of research (Johnson, 2004) as well as the analytic framework of principlism, the prevailing ethical system within bioethics (Shore, 2006). Neither of these assumptions is appropriate for interpretive qualitative research.

The principlism framework tends to over simplify ethical considerations to facilitate adherence resulting in the principles becoming normative guidelines. Such simplification calls into question who should have the power to define the principles within qualitative research when culture and community often play a pivotal role. Without careful reflection of the intended definitions, they may simply reflect beliefs and assumptions of race, gender, and class supporting the status quo and potentially impeding the viability of interventive or change focused research (Antle and Regehr, 2003; Malone et al., 2006). While it is not the position of this author to imply that oversight is not necessary, it is the author's assertion that the positions often taken by IRBs are worth critically considering, especially for interpretive qualitative research when issues of risk are being considered.

The Research Project

The research project being used as an example of the ill fit between the interpretation of risk and protection by a US University IRB and qualitative research was a dissertation constructivist inquiry into the meanings of the term domestic violence. Constructivist inquiry is an interpretive qualitative research methodology that incorporates multiple standpoints in an effort to achieve a more sophisticated understanding of the issue being explored for all the participants, including the inquirer. Multiple perspectives are brought together in a non-hierarchical manner, valuing all positions as equally relevant and important for investigation and analysis (Leisey, 2007; Rodwell, 1998).

The intention of this inquiry was to explore the multiple meanings of domestic violence with the multiple stakeholder groups involved with the problem of domestic violence. It was hoped that engaging members of the community in this project would assist in the understanding of how the term domestic violence was understood and the subsequent policy and intervention implications. Facilitating a dialogue between the participants in ways that would increase their knowledge about their own perceptions and the perceptions of others who either provided or received domestic violence services was also an

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important dimension of the project. Inquiry participants were members of five stakeholder groups identified as being connected with the problem of domestic violence. These stakeholder groups included domestic violence advocates, individuals who provided batterer intervention programs (BIPs), members of the criminal justice system who responded specifically to this problem, and individuals who had received services, either as someone who had been hurt in a relationship or who had at least been accused of hurting someone else in a relationship. These stakeholder groups were chosen after a prior ethnography (Rodwell, 1998) indicated that these groups would have significant and unique perspectives on the meaning of the term domestic violence.

Constructivist inquiry is designed to provide safe space for multiple perspectives to be heard and explored (Leisey, 2007) while also providing guidelines for incorporating the multiple perspectives sought (Rodwell, 1998). To achieve maximum variation in the data, purposive sampling is used. Typical cases are sampled along with extreme cases and critical cases. Convenience sampling is a recommended sampling strategy when paired with serial nomination or snowball sampling in order to incorporate multiple perspectives that may not be known to the inquirer at the beginning of the project. Expanding the pool of participants in this way makes it possible to include all voices available to the inquirer – especially those that the inquirer would not otherwise have heard. This is especially important for projects that include voices often marginalized, such as individuals who receive domestic violence services.

In the process of designing this constructivist inquiry, snowball sampling was chosen as a logical sampling method. Discussed with the dissertation chair and the dissertation committee, it appeared to be the best way to find service receivers for the project. Issues of privacy were discussed especially for those individuals who received services. It was decided that the benefit of inclusion of voices from those who are often not included outweighed the potential privacy issues. Additionally, because the goal of the inquiry was to raise the consciousness of both the participants and the inquirer, it was believed that this project could also be understood as interventive research, providing additional benefits to the participants. Subsequently snowball sampling was written into the IRB application and submitted for the IRB panel's approval.

Other than a request for clarification, the only change required by the IRB was a change in the sampling strategy for those potential participants who received services from domestic violence advocates. Service receiver participants who received services from BIP providers or the criminal justice system did not require an alternative sampling strategy. The suggested change was to have an inquiry participant provide potential participants with information regarding the inquiry, leaving the potential participant to contact the inquirer if interested. Because the change was only required of recruiting individuals who received domestic violence advocate services, the IRB was asked to reconsider based on two important conceptual considerations.

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First the IRB was asked to re-evaluate the sampling method in light of the historical use of snowball sampling to collect information from marginalized and hard to reach populations (Browne, 2005; Kaplan et al., 1987; Monette et al., 2005). Recruiting participants for a project is often the most difficult step in the research process, especially when the participants desired are members of a marginalized group. Browne (2005) found that snowball sampling provided a way to find, recruit and maintain such participants. The hermeneutic process used in constructivist research requires engagement over a period of time, with multiple interviews, member checks, and reviews requested of the participants. Browne's (2005) findings, especially in regards to maintaining participation, supported the use of snowball sampling.

Second, the IRB was asked to consider the importance of the sampling method in regards to the conceptual design of the project. Important to the hermeneutic process was the inclusion of participants who have something to contribute to the process, or, as Miles and Huberman (1994: 28) say of snowball sampling, it is important to have cases that are 'information rich'. The importance of the emergent nature of the project was highlighted, pointing out that participants with diverging beliefs and attitudes needed to be included. Requesting a participant to act as an intermediary between the inquirer and a potential participant would create a situation where it is possible that only people who agree with the current participant would be invited to be part of the inquiry.

Unfortunately, the IRB would not be swayed. In order to gain IRB approval, the recruitment strategy, and hence the sampling methodology had to be changed. The strategy decided upon and ultimately approved included the use of snowball sampling for all service providers and the use of flyers to recruit all domestic violence service receivers, regardless of the services being received. Flyers were distributed and posted at service provider agencies and during group meetings. When the flyers were to be distributed at group meetings, the inquirer was located within the agency in case a potential participant had questions concerning the project or the participation process. At no time was any service provider made aware of who had participated, or how many participants there were.

When the inquiry concluded, there were a total of 23 participants. Seven of the participants belonged to the criminal justice community. The other 16 were equally divided among the other 4 communities: domestic violence advocates, BIP service providers, and individuals who received domestic violence services, 4 identified as receiving domestic violence advocacy services, 4 identified as receiving BIP services. It is not possible to know the number of voices silenced, as the process of identifying those voices was not permitted.

Although the number of service receivers was similar to the number of service providers in each category, it was not felt that the same level of saturation was attained in the service receiver categories. Saturation, the collection

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of data to the point of redundancy, was attained in the service provider categories relatively quickly, even across dimensions of ethnicity and gender. There was also much diversity in age and ethnicity among service providers. While able to ask service providers to suggest potential participants who had life experiences that were dissimilar, this search for diversity was much more challenging when searching for different life experiences among service receivers. Among the service receiver participants, there seemed to be much more diversity in experience and perception of what the term domestic violence meant to each of them. Rigor for constructivist inquiries is determined by the inclusion of different perspectives, not on the range of participants as determined by demographics or other measurements. It is impossible to know what perspectives were not identified.

For the inquiry, the result of the amended recruiting strategy was the potential absence of some voices and perspectives. It is difficult to recruit participants for a research project when concerns of being judged and feelings of shame and embarrassment are present. Yet it is important to hear those voices especially when considering the effectiveness or adequacy of social policy. While it is understandable that issues of social risk are incorporated into IRB considerations, it is also important to consider the context of the research being proposed, the identity and experience of the researcher submitting the application, and the benefits of the process for those who choose to participate. As an interventive research methodology, constructivist inquiry is not a traditional research methodology. Consequently, it is possible that a more thorough understanding of the inquiry process would have engaged more potential participants with alternative and dissimilar experiences. The inclusion of these voices could have been important for both the participants and the inquiry itself. As the intention of this research methodology is increased self-awareness and more sophisticated topic understanding (Rodwell, 1998), it may have been empowering for service receivers to hear what other members of the community understood about the term domestic violence. In fact, many of the service receiver participants found the information shared with them after the analysis to be enlightening and interesting to consider (Leisey, 2007).

For a constructivist inquiry, the process of informed consent is not a single task to be completed prior to data collection; it is an ongoing occurrence. Each time a participant was contacted consent was again sought. This included a conversation in regards to the amount of confidentiality the inquirer could warrant as well as the intention of the project. Ensuring that the participants understood their role in the project was integral to the process of the inquiry. Expecting them to decide upon their interest or their willingness to participate without this understanding is unrealistic. None of the participants had ever heard of a constructivist inquiry, and therefore needed the introductory conversation to make an informed decision.

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One of the justifications for not allowing snowball sampling for participants receiving domestic violence advocacy services was that identifying as a domestic violence *victim* would be embarrassing. The IRB required the use of an alternative strategy only for participants receiving services from a domestic violence advocate. There was no similar or parallel concern for individuals receiving services from either BIP providers or the criminal justice system. Concern for feelings of embarrassment and shame are important considerations, especially considering the continued stigma of domestic violence. In fact, some of the service receiver participants shared that the idea of talking with someone they did not know about their experiences was intimidating. Concerns about being judged and feelings of shame and embarrassment made most of them question participation, regardless of the type of services they were receiving. Those who received domestic violence advocate services felt embarrassment and shame for not making better decisions. Service receivers were ashamed and embarrassed for having gotten into trouble and for needing help. Overcoming these concerns seemed to be possible during the informed consent process, but getting participants to that point was a difficult task. Addressing these issues directly through the use of snowball sampling may have resulted in larger numbers of service receiver participants. Allowing potential service receivers to interact with the inquirer prior to making their decision, respecting their ability to decide for themselves, could have provided the opportunity for other service receivers to participate. Volunteering to participate in a project such as this can only happen once the expectations of the project are understood.

Those who were able to participate shared that the project encouraged them to consider domestic violence from perspectives that they had not thought about previously. According to them, the deeper and more sophisticated understandings gained would (and did) influence their interaction with the problem of domestic violence. The denial of this potential benefit was, perhaps, an unanticipated consequence of the snowball sampling decision, yet potential participants did not have the same opportunities to gain new insight and understanding.

The opportunity to have one's voice heard and considered equally among all the other voices within the inquiry is a basic tenet of constructivist inquiry (Leisey, 2007; Rodwell, 1998). For many service receivers, it seemed to be important that their experiences and perspectives would be shared with service providers and that this sharing might influence service provision in the future. One participant shared that it was only because of this that he agreed to be a part of the inquiry. He felt that his experience was never considered in how services are provided. This dimension of the methodology is difficult to convey through the use of flyers.

The sampling and recruitment requirements of a constructivist inquiry are based on the underlying assumptions of the method (Rodwell, 1998).

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Included in the assumptions are the beliefs that knowledge is constructed, contextual, multiple and value laden, and that it exists in the participants of the exploration. Research is believed to be a social activity that should be non-hierarchical, honoring the expertise of the participants' multiple perspectives (Leisey, 2007). These underlying assumptions are neither similar nor congruent to those that support research conducted in a more traditional methodology and on which the common rule was created.

The Common Rule

When considering the sampling and recruitment requirements of this constructivist inquiry, it is worth interrogating The Common Rule as to how it is understood. The Common Rule is currently used by seventeen different federal agencies, necessitating a one-size-fits-all approach (Pritchard, 2002). The criteria for IRB approval of research include protecting the privacy and confidentiality of participants and the data they share (protection), obtaining informed consent (respect), and maximizing the benefits and minimizing the risk for human subjects (beneficence) (Forster, 2002).

Generally speaking, IRB approval is sought in order to protect research participants, but the biomedical model is a poor fit for qualitative research (Johnson, 2004). Much has already been written discussing the poorness of fit between the guiding principles of the Belmont Report and qualitative research. The biomedical model on which IRB approval is often based presumes that the researcher is the expert, fully in control of the project, able to identify the specific settings, time frames, procedures, and the risk-benefit judgments necessary to complete the IRB application (Lederman, 2006). Often it is this presumption of researcher as expert that creates a lack of fit. Johnson (2004), Lederman (2006) and Shore (2006) explore the inherent vertical power hierarchy between the researcher and the researched as often interpreted by IRBs. Even the reliance of the IRB on the use of biomedical models, Gambrill (2001) points out incorporates the inherent hierarchies found within most universities. Lederman (2006), Shore (2006) and White (2007) also explore how issues of sampling and protection are often paternalistically defined. Commonly, the presumption is that all research participants require protection, that all power resides within the researcher, and that risk is defined similarly by all involved.

Privilege and Protection

While acknowledging that all researchers, including interpretive qualitative researchers, are in a position of relative privilege in relationship to the research process (knowledge of the research process, research skills, and often research experience), research participants in constructivist inquiries are considered co-creators of the knowledge that emerges. Intrinsic to traditional biomedical model research, though, is the paternalism of the experts determining normative

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functioning, or in this case of domestic violence, determining what is, or should be, shameful (Gambrill, 2001; Ungar and Nichol, 2002). Because most IRB panel members have been socialized to understand research from a traditional medical model they are left without enough understanding of interpretive, qualitative proposals to make decisions that match the needs of the research methodology being presented (Pritchard, 2002).

The reliance on predetermined labels of who is and is not vulnerable implies that those who have been labeled as such do not have the capacity to determine if they would be at risk, given the context of the project. Without distinguishing between behavioral and biomedical risk, it is not possible to understand what risk a potential participant may experience. According to Forster (2002: 171), IRBs should consider the degree of sensitivity of the information, but should also use 'the standard of a reasonable member of the research population, and consider whether such a reasonable member would consider the information collected in the research to be private'. In fact, Gallant (2002: 406) reminds researchers that, 'It is not the IRB's responsibility to eliminate risk, which is often an inherent component of research on sensitive topics'. For domestic violence survivors and other stigmatized populations, inclusion in a research project that provides an opportunity to be heard without being judged may be empowering (Israel and Hay, 2006).

In the constructivist inquiry discussed, the decision to deny the use of snowball sampling for domestic violence advocate service receivers implies that there is something shameful about receiving those services, a perspective that is not shared by many who provide or receive those services. Subsequently, as Gambrill (2001) suggests, potential voices may have been protected into silence, removing their voice even without their consent. The Belmont report states that:

> To show lack of respect for an autonomous agent is to repudiate that person's considered judgments, to deny an individual the freedom to act on those considered judgments, or to withhold information . . .when there are no compelling reasons to do so. (National Commission for the Protection of Human Subjects of Biomedical and Behavior Research, 1979).

Socio-behavioral Risk and Protection

As much qualitative research is not designed according to biomedical principles (Malone et al., 2006), applying the same assessment process of risk is also not a good fit. Many qualitative research designs incorporate less researcher control of the process than is purported in quantitative research. Structured less linearly, room for emergence is often an important feature (Ungar and Nichol, 2002). Fieldwork, the experience of collecting data through persistent observation, interaction, and relationship with the participants of a research project in context (Moeran, 2005), has been explained as a 'disciplined' relinquishing of control (Lederman, 2006: 485), requiring an openness to contingency, an openness to

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shifting slightly in order to respond to participants needs, that is not as important in biomedical research.

Additionally, issues of culture, of both the researcher and the participants, must be included in the contextualizing of the risk assessment and all other ethical decisions (Makkar, 2002). Studying a problem while ignoring the social construction of that problem may also cause harm to the participants and the greater community (Ungar and Nichol, 2002). Choosing models that 'legitimize the experiences of those who have historically gone unheard, or whose experiences have been misunderstood or misrepresented' (Antle and Regehr, 2003: 142), is a way to reduce this risk as well as incorporate a dimension of fairness within the research project, perhaps even attending to a more equitable distribution of risks and benefits (Shaw, 2003).

Based on the promotion of possible social change – of *doing good* (Childress, 2006; Israel and Hay, 2006) rather than principlism, much interpretive qualitative research turns the expected power hierarchy upside down and assumes that the researcher is not all-powerful. Consent is conceptualized as a negotiated development, not something that can be granted in the beginning based on the research design provided. Prefaced on the expectation of emergence, agreeing to participate in such a project requires interaction and understanding between the researcher and the potential participant throughout the project. Often, this type of research is conducted as an intervention with the intention of spurring change; making louder the voice of those who are generally without voice within more traditional research (Ungar and Nichol, 2002). Through such a process, participants may become empowered by their participation (Johnson, 2004) as domestic violence service receivers reported (Leisey, 2007).

When including marginalized voices is important, the risk of excluding a voice that, although difficult to access, may provide invaluable insight and wisdom to the process is an important risk to consider. This risk of exclusion is not an inherent aspect of the biomedical risk assessment. Because constructivist inquiry is, by its very nature, interventive, service receivers had the potential for social benefits, such as increased self awareness and the social consciousness raising of those who were providing services (Antle and Regehr, 2003).

Denying the opportunity to decide whether or not to participate in an interventive research project could be interpreted as an inappropriate risk; a consequence of a focusing on doing no harm as opposed to doing good. 'We should not forget that most research subjects are competent, autonomous adults and – absent from willful deception by the investigator – can usually judge for themselves the degree to which they choose to reveal information about their personal lives' (Gallant, 2006: 406). Protecting potential participants from this experience can be interpreted as a disempowering act, creating barriers to providing services (Ungar and Nichol, 2002). Often simply the process of interventive

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qualitative research is as much a benefit as the findings or results of the entire project (Childress, 2006). Specifically for domestic violence research, Felson and Outlaw (2007) report that individuals who experience domestic violence are often working to reclaim their right to self-determination as a consequence of a controlling relationship.

CONCLUSION

Socially just qualitative research has the capacity to bring forward the voices seldom heard as a way to include marginalized groups into our discussion and into our community. Without these voices only a partial understanding of our society is possible. Including members from all of the identified stakeholder groups is imperative to a constructivist inquiry. Through the inclusion of multiple voices and perspectives in this example, a more sophisticated and informed understanding of the term domestic violence was able to be reached. It is likely, however, that the understanding would have been richer with the inclusion of more service receiver voices. As researchers it is important to continue to explore ways to bring forward the voices of those seldom heard. It is equally important to continue to interrogate the inherent assumptions of the policies under that the research is done, especially as it impacts the capacity to do socially just research.

Recognizing the complexity of the issues involved, it seems appropriate to encourage the self-awareness of panel members as they relate to personal and professional values. Specifically, panel members should explore their values and beliefs in regards to research pertaining to social problems and issues. In this experience, it seemed that IRB decisions about sampling were based on projections from panelist's own experiences and opinions. Unfortunately, they were not shared by the service receivers who participated. At issue was the amount of risk inherent in being identified as someone who had experienced domestic violence. This risk was considered large enough for the IRB to withhold approval of the application until snowball sampling was replaced with another sampling strategy. Participants in the study were surprised by the IRB decision, especially since it did not include the risk for those accused of causing harm. The implication of this decision for the project participants was that it must be more embarrassing to be the person hurt than the person accused of doing the hurting. The stigma of being involved in a domestic violence situation is one of the barriers to seeking help. Changing the perception that being involved in a domestic violence situation is shameful is something the domestic violence advocacy community has attempted for many years.

Self-reflection should not only be related to research participants but also to the panelists' values, beliefs, and skills as they pertain to research methodology and subject matter. This reflection would be enriched through

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the continued education of IRB panel members in regards to new and or alternative research methods and their underlying assumptions, especially those research methodologies that are focused on change.

Simply understanding the tenets of the research being proposed will not be enough. IRBs need to incorporate the potential benefits of the research for participants and the greater community as well as the unanticipated risk of not making interventions available into their risk assessment. This broader perspective may provide opportunities for social change as well as for knowledge generation that has not been possible in the past.

When published in 1979, the Belmont Report was an important addition to the research community. A response to egregious research practices; it provided oversight guidelines created to ensure participants safety. After two decades, however, it may be time to re-examine the federal interpretation and implementation of this important document. Social science research has continued to evolve. It may be time for a more sophisticated understanding of what protection means within the social-behavioral research community, resulting in the development and implementation of new procedures to ensure participant's safety regardless of the research methodology involved.

While IRBs follow federal regulations and policies, IRB panelists are in the unique position of interacting with researchers and observing the unanticipated consequences of the policies they enforce. Experienced IRB panelists need to share their experiences and observations in order to have policies that do not impede the protection of potential research participants regardless of the research methodology being employed.

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