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Investigators' Successful Strategies for Working with Institutional Review Boards

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Abstract

This study was designed to identify successful strategies used by investigators for working with their Institutional Review Boards (IRBs) in conducting human subjects research. Telephone interviews were conducted with 46 investigators representing nursing, medicine, and social work. Interview transcripts were analyzed using qualitative descriptive methods. Investigators emphasized the importance of intentionally cultivating positive relationships with IRB staff and members, and managing bureaucracy. A few used evasive measures to avoid conflict with IRBs. Few successful strategies were identified for working with multiple IRBs. Although most investigators developed successful methods for working with IRBs, further research is needed on how differences in IRB culture affect human subjects protection, and on best approaches to IRB approval of multi-site studies.

All human subjects research in the United States (US) is governed by principles outlined in The Belmont Report: respect for persons, beneficence, and justice (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1979). These principles are codified in federal regulations under 45 CFR 46, or The Common Rule, which governs institutional review board (IRB) reviews of research protocols involving human subjects (Office for Human Research Protections from Research Risks, 2009).

IRBs vary considerably in how they interpret these regulations (Larson, Bratts, Zwanziger, & Stone, 2004), and tension has been reported in relationships between investigators and IRBs (Keith-Spiegel & Koocher, 2005; Klitzman, 2011). This tension may be related in part to federal requirements focused on detailed documentation, and institutional policies that seem to some researchers to be designed to protect institutions more than human subjects (Fost & Levine, 2007; Pritchard, 2011). Although investigators acknowledge the importance of human subjects protection and the need for research oversight, they also report that many IRBs lack members with sufficient expertise to judge the ethical merits of some research. IRB reviewers are sometimes perceived as arbitrary and inconsistent in their reviews, recommendations, and decisions about protocols (Burris & Moss, 2006; Communication Scholars' Narratives, 2005).

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Strategies have been recommended previously for improving relationships between medical education researchers at the departmental level and IRBs (Carline, O'Sullivan, Gruppen, & Richardson-Nassif, 2007), but little is known about strategies used by individual investigators when working with IRBs. Our goal was to identify strategies used by funded investigators to deal successfully with their IRBs for protection of human subjects.

Methods

The data for this report come from a qualitative study of the effect of ethical concerns on palliative and end-of-life care research. The details of the study approach have been previously described (Hickman et al., 2012). This report is based on an analysis of interview data describing investigators' general IRB strategies that were not specific to palliative and end-of-life care research.

Sampling Plan

The target population for the parent study was principal investigators of studies of terminally ill people and their families. Exclusion criteria, adapted from Lorenz et al. (2004), were studies conducted outside the US, clinical trials focusing on the treatment of primary disease processes, studies with physiologic indicators as the only outcomes, and studies in which investigators addressed professional education programs, legal, or regulatory issues. Also excluded were studies in which data were collected prior to 2005.

Potentially eligible studies were identified through publicly available sources including the National Institutes of Health (NIH) grant database, foundation websites, and conference proceedings. A purposeful, stratified sampling procedure was used to ensure proportional representation of studies by funding source (NIH, private, other), methods (quantitative, qualitative, or mixed), and design (intervention or descriptive). The principal investigator (PI) of each study was invited via electronic mail to participate. Sixty-five studies were identified that met eligibility criteria. Of these, 21 (28.4%) investigators either refused or did not respond to the invitation to participate. Non-participants' studies were similar to the final sample in terms of design, methods, and funding mechanisms.

Sample

The final sample consisted of 43 studies represented by 46 investigator participants. Studies included mixed methods (n = 20; 47%), solely qualitative methods (n = 10; 23%), and solely quantitative methods (n = 13; 30%). Additional characteristics of the studies have been described elsewhere (Hickman et al., 2012).

For 40 studies, the PIs were interviewed. For the other 3 studies, a project director alone, a project director with the PI, and a co-investigator with the PI were interviewed. In one case for which only the project director was interviewed, the overall nature or quality of the interview data did not differ from investigator interviews. In the two cases where a PI and co-investigator or PI and project director were interviewed together, the participants interacted during the interview to clarify timelines and logistical details.

The participants were primarily female (n = 32; 74.4%) and Caucasian (n = 41; 95.3%). Their professional backgrounds included medicine (n = 18; 41.9%), nursing (n = 16; 37.2%), the social sciences (n = 7; 16.3%), and related fields (n = 2; 4.7%). Twelve investigators (27.9%) had conducted 3 or fewer end-of-life studies, 19 (44.2%) had conducted 4 to 10 studies, and 12 (27.9%) had conducted between 11 and 30 studies. Thirty-one investigators (72.1%) had experience as grant reviewers, and 12 (27.9%) had experience as IRB members or chairs.

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Procedures

Investigators were interviewed via telephone using a semi-structured, open-ended interview guide in which they were asked to describe their experiences managing ethical concerns in the development, review, and conduct of palliative and end-of-life care studies, and to share information about the IRB review process, including initial reviews, IRB-requested changes, and review of investigator-initiated amendments. Demographics (e.g., age, gender, discipline) were recorded for respondents. When more than one team member participated, demographics were recorded only for the more senior respondent.

All interviews were digitally recorded and transcribed without participant identifiers. Investigators compared the transcripts with the audio tapes to ensure accuracy of the documents. Qualitative data were stored and managed using NVivo 8 software (QSR International, 2010); quantitative data were analyzed using SPSS, version 19 (IBM, 2010).

Analysis

Interview data were analyzed using qualitative descriptive methods (Ayres, Kavanaugh, & Knafl, 2003; Miles & Huberman, 1994). Preliminary analysis involved line-by-line, open coding of data to assign labels to key ideas (Miles & Huberman, 1994). The analysts individually read and labeled text data in the first nine transcripts and then met as a team to compare labels and develop an initial set of codes. At least two analysts read and coded each of the remaining 34 interviews. Differences in coding were discussed by all three analysts and resolved through consensus. The team met regularly to discuss coding interpretations and thematic analyses, and resolve discrepancies. A methods expert reviewed the analysis for overall quality (described in Hickman et al., 2012).

Examination of individual cases revealed recurring ideas or codes. Individual codes were then examined across the cases to identify common manifestations and variations in how phenomena were experienced. Cross-case comparisons yielded patterns of investigator-IRB relationships that crossed study designs, methods, and populations. Through these comparisons we identified commonly used strategies for working with IRBs as well as variations in how participants responded to the challenges they encountered. The team also examined differences in strategies associated with attributes of the investigators (Ayres et al., 2003), such as prior experiences with IRBs, academic discipline, and past or current participation on IRBs. These analytic processes resulted in descriptions of types of strategies investigators used to receive IRB approval.

Findings

Investigators used four kinds of strategies for successfully working with IRBs. Two strategies were common to all: cultivating a positive relationship with the IRB staff and/or board, and managing bureaucracy. The third strategy, avoiding conflict, was identified by several investigators. Finally, working with multiple IRBs was a recurring challenge for which few successful strategies were identified. Strategies and illustrative quotations are provided in Table 1.

Cultivating a Positive Investigator-IRB Relationship

Relationships with IRB staff and members were considered critical to successful and minimally burdensome IRB reviews. More experienced investigators indicated that cultivating a relationship with an IRB was a developmental process that took time and built on a record of IRB-approved studies without adverse events. Investigators talked about intentionally reaching out to IRB staff or members in a cordial fashion through meetings and telephone conversations. These interactions provided opportunities for investigators to

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demonstrate their knowledge of the study topic and sensitivity regarding participants. Each study provided a new opportunity for interactions that could build an investigator's credibility and foster a positive working relationship with the board and staff. One very experienced participant emphasized that it was especially important for new investigators to learn the value of intentionally building relationships with IRBs.

IRBs differed, however, in the extent to which they encouraged interaction between investigators and IRB staff and board members. Some participants experienced their IRBs as partners whose role was to facilitate the ethical conduct of research and compliance with federal regulations. A climate of partnership enabled investigators to call or visit with IRB staff or board members to discuss ethical concerns and strategies for managing these concerns even prior to submitting application materials. In contrast, other boards operated with a more autocratic style that provided little or no assistance or feedback to the investigator beyond identifying potential issues or concerns. In these situations, IRBs identified problems and expected investigators to determine how to satisfactorily resolve the concerns before the study could receive final approval. In these situations, investigators noted that the absence of shared problem-solving could result in substantial delays in the final approval of study protocols, as investigators tried to guess what would be acceptable to the IRBs. Several investigators noted also that changes in membership and leadership of IRBs could result in major changes in how the IRB worked with investigators, necessitating the development of new strategies by the investigator to sustain positive working relationships.

Develop personal relationships—One successful strategy was to cultivate positive relationships with IRB staff and board members through personal contact, while taking care to be respectful and responsive during all interactions. Investigators requested in-person meetings whenever possible and called to ask questions rather than communicating by electronic mail. They also perceived their attendance at board reviews as part of cultivating relationships and building credibility, especially regarding sensitive or complicated issues. With multiple study reviews over time, in-person discussions created opportunities to educate boards about the study population and the science. For example, one investigator believed that her positive and long-term relationship with an IRB led to changes in mandatory reporting of anticipated deaths as adverse events in studies for which the eligibility criteria included the expectation of death.

Opportunities to talk with staff or board members informally or during board reviews enabled investigators to share their clinical and/or research expertise and to demonstrate their understanding of sensitive issues that might arise. Investigators reported that although it was sometimes inconvenient, it was critically important to take the time to develop and sustain long-term relationships with IRB members and staff.

Demonstrate expertise—Part of building relationships included appearing confident and knowledgeable about one's research. Both during in-person interactions with IRB members and staff and in their written application materials, investigators established their expertise by describing their relevant research, clinical and educational experiences. Additionally, in proposal documents or IRB presentations, investigators cited evidence of participants' positive experiences in similar studies. At institutions where researchers were routinely invited to present their proposals during IRB review processes, investigators reported that face-to-face interactions enabled them to present themselves as trustworthy and knowledgeable while addressing concerns or clarifying information. Several participants noted that review processes had become easier over time because they had repeatedly demonstrated their ability to conduct studies without adverse effects, thus earning IRBs' trust.

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Make life easy for the IRB—Part of building positive relationships with IRBs involved making the process as smooth and trouble-free as possible for staff and board members. This included carefully following the rules particular to that IRB. Investigators reported that IRBs had particular styles, and the investigators were focused on submitting materials that were consistent with what they understood to be the IRB's preferences.

Examples of following IRB guidelines and preferences included ensuring consistency between protocols and grant application materials and always using IRB-developed consent templates and language. Another strategy to ease the process for an IRB was to proactively anticipate concerns by providing detailed information that addressed potential issues. As an example, several investigators included as part of the consent form specific procedures for responding to emotional distress during data collection. Another investigator developed boilerplate language about qualitative approaches to include in all qualitative proposal applications to help board members understand the methodology. Finally, investigators described the importance of attending to details and making sure that all IRB forms were complete.

Proactively seek IRB advice—Asking IRBs for guidance was an effective way to move the research forward while developing positive relationships. Investigators described meeting with staff members in advance to learn about issues of concern to the IRB and to collaboratively solve potential problems. Examples were given in which staff or IRB chairs facilitated initial or study modification approval based on earlier, in-depth discussions with investigators. If problems arose during a study, existing investigator-IRB relationships facilitated developing solutions. Thus, relationships fostered collaborative problem-solving, and the process of shared problem-solving in turn strengthened positive relationships.

Managing Bureaucracy

Participants almost universally acknowledged that IRBs could be very bureaucratic and often appeared more focused on the accuracy of paperwork than on how human subjects would be protected. Several investigators described many modifications required by IRBs as "nitpicky." The nature and extent of bureaucracy was influenced by the composition of the board, which influenced members' approaches to risk assessment for study participants and for the organization. In some organizations, rules and application formats changed frequently, making it difficult for investigators to keep up to date on review processes. Additionally, local and national events influenced board regulations and the degree of restrictiveness boards applied to applications. Several participants described increased documentation requirements and scrutiny by their boards after internal audits or negative publicity regarding other university boards. The following strategies were used to manage bureaucratic issues in working with IRBs.

Anticipate bureaucratic processes—Participants indicated that challenges of paperwork and changing IRB policies and rules were common and to be expected. Experienced investigators built extra time into their study timelines to manage anticipated delays and came to view IRB reviews as part of the process of study development. One investigator noted that, no matter how carefully an IRB application was completed, there always would be required changes before approval, and this should be planned for in study timelines. Some researchers initiated IRB applications as soon as grant proposals were submitted, to avoid delays when granting agencies required IRB approval before releasing funds.

Investigators also consulted with IRBs in advance on specific issues and requested pre-reviews to minimize delays in the review process. Using precise IRB terminology and

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current forms was important, although additional work-around materials and processes sometimes were needed for specific study populations. For example, one investigator developed a board-approved brochure that used population-appropriate language and graphics to help participants understand the jargon-laden, multi-page consent document. In this case, the IRB approved use of the brochure in conjunction with the standard consent form. When IRBs were perceived as less willing to collaborate, investigators tracked how these boards had responded to previous study applications as a means of anticipating that board's ethical concerns.

Investigators noted that it also was important to recognize any non-negotiable IRB requirements (e.g., proxy consent would not be permitted for a non-interventional study) and to design studies that adhered to these requirements. One participant commented that this meant some research deemed important to advancing science was simply not going to happen at that institution.

Learn from other investigators' successes—Consultation with experienced and successful investigators who were familiar with a particular IRB was useful in preparing application materials that conformed to that IRB's preferences. This approach helped to minimize or avoid delays associated with rejection of the application or requests for major modifications. Participants from large organizations with multiple review boards learned from colleagues of the boards with reputations for being more flexible and open-minded in their approach to human subjects oversight and tried to have their studies reviewed by those boards.

Influence IRB composition—More than 25% of investigators had prior or current IRB service experience. Investigators recommended that colleagues with critical topical content or methodological expertise serve on IRBs to ensure an appropriate breadth of knowledge among board members. Some investigators encouraged their own study staff (e.g., project directors) to serve on IRBs. These approaches had at least two benefits: investigators learned about the IRB's processes from an insider perspective that helped them in planning study protocols and materials, and investigators were able to use their own or a colleague's presence on the board to encourage changes in processes that were difficult to navigate. Being on IRBs was also described as an excellent way to develop positive and trusting relationships with staff and other board members.

Avoiding Conflict

A small number of investigators reported using ethically questionable avoidance tactics in working with their IRB. Avoidance tactics were used when the investigators believed IRBs did not understand the science, the population, or the setting and would be unwilling to consider alternative ways to conduct research that involved minimal risk. The strategies seemed designed to minimize the likelihood of close scrutiny by the IRB or outright refusal for approval of a study. Examples included overwhelming an IRB with excruciating detail, telling an IRB only what the investigators believed the IRBs really needed to know, or telling an IRB what it wanted to hear, even if this was not an accurate representation of the research. These investigators believed that they were just "playing the game" and had no bearing on the ethical protection of study subjects. They did not believe they were putting study subjects at risk. Rather, they perceived that their IRBs lacked understanding of real-world conditions and were more concerned with appearing vigilant in their oversight of studies.

Although only a few participants reported using these tactics, they all had more than 10 years of experience conducting funded studies and had clinical as well as research

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experience in their areas of study. Their studies included both descriptive and interventional designs and qualitative, quantitative and mixed methods.

Several other experienced investigators who did not mention avoidance tactics nonetheless expressed frustration at IRBs' barriers to approval of non-invasive studies. They observed that behavioral research using surveys, interviews, or observations seemed subject to far more scrutiny by their IRBs than clinical drug or instrumentation trials or invasive study procedures. These experienced investigators also perceived that some IRB members seemed more pre-occupied with protecting the reputation or legal status of the institution than with human subjects protections. These examples illustrate some investigators' perception that requirements by their IRBs might not be aligned with actual study risks or federal regulations.

Working with Multiple IRBs

Several participants identified challenges in working with multiple IRBs for multi-site studies. They noted that institutions viewed risk differently and had different ethical concerns related to recruitment, consent, data collection, and data management. Further, investigators described areas of disagreement between IRBs on issues that had little to do with human subjects protections, such as which institution's name would appear on study letterhead. Investigators reported they were often the messengers between organizations' IRB staff who should have talked directly with each other. Study delays could be significant in these situations.

Although investigators described their frustrations with institutional differences, they were generally unable to identify satisfactory strategies for avoiding or resolving differences unless there were ongoing, multi-site partnerships. One investigator, who regularly partnered with colleagues at another institution, indicated that colleagues completed all IRB documentation for their own sites rather than using a shared IRB application, which worked well. Most investigators expressed concerns that differing views of risk as well as logistical variations across IRBs discouraged multi-site research at a time when large samples are needed to advance science.

Discussion

The most common strategies investigators used to work successfully with their IRBs were based on building and sustaining respectful, personal relationships, which enhanced trust and collaboration between investigators and IRB members or staff. Key components for actively cultivating these relationships were personal contact, proactive and ongoing communications, demonstrating expertise in one's area of research, minimizing the IRB's administrative burden, and proactively seeking advice from the IRB. Investigators also paid careful attention to IRB policies and preferences regarding human subjects approval at their institutions. These strategies were all described by highly experienced investigators and support the importance of developing positive investigator-IRB relationships as part of junior investigators' education. Others have reported that IRBs perceived as fair, willing to hear the investigator's perspective, and open to respectfully working with investigators are considered "best practice" IRBs (Carline et al., 2007; Keith-Spiegel, Koocher, & Tabachnick, 2006).

Although bureaucratic procedures and processes frustrated many investigators, they identified several strategies to minimize their influence on time and resources. Although most participants viewed bureaucracy as inevitable, this view did not ameliorate feelings of irritation, particularly when an IRB was perceived as more interested in the use of preferred

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language or grammar and organizational protection than in substantive issues related to protecting human subjects.

The avoidance tactics described by a small number of investigators are similar to those reported by Keith-Spiegel and Koocher (2005), who used an organizational justice framework to help explain these behaviors. Investigators who believe they have been unfairly treated may intentionally deceive the IRB because of frustration about excessive oversight, perceived inconsistencies in decisions, and demeaning or disrespectful IRB interactions with investigators. In an interview, Keith-Spiegel suggested, “an IRB’s overzealousness or uncooperative attitude could drive some research underground” (*IRB Advisor*, 2006, p. 75). Although deceptive strategies are unacceptable on ethical and scientific grounds, Keith-Spiegel et al. (2006) indicated that IRBs have the opportunity to ameliorate negative practices by assessing how investigators perceive the board and creating a climate of justice and fairness in their deliberations.

The investigators identified few strategies for successfully negotiating burdensome processes associated with multi-IRB approvals for multi-site research. These findings affirm the growing body of evidence that although multi-site research is highly desirable, multi-site IRB approvals are time- and resource-intensive for investigators (Burman et al., 2003; Larson et al., 2004; Mansbach, Acholonu, Clark, & Camargo, 2007). Of note, the Common Rule has no requirement that each institution in a multi-site study conduct its own IRB review (Presidential Commission for the Study of Bioethical Issues, 2011). There is little evidence that multiple agency reviews add to human subjects protections (Menikoff, 2010; Presidential Commission for the Study of Bioethical Issues, 2011), and some authors have suggested that duplicative, multi-site reviews may diminish scientific rigor (Burman et al., 2003; Larson et al., 2004). Bierer (2011) has recommended exploring alternatives such as the model used by the Central Institutional Review Board for cancer research (Christian et al., 2002).

Limitations

Our findings reflect only the experiences of investigators who agreed to be interviewed. The strategies they identified may be different than strategies of those who chose not to participate or did not meet our parent study inclusion criteria. The data were collected during a study of ethical challenges in conducting palliative and end-of-life research. The findings may have been different if collected from investigators of other topical areas. A particular strength of the study is the inclusion of investigators who used a range of study designs and were, overall, highly experienced investigators with long histories of working with IRBs.

Conclusions and Recommendations

Investigators recognized that IRBs have authority to review human subjects research, and investigators are interested in working collaboratively with IRBs to enhance the safety of research participants. Many successfully used a collaborative approach that involved deliberately striving to develop positive relationships with IRB staff, taking bureaucracy into account, and shaping IRB membership.

Investigators reported frustration and challenges in obtaining multiple IRB approvals for much-needed multi-site studies. We support the view that the Common Rule may need updating specifically to address research that happens across multiple sites amid expanding regulatory requirements (Bierer, 2011; Fost & Levine, 2007; Presidential Commission for the Study of Bioethical Issues, 2011).

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It is troubling that a small number of highly experienced investigators reported using unethical strategies to avoid what they consider as inappropriate, unnecessary, or self-serving oversight by IRBs. More research is needed to evaluate how investigators interact with IRBs, both from the investigators' and IRBs' perspectives, and create a collaborative rather than an adversarial culture.

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Table 1

Investigators' Strategies for Working with Institutional Review Boards

Focus	Strategy	Exemplar Statements
Cultivating a Positive Investigator- IRB Relationship	Develop a personal relationship with IRB staff and board members. Demonstrate expertise	The number one, two and three things to do are to get to know the chair and spend time with them seeking their advice and counsel. There is a developmental process to working with an IRB that investigators need to know about. … No one has time, but you save yourself a lot of time [by doing this]. …each protocol is an opportunity to educate people… I tell them we have a lot of experience, and we have trained researcher interviewers to empathically engage patients and if any distress comes up to be able to deal with that. We give them data on how infrequent it is for patients to get distressed by questionnaires…and try to establish that we have been able to conduct research in this population without interfering with a patient's care and comfort, things like that.
	Make life easy for the IRB	Our IRB has [a template] that gives you verbiage to use for qualitative research. They like to see that in the IRB application. …it is important really to understand how to complete all the forms sufficiently so the IRB really understands the context of the study.
	Proactively seek IRB advice	We tend to meet with them [IRB] first because most of the time you can get 90% of the biggest problems worked out before you submit everything and then you're more ready to go than going in cold… They [IRB] told me the questions I would have to answer in an IRB amendment so I wrote up a justification and they offered to review a draft…and send it to the chair who would probably review my request, again as a draft.
Managing Bureaucracy	Anticipate bureaucratic processes	While the IRB approves almost everything with modification, nothing gets approved the first time or rapidly. There is always something they want you to change. It may take 4 to 6 months. So, we start the IRB protocol before receiving the notice of funding. The IRB has a lot of very specific language that they want in there and they want it worded in a very specific way… [there] is a lot of going back and forth until we get it just so.
	Learn from other investigators' successes	It is very helpful to talk to someone who has worked with your IRB before, using similar methodologies to what you are using.
	Influence board composition	I'm on the IRB so I know the kinds of things that they are interested in. I finally got one of the members of the health board to sit on the social and behavior sciences IRB, and then got it through.
Avoiding Conflict	Playing the game	So we pad the number of subjects that we say will be enrolled…. They aren't concerned if we enroll less, yet go ballistic if you enroll two more subjects than you said you will… You tell the IRB only what you have to tell them. I don't mean that you lie… I think sometimes you dig yourself a hole by saying too much.
Working with Multiple IRBs	On-site help	If I had to do it from scratch, I just wouldn't even want to think about it because it's just crazy…the number of forms and the amount of things they ask about…I have somebody over there who does most of that work for me.