

Article 79

The Complete Proposal: Integrating IRB Requirements Into the Research Proposal Development Process

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Introduction

Federal regulations (HHS Human Subject Protection Regulations, 2009) require that persons participating in research studies be treated in an ethical manner during the course of their participation. To ensure that these standards are met, regulations further mandate the review of research proposals by Institutional Review Boards (IRBs; also called Human Subjects Committees) and require researchers to have obtained approval from an IRB prior to conducting their research.

The American Counseling Association Code of Ethics (2005, Section G.1) are in accordance with these federal regulations and acknowledge that the appropriate treatment of research participants is a fundamental ethical responsibility. As such, most, if not all, counselors and counselor researchers appreciate the value and importance of IRB review and approval. However, it is often the case that researchers wait until their research proposals are completed to begin work on their human subjects' application and hurriedly complete this application in their rush to begin collecting data. Rather than being viewed as a vital and integral component of the research process, the creation and submission of an IRB application is often considered a hoop to jump through (Dell, Schmidt, & Meara, 2006) and an inconvenience blocking the path to actually "conducting" one's research.

Waiting until a research proposal is completed before beginning an IRB application fails to recognize that consideration of the components/details required for IRB review during the development of a research project may, in fact, improve the quality of that research. Many aspects of an IRB application require elucidation of the practical details surrounding the conduct of various parts of a research project. Consideration of these details as one works their way through the conceptualization of a project, particularly the methods and procedures, not only ensures that an ethical research project has been developed, it also minimizes the chances that the IRB will require extensive modification and revisions to one's project. Early consideration of these details saves time, rewrites, and having to redesign one's research. In other words, it allows for

the creation of a stronger proposal from the beginning, one that will readily receive approval from the IRB.

The purpose of this paper is to present the ways in which the specific components of an IRB review can be integrated into the conceptualization and design of a research project. Rather than blocking the path to conducting research, incorporating these details and considering IRB requirements clears the path so that indeed the counselor researcher is truly ready to begin their project.

IRB Review: Content and Process

Although most researchers understand the overall purpose of the human subjects review, for many, particularly student and novice counselor researchers, the specifics of the review process and the content of an IRB proposal remains a mystery.

Background

In 1974, following the passage of the National Research Act, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research was formed and commissioned to identify ethical standards and guidelines for the conduct of research with human participants. The Belmont Report was written as a result of the Commission's work (1979). This report identifies justice, beneficence, and respect for persons as the three ethical principles which serve as the foundation for ethical research. The Commission further identified three applications of these principles: informed consent, assessment of risks and benefits, and recruitment of subjects as the guidelines which must be met to assure ethical treatment of research participants.

Specific Guidelines

Following the Belmont Report, specific requirements regarding the protection of human subjects as well as guidelines regarding the creation and functioning of IRBs were set out in Federal Policy Title 45 of the Code of Federal Regulations, Part 46 (HHS Human Subject Protection Regulations, 2009). These regulations identify four primary areas in which proposals are reviewed to ensure compliance with federal guidelines. The first and foremost is the risk/benefit analysis (the fundamental purpose of the IRB review) which ensures that the potential benefits to society outweigh any risks that might be associated with participation. Second is informed consent, ensuring that participants are sufficiently informed about the research to give appropriate consent regarding participation. Third is the selection of subjects, ensuring there is fair and equitable decision making in the choice and recruitment of participants, and finally, privacy and confidentiality, ensuring that the privacy of participants will be maintained and the data collected as part of participation will remain confidential and/or anonymous.

Content: Components of an IRB application

For the members of an IRB to be able to accurately assess whether a research project meets ethical standards, they need enough documentation about the project to get a complete picture of the research. This means they need detailed information not only about the design of a project but also about the procedures that will be followed

throughout the research from recruitment and gaining informed consent, to participation and possible debriefing, to keeping the data confidential and monitoring the project.

The specific documentation required by an IRB varies from institution to institution (Mertens, 2010), but typically includes the following components:

- Cover sheet – A listing title of project, researchers' names and contact information
- Description of design and procedures for the project
- Recruitment of subjects including specific documents related to that recruitment
- Risk/benefit analysis
- Discussion of confidentiality
- Debriefing procedures, if appropriate
- Informed consent procedures
- Informed consent documents

Process: Overview and Purpose of the Review

As the primary purpose of a human subjects review is to ensure the protection of persons who choose to participate in counseling (and other health related and psychological) research, human subjects committees and IRBs are given the authority to approve, deny approval, and perhaps most importantly, require changes be made to the research proposals that are presented to them. Additionally, it should be noted that institutions and organizations also retain the authority to approve and disapprove research. The caveat is that an institution cannot *approve* a research project that has been *disapproved* by a human subjects committee or IRB (HHS Human Subject Protection Regulations, 2009).

In the author's experience, most research conducted in a college setting does not place an undue risk on participants, and as such will be approved by an IRB. The few that are not approved are rejected because they have not been conceptualized or designed properly. However, given the level of detail and specification required for a human subjects application, it is rare that *any* research project is approved outright without any changes or modifications. Rather the process of IRB review usually follows a typical pattern: proposals are reviewed by committee members and recommendations for changes and/or modifications to the research protocol are made; these recommendations are sent back to the researcher who either incorporates the recommended changes into their proposals or presents additional information and a justification for the project to remain as originally designed. This process continues until the committee accepts the revised proposal, votes to approve it, and permission to conduct the research is granted.

Conceptualizing Ethical Research

Integrating the components of an IRB review into the design of a research project (and therefore, a proposal) consists of several interconnected steps. The highest priority is to address the ethical issues related to the project. Secondly, one may recognize that the IRB review process and IRB questions and components are general questions about research design and methodology. The last step is the inclusion of additional documentation required by the IRB that is not typically included in a research proposal.

Integrating these elements into the conceptualization and design of a project will make for a complete proposal.

Reframing the IRB questions/components as general questions about design is an essential step in the process of integrating the IRB review into the development of a proposal. The conceptualization of a research project is strengthened when one steps back from addressing these questions solely from an ethical stance, and views the ethical questions as methodological questions. Thinking about the ethical issues as design issues allows researchers to take into account not only *what* they are doing but also *why* they are doing it. The result is a proposal that is not only strong from an ethical point of view; it is also strong from a design point of view.

Additionally, although several components of an IRB review are regularly presented in research proposals, other more practical details, though vital to the actual conduct of research, are not usually considered explicitly in a research proposal. Including these components during the design phase of a project also saves time and energy as one begins the process of the IRB review.

The following sections of this paper provide details on the ways these interrelated steps might be utilized when conceptualizing the design, procedures, and participants section of a research proposal.

Integrating IRB Review: Design & Procedures

Initial considerations. Although surprising to some, creating a research project that utilizes sound research design is an ethical requirement. *Protecting Human Subjects, Institutional Review Board Guidebook* (Office for Protection from Research Risks (OPPR), 1993), which was created to provide additional guidance for members of IRB committees, states: "...if a research study is so methodologically flawed that little or no reliable information will result, it is unethical to put subjects at risk or even to inconvenience them through participation in such a study" (p. 4-1). This statement makes it clear that conceptualizing a valid research design is a fundamental ethical goal.

While the design of a study is a vital component of any research project, designs are typically only briefly described in research proposals. Additionally, when designing a project, many researchers also only briefly consider the design that will be used in their project whether it is an experiment, an interview, or a survey. They don't stop to consider specifics of each experimental condition, the process of the interview, and/or the length of time a survey or other instrument will take to complete. That being said, it is these considerations that are needed for an IRB review. To adequately assess potential risks associated with participation in a research project, the particular procedures and other information about methods needs to be presented. In other words, it is the nuts and bolts of the research project that needs to be outlined and described clearly for an IRB review. Moreover, consideration of these details prepares the researcher for the actual conduct of the research. And by taking the time to clearly articulate all of these aspects of the research during the conceptualization of the project, the stronger that research project will be at the end.

Addressing risks and benefits. More than any other area of relevance to an IRB, the assessment of risks and benefits is probably the one most researchers are aware of and at least minimally consider in the development of the proposal. Two broad questions need to be asked to address the risks/benefits of a specific design. First, does the design

minimize the risks to participants? Secondly, do the benefits outweigh the risks of participating? (HHS Human Subject Protection Regulations, 2009).

To begin to evaluate whether the design is structured in a way that minimizes risks to participants, one must first examine the proposed procedures and identify any possible harm or injury that might result from participation. In other words, one must ask whether the activities associated with participating in the study might put a person at risk in any way and then clearly identify what these risks might be. Specifically, when weighing the risks related to design, researchers need to look at the potential for physical harm, psychological harm, and social and/or economic harm.

Types of risk. Typical designs utilized in counseling research (i.e., outcome studies, surveys, qualitative studies, focus groups) are primarily behavioral in nature and usually do not have a lot of physical risk associated with them. Additionally, given that IRB guidelines specify a distinction between therapeutic practice and research (HHS Human Subject Protection Regulations, § 1, 2009.), risk is not traditionally assessed related to a particular treatment per se, but rather to those additional experiences that are related solely to the conduct of counseling research.

For counselors, the most likely risk is the psychological risk to participants. Counseling research often involves asking questions that may/will be invasive in some ways. We ask about psychological health and other issues that may cause distress to participants. These risks need to be identified as one develops a project.

Additionally, one must also consider potential social harm, or harm to one's reputation, that might result from participation in counseling research. The social risks related to participation in counseling research seem to fall in two categories, although both are also related to a violation of confidentiality of the data. First, is the risk related to simply choosing to participate (in contrast to the risk of participation itself). In other words, is there a risk professionally regarding participation? For example, if your participants are members of a stigmatized population, there is a potential for risk if others find out about their participation in the research. Thus, measures must be taken to ensure that participants are not 'outed' in a way that may harm them, such as providing a confidential location for the conduct of a study and not discussing the study with participant colleagues in a way that might harm them socially. Social and professional risk might also occur if the responses to a survey or interview were known to others. This is particularly an issue when group interviews are conducted. To mitigate this risk, group members are often asked to keep what was revealed in the group confidential.

Assessing the level of risk. Not only do counselor researchers (and the IRB) need to identify the risks and benefits associated with their research, they also have to determine the extent to which these risks might impact their participants. This is done by assessing the impact of the risks in two separate yet related ways. First is an assessment of the probability that any given participant may experience harm or discomfort, and second is a determination of the amount or degree of the "harm" or discomfort that may occur. These two judgments are then utilized to make an overall determination of the level of risk in any given project. Federal regulations identify two levels of risk related to any research project: those that pose minimal risk to participants and those that pose greater than minimal risk to participants (HHS Human Subject Protection Regulations, § 46.102, 2009). Research projects that pose a minimal risk are those where the likelihood and extent of the risk faced by participants is not more than what would be experienced in

daily life or by taking a physical and/or psychological examination or test. Accurate determination of the level of risk is important for counselor researchers to assess because research that presents no more than minimal risk to participants (including surveys, some interviews, and focus groups) may be eligible for an expedited, less extensive review by an IRB.

Minimizing risks. Once risks have been identified and level of risk determined, researchers must re-examine the design and procedures they have chosen to ensure that these specific procedures will minimize, to the extent possible, the potential risks to their participants. Additionally, they must identify and incorporate additional procedures that will mitigate the risks that remain.

Assessing benefits. Finally, to assess the relationship of risks to benefits, the researchers must identify the potential benefits related to the research. Is there any potential benefit to the specific participant, or is it more the benefit of knowledge gained? What are the incentives that will be offered? Is it possible that the incentive will be coercive? These are the questions that need to be answered as one conceives a research project. Although the benefits of outcome research may be easy to see, identifying the benefits of more basic research is more difficult. However, doing so may also help a researcher determine the particular justification and/or rationale for a study.

Specific IRB requirements: The first person scenario. To facilitate the IRB members' understanding of the design and procedures, some IRBs include a narrative of the project from the participant's point of view (sometimes called a first person scenario). This process provides an in depth understanding of the experimental and other procedures involved in a particular research project, which in turn allows IRB members to better assess potential risks to participants. Similarly, writing a first person scenario as one is conceptualizing research serves the same function as a pilot study, as it allows the researcher to more fully examine their procedures, again not only to ensure the ethical treatment, but also to closely examine whether the procedures they intend to implement and the structure of the design has strong internal validity.

Integrating IRB Review: Selection and Recruitment of Participants

Initial considerations. Research texts and writings about research design include discussions of targets and accessible populations as well as appropriate sampling techniques. From a human subjects' perspective, the important issue is not sampling, but rather consideration of the how the actual recruitment of participants occurs. While the proposal may include a discussion of the power analysis used to determine the number of participants needed to ensure statistical significance, the recruitment process ensures that one has considered the specific location from which participants will be recruited. As with many of the aspects of the human subjects' proposals, it is the specifics of recruiting that must be taken into account at this point. Not just the sampling technique – but from whom. What is the total number of clients to be recruited? What will the inclusion and exclusion criteria (if any) be? All these are questions that need to be addressed in the design of a project. Not just the population in general, but the specific group from which the sample will come. Not just the sampling technique to be used, but what very specific group is to be sampled from.

Addressing the equitable selection of participants. The ethical standard that underlies this component is justice; an understanding that those who “endure” the risks of research may also be expected to receive the benefit of the research (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1978). Historically, the poor, institutionalized, and prisoners were often used as research subjects without any hope or intention that they might also receive the benefit of the studies they participated in. While these injustices are not apparent today, it remains necessary for researchers to consider who they are choosing to participate in their research and why they are choosing them. Are only those who are readily available being considered? Is there a potential for coercion due to the economic or other status of the participants? These are the questions that need to be addressed.

Inclusion of racial and ethnic minorities. As stated above, the concern over selection of subjects has historically been the placing of an undue burden on particular groups or segments of the population without ensuring that they would also receive the benefits of research. Currently, the dilemma is the opposite; that *not* including certain groups in studies, specifically ethnic and racial minorities, also denies them the benefit of research (OPRR, 1993). To ensure this ethical standard is met, organizations such as the National Institutes of Health require that minorities and women be included research populations of those who are applying for grants, and/or that specific reasons for why they are not being included be presented in the grant documentation.

Given this standard, it becomes clear that it is not enough to just select participants from groups that are easily and readily accessible. Rather it is incumbent upon counselor researchers to take an extra step and ensure that minority participants are recruited to participate in their research.

Specific IRB requirements: Recruitment methods and materials. The additional documentation required by the IRB related to the selection of subjects is the recruitment materials to be used and methods by which these materials are posted. Participants may be recruited via a variety of methods including letters and/or emails to posters and posts on craigslist and other social networking sites. Although the materials used for recruitment vary, the content of the materials should not. All recruitment materials need to include a general overview of the research project, the amount of time participants will be asked to spend, and any incentives offered for participation.

To encourage a broad cross-section of participants, and ensure that minority and or other marginalized participants are recruited, counselor researchers should become aware of local and national newspapers or other outlets that have high minority readership and be sure to place ads or notices in papers that serve a variety of different minority communities.

Integrating IRB review: Informed Consent

The overarching purpose of gaining informed consent is to ensure that potential participants both *understand* the research they plan to become involved with and *voluntarily* choose to participate. To ensure this, very specific information needs to be presented to participants in a way that they can understand. This information has been outlined in the federal regulations (HHS Human Subject Protection Regulations, §46.116, 2009). Generally, for counseling research, the following specific statements or elements need to be included in a consent document. These elements should seem familiar to

counselor researchers as they parallel the components of an informed consent to provide counseling services (see ACA Code of Ethics, 2005, Section A.2). The elements include:

- A statement describing the research. This statement needs to include the purpose of the research, the total amount of time participation will take, the procedures to be followed, and the specific activities participants will be asked to complete.
- A statement regarding risks related to participation
- A statement regarding benefits to the participants or others that will result from the study. This statement should include any incentives that will be given for participating.
- A statement about the steps the researcher will take to keep participants' data/information confidential.
- A statement about who to contact regarding the study and who to contact if there are any concerns about the study. This statement usually includes the researcher's name, phone number, and email address, and also includes the contact information for the IRB that approved the study.
- A statement that participation is voluntary. This statement includes the caveat that participants may refuse to participate or may choose to terminate participation without penalty.

Although not specified by the federal regulations, most informed consent documents also include the following:

- A statement acknowledging that participants are adults over 18.
- A final summary statement indicating that the participants understand what they have read and are being asked to do and give their consent to participate.

For certain types of research, additional information needs to be included in the consent document. For example, when conducting interviews or focus groups that will be audio or videotaped, a statement letting participants know they will be taped needs to be included in the consent document. Additionally, in qualitative studies, if the researcher plans to use direct or exact quotes from participants in his or her write-up, the informed consent document typically includes a statement indicating this intent on the part of the researcher.

As stated above, an overarching purpose of gaining informed consent is to ensure that participants understand the research they are becoming involved with. This means that it is important to remember that consent is a process, not just the signing of a form. It is also essential that informed consent documents and/or scripts be written in language that is appropriate (due to age or education) for the participants. Too often, informed consent documents are written in very technical or academic language that is unfamiliar to participants. It is incumbent on the researcher to change the language to ensure that the information contained in the document is understood by the participants so that they may make an informed decision about participation.

In many ways the informed consent is the culmination of conceptualizing and integrating the components of an IRB application into the design of a project. By

addressing the pieces of the IRB application that have been discussed so far, all of the areas/items that need to be included in an informed consent document have also been addressed. Counselor researchers who follow the guidelines set out above will then have addressed all of the components that need to be included in the informed consent document. All that is left is writing the document itself.

Summary

The intent of this paper was to highlight the ways various aspects of a human subjects' application can be integrated into the conceptualization and design of a research project. Consideration of these elements forces researchers to look at the details of a research project, not only the overarching design and method.

In this way, the components of a typical research proposal and the components of a research project described in an IRB proposal are like a blueprint and specifications for the building of a house. Both are needed to ensure that permits are given and the house is built correctly, expediently, and without wasted resources. Similarly both the basic research proposal and the procedures described in the IRB proposal are needed to ensure that the research project will be designed in the best way possible. Indeed, only with both will we have the "complete" proposal.

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