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EIGHTEEN

Ethical Considerations in Research Involving Human Participants

Fernando Garzon

Ethical principles are critical in the development of a dissertation that uses people as research participants. This chapter highlights how correct application of these principles can reduce problems and unnecessary delays when doctoral students seek institutional review board (IRB) approval of their research studies and dissertation research.

CASE STUDY

Juanita is elated; she just passed her proposal defense. As she begins talking with Dr. Smith about implementing her study, he surprises her with his initial comment.

"You'll need to consider the ethical aspects of your study and get IRB approval first," he states.

"You mean the institutional review board? As my proposal has been approved by my committee, why can't I beg collecting data?"

"Well, I you understand. The following s practices. For example, John was giving a survey to elementary school teachers at his school to find out ho they felt about the level of support they receive from school administration. The principal saw some unflattering survey results laying on John's desk, and three teachers with the most negative views 'mysteriously' did not have their contracts renewed the next year."

"That's an obvious blunder. You shouldn't leave your data lying around," Juanita observed.

"Yes, but sometimes ethical violations are more subtle. Mark conducted excellent interviews with recent Latino immigrant high school students about their challenges in adjusting to the United States, but he hadn't anticipated a few of them becoming emotionally distressed as they described their experiences. Some even had flashbacks of traumatic experiences. He had no plan in place (like a referral to a mental health professional) to get additional help if something like this occurred and he didn't know how to help them himself. It was a mess."

"Yikes!" Juanita moaned.

"Susan was surveying tenth graders to find out how the quality of their relationship with their parents impacted career goals. She was shocked when she got several angry calls from parents who complained about not being informed of her study and not giving permission for their children to participate. Do you see what the problem was?"

"Well, sort of. The parents should have known about the research, right?"

"Yes. When minors are involved in research, parents need to know under most circumstances. That's a United States federal regulation. You see, the IRB focuses on research ethics in projects like yours that involve human subjects. They help you identify areas that you might inadvertently miss that could produce big ethical problems later. They ask you to think through the safeguards needed in your methodology to protect your participants."

"Okay, that makes more sense. What are the key ethical principles I need to keep in mind and where do I start?" Juanita asked.

WHAT THE RESEARCH SAYS

Institutional review boards (IRB), also sometimes called human subject review boards, are federally mandated and regulated entities that insure the rights and welfare of people participating in any research study. As discussed below, IRBs are guided by a set of ethical principles and play an integral role in institutions with faculty and students conducting research with human subjects.

Key Ethical Principles

The ethical principles that currently guide research involving human subjects were initiated out of tragic human experiments. The Nuremberg trials after World War II revealed horrendous Nazi studies on people. Even in the United States, harmful investigations have occurred. For example, sponsored by the U.S. Public Health Services, the Tuskegee Study of Untreated Syphilis in the Negro Male took place over a forty-year-period (1932–1972) and denied medical treatment (including antibiotic cures) to 399 African Americans in order to "study" the course of the disease. Over one hundred patients died.

Public outrage led Congress to establish a commission to develop basic ethical principles to guide future research with human subjects. The commission released its report in 1979, which became known as the Belmont Report (National Institutes of Health, 1979). The Belmont Report's three basic ethical principles now are codified into federal law and provide the foundation for the functioning of IRBs. The American Education Research Association has also adopted these principles.

The first principle involves *respect for persons*. Individuals must be free to make their own decisions on whether to be involved in a study, without coercion, and they must have enough information about the study to make a reasonable choice. Those with limited autonomy (e.g., children and people with limited mental capacity) must have extra protections to insure their rights and safety are maintained.

The second principle focuses on *beneficence* or "do no harm." Research must minimize potential harm to participants and maximize possible benefits. This principle directly relates to how the study is designed, how well-trained the researcher is to do the study, and what plan he or she has in place to handle potential risks and problems that could arise for participants during the course of the study.

The third principle examines *justice*. People are equal and should be treated fairly. Experiments should not take advantage of one participant population to have all the benefits of the study given to another population. For example, a breakthrough in instructional techniques for students with problems in math should not be developed on students in poor school districts and then given only to students in wealthy school districts after empirical support is gathered. Vulnerable populations must not be exploited. The burdens and benefits of research studies should be shared equitably.

Institutional Review Boards

Conceptually, IRBs help researchers apply the Belmont ethical principles to their studies. All universities in the United States with students or faculty conducting experiments with human subjects have an IRB. Two Department of Health and Human Services subdivisions (the Office of Human Research Protection and the Food and Drug Administration) are the agencies that regulate the IRB.

IRBs have significant power. They may approve a study, disapprove it, or modify its design to protect participants. They may also observe any aspect of the study's actual implementation, conduct continuing reviews of the study on at least an annual basis, and suspend or terminate a study at any time if the risks to the participants outweigh the benefits (Miser, 2005).

Students, such as Juanita, who are working on dissertations or other doctoral research projects that involve people as participants, must submit their research proposal to the IRB for approval. Class research projects also need to be reviewed at times, so students should check with their instructors about whether permission from the IRB is necessary.

There are severe consequences for students who try to by-pass the IRB when they are doing dissertations or other doctoral research projects involving human participants; this can include dismissing offending students from their academic programs. In all U.S. universities, at the very least, doctoral students will not be allowed to utilize any data in their research that was collected without IRB approval. Depending on the proposed research, this can result in some students starting their dissertation completely over from square one if the data is of the nature that it cannot be collected a second time.

The IRB consists of a committee of at least five persons from differing professions; these individuals serve as reviewers for the research projects submitted to the organization. The IRB has three levels of review, depending upon the research design, type of human subjects involved, and the risk level involved in the experiment.

Many research projects fall into the two lower levels (exempt and expedited) rather than the highest level of scrutiny (full review). The term *exempt* does not imply that the doctoral student can skip IRB application process and review. The IRB alone determines each project's official status. Projects the IRB may categorize as exempt after the review include research involving normal educational practices that occur in typical educational settings; anonymous surveys and interviews when these involve nonsensitive subjects; some anonymous cognitive, aptitude, and achievement testing; certain observation studies of public behavior; and some deidentified archival research. Studies classified as *expedited* include recorded interview studies (e.g., video, audio, photographic) and studies examining group characteristics (e.g., perception, cognition, communication, cultural beliefs). Certain medical studies may also be categorized as expedited.

All exempt and expedited projects are minimal risk, meaning that the stress involved in the studies is no more than would be experienced in daily life or routine medical or psychological examinations. *Full review* projects do not fall into the exempt and expedited categories and often involve higher than minimal risk for participants. A study's specific focus on vulnerable populations (such as children, prisoners, low SES groups) also influences how the IRB categorizes and reviews a research project.

The review time involved for exempt and expedited reviews is typically shorter than that for a full review, though the time still may be substantial. In all situations, doctoral students must plan sufficient time for the IRB review in the research timeline. The review time will vary

depending on the university and the varying responsibilities of the individuals serving on the committee.

Additionally, some IRBs send the research applicant questions and requested revisions to address prior to approval. The timeliness of responses to IRB questions and revision requests are a critical aspect of how long the entire review process takes. Talking with the dissertation committee, other faculty, and the IRB can give a general idea of the potential timeline.

Sometimes an IRB will have two different applications (one for exempt and expedited projects) and another more detailed application for more complex studies that require full review. In those cases, to help students decide which application to use, the university's IRB website will often have decision trees or other helpful guidelines. In other cases, the IRB will have just one application for all three levels of review so the distinction is less important.

The IRB Application Review Process

IRB applications are very detailed and reflect the Belmont ethical principles previously discussed. This section describes general aspects that IRBs consider in applications. For more specific information, university IRB websites and federal regulations such as 45 CFR 46 should be reviewed.

IRB applications require the principal investigator (e.g., the doctoral student) to provide a complete description of the proposed research project. The description should be written in nonspecific discipline language so reviewers from different disciplines can easily understand the study. Detailed information is required about who the participants will be, how they will be recruited, how the privacy and confidentiality of their data will be protected, a thorough analysis of the potential risks and benefits of the study, and what the informed consent process looks like in the investigation.

The application must be completed correctly with appropriate grammar and spelling. Failure to complete the application or adhere to the use of correct grammar and spelling may result in the application being returned and not reviewed.

Informed consent involves presenting information to participants about the study's purpose, procedures, risks, benefits, and the participant's rights in a manner readily understandable for the person's cultural background, language, and educational background. Many university IRB websites have templates to assist in the creation of this document. While in most exempt or expedited studies in which participants are anonymous this information is given to participants for them to keep without the researcher retaining a signed consent copy (with IRB permission),

other studies require the researcher to retain a signed informed consent document.

IRBs also have special rules for *deception-based studies* where revealing the purpose of the study in the informed consent could ruin the investigation. These rules are described on most IRB websites. Research involving children or populations with limited mental capacity generally include guardian informed consent and *child assent*. An assent provides information found in the informed consent but is provided in a manner that is consistent with the individuals' developmental stages and mental capacities.

Exceptions to the general requirement for parental consent exist in some types of research on children. For example, educational studies that focus on teaching strategies and curricular development do not need parental consent as long as the research involves minimal risk to the children.

If doctoral students conduct their research in businesses, schools, religious organizations, government entities, and other readily identifiable organizations, outside of the university, they need to gain permission to conduct their research at the location and may need to supply the IRB with documentation showing that the organizations give permission for the study to be conducted. Students always need to secure IRB approval from their sponsoring universities; they may also need to garner IRB approval from research site IRBs.

The IRB committee also examines the application to determine whether adult or child participants for the research study might be unduly coerced into participating. Employers, teachers, managers, or administrators who seek participants from their organizations must be careful about this aspect.

Appropriate safeguards to assure genuine free choice must be present. Some sample questions the IRB will consider include the following: Are there "unstated but implied" consequences for failing to participate? If volunteers get a reward at work or extra credit in a class for participating in the study, would they have other options to get a reward or extra credit if they choose not to participate? Do these other options involve about equal time and effort?

For those who choose to participate in the study, the committee will consider how their research data is safeguarded to protect privacy and confidentiality. Password protection of electronic data files, locked storage of surveys, coding of potentially identifiable individual information, and other strategies are essential. Finally, the potential benefits of being in the study (for the participant or society as a whole) are weighed against the potential risks. A sense of justice and fairness in the risks and how the benefits of the study will be shared must be clearly articulated.

STRATEGIES FOR SUCCESS

The following strategies can help students apply what is presented in this chapter and be successful when planning for and submitting an IRB application for doctoral research.

Strategy 1: Apply Ethical Principles

The key ethical principles described in the Belmont Report are critical in understanding how the IRB review process relates to any research study that involves people. It is important for the doctoral student to consider carefully how the Belmont ethical principles apply to the specific design of the study. By doing this, students can avoid the unethical practices similar to those Juanita's chair outlined in the case study and insure that the study is ethical.

Strategy 2: Always Gain IRB Approval and Plan Sufficient Time for the IRB Review

It is important that doctoral students never try to "bypass" the IRB. Severe penalties, such as dismissal from the degree program, exist at all universities. At a minimum, collected data without IRB approval must be discarded and cannot be used in the dissertation. Doctoral students should also remember that the IRB process can be lengthy (e.g., several months) and plan sufficient time for the IRB review. Talking with the dissertation committee, other university faculty, and the IRB to get an idea of the potential timeline is helpful in the planning process.

Strategy 3: Seek to Understand IRB Guidelines

When planning research and completing an IRB application, it is important for doctoral students to explore the university's IRB website thoroughly for valuable guidelines, training resources, and suggestions in completing the IRB application. When in doubt about a guideline, doctoral students can ask the IRB. For example, Juanita's planned research involves archival data from children within a school system. She is unsure if she will need to gain parental consent and child assent. Her chair advises her to email the the IRB to determine the answer to her question.

Strategy 4: Gain Multiple IRB or Organizational Approvals When Needed

Doctoral students need to begin working on obtaining any needed organization permissions while engaged in the IRB application process so it will be known whether the organization requires IRB approval before

or after it will give approval. Also, it is important to see if the organization has a research ethics committee or IRB that also requires an application process.

In the case study, when Juanita seeks permission from the school system she has selected to serve as a research site, she finds out that the school district has a research ethical board. A representative from the district tells Juanita that she will need to gain approval from this board. She is confused because she thought she only needed to obtain IRB approval from the university. Her chair informs her that it is not uncommon for researchers to gain IRB approval from their sponsoring university as well as the research sites.

QUESTIONS FOR REFLECTION

The following questions may be useful in considering how to apply the Belmont ethical principles to the IRB application.

1. How do the research methods convey a respect for the persons involved in the study?
    - Is the need for participants to have information about the study (the informed consent/assent process) adequately addressed?
    - Is it clear that there is no sense of coercion in the study?
2. In what ways does the study reflect beneficence (limiting potential risks while maximizing potential benefits to participants and society)?
    - Are sufficient safeguards for securing and protecting the data collected from participants present?
    - Are the risks sufficiently considered and is there a clear plan should a "worst-case scenario" actually occur?
    - Are there ways the study can help the participants in the future?
3. Does the study reflect justice (treating people equally and fairly)?
4. What is the average review/approval time at the university's IRB and is sufficient time included in the research timeline for this process?

RECOMMENDED RESOURCES

Office of Human Research Protection website
Your University's IRB website

Amdur, R., & Bankert, E. (2011). Institutional review board: Member handbook. Sudbury, MA: Jones and Bartlett Publishers.

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