Peter R. Finn's Commentary on "Bypassing the IRB"

Commentary On
Bypassing the IRB

This case presents a great example of a scenario that reflects the kinds of the experiences and questions that face many researchers while they plan their studies and consider the requirements for oversight by their Institutional Review Board (IRB). The case directly addresses the question of “when is IRB oversight necessary?” The cases highlights how research progress might be given priority over regulatory and ethical issues, how pressure to proceed with research may cloud one’s judgment when considering regulatory and ethical issues, how researchers may misunderstand what the regulations (45 CFR 46) mean by the term, “research,” how researchers may not fully appreciate the role of “pilot data” in the development of knowledge, and how researchers tend to put more weight on the ethical issue of beneficence and the question of risk and fail to consider the central role for the ethical principle of respect for persons.

The case describes a situation where Joshua, who appears to be an enthusiastic and well-motivated graduate student in Psychology, is about to defend his dissertation proposal in a week, but he is concerned that he does not have enough data to convince his dissertation committee of the value of his proposed method of assessing decision-making, which is new to his laboratory. He decides that the best solution is to collect some pilot data using this new method. He apparently realizes that he might need IRB review and approval for this pilot data collection, but he decides that, since he is not planning on publishing these data, he does not need IRB review and approval. He also explains to a friend that the experiment is relatively innocuous, there is not much risk involved, and the payment is too small to be coercive. Being somewhat concerned, Joshua consults with a committee member, Dr. Johanson, who is apparently enthusiastic about the new method. Dr. Johanson assures Joshua that there is no need to have the IRB review and approve the study. Finally, another graduate student likens Joshua’s experiment to didactic student projects in her research methods courses that do not need IRB oversight.

First, this case highlights how research progress can, and often is, given priority over regulatory and ethical issues. Although not explicitly stated in the case, one would imagine that Joshua, with the help of his research advisor, has been planning and working on the proposal for his dissertation project for quite some time, perhaps months. Yet, only at the last minute does he consider the ethical and regulatory issues that might affect his plans. He clearly has given a higher priority to the actual research than to the ethical or regulatory issues. In order to develop his dissertation proposal, Joshua is likely to have spent a lot of time reading the literature, conducting earlier studies, and conferring with his mentor. Apparently, he has not thought of the ethical and regulatory issues until the last minute. In fact, it would appear that the lack of time is a key factor that is affecting his decision-making regarding whether to have the IRB review his pilot project. He appears to be looking for reasons not to submit his project to the IRB, rather than carefully considering the issues and whether his project really should be reviewed by the IRB. This illustrates that Joshua is not taking seriously his responsibility as a researcher to carefully consider the ethical and regulatory issues in research with human participants, and his responsibility as a member of his university to follow university policy regarding the necessity of having all research involving human subjects reviewed by the IRB.

Second, the case illustrates how pressure to proceed with research may cloud one's judgment when considering regulatory and ethical issues. The case suggests that Joshua's primary motive is to get some data for the proposal defense, rather than to consider carefully the issues. Joshua appears to be looking for excuses by saying that he does not plan to publish these data and that there is no risk involved. Both of these explanations are fallible. First, as noted below, whether or not one plans on publishing something is not the universal definition of what is meant by "research" by the regulations. This issue is explained in more detail below, but the key to the definition of research is whether the research activity (experiment, study, etc.) is designed to develop or contribute to generalizable knowledge. Pilot data can and often does contribute to generalizable knowledge. Second, just because a project apparently does not carry appreciable risk to participants does not then mean that it does not need to be reviewed by an IRB. There are other ethical principles, such as respect for persons, legal issues, and responsibilities to one's institution that need to be attended to. Joshua's judgment appears to be clouded by his apparent conflict of interest between his primary goal of getting his proposal defended and his responsibilities regarding IRB approval. The same can be said of Dr. Johanson, whose reasons for side stepping the IRB process are even more egregious. To say that you

know what the IRB would decide and that the experiment seems fine as a rationale for not having a study reviewed is essentially telling the student that you are going to replace the IRB for this decision. Such a response is unethical and represents a clear conflict of interest and lack of understanding the reasons that universities have IRBs in the first place.

Third, this case illustrates how researchers may misunderstand what the regulations (45 CFR 46) mean by the term, “research,” and how researchers may not fully appreciate the role of “pilot data” in the development of knowledge. Research as defined by 45 CFR 46 and articulated by the Indiana University IRB means “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Not all data gathering or experimentation is necessarily research; it could be education or therapy. The difference is one of intent or primary goal.”

Some people operationalize the definition of research to say that any study constitutes research when it is possible that you will publish the data in a scholarly journal, or publish on the web for the same reasons as one would publish in a scholarly journal, or present the data to other researchers at a professional meeting, conference, seminar, or symposium. Whether or not the data is published is only part of that limited definition. Furthermore, pilot data often finds its way into dissertations and presentations at different meetings. In addition, even if one concludes at one point that the data will not ever be published or presented at a meeting, what happens if the data turn out to be far more interesting that one anticipated and one changes one’s mind about publishing and presenting? What does one do then? IRB approval cannot be given to a study that already has been completed. Finally, by its nature the purpose of pilot data is to inform scientifically the researcher about specific aspects of the experimental procedures. In many cases, such data contribute in important ways to the overall knowledge gained through the development of the experimental procedures. To say that the pilot data are not part of the actual study is often inaccurate. Along this line of reasoning, the pilot data that Joshua wants to collect is not at all the same as undergraduate didactic research training projects that are typically conducted in research methods courses. The purpose of the latter is to teach students how to do research; the purpose of the former is to provide data that will inform scientific progress. These are entirely different activities with clearly different intents.

Fourth, this case also illustrates how researchers tend to put more weight on the ethical issue of beneficence and the question of risk and fail to thoroughly consider the central role for the ethical principle of respect for persons. Joshua explains that the study is innocuous and there apparently is no real risk, which he considers as justification for bypassing the IRB. While it may be true that the experiment does not involve more than minimal risk, there is absolutely no consideration of the ethical issue of respect for persons, which involves a consideration of informed consent, how informed consent is achieved and how subjects are recruited such that they are not subject to any undue influence. The case does not discuss exactly how Joshua will attract participants at the health fair, what he will say to them, or whether he has them sign an informed consent statement, so it is unclear whether he has considered these issues. Nonetheless, the case suggests that these issues are not as important to Joshua, or to Dr. Johanson, as they should be.

Finally, the case illustrates the value of having a third party provide input when making ethical decisions about one’s own research. Researchers can become so wrapped up in their research, or so driven by their enthusiasm for their research, that they might not have the objectivity necessary to make ethical and legal judgments about their own work. Both Joshua and Dr. Johanson were so focused on the desire to get on with the research, that they missed very important issues and responsibilities regarding oversight by the IRB.