

Author's Commentary on "Bypassing the IRB"

Commentary On Bypassing the IRB

This case raises issues of the role of the IRB and the relationship between this ethical governance board and the individual researcher. Initially some issues raised by the case may seem ethically blurred. However, this is a case in which the researcher has a clear and well-established responsibility to submit a human subject's research proposal to formalized, peer oversight.

The National Research Act, Public Law 93-348, requires that any institution conducting research that involves human participants establish an Institutional Review Board. All proposals for research involving human participants must be submitted to this board, which is charged with determining the legality of the research, and more importantly, compliance with higher ethical standards. The jurisdiction of the board extends to all research conducted to add to "generalizable knowledge." These boards have ultimate authority over what research can and cannot be conducted at an institution. Research that has not yet been approved (or more obviously, been rejected by the board) cannot be pursued. The question of what constitutes "research conducted to add to generalizable knowledge" and hence, what forms of research obligate a researcher to submit to board oversight is perhaps best answered in the negative. That is, what kind of "research" falls outside the jurisdiction of the Institutional Review Board? (See Title 45 CFR Part 46.101 for complete exemptions) Pilot testing is one form that may not require formal oversight. In many cases, pilot testing of a new method or measure is first conducted with a small number of people. Often these pilot participants are members of the laboratory, graduate students, or a few of the researchers close friends. These pilot tests, of extremely limited scope, with little risk, and participants who are often also formally involved in the research, are typically exempt from IRB oversight. Note that this exemption is quite narrow. It does not include research with any possibility of risk or "pilot" research that includes participants with little connection to the laboratory. Given the limited nature of the

exemption, it may be prudent for researchers to check informally with their IRB before deciding to proceed without board oversight.

Second, data collected solely for administrative purposes are not subject to IRB oversight. For example, university Registrar offices maintain large databases of student academic records. These data are employed to track student and university progress, but are not systematically collected to answer scientific research questions. For this reason, university administrators are not required to submit their tracking system (or similar databases) to the IRB for approval.

Finally, research that is conducted in the classroom for didactic purposes is also considered exempt. For example, a professor teaching a statistics course might collect a small data set from his students in order to illustrate a statistical technique (for example, the physical height of men and women in the class). The data are clearly not collected to add to scientific knowledge and carry no potential for harm. As such, it would be unwieldy and excessive to ask this professor to submit a proposal and wait for formal approval (not to mention, a waste of time for the reviewers). This exemption is slightly less clear in the case of student led research. For example, research methods courses in psychology and sociology often involve a component in which each student (or groups of students) conducts a small study in order to provide hands-on experience with research design, data collection and statistical analysis. Typically, the student's classmates serve as the research participants. This student research is technically exempt. However, the instructor should be sensitive to ethical considerations and ensure that student research meets the same standards required of research intended to add to scientific knowledge.

It is a common misconception that research not intended to be published is also an exempt category. It is sometimes mistakenly believed that the "generalizable knowledge" clause refers only to research that is published in scientific journals. In fact, the clause should be interpreted more broadly. For example, a graduate student who conducts a small study and who plans to present this data at a departmental colloquium, but not to publish, is indeed adding to generalizable knowledge. The study was conducted to answer a research question and the obtained answer was shared with a small group of the research community. Extensive pilot testing, whether or not it is published, is also not exempt. Data obtained from these pilots contributes to the researchers understanding of the research question and even if not directly published, informs the direction of future

published research. Lack of intent to publish is not considered a legitimate reason to bypass the oversight of an ethics board. Human participants have the right to be protected by independent ethical oversight whether or not the data they contribute is ultimately printed on the published page.

The study that Joshua plans to conduct does not meet requirements for exempt research. Although the study is a “pilot” study, the use of community participants moves this proposal outside the confines of typical pilot work and must be considered by an IRB like all other research. There may be a temptation for researchers to do the work of the IRB themselves. This is illustrated by Joshua’s argument about the non-coercive nature of the gift and the limited risk of the project. However, researchers have a vested interest in the process and may not be capable of making an unbiased decision about the risks involved in their research. For example, Joshua does not seem to consider the risk the experiment may pose to individuals with gambling problems. IRB members may have noticed this risk and been able to work with Joshua to mitigate it. By pursuing his research without the input of the IRB, he lost this valuable insight. Joshua’s committee member, Dr. Johanson, also demonstrates the temptation of researchers to predict the ruling of the IRB. In addition, he provides a poor example to a graduate student. His behavior indicates to Joshua that IRBs and ethics are not primary concerns in psychological research.

Finally, the graduate student who counsels Joshua that research conducted for didactic purposes is exempt from IRB approval is correct in this point. However she is incorrect to stretch the exclusion to cover Joshua’s research. While it is true that graduate training is a learning process, it also produces (and is intended to produce) empirical findings with implications outside of the classroom. As such, the fact that the research was conducted during graduate school does not constitute a broad exemption from ethical oversight. In fact, part of graduate training ought to be in research ethics and in the applied skills of communicating with an IRB.

This case study includes many of the arguments hurried or frustrated researchers may use to justify bypassing the oversight of an ethics board. When deadlines approach it may be particularly tempting to find ways to avoid an extra step in the research process. However, all researchers who employ human subjects should be grateful for the donation that participants make to scientific knowledge and should repay this debt with a genuine consideration of their welfare. Submitting research proposals to the IRB is only one way, but an extremely important way, to ensure

that subjects are protected.

Reference

Title 45 CFR Part 46.101.