

Robert V. Labaree

Working successfully with your institutional review board

Practical advice for academic librarians

I have had several opportunities to speak at conferences about how qualitative research methods can be used to improve library practice and deepen our understanding about the relationship between libraries and those that they serve. Among the most common questions I get from people in attendance are those concerning the role and function of institutional review boards (IRBs). Some of the questions have been: “How do I know my study qualifies for review by my IRB?” “How can I speed up the application process?” “How much work is involved?” And perhaps most disconcerting to me, “What is an IRB?”

To help bring some clarity to what an IRB does and how to work effectively with staff when designing a study that uses observation, interviews, and other qualitative methods, I will explore the key features of an IRB review and discuss common challenges researchers may encounter. My intention is to provide some practical advice for academic librarians preparing application materials for studies that require oversight by their institution’s IRB. First, however, it is useful to outline the history and development of IRBs in higher education.

History

The purpose of an IRB is to examine initial research plans involving human subjects to ensure that the researcher provides individuals the opportunity to give informed consent and that they are not exposed to unreasonable risks as a consequence of their involvement in the study. IRB authority to review, seek modification of, and, in some cases, suspend

research, can be traced back to the Nuremberg Trials at end of World War II. The trials involved prosecution of 23 Nazi scientists accused of murder and inhumane treatment of prisoners used as subjects in experiments without their consent or knowledge about the consequences of their participation. In addition to issuing convictions, including sentencing seven defendants to death, the Nuremberg court set forth ten principles to guide investigators in studies involving human subjects. These principles became known as the Nuremberg Code. In 1964, the World Medical Association expanded the ethical guidelines of the Nuremberg Code by adopting the Declaration of Helsinki. These guidelines, subsequently modified several times, laid the early groundwork for the implementation of a research oversight system in higher education.^{1,2}

In the United States, the Nuremberg Code had little influence within the medical community because, as Katz noted, “It was a good code for barbarians but an unnecessary code for ordinary physician-scientists.”³ As a consequence, several ongoing medical research projects continued. The most infamous was the Tuskegee Study of Untreated Syphilis in the Negro Male, which began in 1932. This research involved enrollment of 399 illiterate and poor African American males by the U.S. Public Health Service. The study’s purpose

Robert V. Labaree is head of The von KleinSmid Library for International and Public Affairs at University of Southern California, e-mail: labaree@usc.edu

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was to track the natural progression of syphilis during a time when effective treatment was unavailable. When the *Washington Star* newspaper reported that the Tuskegee Study continued well after penicillin had become available to treat syphilis in the 1940s and that, as a consequence, 128 participants had died, 40 of their wives had caught the disease, and 19 of their children were born with congenital syphilis, Congress responded by forming the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.⁴ In 1978, the National Commission summarized three basic ethical principles—respect for persons, beneficence, and justice—underlying the acceptable conduct of research involving human subjects. This became known as the *Belmont Report*. These principles were placed into law as the Code of Federal Regulations, Title 45, Public Welfare, Part 46 Protection of Human Subjects (45 CFR 46) and are overseen by the Office for Human Research Protections within the U.S. Department of Health and Human Services. The law not only requires that any institution receiving federal funding must comply with all regulations governing research involving human subjects, but it also mandates that these institutions have in place a committee of reviewers responsible for interpreting and applying the regulations.

Potential problems and how to avoid them

There are numerous cases of researchers in the social and behavioral sciences coming into conflict with their IRBs.⁵ This has led to criticism of the regulatory oversight system in higher education that generally encompasses three broad issues: 1) as a local entity, an IRB often takes on the distinct culture of the institution it serves, leading to variations in application procedures and in how volunteer reviewers interpret the regulations;⁶ 2) IRBs were established to review research at institutions that receive federal funding, but the reality in practice is that most researchers must obtain approval for studies involving human subjects whether the research is supported by

federal funding or not; and, 3) volunteer reviewers are often physicians and biomedical researchers and, thus, may be ill prepared to apply a regulatory model developed for their disciplines to qualitative inquiry that relies on methods, such as naturalistic observation and interviewing.⁷ This criticism points to several areas of potential conflict.

A conflict can arise if the researcher is not fully versed in the application process. Because the process can vary from one institution to the next, it is important that you become familiar with the application process beforehand. Preparing an application is not unlike writing a grant proposal in that failure to pay close attention to details can lead to unnecessary delays in receiving constructive feedback and final approval. Therefore, determine whether the study requires a full IRB review or can be granted exempt or expedited status because the study involves no more than minimal risk to participants. Unnecessary delays can also be avoided by answering all of the questions on the application form and being as explicit as possible in explaining how you will conduct the research in an ethical manner and adhere to all regulations.

A second potential problem is that an IRB review can be time consuming and, in many ways, particularly constraining for qualitative researchers. The co-construction of knowledge between the researcher and participants relies on developing a trusting relationship, a process that does not conform easily to predictable schedules and deadlines. In addition, the gathering of qualitative data often must be conducted within specific time frames dictated by critical events or the availability of study participants. Given this, you should always start the application process early, at least several months before you intend to begin collecting data. Note as well that IRBs are constrained by federal regulations that have strict criteria for establishing a reviewer quorum and prevent reviews from being conducted by e-mail or proxy. To avoid frustration over the time needed to obtain IRB approval, always take into account

when faculty and staff are particularly busy or your campus may be closed. The good news is that, with the development of online application systems, the overall turnaround time for reviewing applications has been greatly reduced. These systems help eliminate redundant paperwork and streamline the review process by routing applications directly to IRB staff and providing an opportunity to continuously monitor the status of your application.

A third area of potential conflict can result from an overall lack of experience working with IRBs. All research involving human subjects must be reviewed and approved before recruitment of study participants and data collection can occur. As a result, it is an unavoidable fact that application procedures add a layer of work to the overall research process. Even if involvement of human subjects falls under the exempt category that most likely applies to practitioner research in academic libraries as defined by 45 CFR 46.101(b), "Research conducted in established or commonly accepted educational settings, involving normal educational practices . . ." you still must submit your initial research plans for review because only your IRB can determine the level of risk to participants.

To help ensure your application is reviewed in a timely manner, visit your institution's IRB Web site and note important deadlines. Set aside time during the early stages of designing a study to familiarize yourself with the application process and approval criteria. Fortunately, most IRBs post estimates for how long a review will take once an application is received, so it is relatively easy to anticipate additional workloads.

Concomitantly, potential friction can arise because IRB reviewers are unfamiliar with library practice and the underlying intentions of practitioner research in academic librarianship. Studies conducted by practicing librarians consist largely of intra-organizational research focused on assessment and seeking ways to improve programs and services within one's own institution or developing explanatory case studies of best

practices for others to consider and learn from. For IRB reviewers more familiar with mainstream academic research, this type of scholarship may appear less rigorous. Therefore, pay particular attention to describing the purpose of your study and its benefit risks and rewards. Note that this latter issue can be especially problematic. Of the three ethical principles summarized in the *Belmont Report*, the principle of beneficence is often the most difficult to interpret. This principle requires researchers to use the best possible research design to maximize benefits and minimize potential harm to participants. In the context of insider practitioner research involving human subjects, the requirement that you must state potential benefits and risks can be ambiguous and only indirectly assumed. For example, if you are evaluating your library's information literacy program and it includes interviewing undergraduate students about their experiences using digital resources, the principle of beneficence could be stated as follows:

There are minimal risks to participation in this research project. Although tangible benefits are not included in this study, the research will give participants the opportunity to reflect and share their experiences about using the library's resources. These experiences could offer valuable information and insights for librarians developing better strategies for measuring effective learning outcomes in information literacy courses in the future.

Building a constructive relationship with your IRB

Given some of the potential problems that can arise between researchers and IRBs, I would recommend following these simple steps:

1. *Visit your IRB Web site.* Review application procedures established by your local IRB and take note of schedules, mandatory training sessions, and submission guidelines. Determine if your study meets the criteria for exempt or expedited review. Reviewing infor-

mation posted by your local IRB will help you estimate additional workload associated with developing details for conducting the study, including recruitment, informed consent protections, and data collection procedures.

2. *Contact IRB staff beforehand.* IRB staff are there to help guide you through the application process, not to hinder your efforts. If you have any questions, e-mail your IRB (I prefer to put things in writing so it is easier to keep a record of my contact with them). There are no shortcuts and seeking retroactive approval is risky. Contacting staff ahead of time with specific questions will move the process along and help them anticipate the arrival of your application.

3. *Seek out other faculty for advice.* Ask others to read your application and informed consent documents. Advice from faculty who have already been through the process can also help you gain a clearer understanding your institution's regulatory culture.

4. *Craft your application and supplementary documents carefully.* Key points to keep in mind: a) be sure when you submit your IRB application that all forms are filled out correctly; b) stick to a philosophy of less is more; for example, there is no need to state risks to participants that are unlikely to occur, thereby raising unnecessary red flags; c) know the difference between confidentiality and anonymity and which you are promising to uphold; d) state clear ethical guidelines for protecting your participants' privacy; and e) do not make promises you may regret later, such as stating you will destroy interview transcripts rather than simply promising to remove any identifying information.

5. *Volunteer to participate on an IRB panel.* Participation on campus-wide curriculum or research committees is a common way for academic librarians to monitor research at their institution. However, volunteering to be an IRB reviewer offers an intimate look into research that involves studying human behavior, thought, and action. As a result, volunteering on an IRB can be particularly rewarding for librarians in the social and behavioral sciences.

Conclusion

Submitting research proposals to an IRB does not have to be a frustrating experience. There are benefits to working effectively with an IRB. For example, the application process can help bring clarity to your research by requiring you to define the study's purpose for an outside audience, stating clearly the specific methods used for gathering, recording, and archiving data and reporting findings, and helping reveal tangible benefits and study outcomes that may not have been obvious initially. IRB approval also provides an important ethical "seal of approval" to your work, thereby improving impressions of validity and reliability. Educating yourself about the application process and working with IRB staff ahead of time can save you time and avoid potential problems.

Notes

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4. James Howard Jones, *Bad Blood: The Tuskegee Syphilis Experiment*, New York: Free Press, 1993.

5. Yvonna S. Lincoln and William G. Tierney, "Qualitative Research and Institutional Review Boards," *Qualitative Inquiry* 10 (April 2004): 219–34.

6. Georgine S. Burke, "Looking into the Institutional Review Board: Observations from Both Sides of the Table," *The Journal of Nutrition* 135 (April 2005): 922.

7. J. Michael Oakes, "Risks and Wrongs in Social Science Research: An Evaluator's Guide to the IRB," *Evaluation Review* 26 (October 2002): 447–50. ♪