

Peter R. Finn's Commentary on "Oral History Projects and Research Involving Human Subjects"

Commentary On
Oral History Projects and Research Involving Human Subjects

The Institutional Review Board as adversary

This case illustrates some of the tensions that exist between Institutional Review Boards (IRBs), the Office for Human Research Protections (OHRP), and disciplines that previously had not been included in the IRB review process. It was not until the late 1980s to early 1990s that the Department of Health and Human Services (DHHS) came to realize that the regulations governing the protection of human subjects in research (45 CFR 46) covered a broader range of research activities than what was traditionally included. Up until then, IRBs typically reviewed studies from the medical, behavioral, and social sciences, including education. However, research in history, oral history, ethnography, anthropology, and folklore was not generally reviewed (although this varied across different universities). After considering a number of issues and cases, the DHHS noted that 45 CFR 46 covered all research that included humans as participants, including those disciplines that did not consider themselves subject to the regulations. The change in how the law was understood and the subsequent requirement that these disciplines submit their projects for IRB review and approval contributed to a strong adversarial relationship between researchers in these disciplines and IRBs.

These disciplines expressed many legitimate concerns about having their research reviewed by IRBs. These concerns included a lack of understanding of qualitative research on the part of IRBs, a lack of representation on the IRB of people from their discipline, and an incompatibility of the model of research for their discipline with

scientific — quantitative — experimental models of research that appeared to be the basis for the development of 45 CFR 46 and the different policies and procedures of IRBs. For instance, a very legitimate point made by ethnographers was that they could not outline in their applications to the IRB exactly what would be asked in an interview, because the topic and focus of the interview developed as a result of the comments, experiences, and interests of the interviewee. This presented problems with the IRB requirement of being informed of exactly what would be asked in an interview prior to approving the interview. Many also pointed out that the traditional method of documented informed consent via written forms actually could impede research as it introduced an awkward formality into the relationship between the researcher and subject, which seemed to counter the attempts to form long-lasting trusting collaborations between researcher and subject. Ethnographers also pointed out that using written forms of documented informed consent in non-western cultures could create tension and a lack of trust in the subject for the researcher. These very legitimate concerns required flexibility and some change in the IRB review process for these kinds of studies. It is extremely important that IRBs reach out to researchers in these disciplines, learn more about and better represent these disciplines, and work with researchers in these disciplines to solve the problem of how to do a reasonable and fair review of this kind of research while still protecting subjects and remaining within the limits of the regulations. Clearly, there is flexibility in the regulations to handle different approaches to obtaining consent and to deal with other specific concerns raised by researchers in oral history and other disciplines previously excluded from review.

A more contentious issue raised by researchers in these disciplines was that IRB review represented an infringement on their right to academic freedom and general freedom of speech. It is true that some IRBs can be inflexible and pose unreasonable constraints on research in these domains. Such IRBs need to work with these disciplines. However, the basis for the complaint that IRBs infringe on academic freedom is based to a great degree on the misunderstandings that IRBs would change the substance of the researcher's study, and misunderstandings about what constitutes academic freedom. It is a very rare event that an IRB will tell a researcher in the humanities that they cannot conduct a particular study. Usually the IRB will require minor changes in the manner of subject recruitment and the process of obtaining informed consent. If an IRB does not allow a particular study it is because the risks associated with that study are not managed properly. There are limits to academic freedom. Academic freedom does not mean that academics can

do what they want no matter what. Academic freedom means that academics can express their ideas, take specific stances on issues, and research those issues, but the research must be done within the confines of commonly held ethical principles.

Oral History, the OHRP, and 45 CFR 46

The case provides a scenario that exemplifies the disagreement between some oral historians and IRBs or the OHRP, and the misunderstanding about what constitutes research according to the regulations. The case seems to suggest that the primary goal of the AHA and OHA is to find a way to side-step the requirement of IRB review, rather than carefully considering the primary issue of how to make sure that research is done in an ethical manner whether or not the regulations really do cover their research.

All parties agree that research should be done ethically and within the law, but there is disagreement on how to accomplish this goal. The OHRP - IRB perspective is that a third party review has great value because researchers are likely to be biased when left on their own to monitor themselves, there have been many cases of studies where unethical behavior and simple failure to think through all of the ethical issues have led to significant harm, and a common system is likely to work best as it should be able to structure and organize the process. The AHA/OHA perspective is that they can do it on their own having historians be informed by their own professional ethics; all the problems noted in the past have been the responsibility of biomedical or psychological researchers, not people in their discipline; and the IRB review system, even the definition of research, was not designed for historians. The case suggests that the decision of the research advisor not to support the project if it was submitted to the IRB is based on the strong opposition to the IRB review requirement and the animosity felt toward IRBs and the OHRP, rather than on a careful consideration of what an IRB review might accomplish in regards to the shared value of protecting research subjects. The position expressed by the graduate student researcher, Putnam, is that IRB review could be helpful given some of the concerns about the risks involved in the study.

The case outlines the AHA's primary argument against having oral history projects reviewed by an IRB which is based in the idea that oral histories really do not add to generalizable knowledge, and therefore do not fit the definition of research. It is true

that some oral histories are taken simply to understand an individual or group of individuals or to archive such histories in an institution, and not to derive any broader conclusions about individuals, cultures, or historical contexts. However, many oral history projects are planned with the idea that information about certain individual's experiences in certain contexts can lead to a greater understanding of specific periods in history or cultural processes. It is especially difficult to imagine that oral historians who also are university faculty do not do their work to add to generalizable knowledge. The case suggests that some oral historians are motivated more by the goal of side-stepping the regulations, than by fully appreciating what the regulations mean by the term "research."

Formation of Students: When political agendas interfere with faculty responsibility

Finally, this case demonstrates how specific political agendas may interfere with the responsibility of a faculty member to be as objective as possible in providing guidance and support to graduate students. Unfortunately, Putnam's advisor has allowed his political agenda concerning IRB review to interfere with his commitment to advise his graduate student. Rather than responding to Putnam's basic concern about risk and the regulations, he puts his political agenda and self/departmental concerns ahead of the student's concern and takes the extreme position of threatening to withdraw support for the student's project if the student involves the IRB. Such an action clearly puts Putnam and his graduate/academic career in jeopardy. Not only is the advisor not thinking about the ethical concerns in the particular study, but he acts selfishly by putting his own self-interest first, and he acts unethically by threatening the graduate student with withdrawal of support and by encouraging the graduate student to do something that may make him liable for not consulting with the IRB. In fact, in this case, it is the specific behavior of the research advisor in relation to his graduate student that is the most unethical.