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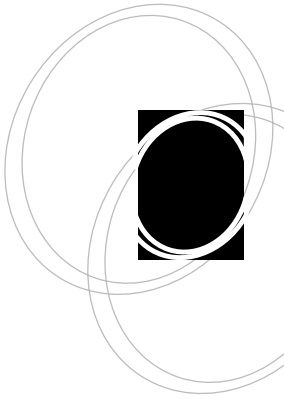*CUNY New York City College of Technology*

Demystifying the IRB: Human Subjects Research in Academic Libraries

Maura A. Smale

abstract: Many academic librarians are interested in pursuing research studies that involve students, faculty, and other library patrons; these projects must be approved by an institutional review board (IRB). This article reviews federal requirements and regulations for human subjects research and explains the IRB application process. The author discusses common types of research projects undertaken by academic librarians that require IRB approval and offers suggestions for successful navigation through the IRB process. Academic librarians should embrace research involving human subjects because the results contribute to the corpus of scholarly knowledge in library and information science as well as in higher education.

Introduction

Many academic librarians, especially those for whom scholarship and publication are requirements for tenure and promotion, actively participate in research projects in the library and on campus. Research involving contact with students, faculty, staff, or other persons—termed "human subjects research"—may require approval from the college or university institutional review board (IRB). An IRB is established at all academic and research institutions and reviews and evaluates research projects, guided by federal regulations, to ensure the protection of study participants. The scholarly backgrounds of academic librarians span a wide range of subject areas, and many disciplines do not rely upon research with human subjects; thus, academic librarians may be unfamiliar with the necessity for IRB approval. The IRB regulations can seem especially daunting for junior library faculty, many of whom are new to academic librarianship and unfamiliar with the nuances of academic research.

Outside of medical librarianship, little has been published that addresses the potential requirement for IRB approval for research projects undertaken by academic librar-

ians. In this article, the requirements for and the process of obtaining IRB approval for research involving human subjects are discussed. After a brief review of the literature, the history of the IRB and the current U.S. federal requirements for regulation of human subjects research are summarized. The process for submitting an application to the IRB and a review of the types of research projects commonly undertaken by academic librarians that may require IRB approval are outlined. Finally, suggestions are offered for successful navigation of the IRB process by academic librarians, and the importance of human subjects research to library scholarship is emphasized.

Literature Review

Although IRB requirements are widely discussed in scholarly journals in many disciplines in the sciences, social sciences, and humanities, a review of the literature reveals that most discussion of the IRB in scholarly library journals addresses the contributions of hospital and medical librarians to the IRB approval process.[1] Medical librarians support doctors, nurses, and other personnel engaged in clinical trials and research studies by assisting with literature searches during the preparation of an application to the IRB. The literature search is a key element of medical research, as was tragically demonstrated in 2001, when an otherwise healthy volunteer at Johns Hopkins University died while participating in a medical study.[2] Investigators concluded that the subject's death "could have been prevented if a search of the medical literature prior to 1966 had been performed."[3] Additional research at the University of Pittsburgh Medical Center suggested that clinical staff were not confident in their search skills and were often unaware of the full range of library resources available for their use.[4]

In the wake of high-profile deaths of research subjects at Johns Hopkins and two other locations, many in the hospital and medical library community called for an expanded role for medical librarians in the IRB process.[5] Since 2001, an increasing number of medical librarians have had the opportunity to serve on their hospital or medical center IRB.[6] Furthermore, additional roles for medical librarians have been created; for example, Eastern Virginia Medical School designated several institutional review board librarians. These librarians complete human subjects protection training and provide backup support should the IRB require additional information about a proposal.[7] In general, increased outreach, education, and collaboration between librarians and medical researchers have been emphasized in recent years to ensure the safety of study participants and regulatory compliance.[8]

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Origins, History, and Purpose of the IRB

The origins of the modern IRB grew out of concerns about questionable ethical practices employed in many biomedical and behavioral research studies during the twentieth century. The Nuremberg Trials exposed the atrocities of Nazi human experimentation

during World War II and prompted the creation of the Nuremberg Code in 1949.[9] These 10 principles serve to guide research with and on human subjects; they stress respect for human life, avoidance of intentional suffering, voluntary participation in research, and the necessity for subjects to provide informed consent prior to joining a research study.[10] As an outgrowth of the publication of the Nuremberg Code, the U.S. National Institutes of Health issued its own guidelines in 1966—the *Policies for Protection of Human Subjects*.[11]

In 1972, news of the "U.S. Public Health Service Syphilis Study at Tuskegee" broke, and the public learned that, during a 40-year research study, the American government had "withheld adequate treatment from a group of poor black men" with syphilis.[12] In the aftermath of this serious breach of research ethics, the *Policies for Protection of Human Subjects* were adopted as official government regulations in 1974. In the same year, the U.S. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research was formed.[13] The commission subsequently published the *Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* in 1979. The recommendations proposed in the *Belmont Report* form the basis of current U.S. federal regulations for human subjects research—title 45, part 46 of the *Code of Federal Regulations*, usually referred to as the Common Rule. Additional protections have been added to the Common Rule for three populations deemed especially vulnerable to ethical lapses in research practices—for pregnant women and fetuses in 1975, for prisoners in 1978, and for children in 1991.[14]

The federal regulations specified in the *Belmont Report* and the Common Rule inform and guide the actions of the IRB at colleges, universities, medical schools, and other research entities. While adherence to these federal regulations is only required for research projects that receive federal funding, most academic and research institutions choose to require all studies that meet the criteria for human subjects research to adhere to the same regulations, regardless of funding source.[15] If the federal government investigates an institution and ethical violations are discovered, penalties can include hefty fines as well as the immediate cessation of both the study under investigation and all other federally funded research across the institution.[16]

The *Belmont Report* provides guidelines for the evaluation of research projects by the IRB. The report begins by clarifying the distinction between research and practice, an important factor in determining whether a study requires approval by an IRB. The commission defined practice as "interventions that are designed solely to enhance the well-being of an individual patient or client and that have a reasonable expectation of success."[17] In contrast, the commission defined research as "an activity designed to test an hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge."[18] Projects that fit the commission's definition of practice are not considered human subjects research and do not require IRB approval.

Three ethical principles that inform the work of the IRB are highlighted in the *Belmont Report*—respect for persons, beneficence, and justice. The principle of respect for persons recognizes that people are autonomous and capable of deciding for themselves whether to participate in a research study and that those who are incapable of such self-determination deserve additional protections. The second principle, beneficence, echoes the sentiment of the Hippocratic Oath in which medical doctors pledge to "do no harm."[19] Beneficence requires that researchers strive to protect their subjects from

suffering, and "maximize [the] possible benefits and minimize [the] possible harms" of their projects.[20] The final principle in the *Belmont Report* is justice. The principle of justice addresses equal distribution of both benefits and burdens of research and underlies the additional regulatory protections for pregnant women, children, and prisoners.[21]

The remainder of the *Belmont Report* discusses the application of the each of the three principles by an IRB in evaluating a proposed research project. The first consideration for an IRB is informed consent. Participation in research must be voluntary, and potential research subjects must be presented with enough information about the study to make an informed decision regarding their participation. Information should be presented in a way that is easily read and understood by potential subjects. Additional consideration must be given to those who are unable to make an informed decision, for example, children or the mentally disabled.[22]

The second area that an IRB must evaluate for a research project is the ratio of risks to benefits. Risks and benefits may be present in a variety of arenas, including physical, legal, mental, and social. The IRB considers these factors holistically; risks and benefits may apply to the research subject, the subject's family and friends, the surrounding community, or society as a whole. This balance between risk to the subject and benefits of the study may mean that, although the subjects may not benefit directly from the research, others will. Comprehensive information about the risks and benefits of a research study is a critical component of informed consent.[23]

The final area for IRB consideration is the selection of research subjects. The IRB must conclude that individuals or populations will not be selected as research subjects simply out of convenience. Subject selection must be fair on an individual level, and researchers may not show favoritism when selecting research subjects. Selection must also be fair at the group level, and federal regulations protect certain populations—pregnant women, prisoners, and children—from being used as convenience samples. Other populations, including minorities, the poor, and the institutionalized, may also be vulnerable to improper selection for research studies. The Tuskegee study is often cited as an example of improper research subject selection and an abuse of the principle of justice.[24]

Obtaining IRB Approval for a Research Project

Any study involving human subjects that meets the definition of research in the *Belmont Report* requires review by the IRB. An IRB must have at least five members "with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution," including a minimum of one scientist and one non-scientist.[25] To speed the process of project review, a large and active research institution may convene more than one IRB. Four members of the IRB are drawn from the staff of the institution (in an academic setting, faculty and administration) and one member must be unaffiliated with the institution. The inclusion of an IRB member from outside of the institution is meant to ensure that the surrounding community is considered in the review process.[26]

There are three levels of IRB review—exempt, expedited, and full. The IRB evaluates each research project and determines the level of review required; researchers may not make this determination on their own. Certain types of studies automatically meet

the criteria for exemption set forth in the Common Rule, including research on "normal educational practices" such as curriculum design, instruction, and assessment.[27] Research involving use of previously collected data is also usually exempt. In both cases the subjects' anonymity must be preserved. Again, even if a study seems likely to meet the criteria for exempt review, an application must be made to the IRB for final determination. Studies eligible for expedited review must involve no more than minimal risk to participants.[28] Full review is required for any project that may feature greater than minimal risk to human subjects.

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Research studies that meet the criteria for exempt or expedited review may be examined by a subset of IRB members, while those that require full review must be approved by the entire IRB. The time it takes for a study to complete the IRB approval process typically reflects the level of review required; exempt and expedited projects can be approved fairly quickly, whereas projects requiring full review take more time. Some institutions require one type of IRB approval for biomedical research and employ another, more streamlined IRB application process for studies in other disciplines, often including social sciences and the humanities.[29]

Most institutions require researchers to complete a training course that reviews the details of the *Belmont Report* and Common Rule before applying for IRB approval for a study. The author's university uses the CITI online training program;[30] some institutions choose to create their own training materials that may be customized for social sciences and humanities disciplines.[31] The certificate of completion that is received upon finishing the training course is usually required with an application for IRB approval, and certification must be renewed periodically by taking a refresher course.

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An application to the IRB for evaluation of a research project requires the thorough explanation of the research protocol or procedures to be followed in the study. The IRB reviews each application and evaluates the research protocol following the specifications of the *IRB Guidebook* compiled by the Office for Human Research Protections.[32] Materials and details required in an IRB application include:

- Purpose of the research
- Source of research subjects and criteria for their selection
- Research procedures, including the text of any survey or interview questions that will be asked of participants
- Potential risks and benefits to the research subjects and the community
- Procedures used to protect the anonymity of subjects

- Procedures to follow in case of an emergency
- Forms to be used to obtain consent from research subjects

Consent forms must include all information about the project that proposed subjects will need in order to provide their consent, including the research protocol, risks and benefits, and emergency procedures. In some cases, a research study would be severely compromised if full disclosure or informed consent were required; thus, it is possible to withhold complete information about the study or waive the consent requirement. A waiver of these requirements depends on the nature of the study and the IRB's complete analysis of the research project in consideration of the principles specified in the *Belmont Report*.

Once IRB approval has been granted, the research project may begin. Note that some funding agencies require documentation of IRB approval for the project before grant money will be disbursed. It is important to apply to the IRB well in advance of the planned project start date so that research is not delayed while waiting for IRB approval. IRB approval is granted for a specific period of time, for example, one year. If the study will extend beyond the expiration date of IRB approval, an extension must be requested. Usually an extension is granted automatically if the research protocol has not been modified since the original application to the IRB. It can be exceedingly difficult or even impossible to secure an extension if the IRB approval has expired, however, so researchers must plan accordingly to ensure the successful completion of a project.

Applicability of the IRB to Research in Academic Libraries

Although it is easy to understand the need for IRB approval for biomedical research projects, which often involve physical risk to the research subjects, IRB regulations can be confusing when applied to the social and behavioral sciences, including library user research. Librarians may be unfamiliar with IRB requirements and procedures, yet many research studies undertaken by academic librarians will require IRB approval. The first question to ask when determining whether a project involving human subjects will require IRB approval

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is "Is it research?"[33] As noted above, "research" is defined in the *Belmont Report* as "an activity designed to test an hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to *generalizable knowledge*" (emphasis added).[34] Will the results of the study be compared to other research in the field? Will the data be disseminated to the library community, academic community, or the general public? If so, the project meets the definition of research and must be reviewed by the host institution's IRB.

For example, at the author's library, college faculty were recently surveyed to assess their interest in library programming and services. The survey results are solely for internal planning and development at the library, thus the survey did not require IRB

approval. However, if the analysis of the survey results were to be published outside of our institution, the collected data would contribute to generalizable knowledge about academic libraries and IRB approval would be required.

Most library research projects pose little to no risk to participants, and those that require IRB approval are usually eligible for exempt or expedited review. As mentioned above, some research projects meet the established criteria for exempt review. Among those most relevant to librarian-researchers are studies in educational settings involving technique or practice—for example, instructional strategies, assessment, and curriculum evaluation. Many library researchers use anonymous surveys to collect data via online polling software (for example, Survey Monkey, Zoomerang), paper forms, or telephone responses; surveys are exempt if the subjects' anonymity can be assured. Studies that involve observation in public locations, if completely anonymous, are also usually eligible for exempt review, as are research studies that use existing data, documents, or records that are publicly available. It is important to remember that, even when research meets the criteria for exempt review, it is the IRB that determines the level of review required; and all studies must be submitted to the IRB before the project may begin.

Library research projects that include procedures in which the researcher is in direct contact with the subject will usually be required to undergo expedited review by the IRB. Many academic librarians conduct interviews and focus groups with students, faculty, and other library patrons or stakeholders. Interviews may take place face-to-face, via telephone, or online using e-mail or chat. Librarians conduct interviews for a variety of purposes—to explore the ways that patrons use the library, to gain insight into information-seeking behaviors, to request

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input on library resources and services, and to perform usability testing of the library Web site, among others. If the project is considered to be research, interviews and focus groups will require IRB approval. The researcher is required to detail procedures for protecting the identity of the research subjects, for example, assigning a unique number to each participant and keeping the coded list of participant names in a locked file cabinet.

Many researchers have discussed their discomfort with the application for IRB approval for certain types of projects common to library and information science and other disciplines in the social sciences and humanities, for example, ethnography and oral history. Rachel Vagts, an archivist at a college library, expressed concern over the requirement to submit survey and interview questions to the IRB for review; conversations during interviews and focus groups often stray from prearranged questions.[35] Vagts also pointed out that consent forms might be difficult for people with poor language skills and "could potentially be confusing and unnecessarily frightening."[36] Similar concerns are present in ethnographic research, which may include interviews, focus groups, or observation.[37]

There is much debate over whether the current federal regulations of human subjects research are appropriate for the social sciences and humanities, in which studies tend to pose relatively low levels of risk to participants; a detailed discussion of the debate is beyond the scope of this article.[38] Nevertheless, IRB approval remains a requirement

for most studies involving human subjects at academic and research institutions in the United States, across all disciplines. It is worth noting that the underlying principles used by the IRB to evaluate projects involve ethical treatment of subjects and preservation of privacy and are similar to the recommendations of many discipline-specific professional organizations, including the Oral History Association and the American Anthropological Association.[39]

Successfully Navigating the IRB Approval Process

The author has been through the IRB approval process for two recent research projects, experiences that were both fascinating and enlightening, if occasionally frustrating. Fortunately, the college and university offered several presentations about the IRB application process. This information was extremely valuable when preparing research materials for consideration by the IRB.

The author's institution requires researchers to complete a training course—the CITI program—before IRB approval is granted, so the first step was to complete the training. The online course is divided into 18 modules, which can be completed over a few days. The course covers the history and background of the IRB and the *Belmont Report*, elaborates on procedures followed by the IRB when evaluating projects, and features many examples and case studies. Although much of the CITI course covers information about biomedical research topics that are unlikely to apply to research in academic library settings, learning about these topics provides a more complete understanding of the IRB requirements and process. Such knowledge will encourage researchers to consider all of the requirements for IRB as they specifically relate to particular studies.

The author is collaborating with a colleague from another college on both research projects, so the proposals must be approved by the IRB at each of our colleges. This process is fairly straightforward because we are within a single university system that has a central research office to oversee the IRB on all campuses. For each project, one researcher was designated principal investigator (PI); the PI submitted the application to her campus IRB. Once the PI's IRB had approved the project, the materials were sent to the co-PI's campus IRB, which reviewed and approved the materials fairly quickly. Michele Tennant offers additional advice for those engaging in research at multiple, unrelated institutions.[40] Although the multi-campus IRB approval was not difficult, it added time to the overall IRB process; it is wise to plan ahead if IRB approval at multiple institutions is required.

In the first research study, both authors analyzed the results of an assessment given to students in several sections of an English composition course that had received library instruction. This study used archived data collected during the normal course of educational practice at my colleague's institution, so our research was classified as exempt by the IRB. Since students were required to participate in the assessment as part of their course, signed consent forms were not required for this study, and there were no additional materials to submit other than our application. This exempt study only required review by a subset of the IRB at each of our institutions, thus the IRB process was fairly simple and only took a few weeks.

The second research project for which we sought IRB approval is a large study that involves an anonymous survey of students and four types of one-on-one, in-person interviews with students and faculty. Since we planned to conduct face-to-face interviews with our human subjects, this project met the criteria for expedited review by the IRB. Although we did successfully obtain IRB approval for this study, the timeline was much longer than for our other project and involved two sets of revisions that stretched over the course of five months. A positive outcome was that we gained valuable experience in preparing our IRB application; we feel confident that the process will go much more quickly the next time we submit a project requiring expedited review to the IRB.

To complete the second IRB application, all of the materials to be used in our study were prepared and submitted to the IRB—our research protocol (the structure of our study and the procedures we will use to collect data), all survey and interview questions, content for recruiting materials (for example, the text of flyers and e-mails), and complete consent forms for both faculty and student participants. While preparing our application, we had to ask ourselves many critical questions about our project: What are the benefits that we hope our subjects will accrue? Are there any risks, however minimal? What questions do we plan to ask of our subjects and why? How will we present the project to our participants, our institutions, and the larger library and academic community? And, ultimately, what do we expect to gain from the study?

While it was a lengthy and labor-intensive process, obtaining IRB approval was an experience with real value, not simply a bureaucratic hurdle to overcome. Applying to the IRB required us to think deeply and critically about the goals for our research project while still in the early planning stages of the study; navigating the IRB approval process helped us make our research project both stronger and more relevant. Additionally, because we created all of our materials for the IRB application, we were ready to get started on our project as soon as the IRB approval came through, which saved us time at the beginning of our study.

Although federal regulations and the IRB approval process may seem daunting, academic librarians are heartily encouraged to embrace research projects of interest that require IRB approval. Studies that include human subjects research can produce data that are relevant to many stakeholders, and the resulting publications will increase the body of scholarly literature and inform the practice of librarianship, as well as add to tenure and promotion portfolios. If research studies that incorporate surveys, assessments, interviews, focus groups, or other methods involving human subjects are of interest, start early and get informed. Contact the IRB office on campus, attend workshops and training sessions if they are available, and ask questions. Keep in mind that the IRB exists to protect human research subjects. Consideration of the goals, purpose, and benefits of a study involving human subjects can strengthen a project and its contribution to both librarianship and scholarship.

Conclusions and Implications for Library Scholarship

An ever-increasing body of fascinating research in academic libraries involves human subjects. One of the most comprehensive recent studies—*Studying Students: The Undergraduate Research Project at the University of Rochester*—used ethnographic methods

including interviews, time-log analyses, photographic surveys, and focus groups to explore the ways in which students use the library for their coursework. Results from the project inspired changes to reference services, contributed to the redesign of the library Web site, and guided plans for the library's renovation.[41] Other research studies in libraries have employed quantitative (surveys) and qualitative (interviews, observation, focus groups) methods and used the data collected to inform changes that aim to help students and faculty find research resources more easily.[42]

Projects in academic libraries that incorporate human subjects research benefit many beyond the library and librarians who undertake them, and this research has real value to other members of the campus community. Studies involving students, faculty, and other library users can provide detailed insight into the use of space in the library, which can be valuable for construction planning and facilities management on campus.[43] Library research studies can also produce results that encourage collaboration between the library and other student and faculty support services and programs on campus. For example, the data gathered by the University of Rochester helped spawn a collaboration between the library and the campus writing center, in which several librarians were trained as writing tutors and also provided research training to writing instructors.[44]

Human subjects research in academic libraries also adds to the body of scholarly literature on the educational behaviors and practices of college and university students. Recent books such as *My Freshman Year: What a Professor Learned by Becoming a Student*, by anthropologist Rebekah Nathan, and *The First Year Out: Understanding American Teens After High School*, by sociologist Tim Clydesdale, discuss the contemporary college student experience in the United States.[45] Library research adds another dimension to higher education research and contributes valuable data that are of use to the broader academic community.

Finally, sustained, in-depth research projects involving college and university library users enhances the visibility of the library on campus. This may be especially valuable at institutions where librarians do not hold faculty status. While librarians certainly agree that important scholarly research takes place in academic libraries (and that librarians should engage in important scholarly research), other campus faculty and administrators may not be aware of the potential contributions of these projects. Research involving human subjects reinforces the academic library as a critical component of the college and university mission and a full and active participant in the scholarly life of the institution.

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Notes

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4. Charles B. Wessel, Nancy H. Tannery, and Barbara A. Epstein, "Information-Seeking Behavior and Use of Information Resources by Clinical Research Coordinators," *Journal of the Medical Library Association* 94, 1 (2006): 51.

5. Sally Harvey, "Institutional Review Boards: Another Way for Hospital Librarians to Add Value to their Organization," *Journal of Hospital Librarianship* 3, 2 (2003): 99; Tomlin, 89.

6. Bandy, Condon, and Graves; Frumento and Keating; and Harvey, 99–102.

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8. Tomlin, 92–3; Wessel, Tannery, and Epstein, 52.

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10. "The Nuremberg Code" in *Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10* (Washington, D.C.: U.S. Government Printing Office, 1949), 2: 181–2, http://www.hhs.gov/ohrp/references/nurcode.htm (accessed March 29, 2010).

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12. Centers for Disease Control and Prevention, "U.S. Public Health Service Syphilis Study at Tuskegee: Tuskegee Study, 1932–1972," Centers for Disease Control and Prevention, http://www.cdc.gov/tuskegee/ (accessed March 29, 2010).

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14. Penslar and Porter.

15. American Association of University Professors, "Research on Human Subjects: Academic Freedom and the Institutional Review Board," AAUP, http://www.aaup.org/AAUP/comm/rep/A/humansubs.htm (accessed March 29, 2010).

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18. Ibid.

19. Ibid.

20. Ibid.

21. Ibid.

22. Ibid.

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25. Penslar and Porter, "Institutional Administration," in *Institutional Review Board Guidebook*, http://www.hhs.gov/ohrp/irb/irb_chapter1.htm (accessed March 29, 2010).

26. Penslar and Porter, "Institutional Administration."

27. *Code of Federal Regulations*, title 45, part 46 (July 14, 2009), http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm (accessed March 29, 2010).

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33. Patricia A. MacCubbin, "Human Research Protections: The IRB Process and Its Importance," (presentation, program of the Library Association of CUNY Professional Development Committee/Junior Faculty Research Roundtable, New York, NY, February 26, 2009).

34. *The Belmont Report.*

35. Rachel Vagts, "Clashing Disciplines: Oral History and the Institutional Review Board," *Archival Issues* 26, 2 (2002): 147.

36. Ibid., 150.

37. Christopher Shea, "Don't Talk to the Humans: The Crackdown on Social Science Research," *Lingua Franca* 10, 6 (2000): 26–34.

38. Many voices (and in increasing numbers) in the past decade have raised objections that federal regulations, as currently interpreted by many academic IRBs, are too restrictive of social science and humanities research. In the 2006 report *Research on Human Subjects: Academic Freedom and the Institutional Review Board*, the American Association of University Professors (AAUP) asserted that requests for significant changes to a research protocol, as well as the inability to appeal rejection of a research project by the IRB, constitute a serious infringement on academic freedom. The AAUP suggests a revision to the regulations such that "research whose methodology consists entirely of collecting data by surveys, conducting interviews, or observing behavior in public places be exempt from the requirement of IRB review." The AAUP also recommends that colleges and universities cease their common practice of evaluating all research projects based on the same criteria rather than solely federally funded projects as is required by law. See AAUP, "Research on Human Subjects."

   Zachary Schrag details the fascinating results of his historical research on the inclusion of social science research under the same IRB regulations and requirements as biomedical research. His examination of archival materials reveals that, while the social sciences were included in discussions of human subjects research from the outset, "application of the regulations to the social sciences…was far less careful than was the development of guidelines for biomedical research" See Zachary M. Schrag, "How Talking Became Human Subjects Research: The Federal Regulation of the Social Sciences, 1965–1991," *The Journal of Policy History* 21, 1 (2009): 4.

   Shea suggests that several high-profile research lapses in the late 1990s brought an increase in IRB attention to all research projects involving human subjects, including projects with little to no risk for subjects. See Shea. Adil Shamoo echoes concerns raised by Shea and others and asserts that academic researchers in the humanities and social sciences have abandoned projects because the IRB process is viewed as a hassle and the timelines too lengthy. See Adil E. Shamoo, "Deregulating Low-Risk Research," *The Chronicle of Higher Education*, August 3, 2007, 16.

39. Vagts, 151; American Anthropological Association, "Code of Ethics of the American Anthropological Association" (February 2009), http://www.aaanet.org/issues/policy-advocacy/upload/AAA-Ethics-Code-2009.pdf (accessed March 29, 2010).

40. Michele R. Tennant, a medical librarian at the University of Florida's Health Science Center Libraries, discussed her "negotiation through the IRB process at 18 separate institutions in support of two multi-site studies" in a paper presented at the 2008 conference of the Special Libraries Association. She offers an overview of the complexities of navigating the IRB process when engaged in a research project at medical centers outside of one's home institution. Her paper concludes with valuable suggestions for librarians seeking to perform research that involves multiple locations and IRBs. See Tennant, 1.

41. Nancy Fried Foster and Susan Gibbons, *Studying Students: The Undergraduate Research Project at the University of Rochester* (Chicago: Association of College and Research Libraries, 2007).

42. A selection of recent projects includes: Randall McClure and Kellian Clink, "How Do You Know That? An Investigation of Student Research Practices in the Digital Age," *portal: Libraries and the Academy* 9, 1 (2009): 115–32; Tracy Gabridge, Millicent Gaskell, and Amy Stout, "Information Seeking Through Students' Eyes: The MIT Photo Diary Study," *College & Research Libraries* 69, 6 (2008): 510–22; Eric Novotny and Ellysa Stern Cahoy, "If We Teach, Do They Learn? The Impact of Instruction on Online Catalog Search Strategies," *portal: Libraries and the Academy* 6, 2 (2006): 155–67; and Melissa L. Becher and Janice L. Flug, "Using Student Focus Groups to Inform Library Planning and Marketing," *College & Undergraduate Libraries* 12, 1/2 (2005): 1–18.

43. Doug Suarez, "What Students Do When They Study in the Library," *Electronic Journal of Academic and Special Librarianship* 8, 3 (2007): http://southernlibrarianship.icaap.org/content/v08n03/suarez_d01.html (accessed March 29, 2010); Foster and Gibbons, 20–9.

44. Foster and Gibbons, 6.

45. Rebekah Nathan, *My Freshman Year: What a Professor Learned by Becoming a Student.* (New York: Penguin, 2005); Tim Clydesdale, *The First Year Out: Understanding American Teens After High School.* (Chicago: University of Chicago Press, 2007). Nathan's book was written using a pseudonym; just before publication, its author was revealed to be Cathy Small, a professor of anthropology at Northern Arizona University.