IRB got your hands tied? Did they get permission?

Pamela Howard and Mira Foster
San Francisco State University

Abstract

Ethical standards and guidelines within librarianship have a long, well regarded history with respect to patron rights and privileges, but academic research has another specific set of ethical standards and guidelines that apply to research on people. Human subject protections originated to insure the ethical treatment of people in biomedical research. But recent institutional concerns about federal regulations, funding, and the Common Rule have led to what some call "*mission creep*" and increased oversight of social science research. This conference session included a primer on the institutional review process, a report on its current controversies, and a discussion of its importance for research in librarianship. As the profile of library scholarship rises and the importance of oversight grows, librarians will benefit from increased knowledge of the institutional review process, its complications and contentions, and the mapping of our professional ethics to those for research in the field.

Introduction

Research on human subjects requires oversight to ensure it is ethical. Institutional Review Boards (IRBs) monitor and regulate research within academic institutions as mandated by federal law and described by the Code of Federal Regulations Title 45, Part 46 ("Protection of Human Subjects," 2009). Academic institutions have expanded IRB processes to include research in the behavioral and social sciences, where library research resides. This expansion of IRB regulation has been termed "*mission creep,"* and the evolving oversight process has had a measurable impact on research in a number of fields (Pritchard, 2002; Gunsalus, et al., 2007). Awareness within the library profession of the need to meet federal regulation is an important first step in developing professional guidance within the library field. The discussion provided a framework for academic librarians to share basic information about the oversight rules, processes, and controversies surrounding this issue with the goal of helping others to prepare for future research endeavors.

Description

Prior to the conference, the presenters invited several conference attendees to contribute their real-world experience with research and IRB processes to the session discussion. Additionally, other audience members that had undergone IRB review volunteered their experiences, remarking upon some of the notable differences between doing research at University of California (UC) system and planning research projects at individual California State Universities (CSU). Others offered their experience in research outside of librarianship, particularly in psychology, one of the more heavily scrutinized disciplines.

Our session began with a definition of research as defined by federal law, and discussants shared details of their current and upcoming human subjects research. Next was a summary of

the laws surrounding human subjects protection and the institutional review process. This included an introduction to the Common Rule and its tenets of beneficence, justice, and respect for persons; and the importance of measuring harm and risk in research. The presenters also provided an introduction to the sometimes intimidating terminology of the institutional review process, including an alphabet soup of acronyms - CFR, HSR, IRB, OHRP, OHSR, and ORSP - and materials such as research protocols and human subjects certifications.

After arming participants with terminology, the presenters gave a general description of the IRB process. This included the sometimes fuzzy distinctions between research requiring full committee review, expedited review, exempt review, or no institutional oversight (Kaktins, 2009; Lynn & Nelson, 2005). Participants then considered their own research projects both past and present. In small groups, they classified their work into appropriate categories for full review, expedited review, exemption, or outside of the IRB's sphere of influence and oversight. A common discussion involved distinguishing between projects that were considered exempt and those that did not belong within the oversight of the IRB. There was some confusion as to where typical research projects in librarianship should belong. This is partly because institutions' IRBs differ in their attention and scrutiny of social science research, and also because participants interpret the concepts of harm and risk differently.

Following these small and large group discussions, the presentation moved to a literature review confirming these same confusions and controversies about the review process. In recent years social science literature has housed a debate over the impact of IRB oversight on research time lines, academic freedom, and social scientists' ability to conduct research, leading to accusations of IRB "*mission creep"* (Pritchard, 2002; Borenstein, 2008). Presenters shared the findings of three surveys which determined that the time involved in institutional review has a tangible impact on research activity, that knowledge of the process is related to research experience, and that in some cases research protocols are modified without additional IRB oversight. Discussants responded to the evidence by confirming some of these sentiments and findings, while also sharing a strong sense of the importance of ethical practice in their future research and their use of the institutional review process.

Key Points

Library Ethics and Research

Most federal mandated education about the IRB process begins by offering historical reasons for its existence, including tragedies such as the Nuremberg experiments and the Tuskegee Syphilis experiments. It is difficult to connect these examples to the practical and evidenced based research common in librarianship. Additionally, librarians have a strong code of professional ethics, and many of these values relate to the main principles important for human subjects protections. The ALA Code of Ethics (ALA, 2008) emphasizes the importance of service to all patrons and the responsibility to defend intellectual freedom, the right to privacy, intellectual property, and library employee welfare. Because librarians uphold a set of ethical standards, and also conduct social science research, they need to consider the impact of federal rules about human subjects protection on their research (Labaree, 2010).

While librarians come from every discipline, the methods librarians use for human subjects research are those common to social science. Librarians use their professional literature

to report on the programs and services they have implemented at their institutions, and in these reports they share anecdotal information and the results of their assessment instruments. According to Beck and Manuel (2009), there are nine major approaches commonly used within librarianship: content analysis; interviews; focus groups; observation; usability testing; experimental studies; bibliometrics; action research and classroom research. Discussion participants shared their own research areas and project types, and these included usability studies; empirical studies involving long term observation; student focus groups; surveys; and interviews.

Principles of Human Subjects Protection

The principles of human subjects protection were first codified internationally by the Nuremberg Code (1947) and the Declaration of Helsinki (1964) and were grounded by the following three principles: respect for persons, beneficence and justice (Yanow & Schwartz-Shea, 2008). The Belmont Report (1979) took these three principles and added the considerations of informed consent, risk assessment and research population selection (Lynn & Nelson, 2005). Federal law requires academic research on human subjects to be overseen by an IRB. From the viewpoint of academic institutions and federal agencies, an IRB assures the adequate protection of participants in research, protects the researcher by adhering to commonly accepted practices, and provides proper institutional oversight of the research process (Kennedy, 2005).

Risk and harm underlie the principles of the Common Rule; with respect to human subjects protections, both should be minimized (Campbell, 2003). The idea of a "spectrum of risk" in research disciplines is an important concept when considering human subjects protection. The risk spectrum ranges from mere annoyance to potential death. Harm can also be measured on a spectrum and measures the consequences of an adverse event to an individual. Most types of research in librarianship do not advance beyond annoyance on the risk and harm spectrums. Regardless, the oversight process is essential for validating library research as ethical, and designed with the principles of equity, minimal risk and harm, informed consent, privacy, and respect.

Empirical evidence about the effects of the IRB process on research is limited, but there are some notable findings. Three empirical surveys - in education, economics, and psychology - queried the effect of IRB oversight on researchers and their research efforts. Fahy and Spencer (2004) were concerned with how others in the distance education sector understood the principles of human subjects protection and if research experience played a part in that understanding. They concluded that the more a researcher had published their research the greater their understanding and application of human subjects protection principles. A second set of studies with economics educators examined the time involved in institutional review and its impact on research design (Lopus, Grimes, Becker & Pearson, 2007a; Lopus, Grimes, Becker & Pearson, 2007b). These found that compliance with the oversight process was a barrier to research a significant percent of the time (23% with 19% unsure). The third study of psychologists revealed that some research protocols are carried out without IRB submission, where in essence researchers are "going solo" (Ashcraft & Krause, 2007). In some cases IRB approved research protocols are modified without going through additional IRB oversight.

Librarian research and the IRB

Some librarians shared that though the IRB process had slowed their research timelines they felt that it had fostered improvements to their projects. Others expressed that getting permission from students during research projects was extremely important in maintaining trusting relationships. However, open questions remained regarding receiving IRB approval when developing publishable articles from programmatic reviews and assessments. Additional concerns arose around the use of statements from social media for content analysis in the publication process.Some pointed out that a common problem in library research stems from publishing the results and findings from internal assessments without having obtained informed consent.

While there was question as to whether librarians have been “going solo” without knowing about the institutional review processes, there was recognition among discussants that using the IRB can help boost both the credibility and quality of research in the library field. The discussion confirmed the need for continuing education about the IRB process and the importance of using IRB's to improve the profile of librarian research, but revealed that IRB oversight can be cumbersome and inhibiting.

The library research community within California libraries is varied, so given the three levels of public academic institutions and the many types of private institutions it is no wonder that there is no one-size-fits-all oversight process. In the CSU and UC systems, there are codified procedures for submitting research proposals for institutional oversight, but the designated oversight offices differ in name and responsibilities. The most important first step for a researcher is determining their own school's oversight office, and its particular requirements.

Many of the authors (Campbell, 2003; Kennedy, 2005; Oakes, 2002; Pritchard, 2002) included in the literature review reported how professional or nationally representative organizations had developed guidance that specifically dealt with the federal regulations of IRB oversight. Professional organizations as varied as the American Medical Association, American Educational Research Association and the American Anthropological Association have invested time in the discussion and development of official, educational materials that help their constituents map professional ethics to the federal code. As research by academic librarians grows more complex and the profession evolves, it may be time to match the librarians' professional ethics with the federal guidelines regarding ethical research.

References

ALA. (2008, January 22). Code of Ethics of the American Library Association. Retrieved from http://www.ala.org/ala/aboutala/offices/oif/statementspols/codeofethics/codeethics.cfm

Ashcraft, M. H., & Krause, J. A. (2007). Social and behavioral researchers' experiences with their IRBs. *Ethics & Behavior*, *17*, 1-17. doi:10.1080/10508420701309614

Beck, S. E., & Manuel, K. (2008). *Practical research methods for librarians and information professionals*. New York, NY: Neal-Schuman.

Borenstein, J. (2008). The expanding purview: Institutional review boards and the review of human subjects research. *Accountability in Research*, *15*, 188–204.

Campbell, R. T. (2003, April). *Risk and harm issues in social science research*. Position paper presented at the Human Subjects Policy Conference, University of Illinois at Urbana-Champaign. Retrieved from www.law.uiuc.edu/conferences/whitepaper/papers/risk_and_harm_v2rc.pdf

Fahy, P., & Spencer, B. (2004). Research experience and agreement with selected ethics principles from Canada tri-council policy statement--Ethical conduct for research involving humans. *Journal of Distance Education*, *19*, 28-58.

Gunsalus, C. K., Bruner, E. M., Burbules, N. C., Dash, L., Finkin, M., Goldberg, J. P., & Greenough, W. T. (2007). The Illinois White Paper: Improving the system for protecting human subjects: Counteracting IRB "Mission Creep". *Qualitative Inquiry*, *13*, 617.

Kaktins, N. (2009). Faculty guide to the institutional review board process. *Nurse Educator*, *34*, 244-248.

Kennedy, J. M. (2005). Institutional review boards and institutional researchers. *New Directions for Institutional Research*, *127*, 17-31.

Labaree, R. (2010). Working successfully with your institutional review board. *College & Research Libraries News*, *71*, 190-193.

Lopus, J. S., Grimes, P. W., Becker, W. E., & Pearson, R. A. (2007a). Effects of human subjects requirements on classroom research: Multidisciplinary evidence. *Journal of Empirical Research on Human Research Ethics*, *2*(3), 69–78.

Lopus, J. S., Grimes, P. W., Becker, W. E., & Pearson, R. A. (2007b). Human subjects requirements and economic education researchers. *American Economist*, *51*, 49-60.

Lynn, M. R., & Nelson, D. K. (2005). Common (mis)perceptions about IRB review of human subjects research. *Nursing Science Quarterly*, *18*, 264-270.

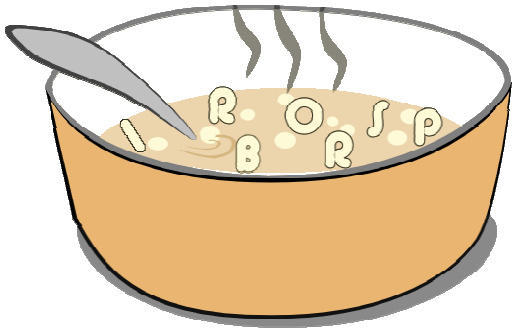
Oakes, J. M. (2002). Risks and wrongs in social science research: An evaluator's guide to the IRB. *Evaluation Review*, *26*, 443-479.

Pritchard, I. A. (2002). Travelers and trolls: Practitioner research and institutional review boards. *Educational Researcher*, *31*, 3-13.

"Protection of Human Subjects." (2009, January 15). 45 CFR PT. 46 Retrieved from http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm

Yanow, D., & Schwartz-Shea, P. (2008). Reforming institutional review board policy: Issues in implementation and field research. *PS: Political Science and Politics*, *41*, 483–494.

Appendix I: IRB Alphabet Soup



CFR: Code of Federal Regulations

HSR: Human Subjects Research

IRB: Institutional Review Board

OHRP: Office for Human Research Protections

OHSR: Office of Human Subjects Research

ORSP: Office of Research and Sponsored Programs, a typical name for the university office that handles IRB applications

Belmont Report: A statement of basic ethical principles governing research involving human subjects issued by the National Commission for the Protection of Human Subjects in 1979. The report was developed in response to concerns about research studies in which subjects had been placed at serious risk and sometimes seriously harmed. It describes three ethical principles: (1) respect for persons, (2) beneficence, and (3) justice.

Common Rule: Federal Policy regarding protection of human subjects adopted by a number of federal agencies in 1991 and described in CFR Title 45, Part 46.

Straight from the Code of Federal Regulations
Title 45, Part 46: Protection of Human Subjects

§46.102 Definitions

(a) Department or agency head means the head of any federal department or agency and any other officer or employee of any department or agency to whom authority has been delegated.

(b) Institution means any public or private entity or agency (including federal, state, and other agencies).

(c) Legally authorized representative means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.

(d) Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

(e) Research subject to regulation, and similar terms are intended to encompass those research activities for which a federal department or agency has specific responsibility for regulating as a research activity, (for example, Investigational New Drug requirements administered by the Food and Drug Administration). It does not include research activities which are incidentally regulated by a federal department or agency solely as part of the department's or agency's broader responsibility to regulate certain types of activities whether research or non-research in nature (for example, Wage and Hour requirements administered by the Department of Labor).

(f) Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains

(1) Data through intervention or interaction with the individual, or

(2) Identifiable private information.

Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject. Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

(g) IRB means an institutional review board established in accord with and for the purposes expressed in this policy.

(h) IRB approval means the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and federal requirements.

(i) Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

(j) Certification means the official notification by the institution to the supporting department or agency, in accordance with the requirements of this policy, that a research project or activity involving human subjects has been reviewed and approved by an IRB in accordance with an approved assurance.

Appendix II: Tied in Knots

1. Institutional review is based on the following principles:

U.S. Policy Principles and International Sources

	Articles in US Policy	Sources
	Belmont Report (1979)	Nuremberg Code (1947) Declaration of Helsinki (1964)
Principle 1	Informed consent*	Respect for persons
Principle 2	Risk assessment	Beneficence
Principle 3	Selection of research population	Justice
	IRB Guidebook (1993)	
Principle 4	Privacy and confidentiality	

*Ability to give consent, voluntarily – legal capacity to give consent, freedom of choice, and capacity to understand

Yanow & Schwartz-Shea, 2008

3/29/2010 Foster/Howard 14

2. Federal Regulations *may* apply to all research at any given institution.

Library Research

1. Content analysis
2. Interviews
3. Focus groups
4. Observation
5. Usability testing
6. Experimental studies
7. Bibliometrics
8. Action research
9. Classroom research

3/29/2010 Foster/Howard 5

3. Federal regulations about institutional review *allow* institutions to implement the **Common Rule** in different ways.