

## Research Ethics and Working with the Institutional Review Board

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Emma, the chemistry library manager at a large state university, had spent much of her morning reviewing responses from the student and faculty user survey when she received a notice that she had a new email. Ready a break, she decided to take a look and immediately regretted it. It was a notice from the university's Institutional Review Board (IRB) stating that there a participant had complained about the survey process. When IRB staff looked for the study in its records, they didn't find it. Was Emma engaged in human subjects research without IRB approval? Perhaps she could find some time in her schedule to come to a meeting of the Institutional Review Board and talk about it? Emma was confused and a little concerned. It wasn't like she was giving the patrons drugs or anything. It was just a survey. How was this a problem?

**Introduction.** This article focuses primarily on librarians in academic institutions with IRBs, however, knowledge of human subjects protections is also useful for librarians in other settings who conduct research such as user needs analyses, patron surveys, or interviews.

**What is the IRB?** Most colleges and universities where research is conducted have an Institutional Review Board that has oversight over human subjects research. The [federal regulations](#) state that a human subject is a living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual, or identifiable private information. Therefore, if you interact with living people and obtain information from them, you may well have human subjects research. And, if you are conducting human subjects research, you need to be aware of the protections for subjects in general and for vulnerable populations specifically.

The IRB (and qualified staff) reviews and approves applications, investigates complaints, and reviews most studies at least once a year. They are guided in their actions by federal and institutional rules and regulations. Depending upon the institution, IRBs may review

everything from mostly minimal risk undergraduate projects, to social science research and cutting edge biomedical research requiring input from consultants or community experts. Most IRBs have staff that provides education to investigators through one-on-one consultations, online tutorials, presentations to the research community, and targeted group presentations such as to new graduate students. IRBs also select or oversee auditing (which may be known by other names such as ‘review’ or ‘monitoring’) of investigators for a number of reasons, including new investigators with complex or greater than minimal risk research, research that includes vulnerable populations, or general oversight to check that rules and regulations are being followed. When things go wrong, such as failure to seek IRB approval where appropriate, failure to obtain consent, or a subject complains, the IRB can send an auditor to review the investigator’s research methods and data management. Auditors may review documentation, consent forms, or even the consent process.

When problems are found, the IRB can stop the study, prohibit the use of data from subjects who were not properly consented, or require subjects to be re-consented if possible. There may be institutional and governmental sanctions – including being barred from conducting research – for investigators who are found to be noncompliant with the rules and regulations.

Contrary to what some investigators may believe, the IRB is not in an adversarial position against them, but exists to protect research participants and to provide education so that investigators are aware of their duties and obligations to them.

**How did we get here?** Concern for human subjects developed from a realization of the horrors of Nazi experiments on concentration camp victims during World War II. The [Nuremberg Code](#) sets forth ten points to consider when working with human subjects. Points of most interest to librarians engaged in research include:

- Voluntary consent – Participants must be volunteers. You can’t make a person participate in research. You can’t threaten them. You can’t bribe them. The Informed Consent Document has to have enough information about the study, its risks, and benefits (either to society or to the individual participant) for the participant to decide whether to participate in the research or not. [Federal regulations](#) regarding consent, and as applicable to the usual LIS research, state that a consent must have statements about the research and its purpose, reasonably

foreseeable risks and benefits, and confidentiality of records that identify the subject. It must also have the name and contact information of a person the subject can ask about his/her rights, and a statement that participation is voluntary and no penalty or loss of benefits will occur for refusing to participate in the research or terminating participation in it at any time.

- Subjects should not experience unnecessary physical and mental suffering and injuries – It is unlikely that most LIS research will cause physical suffering, but it can cause mental suffering, which may include embarrassment, anxiety, and fear of being found out. If you conduct research in the workplace, the participant's remarks may adversely affect his/her job. There is always a risk of something and your application may be returned to you if you assert that there are no risks. At the very least, loss of confidentiality is usually a risk. It is your job to determine the risks given the study and the population. For example, you may be comfortable talking about using a computer to find information, but some participants may feel embarrassed about their lack of online search skills or general computer savvy.
- Staff conducting the experiment should be trained and scientifically qualified – Even if you are 'just' interviewing participants, you have to know what you are doing. How will you interact with participants? What methods and theories do you plan to use? Does everyone on the research team understand the concepts of privacy and confidentiality in regards to consent and protecting subject data? If you are interviewing, for example, the IRB will generally expect you to do so in private (other than a focus group or the type of marketing interview you might see in a mall). Put yourself in the participant's shoes – would you want to answer your interview in public?

An important part of protecting human subjects is the proper storage of study data. If you have paper records, they must be kept in a secure location such as a locked file cabinet, not just sitting on your desk. Electronic data should be minimally secured by password and with limited access to the research file on the server. If you have IRB-approved human subjects research data in a file on your shared drive, only research team members should be able to access that file, not your whole department. You may need to work with your organization's IT department to determine what level of electronic security will meet the IRB's requirements.

- Subjects must be free to leave the study – This includes not only letting them stop interacting with you and walk away, but also telling them they don't have to answer questions they don't

want to answer. 'Free to leave' also encompasses crafting online surveys so that participants can skip questions.

In addition to the Nuremberg Code, the [Belmont Report](#) also provides ethical principles and guidelines for human subjects research:

- Respect for persons – people have a right to choose to participate and those with diminished intellectual capacity or under the control of others, such as prisoners, should be protected. The current trend in human subjects research is to permit people to participate to the extent they are able. Therefore, someone who is schizophrenic or who has intellectual disabilities should not be automatically excluded from participation. Protection may also be needed for those with limited education, the homeless, or the economically disadvantaged. The IRB can provide information about working with these populations. Other organizations, such as the [US Veteran's Administration](#) and the [Department of Defense](#) have additional guidelines. For example, the Department of Defense considers subordinates, deployed personnel, and very sick people to be vulnerable populations. If you are doing research with tribal communities, you will probably have to work with the tribe to obtain permission to access people and places, in addition to your organization's IRB.<sup>1</sup>
- Beneficence – There is an obligation not to harm participants and to maximize benefits while minimizing possible harms.
- Justice – Is research equally distributed? People who will not benefit from the research should not bear its burdens. Investigators should not recruit subjects from institutionalized populations or the economically disadvantaged just because the warden provides access or the person needs the compensation and will agree to almost anything.

Despite these guidelines, researchers continued to abuse subjects. Most adults are probably familiar with the 40 year [Tuskegee Syphilis Experiments](#), in which black men were told they had 'bad blood,' were not treated for their syphilis, did not give consent, and perhaps worse of all, were not treated for their disease. The investigators did promise to provide burial insurance, so there was that. Readers may be interested in Allen Hornblum's *Acres of Skin*,<sup>2</sup> which uses firsthand prisoner accounts to present the unethical experiments carried out in a Philadelphia prison. [Stanley Milgram's](#) experiment used deception (more on deception in LIS

research later) to determine if people would obey orders to harm another and found that 65% of ‘teachers’ in the experiment were willing to give what they thought were high voltage shocks to ‘learners’ who provided incorrect answers or were silent. Participants did so even when they thought learners begged them to stop the shocks and were crying out in pain.

**The IRB and you.** Much LIS research, such as surveys and interviews about information behavior, will meet the guidelines for [expedited](#) research. Expedited research includes, but is not limited to surveys, interviews, focus groups, program evaluation, and communication, and can include audio or video data collection methods. Expedited research can be reviewed by one board member or a designee. If your research includes vulnerable populations, has questions about sensitive topics, or uses deception, the full board may want to review the application.

Your research may qualify for [exempt](#) status. For LIS researchers, this category broadly covers research for normal educational practices such as comparing instructional techniques; research using educational tests (unless disclosure of responses could damage financial standing or employability, or have other damaging consequences); the use of existing data, documents, or records if the sources are publicly available or the investigator records the information so that subjects cannot be identified. Be advised that the IRB, not you, makes the decision as to whether research is expedited, exempt, or requires a full board meeting.

So, what kind of LIS research uses deception? A typical study using deception would be having a member of the research team ask for assistance at the information desk where the purpose of the research is not to see if the librarian provides the right answer, but to review the librarian’s behavior or level of service. Research using deception must provide a way to inform subjects of the deception as soon as possible and the IRB will require that your application state how you will do this. Of course, it would be hard to deceive subjects if you’ve made them sign a consent form first, so [45 CFR 46.116\(d\)](#) permits a waiver of informed consent under specific circumstances if the study is minimal risk and subjects will be debriefed after participation.

**The IRB application.** If you’ve never filled out an IRB application before, it’s good to know beforehand what you will need. The IRB will require an overview of the research, a literature review, how many participants you want to recruit and whether they are male and/or

female, minors and/or adults, a list of research team members and their academic qualifications, and, if applicable, permission from someone with the authority to permit you to access their site. For example, you will need permission from the principal or the school district to go into a public school. Similarly, you will need permission from the manager or corporate headquarters to access seniors in an assisted living facility. You will need to submit additional documents such as funding and grant materials and any documents that the subject will see. The IRB will want to review any images and text for recruiting material that you use. You will not be permitted to have flyers that say something like, “Students! Earn big money! Call us to find out how.” There are guidelines for what can be said in recruiting materials, so you may need to contact your IRB for the exact elements they require. As stated above, there are also guidelines for consent documents. Your IRB may provide templates for consent documents, so that you don’t have to start from scratch. Once you receive IRB approval, you cannot change them without submitting a modification and having it approved by the IRB. Before starting any of this, if you are unsure whether your study is human subjects research, contact your IRB, the staff can help you with this determination.

**Conclusion.** Librarians in educational or medical organizations are likely to be subject to IRB oversight, but even if that is not your situation, it is useful to know the history of human subjects research, why the ethical guidelines were developed, what they are, and how you should apply them in your research. As a member of a service-oriented profession, the quality of your interaction with patrons is important to you. It should be just as important, when conducting research, to treat them ethically, to be mindful of the risks of participating in the research, how to reduce that risk, and the extra precautions you may need to protect subjects who are members of vulnerable populations. Securing data, making sure research is conducted in the manner as approved by the IRB, and recruiting and consenting properly may seem like a lot of work for the research usually conducted by practicing librarians, but all of these requirements are the least we can do when it comes to protecting the people who participate with us in our research.

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