



Institutional Review Board 101

Librarians and the IRB

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Agenda

- Introduction
- Background
- Librarian's roles and the IRB
- Questions

Introduction

Librarians have always been part of the research process especially in academia, however they rarely served on Institutional Review Boards (IRBs) or evaluated research proposals.

As more librarians conduct research and are given faculty status they are sought after by IRBs for their expertise. Even librarian's who do not have faculty status are being recruited for the research skills and ability to consult on literature reviews and research methods.

Introduction

Having knowledge of Institutional Review Boards or serving as a member expands a librarian's knowledge of the regulatory factors that affect research and helps establish the librarian within the university community as an integral part of the research process.



Background & History of IRB's

What is most likely the main reason(s) IRB's were created:



- a. Because all living organisms including animals deserve to be treated with respect.
- b. To eliminate deception in research studies.
- c. Because of problems that arose from the Tuskegee Syphilis Study.
- d. All of the above
- e. None of the above.

Background

IRBs--part of research procedures in academia around 1974
Tuskegee Syphilis Study

Paid \$5.00



Placebo given

Untreated



Image located at: <http://health-equity.lib.umd.edu/347/>
Government file photo

Timelines and Terms

- 1932 (1940)-1972—Tuskegee Syphilis Study— lead to the establishment of the Office for Human Research Protections (OHRP)
- 1946--Nuremberg code-- basis for the Code of Federal Regulations Title 45 Part 46
- 1974—National Research Act--created the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research to regulate human experimentation in medicine.
- 1978—Belmont Report--summarizes ethical principles and guidelines for research involving human subjects, three core principles are identified: respect for persons, beneficence, and justice
- 1981—Common Rule—Standards for government funded research. The main elements of the Common Rule include, compliance requirement for research institutions, researcher's requirements for informed consent, requirements for IRB membership, function, reviews, record keeping, etc.
- 2019—Common Rule (revised)

Since that time various other studies have been documented that raise questions concerning ethics in research. (Oct 2004)

The CAMBODIA DAILY

All the News Without Fear or Favor | The Daily Newspaper of Record Since 1993

“Cambodian sex workers and health officials on Monday expressed skepticism over the ethics of a \$1 million HIV study, funded by the US National Institute of Health and computer tycoon Bill Gate’s charity foundation (Doyle & Karen, 2004).”

paid \$3.00

Placebo given

Untreated



<http://news.bbc.co.uk/2/hi/health/7474600.stm>

The primary responsibility of an IRB is to protect the rights and welfare of human research subjects and to ensure that risks undertaken by subjects are reasonable in relation to the potential benefits.

If your institution accepts federal funding, you must adhere, even if your research is not federally funded: although not required by the Code of Federal Regulations Governing the Protection of Human Subjects in Research, currently IRBs extend federal regulations to all nonfederal research.

IRBs are essential for policing unethical behavior, whether it is accidental or intentional.



Librarians & IRB

Librarian's Roles

- Ex-officio member or research consultant for the IRB
- Principal investigator in their own research, Sponsored Program or grant
- Reviewer/board member for the IRB



Librarian as IRB Consultant

- Used to analyze literature reviews
- Used as a consultant in evaluating library protocols
- Used to assist in plagiarism detection





A library doctoral student is investigating software used in India to improve information literacy. He will track student's progress over the course of several semesters. His university's IRB doesn't have a librarian on board and wants to contact a librarian in India as a consultant. Do you think this is a good idea?

- a. Yes
- b. No
- c. Not sure



Librarian as Researcher

The IRB requirement for human subjects research can seem vague. Requirements for what constitutes “research” and “human subjects” can be confusing. Also, the levels of approval--exempt, expedited and full board have different requirements and vary per institution.

Before the review process has even begun, researchers are required to complete a training course that can take 10-12 hours at a time.

There is also the IRB application, which can be pretty extensive, and the length of time that approvals can take (especially when revisions are needed), which is why many librarians may hesitate to engage in research involving human subjects because they are reluctant to go through the IRB process. (<http://acrlog.org/tag/institutional-review-board/>)

Examples of Library Research

Multiyear study of the scholarly habits of undergraduates, involves interviews with students and faculty at six campuses about how students do their academic work, all of which is recorded and transcribed with student's information to place into categories.

Study on the impact of digital badges on student motivation for learning information literacy skills in a one-credit course offered by the library. The librarian hopes to perhaps present the results at ALA Annual.

Which of the previous examples do you think would be most concerning to a reviewer and might require full board review:



- a. The multiyear study on students study habits
- b. The digital badges study
- c. Both research projects
- d. Neither research project

Tips for Researchers

Research according to federal definition has to be replicable and generalizable (meaning it could be applied to similar studies).

The essential elements of exempt research are that risks are minimal and subjects' identities are unknown.

If data are obtained from individuals whose identities cannot be ascertained, the study is not considered human subjects research and thus is not subject to regulation. It is therefore exempt from review. In this category processes must be created that ensure the researcher cannot determine the identity of the participants.

(Pagowsky & Smale, 2013)

Librarian as IRB Reviewer



- Board members may be selected or appointed by the university President, or referred from other members on the board or Head of Research, however, generally the approval rest with the university President.
- One requirement for an IRB is that at least one member must be a non-scientist, many librarians fall into this category which makes them ideal candidates.

Requirements of IRB Members

- Attend meetings
- Review protocols
- Confidentiality very important
- Open mindedness
- “Tough skinned”
- Follow regulations
- Take require trainings and frequent tests

Requirements of IRB Members

Regular training and
testing

REQUIRED AND ELECTIVE MODULES ONLY

	DATE COMPLETED	SCORE
Biomedical Refresher 2 - Conflicts of Interest in Human Subjects Research (ID: 17545)	19-May-2018	5/5 (100%)
Biomed Refresher 2 - Instructions (ID: 764)	19-May-2018	No Quiz
How to Complete the CITI Refresher Course and Receive a Completion Report (ID: 922)	19-May-2018	No Quiz
SBE Refresher 1 – History and Ethical Principles (ID: 936)	19-May-2018	2/2 (100%)
SBE Refresher 1 – Federal Regulations for Protecting Research Subjects (ID: 937)	19-May-2018	2/2 (100%)
SBE Refresher 1 – Informed Consent (ID: 938)	19-May-2018	2/2 (100%)
SBE Refresher 1 – Research with Prisoners (ID: 939)	19-May-2018	2/2 (100%)
SBE Refresher 1 – Research in Educational Settings (ID: 940)	19-May-2018	2/2 (100%)
SBE Refresher 1 – Instructions (ID: 943)	19-May-2018	No Quiz
Biomed Refresher 1 - Instructions (ID: 960)	19-May-2018	No Quiz
Biomed Refresher 1 – Research Involving Prisoners (ID: 973)	19-May-2018	2/2 (100%)
Biomed Refresher 1 – Research Involving Children (ID: 974)	19-May-2018	4/4 (100%)
Biomed Refresher 1 – History and Ethical Principles (ID: 975)	19-May-2018	2/2 (100%)
Biomed Refresher 1 – Informed Consent (ID: 980)	19-May-2018	2/2 (100%)
Biomed Refresher 1 – Regulations and Process (ID: 981)	19-May-2018	3/3 (100%)
Biomed Refresher 1 – SBR Methodologies in Biomedical Research (ID: 982)	19-May-2018	3/3 (100%)
Biomed Refresher 1 – Records-Based Research (ID: 983)	19-May-2018	2/2 (100%)
Biomed Refresher 1 – Genetics Research (ID: 984)	19-May-2018	4/4 (100%)
Biomed Refresher 1 - Populations in Research Requiring Additional Considerations and/or Protections (ID: 985)	19-May-2018	2/2 (100%)
Biomed Refresher 1 – Research Involving Pregnant Women, Fetuses, and Neonates (ID: 986)	19-May-2018	3/3 (100%)
Biomed Refresher 1 – FDA-Regulated Research (ID: 987)	19-May-2018	3/3 (100%)
Biomedical 101 Refresher Course - Complete the course (ID: 990)	19-May-2018	No Quiz
Biomed Refresher 3 – History and Ethical Principles – Research vs. Practice (ID: 993)	19-May-2018	3/3 (100%)
Biomed Refresher 3 – Informed Consent (ID: 1003)	19-May-2018	2/2 (100%)
Biomed Refresher 3 – SBR Methodologies in Biomedical Research (ID: 1004)	19-May-2018	1/1 (100%)
SBE Refresher 2 – Informed Consent (ID: 12620)	19-May-2018	1/1 (100%)
SBE Refresher 2 – Privacy and Confidentiality (ID: 12622)	19-May-2018	1/1 (100%)
SBE Refresher 2 – Assessing Risk (ID: 12624)	19-May-2018	1/1 (100%)
SBE Refresher 2 – Research with Prisoners (ID: 12627)	19-May-2018	1/1 (100%)
SBE Refresher 2 - Instructions (ID: 12629)	19-May-2018	No Quiz
Completing the SBR 201 Refresher Course (ID: 12630)	19-May-2018	No Quiz
Biomed Refresher 3 - Instructions (ID: 12631)	19-May-2018	No Quiz
Biomed Refresher 3 – Genetics Research (ID: 12633)	19-May-2018	3/3 (100%)
Biomed Refresher 3 – History and Ethical Principles – Belmont Principles (ID: 12640)	19-May-2018	3/3 (100%)
Biomed Refresher 3 - Populations in Research Requiring Additional Considerations and/or Protections (ID: 12643)	19-May-2018	2/2 (100%)

Part 1 of a Refresher Course

Sample Questions

1. Which of the following populations, when considering equitable treatment of subjects should special care be given according to IRB criteria for approval?

- (a) Prisoners
- (b) Emancipated children
- (c) Adult education students
- (d) Classroom teachers

2. When research is conducted with children in educational settings, when is the assent of potential student subjects required?

- (a) When the IRB has determined that students are capable of providing assent.
- (b) Assent from children is always required before students can take part in research.
- (c) Assent is required only when the students are over the age of twelve.
- (d) When parents determine that their children should provide assent.

Disclaimer: Questions and answers altered from original.

Medical Librarians

“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. 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 (Smale, M.A., 2010).”

Side Note

IRB's have been sued:

- Grimes (2001)—Informed consent
- Ellen Roche (2001)—Risks
- Robertson (2000)—Negligence (approving revisions without full board)
- Gelsengie (1999)—Conflict of Interest of researcher

(Powell, 2002)

<https://chicagounbound.uchicago.edu/cgi/viewcontent.cgi?referer=https://www.google.com/&httpsredir=1&article=5204&context=uclrev>



Has this presentation assisted in providing a better understanding of Institutional Review Boards and the role librarians can play as consultants, researchers or board members?

Your comments are appreciated, please share your thoughts by completing the anonymous survey below.

https://pvamu.co1.qualtrics.com/jfe/form/SV_25H59MPDjQQobdz

Questions

Thank You



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