IRB and the Librarian Researcher

Hosted by the MiALA Librarian Scholarly and Creative Activity Interest Group (LSCA IG)

Caitlin Benallack, LSCA IG Chair

Agenda

1. Panelist Introductions
2. IRB Terminology
3. Panel Discussion
    a. Questions from the moderator
    b. Questions from the audience
4. Audience Sharing
    a. Padlet: Tips, Tricks, and Experiences
    b. Audience Discussion

Panelists

- Amy Fyn
  - Business Librarian
  - Eastern Michigan University
- Liz Lorbeer
  - Chair of the Medical Library
  - Western Michigan University
  - Homer Stryker MD School of Medicine
- Linda Miles
  - OER Librarian
  - Michigan State University
- Jennifer Rundels
  - Business Librarian
  - Central Michigan University

IRB Terminology

Learning to “speak IRB.”

Institutional Review Board (IRB)

“An institutional review board (IRB) is the institutional entity charged with providing ethical and regulatory oversight of research involving human subjects, typically at the site of the research study.” (National Institutes of Health)

National Institutes of Health. (n.d.) *Institutional Review Board*. NIH Inclusion Outreach Toolkit: How to Engage, Recruit, and Retain Women in Clinical Research. https://orwh.od.nih.gov/toolkit/human-subjects-protections/institutional-review-board.

“Research”

“Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.”

Code of Federal Regulations, Title 45, Subtitle A, SubChapter A, Part 46, Supart A, § 46.102

https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46/subpart-A/section-46.102

Human Subjects

Human subject means a living individual about whom an investigator conducting research:

(i) Obtains information through intervention or interaction with the individual, and uses, studies, or analyzes the information; or

(ii) Obtains, uses, studies, analyzes, or generates identifiable private information.

Adapted from Code of Federal Regulations, Title 45, Subtitle A, SubChapter A, Part 46, Supart A, § 46.102

https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46/subpart-A/section-46.102

Informed Consent

“It is a process that involves conveying accurate and relevant information about the study and its purpose; disclosing known risks, benefits, alternatives, and procedures; answering questions; and enabling the potential participant to make an informed decision about whether to participate.”

East Carolina University University and Medical Center Institutional Review Board (n.d.) I*RB FAQs- Informed Consent*. https://rede.ecu.edu/umcirb/irb-faqs/consent/

Primary Investigator (PI)

“[T]he scientist or scholar with primary responsibility for the design and conduct of a research project, including preparation of the proposal or research protocol.”

East Carolina University University and Medical Center Institutional Review Board (n.d.) I*RB FAQs- Basic Definitions*. https://rede.ecu.edu/umcirb/irb-faqs/definitions/

Exempt (and Non-Exempt)

Some studies that involve humans may be exempt from the requirements in the Federal regulations. Studies that fall into the following categories could qualify for exemptions, including:

- research conducted in established or commonly accepted educational settings;
- research involving the use of educational tests;
- research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if unidentifiable or publicly available;
- research and demonstration projects which are conducted by or subject to the approval of department or agency heads; or
- taste and food quality evaluation and consumer acceptance studies.

(Steneck, p. 39)

Steneck, N. H. (2007.). *Introduction to the Responsible Conduct of Research.* United States Department of Health and Human Services. https://ori.hhs.gov/sites/default/files/2018-04/rcrintro.pdf

Questions for Panelists

Panelist Questions: Getting Ready for IRB

- What kind of training is required at your institution to qualify as a researcher or PI? How extensive is it?

- What types of supports--in-person or asynchronous--are available to help you navigate the process?

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- What were the trickiest questions that came up in filling out the protocol?
- How much time does the process take from start to finish?
- What kinds of mid-project or final reporting is required?
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Panelist Questions: Lessons Learned

- What do you wish you had known or done before starting a project that requires IRB?
- How did the specific circumstances of your projects shape your IRB experiences? (e.g. collaborators, institution type, exempt vs non-exempt)
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Audience Questions?

Place questions in the chat, or raise your hand and be called upon to unmute.

Audience Advice: Padlet

Share your IRB tips ,tricks, and experiences

Padlet:
https://tinyurl.com/irblibrarianresearcher

Audience Advice: Discussion

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