NAVIGATING THE IRB

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Presentation Overview

1. What is "human subjects research"?
2. What is an IRB?
3. What do you do with your research idea?
   - *Categories of research*
   - *Application Process*
4. What does the IRB do with your application?
   - *Review process*
   - *Response*
5. What are your continuing duties as a researcher?

1. What is Human Subjects Research?

- According to the Common Rule (45 CFR 46), human subjects are
  - *"Living individual(s) about whom an investigator conducting research obtains data through intervention or interaction with the individual; or identifiable private information"*

Is the data to be collected or has it been collected (archival, secondary data) from a person? It's probably human subjects research requiring an application….even if it's considered "exempt from IRB review" (*more to come here*)

1. What is Human Subjects Research?

- *Research* is "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge" (45 CFR 46.102 [d]).
- A project or study is research if it is
  - *Conducted with the intention of drawing conclusions that have some general applicability, and*
  - *Uses commonly accepted scientific methods.*
- Key observation: All research has the *potential* to cause harm

2. What is an IRB?

- Interdisciplinary group of scientists and non-scientists, consisting of at least one member not affiliated with a university who review research to ensure that procedures
  - *Are consistent with sound research design (scientific merit)*
  - *Minimize potential risks to participants*
    - Risk-benefit ratio
    - Risk is not just physical!
    - Assure that informed consent is obtained
    - Provide protection for vulnerable populations/with sensitive topics
- Evaluate according to federal guidelines, the *Common Rule* (45 CFR 46)
- IRB approval is not a "university seal of approval"
  The role of the PI, dean, and IRB is different!

NO IRB APPROVAL? NO DATA COLLECTION.

Including pilot studies, and the like…

3. What do you do with your Research Idea?

- Prepare and submit an application *before* you act on your idea!
  - A thoughtfully constructed IRB application can actually improve your research project

3. Categories of Research: Exempt

- Categories of Research: Exempt
  1. *Research in established or commonly accepted educational settings*
  2. *Survey questionnaires, interviews, educational tests, public behaviors without specific possible negative consequences*
  3. *Archival, deidentified data*
  4. *Public service program evaluation*
  5. *Taste and food quality/consumer acceptance studies with safe, wholesome foods*
  6. *Oral history research*

Example: Category 3—Archival, Secondary Data (Exempt)

- Data collected in the "**course of business**"
  - *Accreditation data!*
  - *No "special" questions beyond what is in the scope of accreditation*

Data collected and analyzed for the purposes of accreditation or program improvement. You notice something interesting that you want to disseminate.

De-identified data analyzed and intended for publication.

IRB application and approval happens here!

3. Categories of Research: Expedited and Full Board

- Categories of Research: Expedited
  - *Minimal risk, 8 categories*
- Categories of Research: Full Board
  - *Protected classes*
  - *Sensitive topics*

3. Application Process

- IRB Handbook and Policies—InsideCBU
  - *Provost Tab, Institutional Review Board link on the right ("IRB Overview, Information, and Forms")*
  - *https://insidecbu.calbaptist.edu/ICS/Inst_Research/IRB/*

- Application form (delete irrelevant questions)
- Table of Contents
- Research Description
- Other items, as needed (and listed in ToC)

→ Single PDF

3. Application Process

- **Get specific!**
  - *Research Project Description*
  - *Consent Form (Use examples provided!)*
  - *Recruitment*
- **Remember your audience**
  - *No jargon*
  - *Professional writing*
  - *Details!*

Informed Consent

It can't be "informed" if it's not clearly written!

- Ensuring that researchers obtain informed consent of participants is a major IRB function

- A consent form should include:
  1. *Nature of the study*
  2. *PI contact information*
  3. *Participation is voluntary*
  4. *Statement that project has bee approved by the IRB*
  5. *Time commitment (needs to be real)*
  6. *Possible harm/ benefits & attempts to mitigate risks*
  7. *Alternative procedures (if applicable)*
  8. *Free choice (right to withdraw at anytime)*
  9. *Confidentiality/anonymity of data*

Tips

- Be sure to address each element in the IRB proposal. Don't leave anything out.
- Write clearly and concisely.
- Proofread.
- Create one pdf document including the application form, TOC, research project description, and attachments.
- Be sure to have letters of support or other documents that support what you write.
- Focus on consent form- *very important*
- Risks are O.K. Make every attempt to show that you have mitigated any risks and that benefits outweigh risks.
- Allow 2-4 weeks to get through the IRB review process (without revisions).

4. What does the IRB do with your Application?

- Review Process
  - *Exempt/Expedited are reviewed by 1-3 members of the committee*
  - *Full Board applications are reviewed by a minimum of 5 during a scheduled board meeting*
  - *What do we look for? Has the potential risk to participants been adequately mitigated?*
- Response Possibilities
  - *Approve as is*
  - *Approve with Revisions* (Most common)*
  - *Defer*
  - *Disapprove*

5. What are your Continuing Duties as a Researcher?

- Report potential unforeseen risks/adverse events immediately
- Submit amendments to approved protocol, as relevant (waiting for approval before enacting)
  - *New researchers involved*
  - *Changes in documents, measures, etc., that pose new risks to participants*
- Complete Renewal OR Study Closure Report prior to study expiration date

Be on the Lookout

- Federal guidelines that regulate IRB functions are changing. That means our processes are changing. Please always use the most-up-to-date form for IRB applications to prevent the return of your application.

Once updated, a summary of all Handbook changes will be made available on InsideCBU

Thank you! Questions?

- Additional Resources:
  - *IRB Handbook:* https://insidecbu.calbaptist.edu/ICS/Inst_Research/IRB/IRB_Home_Page.jnz
  - ***Human Subjects Research Tutorial:*** **https://phrp.nihtraining.com/users/login.php**
  - *HHS Decision Trees:* https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts/index.html
  - *Federal Regulations:* https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/
  - *Belmont Report:* https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html
  - ***Email:*** irb@calbaptist.edu