Surviving the IRB Application Process

Andrews University Faculty Institute
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Your Experience with the Institutional Review Board (IRB)

- Past / Present / Future
- Researcher / Advisor
- Good / Bad
- Clear / Ambiguous

The Function of the IRB

- Jurisdiction
  - Research involving human subjects
    - BY AU students and/or faculty
    - ON AU students and/or faculty

The Responsibility of the IRB

- Protect subjects
  - Voluntary consent
  - Informed consent
  - Risk
    - Minimal risk
    - Benefits outweigh risk
- Follow Federal guidelines

The Challenge of the IRB

- Foster good research
- Not create an obstacle to research
- Clear procedures
- Timely processing of applications

The IRB Process

- Proposal submitted to the IRB Office
- Proposal is categorized
  - Exempt from IRB Review
  - Eligible for Expedited Review
  - Needs Full Review
- Proposal is evaluated
- Revisions requested
  - Missing information
  - Clarify procedures
  - Modify procedures
- Final decision (approve/reject)

The IRB Structure

- Institutional Review Board
  - 10+ members
    - Sets policy
    - Monitors all IRB-related activities
    - Evaluates proposals needing Full Review
- IRB Chair
  - Coordinates all IRB activities
  - Does initial categorization of proposals
  - Responsible for Expedited Reviews
- Research Integrity and Compliance Officer
  - In charge of the IRB Office
  - Coordinates the application process
  - Monitors proposals

Who Needs to Submit a Proposal?

- AU faculty member or student
- Conducting “research” with “human” subjects

What does “Exempt from IRB Review” Include?

- Research not involving “humans”
  - No application is required
- Study involving humans that is not “research”
  - Exempt by prior definition by the IRB
    - Administrative data collection
    - “Internal” class projects
      - Requires a group exemption
  - Exempt after evaluation by the IRB Office
- Special cases that involve little risk
  - Pre-existing data collected anonymously

What Needs to be Submitted?

- Application form
  - 3 new forms are being developed
- Protocol
  - if information is not included in the application form
- Supporting documents
  - Recruitment documents
  - Informed consent/assent forms
  - Data collection instruments
  - Institutional approval letters (if off-campus)
  - Training certificates
    - Investigators
    - Advisor

What Information Needs to be in the Protocol - 1?

- Each of the following items will be asked on the IRB application being developed.
  - What is the purpose of the study?
  - Who are the subjects?
    - Minors
    - Vulnerable populations
  - How are the subjects recruited or selected?
  - How will informed consent be obtained?
  - What risk will subjects be subjected to from experimental conditions?

What Information Needs to be in the Protocol - 2?

- What are the data collection procedures?
  - Where will the data collection take place?
  - What data will be collected?
  - How will the data be collected?
  - Who will collect the data?
- How will the data be treated confidentially?

What Issues are Evaluated in a Proposal?

1. Are there minors or other vulnerable populations involved?
2. Is there pressure or coercion to participate?
3. Is there concealment or deception involved in recruitment?
4. Are sensitive topics being studied?
5. Are there physically invasive procedures?
6. Will confidentiality be maintained?
7. Will subjects be exposed to undue risk?

Your Application Will Be "Quickly" Approved if:

- You clearly explain in detail how you will:
  - Deal with minors or other vulnerable populations appropriately?
  - Not use any undue pressure or coercion to participate
  - Not use any unnecessary concealment or deception in recruitment?
  - Treat sensitive topics appropriately
  - Minimize risk if using physically invasive procedures
  - Maintain confidentiality of the data
  - Not expose subjects to undue risk

Questions?