The Nuts and Bolts of Submitting a Successful IRB Application

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Research Rounds

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Objectives

- Introduce members of the SMUIRB
- Describe the history and basic tenants of IRBs
- Describe the process of IRB application including the appropriate document completion
- Identify common errors in application
- Describe best practices in response to IRB requirements/review

IRB at SMU

- SMUIRB established in 1997
- Compliance with federal guidelines under the Department of Health and Human Services (DHHS)
  - OHRP is the Office for Human Research Protections
- Federalwide Assurance Number
  - Required for federal funding
- Members appointed by President
  - Requirements
    - One non-scientific member
    - One member not affiliated with institution
    - Representatives of different knowledge areas and types of research

Current SMUIRB Members

- Nicole Christensen, PhD, PT, MAppSc
- Cecily Cosby, PhD, FNP-C/PA-C
- Jamie Hirota, MPA, IRB Administrator
- Bruce Richardson, PhD
- Eric Stamps, DPM
- Kristi Wessenberg, non-scientist, non-institutional member
- Gail Widener, PhD, PT, Chair

History of IRB

- Atrocities of human experimentation/exploitation
  - Nazi war crimes (1930-40s)
  - Tuskegee syphilis experiments (1930-1972)
- Nuremberg Code (1947)
  - 10 principles of research ethics involving human subjects
- Belmont Report (1979)
  - Respect for persons
  - Beneficence
  - Justice

Ethical Principles

- Respect for Persons
  - Consent
    - Coercion, undue influence
  - Confidentiality/privacy
- Beneficence
  - Benefit versus risk
- Justice
  - Equitable selection of participants

HIPAA

- HIPAA enacted in 1996
  - Protects people from inappropriate disclosures of protected health information
- Privacy Rule enacted in April, 2003
  - Standards for privacy of individually identifiable health information applied to research
  - Enforced by Department of Health and Human Services (DHHS)

Protected Health Information

- Names
- Geographical subdivisions smaller than a state
- Phone number
- Fax number
- E-mail address
- SSN
- Medical Record Number
- Health plan beneficiary numbers
- Dates related to individuals (except year)
- Account numbers
- Certificate/license numbers
- Vehicle identifiers
- Device identifiers
- URLs
- Internet Protocol (IP) addresses
- Biometric identifiers
- Full face photo images
- Other unique identifying number, characteristic, or code

Main Function of IRB Review

- IRB must assure that
  - Risks are minimized
    - Risks are reasonable in relation to anticipated benefits (risk/benefit ratio)
  - There is informed consent
  - Rights and welfare of participants are maintained

Risks Associated with Research

- Direct harm versus potential benefit
  - Physical (injury)
  - Social (reputation)
  - Psychological
  - Economic (financial or employability)
- Coercion or undue influence in recruitment
- Disclosure of research objectives/methods
- Confidentiality of records/data

Confidential versus Anonymous

- Anonymous
  - Researchers cannot identify who is participating
    - Not anonymous if
      - If researchers know individual participants or
      - Collect any identifying information about the participants
      - Size of the sample is so small, identity can be uncovered
- Confidential
  - Data must be coded so that identifying information is protected
  - Master list of participants with codes kept locked
  - Can't keep IC forms with subject data, keep in separate location

Types of Review

- Full committee
  - Reviewed by the full committee
  - Turn in first of each month
- Expedited
  - Reviewed by at least 2 members of the committee
  - Can be turned in any time
- Exempt
  - Subjects are anonymous
  - Names are never associated with individual data
  - Can be turned in any time

Categories of Exempt Review

- Research in educational settings - no identifiers
- Research that uses cognitive diagnostic aptitude or achievement tests
  - Public officials
- Research about
  - Public benefit or service programs
  - Procedures that explain benefits or services
- Collection or study of
  - Existing data, records or documents, specimens available publicly
  - Data that contain no identifiers – BLINDED data sets

Expedited or Full Review?

- Expedited review
  - Essentially includes studies where risks are minimal
  - Minor changes to approved research
- Full review
  - Higher risks
  - Vulnerable population

When is IRB Review Required?

- **SMUIRB MUST** approve all **RESEARCH** involving SMU students, staff or faculty – even if it occurs at locations outside of SMU campuses

NO EXCEPTIONS

When is SMUIRB Review Required: Other IRB Approvals

- **All** research involving SMU faculty, students or staff
  - Research occurring at other institutions in which SMU people are participating
    - Researchers must provide
      - IRB approval from other institution
      - Recruitment plan for individuals at SMU
  - Research occurring at another location involving SMU faculty, students and staff from other institutions must supply SMUIRB with their current IRB approval

Forms to Complete

- **Protocol Approval form**
  - Make sure you look at whether you need to answer all questions
    - Full review does NOT require answering questions 7-11
    - Exempt studies require all questions to be answered
  - Must be signed by PI, co-PI, students, mentors
- **Protocol Format**
  - Fully answer questions
  - Make sure appendices are clearly labeled
  - IC form should be written at the 5th grade level
- **Checklist**
  - Go through each item on the checklist to make sure you have completed each applicable item

Certification of IRB Training

- Training certificates required for ALL members of the research team dealing with participants or data
  - This includes researchers, students, research assistants, recruiters, etc.
  - Anyone who will come into contact with subjects of subject data
- Link to the training is located on SMUIRB webpage
- Two ways to complete (both are free)
  - NIH training
  - CITI through Sutter Health

Response to IRB Recommendations

- Response letter should include:
  - IRB number and title of project
  - Take each point raised by the IRB and respond how you addressed it in the documents
  - Attach corrected documents with corrections highlighted in some way
    - **BOLD**,
    - *Italics*,
    - highlighted

Reimbursement for Research Volunteers

- IRS does not require reporting of a thank you gift given as entertainment
  - Movie tickets, etc.
  - Does not need to be reported if given to SMU employee
- Cash or gift cards of $25 or less are not considered taxable item (cash and gift cards are equivalent to IRS); however anything over $25 is taxable income
  - If the volunteer is a SMU employee - need to report since the employee may receive $25 from more than one source and therefore the income is taxable.
  - If giving gift cards, keep a log and have volunteers sign when receiving the card

Questions?

- SMUIRB page on the SMU website
- Ask any IRB member
  - Jamie will connect you with a member
- Jamie Hirota