Closing the Gaps in Elder Abuse Research

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Introduction

- Are there any aspects of IRB that researchers are not aware of?
- Strategies that reach vulnerable populations and still meet IRB needs?

Training and Education

- Mentoring students, trainees, new study personnel, collaborations/partnerships:
  - Understand the protocol/population/environment/neighborhood
  - Understand responsible conduct in research
  - Understand human subject protection regulations (informed consent, maintaining privacy and confidentiality)
  - Mandated reporting obligations
  - Cultural appropriateness

Informed Consent

- IRBs have the ability to grant waivers to informed consent procedures for minimal risk research:
  - Public demonstration projects
  - Waive elements of consent
  - Waive the requirement for a signed consent form
  - Waive the requirement to obtain consent
  - Short forms of informed consent

Assessing Capacity to Consent

- Innovative/Creative methods of informed consent
  - Use of visual aids (i.e. picture/comic books)
  - Technology
- Teach back method
- Cognitive assessments
- Plans for continual cognitive assessment throughout the duration of the research
- Legally Authorized Representatives

Mandated Reporting

- California law requires mandated reporters to report to appropriate authorities the known or reasonably suspected abuse/neglect of an elder
  - HealthCare practitioners
  - Medical practitioners
  - Non-medical practitioners

Mandated Reporting

- IRBs expect researchers to familiarize themselves and their study team with mandated reporting laws in the state/country where their research is conducted.
  - State laws periodically change
  - Laws vary from state to state or even county to county within states
  - Different countries may define abuse differently and their may be different reporting requirements and penalties.

Mandated Reporting

- Investigator Responsibilities:
  - Explain to the IRB if the investigator/study personnel are mandated reporters as defined by law
  - If not mandated reporters, clarification if the investigator/study team intends to report information about alleged, probable, or known abuse disclosed during the research
  - The Informed consent should include a description of all types of information the research team will report to authorities

Certificates of Confidentiality

- Under federal law, researchers may obtain a CoC from NIH that provides protection against forced legal disclosure of identifiable research information.
  - Research is greater than minimal risk
  - Data/information if disclosed could have adverse consequences for the participant or damage his/her financial standing, employability, insurability or reputation.
  - CoCs do not abdicate investigator's mandated reporting obligation
  - Data/information maintained outside of the United States is not protected under a CoC
  - IRBs expects researchers to inform participants in the consent form and during the consent process about the protections surrounding the CoC and the obligation of the mandated reporting

USC HRPP Flexibility Policy

- USC Flexibility Coalition
  - Unchecked all boxes on Federal Wide Assurance
  - For studies no greater than minimal risk
  - Studies with no federal funding
  - Provide equivalent protections to subjects commensurate with risk level

USC HRPP Flexibility Policy

- Exclusions to Flex Policy
  - Greater than minimal risk studies
  - No-cost extension studies
  - Projects in which a student is paid or supported from a federal training grant or otherwise paid or supported from the faculty advisors' federal funds
  - Federally-sponsored studies, including federal training grants
  - Studies with FDA-regulated components
  - Studies with contractual obligations or restrictions that preclude eligibility in this policy
  - Studies with clinical interventions
  - Studies using prisoners as subjects
  - Studies seeking or obtaining Certificates of Confidentiality

USC HRPP Flexibility Policy

- Established additional exempt categories for no greater than minimal risk activities not covered in regulations.
  - Research that does not conform to a specific exempt category under 45 CFR 46 (USC Exempt 7)
  - online surveys, in-person focus groups, and/or interviews involving minors as long as the information collected does not place the individual at greater than minimal risk
  - behavioral games
  - studies requiring performance of tasks that incur no risk o

USC HRPP Flexibility Policy

- Research where activity is limited to study of existing or prospective identifiable data (USC Exempt 8)
  - medical record reviews where data is extracted from records
  - data analysis of information already collected from court records
- Grant three year approvals for minimal risk research

USC HRPP Flexibility Policy

- For exempt category 4, broaden the interpretation of "existing data" to include data that exist at the time the research is proposed or will exist in the future for non-research purposes
- Establish “Not human Subject Research Policies”
- Create short application for chart reviews
- Create short application for use of de-identified datasets
- Allow study to begin after Certificate of Confidentiality application has been submitted (not necessary to wait until it is obtained)

USC HRPP Flexibility Policy

- Consent Form/Process:
  - Only require necessary signatures based on type of research
  - Do no limit use of short forms to translations
  - Waive documentation/elements of consent for minimal risk research
- IRB Staff
  - Can perform all non-committee functions
  - Appoint as IRB members
  - Appoint as expedited reviewers

USC HRPP Flexibility Policy

- Direct IRB to focus on the regulatory approval criteria (45 CFR 46.111)
- Allow investigators to write protocols in more general terms so alleviate the need for minor modifications
  - Changes in sequence of intervention
  - Ranges in compensation

Other Considerations

- Carefully consider collaborations/partnerships
- Reliance Agreements
  - No two IRBs are the same
  - Reduces multiple IRB reviews
  - Reduces administrative burden on researchers
  - As of May 25, 2017: NIH will require single IRB review for multi-site research
- Access to participants
  - Obtain permission from nursing home/assisted care facility allowing you to be there to conduct your research
- Consider safety of Researchers
  - Going into participants homes where perpetrator may reside
  - Work with your Office of Risk Management

Other Considerations

- Establish a Relationship with your IRB
- If you feel IRB does not have the appropriate expertise to review your type of research…volunteer to serve as a committee member
- Volunteer to serve as a consultant to assist the IRB with the review of challenging research

Contact Information

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