Introduction to the Institutional Review Board System at UIUC

Michelle Lore

Human Subjects Research Specialist

Office for the Protection of Research Subjects

lore@illinois.edu, 244-9666

Presentation for DGS, September 13, 2016

Presentation Overview

- About us
- (Brief) History
- Definitions and Regulations
- Summary of UIUC IRB application submission process and pathways to approval
  - Exempt research
  - Expedited research
  - Full board research
  - Amendments
- Informed Consent
- Research with students (if time allows)

Office for the Protection of Research Subjects

- We:
  - Are the support staff for the two UIUC Institutional Review Boards (Social Behavioral and Biomedical)
  - Review and pre-review protocols submitted to our office
  - Offer other support to the university regarding research ethics and DHHS regulations
- Our office has two main functions:
  - Protect the interests of research participants
  - Protect researchers from unwarranted claims

History of Research Ethics in USA

- Many examples of research that violated ethical treatment of humans, such as…
  - Tuskegee Syphilis Experiment (1932-1972)
  - Willowbrook Hepatitis Experiments (children exposed to hepatitis virus; ~1950-1972)
  - Tearoom Trade Study (1966-1967)
  - Stanford Prison Experiment (1971)

History of Research Ethics in USA

- National Research Act of 1974
  - Created the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research
  - Established the Common Rule (45 CFR 46) – federal policy regarding protections of human subjects; agreed to by 17 federal agencies and offices
- Belmont Report (1979) – summarizes ethical principles and guidelines for research involving human subjects
  - Respect for Persons
  - Beneficence
  - Justice

Belmont Report

- Respect for Persons
  - People treated as autonomous with freedom of choice
  - Protect those with diminished autonomy
  - Respect of privacy
  - Foundation for informed consent
- Beneficence
  - Obligation to do no harm and do good
  - Risk-Benefit Ratio
- Justice
  - Fairness in recruiting
  - Justice is distributed across populations – burdens and benefits shared equally
  - Vulnerable populations are protected
  - Freedom of choice to participate

Definitions

- Defining Human Subjects Research (Department of Health and Human Services)
  - Research – a systematic investigation designed to develop or contribute to generalizable knowledge
  - Human Subject –
    - A living individual about whom an investigator obtains data through intervention or interaction with the individual, OR
    - A living individual about whom an investigator obtains individually identifiable, private information.
  - If one or both of these definitions are not met, it is Not Human Subjects Research (NHSR)

Activities that are NHSR

- Anything that is solely for internal purpose (quality improvement/quality assurance)
- Data collection focuses on factual information, not opinions, thoughts, beliefs of individuals
- Oral history, where data collection focuses on memories of a person or event (agreement between OHA and OHRP in 2003)
- Secondary data provided from another source that is de-identified
- Publicly available data

Our office provides NHSR letters to show researchers have consulted with our office.

Vulnerable Populations

- Populations determined to be "vulnerable" and thus require additional consideration or protection. These populations include:
  - Pregnant women, human fetuses, and neonates
  - Prisoners
  - Children
  - Cognitively impaired persons
  - Students and employees
  - Economically and/or educationally disadvantaged
  - AIDS/HIV+ persons
  - Terminally ill persons

Submitting a Protocol

- Can be submitted via email (irb@Illinois.edu), in person, through campus mail (M/C 419), or faxed (333-0405)
- Make sure to include the application, the research team attachment (if there are multiple team members), recruitment materials, surveys, interview guides, consent forms, waivers, and anything else the participants may see (all forms available on our website – oprs.research.Illinois.edu)
- Responsible Project Investigator (RPI) must be a full time, non-visiting member of the faculty or staff

Exempt Research

- Six categories of low-risk research that are exempt from compliance with the full set of DHHS regulations; up to the university, state, etc. for how they want to proceed
  - UIUC still adheres to federal regulations for exempt studies, but with more flexibility, a shorter application, and reviewed completely by OPRS specialists
- All exempt studies must be determined to be "no more than minimal risk" and fit one of the allowable exemption categories
- Exempt review process usually takes ~2-3 weeks

Exempt Categories

- Category 1 – research in established educational settings involving normal educational practices, or research on the effectives of or the comparison among instructional techniques, curricula, or classroom management methods
- Category 2 – research that only involves surveys, interviews, and/or observations unless the data is personally identifiable AND disclosure of responses could place the participant at risk in some way
- Category 4 – research that utilizes secondary data that has already been collected

Exempt Examples

- The Effects of Intrusive Advising on Students on Academic Probation
  - Analyzed existing data already collected by the school
- iFoundry Academic Advising Project
  - Online survey sent to advisors and undergraduate students in engineering
- English Department Advising Office Study on Career Planning Resources
  - Online survey sent to all current English majors and minors

Exempt Approval Process

- Make sure your research can qualify as exempt! (Contact us or consult our website)
- Make sure all required CITI training has been completed
- Submit exempt application or full IRB application and any supporting documents (e.g. surveys, consent forms, etc.)
- Protocol will be entered, given an IRB number, and assigned to a staff reviewer
- Staff reviewer will review and email with clarifying questions, comments, requests, etc.
- Respond to staff reviewer
- Staff reviewer approves! Exempt protocol approval is good for five years.

Expedited Research

- Nine categories of research for studies that do not qualify as exempt but also do not need review from the fully convened IRB
  - Reviewed by one OPRS specialist and one board member
- Research must be "no more than minimal risk" and fit one of the nine allowable categories of expedited research
  - Studies that are "no more than minimal risk" but include conversations/questions about sensitive topics are usually reviewed as expedited as an extra precaution
- Expedited review usually takes ~2-5 weeks

Expedited Categories

- Category 5 – research involving materials (documents, pictures, etc.) that have been collected or will be collected solely for nonresearch purposes
- Category 6 – research collecting data with voice, video, digital, or image recordings made for research purposes
- Category 7 – research on group characteristics or behavior employing survey, interview, focus group, program evaluation, human factors evaluation, or quality assurance methodologies

Expedited Examples

- Evaluation of the Professional Development Advisors program for practitioners in early childhood care and education settings in Illinois
  - Analyzed retrospective and prospective program documentation originally collected for non-research purposes
- Racial Microaggressions at the University of Illinois College of Medicine
  - Used online surveys and in-depth interviews with College of Medicine students who identified as minorities

Expedited Approval Process

- Make sure all required CITI training has been completed
- Submit full IRB application and any supporting documents (e.g. surveys, consent forms, etc.)
- Protocol will be entered, given an IRB number, and assigned to a staff reviewer
- Staff reviewer will pre-review and email with clarifying questions, comments, requests, etc.
- Respond to staff reviewer
- Staff reviewer sends protocol to one board member and communicates any additional clarifying questions, comments, requests, etc.
- Board member decides to approve, approve with stipulations, or defer
- Approval of expedited protocols lasts for one year and must be renewed annually

Full Board Research

- Studies that do not fit within the expedited categories, have higher levels of risk to participants, or involve specific topics, activities, or populations
- Full board studies are often "more than minimal risk" due to the topics involved, activities participants will engage in, or populations being studied
  - Topics: illegal activities, highly sensitive topics (e.g. PTSD)
  - Activities: X-rays, drug and alcohol studies, maximal exercise
  - Populations: prisoners, people with mental or physical disabilities
- Full board review often takes one or more months for approval

Full Board Examples

- Enhancing the Mental Health of Children of Methamphetamine Abusers: An Intervention Study
- Homophobic Bullying: Individual and School-Level Predictors of Psychological Adjustment
- The Acute Effects of Walking and Cycling Exercise on Cognition in Persons with Multiple Sclerosis

Full Board Approval Process

- Make sure all required CITI training has been completed
- Submit full IRB application and any supporting documents (e.g. surveys, consent forms, etc.)
- Protocol will be entered, given an IRB number, and assigned to a staff reviewer
- Staff reviewer will pre-review and email with clarifying questions, comments, requests, etc.
- Respond to staff reviewer
- Staff reviewer sends protocol to two board members and the protocol is discussed at the full board meeting
- Board members decide to approve, approve with stipulations, or defer
- Approval of full board protocols lasts for one year and must be renewed annually

Amendment Process

- Get the amendment form from our website and complete it, outlining what changes need to be made to the protocol
- Send the amendment form to our office along with any new documents or documents that have been altered in any way

Informed Consent Overview

- Should give potential participants as much information as possible to decide if they want to participate in the research or not
- No coercive language (e.g. "It would be in the best interest of the participant…") or exculpatory language ("By participating in this research, you waive the right…")
- Should be at an 8th grade reading level
- If possible, give potential participants the chance to ask questions before they consent to be in the study

Elements of an Informed Consent

- Required on all consent documents (templates available on our website)
  - Who/what/why/where/when of study – includes procedures, duration, purpose, etc.
  - Voluntariness (not obligated and can discontinue at any time)
  - Confidentiality of data
  - Risks and benefits (to participant and to society)
  - Whom to contact with questions/concerns (both RPI and OPRS information should be included)
  - How they are indicating consent – signing name, clicking "yes" online, etc.

Types of Informed Consent

- Written consent – indicated through signature
- Oral consent – indicated through verbal yes/no; usually accompanied with an information or contact sheet
- Online consent – indicated through accepting a survey link or clicking yes/no on an online survey form
  - Both oral and online consent require a "Waiver of Documentation of Consent"
- Waiver of informed consent – for situations where the research is in no way possible if participants know about it or getting consent from everyone would be burdensome to researchers and risks are low
- Alteration of informed consent – deception is necessary to the study, so participants are not wholly informed about the research; debriefing must be included

Research with Students

- Recruitment should not be conducted in ways that students may perceive as coercive
- Incentives for participation (such as extra credit or gift cards) should not be large enough that they are coercive
  - Alternative and equivalent extra credit assignments should be offered for people who do not want to participate in the research
  - If participating in research is required for course credit, students should be informed of that before they sign up for the course (e.g. in the online course description)

Research with Students – FERPA!

- FERPA protects students' educational records, granting them rights for who has access to their educational records and under what circumstances
- For research, this means:
  - Researchers can ask for consent to use educational records (e.g. grades, GPA, etc.)
  - School officials (usually the Division of Management Information) can strip records of identifying information and provide the data to the researcher