Navigating the IRB Review Process for Human Subjects Research

IRB Education & Outreach Program
Kelly O’Berry and Brent Collinson
irb-outreach@uiowa.edu
Objectives

- Definitions
- Ethical Principles and Regulatory Requirements
- Criteria for approval
- IRB review process
- Flexibility and Exceptions
- Research off-campus/outside the U.S.
- Resources- Help is available!
THE "START-UP SLALOM"

CONCEPT
FUNDING
TESTING
UNPREPARED FINISH
IRB REVIEW
PREPARED FINISH

PATENT ATTORNEYS

Mayne
Definitions

- **Research** – A systematic investigation, including research development, testing and evaluation, designed to contribute to generalizable knowledge.

- **Human Subject** – A living individual about whom an investigator obtains data:
  - Data through intervention or interaction
  - Identifiable private information
What Is Not Research?

1. Case Report
2. Implementation of a proven intervention in a clinic
3. Assessment of health needs in a specific population
4. Quality Improvement/Quality Assurance projects
5. Literature Review
What/Who is Not a Human Subject?

1. Deceased persons/cadavers

2. De-identified data or samples, provided by others

3. Persons who provide information about business operations and/or environmental data
More Definitions

- **Intervention** – physical procedures for collection of data and manipulations of the subject or their environment that are performed for research purposes.

- **Interaction** – communication or interpersonal contact between researcher and subject.
Respect for Persons

Autonomous agents
  • No coercion/undue influence

Coercion- overt or implicit threat of harm

Undue Influence- excessive or inappropriate award or other overture

Diminished autonomy
  • "Vulnerable Populations"
Application

Informed Consent

- Information
- Comprehension
- Voluntariness
Ethical Principles and Regulatory Requirements

- Belmont Report (1979)
  - Respect for Persons -
    - Individuals as autonomous agents
    - Diminished autonomy - entitled to extra protections
  - Beneficence - Maximize benefits and minimize possible harms
  - Justice - Equitable subject selection and burden of participation
Beneficence

• "Do No Harm" vs. maximizing possible benefits and minimizing possible harms

• 5 common types of risk:
  • Physical
  • Psychological
  • Financial
  • Social
  • Legal
Application

• Identifying/anticipating risk

• Minimizing risk

• Examples?
Ethical Principles and Regulatory Requirements

- Belmont Report (1979)
  - Respect for Persons-
    - Individuals as autonomous agents
    - Diminished autonomy- entitled to extra protections
  - Beneficence- Maximize benefits and minimize possible harms
  - Justice- Equitable subject selection and burden of participation
Justice

- Fairness in distribution
- Burden/benefits not placed on one specific group

Application

- Equitable subject selection
Ethical Principles and Regulatory Requirements

- Belmont Report (1979)
  - Respect for Persons-
    - Individuals as autonomous agents
    - Diminished autonomy- entitled to extra protections
  - Beneficence- Maximize benefits and minimize possible harms
  - Justice- Equitable subject selection and burden of participation
Criteria for IRB Approval

- Risks to subjects are minimized
- Risks are reasonable in relation to anticipated benefits
- Selection of subjects is equitable
- Informed consent will be sought from each prospective subject
- Informed consent will be appropriately documented
Criteria for Approval (Continued)

- When appropriate the research plan makes adequate provision for monitoring the data collected
- The privacy of subjects is protected and confidentiality of the data is maintained
- Additional safeguards for vulnerable subject populations
Human Research Protection Program (HRPP)

- Institutional Review Board (IRB)
  - IRB-01 (Biomedical)
  - IRB-02 (Social/Behavioral/Educational)
  - IRB-03 (Veterans Administration)

- Human Subjects Office (HSO)

- Under the Office of the Vice President for Research and Economic Development (OVPRED)
Requirements to Conduct Human Subjects Research

• Collaborative Institutional Training Initiative (CITI)

• Know about federal regulations and UI policies and procedures

• Student PI needs a faculty advisor
  • Named on the research team
  • Sign the Assurance Document

• ClinicalTrials.gov

• IRB Approval!
ClinicalTrials.gov

- **What** is it?
  - Registry/public database of clinical trials information

- **Why** do I need to register?
  - Regulations (FDAAA 801/42 CFR Part II)
  - A requirement to publish by ICMJE
  - Severe institutional penalties from PHS
  - Giving access to public

- **Which** studies need to register?
  - Interventional drug and device trials, studies funded by NIH
  - In US or with US-manufactured drugs/devices
ClinicalTrials.gov

- **When** does my study need to be registered?
  - Federal rule: 21 days after 1st subject enrolls
  - ICMJE: prior to 1st subject enrollment

- **Who** needs to ensure we're registered?
  - Responsible party (sponsor or PI)

Coordinator/PI would need to provide CT.gov registration number (NCT#) in HawkIRB (VII.B.1.b)

- **How** do we register?
  - Contact HSO to get a username (ct-gov@uiowa.edu)
Requirements to Conduct Human Subjects Research

- Collaborative Institutional Training Initiative (CITI)

- Know about federal regulations and UI policies and procedures

- Student PI needs a faculty advisor
  - Named on the research team
  - Sign the Assurance Document

- ClinicalTrials.gov

- IRB Approval!
Human Subjects Research Determination (HSRD) Form

- CITI training not necessary
- IRB Chair Review- 2 business days
- If not HSR- determination memo
- If HSR- draft HawkIRB New Project form
- 557 HSRD forms were submitted in 2015
IRB Forms & Review Process

- HawkIRB Forms
  - New Project Application
  - Modification
  - Continuing Review
  - Reportable Event Forms (REFs)

- Delegate System

- Time frame for IRB approval (4-6 weeks)

- IRB Review Process
  - Administrative Screen
  - Staff Review / Application Analysis
  - IRB Chair or Full Board
Types of IRB Review

• Full Board – greater than minimal risk

• Expedited Review – not more than minimal risk
  • Exempt Status- 6 categories of research
Resources

- Human Subjects Office Web Site
- Policies & Guidance
  - Investigator's Guide
- HawkIRB Training Sessions & Presentations
- IRB ICON Course
- IRB Connection Newsletter
- IRB Office Hours
Questions?

Kelly O'Berry
Email: kelly-oberry@uiowa.edu
Phone: 319-335-8477

Brent Collinsonworth
Email: brenton-collinsonworth@uiowa.edu
Phone: 319-335-9559

Human Subjects Office
Email: irb-outreach@uiowa.edu
Phone: 319-335-6564