NAVIGATING THE IRB REVIEW PROCESS FOR HUMAN SUBJECTS RESEARCH
OBJECTIVES

- Definitions
- Ethical Principles and Regulatory Requirements
- Criteria for approval
- IRB review process
- Flexibility and Exceptions
- Research off-campus/outside the U.S.
- Resources
DEFINITIONS

- Research – A systematic investigation, including research development, testing and evaluation, designed to contribute to ___________ ___________

- Human Subject – A living individual about whom an investigator obtains data or biospecimens:
  - Data through ___________ or ___________
  - ___________ ___________ information/biospecimens
WHAT IS NOT RESEARCH?

• "Scholarly and journalistic activities"

• Public health surveillance activities with the goal to investigate public health signals, outbreaks, or conditions of public health importance

• Collection of data by criminal justice agencies, authorized by law/court order

• Federally authorized activities in support of national security

(45 CFR 46.102(l))
WHAT IS NOT RESEARCH?

- Case Report
- Implementation of a proven intervention
- Needs assessment in a specific population
- Quality Improvement/Quality Assurance projects
- Literature Review
WHAT/WHO IS NOT A HUMAN SUBJECT?

- Deceased persons/cadavers
- De-identified data or samples, provided by ______
- Persons who provide information about business operations and/or environmental data
MORE DEFINITIONS

Intervention – ________ procedures for collection of data and manipulations of the subject or their environment that are performed for research purposes

Interaction – ___________ or interpersonal contact between researcher and subject
ETHICAL PRINCIPLES AND REGULATORY REQUIREMENTS

· Belmont Report (1979)
  · Beneficence-
RESPECT FOR PERSONS

· ___________ 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"
“Do No Harm" vs. maximizing possible benefits and minimizing possible harms

- 5 common types of risk:
  - Physical
  - Psychological
  - Financial
  - Legal
  - Social

- Identifying/anticipating risk
JUSTICE

- Fairness in distribution
- Burden/benefits not placed on one specific group
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 __________
CRITERIA FOR APPROVAL (CONT.)

- When appropriate, the research plan makes adequate provision for monitoring the data collected
- The _______ of subjects is protected and ___________ of the data is maintained
- Additional safeguards for vulnerable subject populations
VULNERABLE SUBJECTS

- Pregnant Women/Fetuses/Neonates
- Prisoners
- Children
- Individuals with impaired decision-making capacity
- Individuals who are educationally/economically disadvantaged
- Groups not otherwise mentioned
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 (OVPR)
HUMAN SUBJECTS OFFICE

- Education- Presentations and trainings
- Review- analyzes application prior to IRB Review
- Compliance- monitors studies after approval
REQUIREMENTS TO CONDUCT HUMAN SUBJECTS RESEARCH

- Collaborative Institutional Training Initiative (CITI)
- Know about federal regulations and UI policies and procedures
- ClinicalTrials.gov Registration
- International Council for Harmonization- Good Clinical Practices
  - Training v. Review
- IRB Approval!
HUMAN SUBJECTS RESEARCH DETERMINATION (HSRD) FORM

- CITI training not necessary
- IRB Chair Review- _____ business days
- If not HSR- determination memo
- If HSR- draft HawkIRB New Project form
- 745 HSRD forms were submitted in 2018
IRB FORMS & REVIEW PROCESS

- HawkIRB Forms
- New Project Application
- Modifications
- Continuing Reviews
- Reportable Event Forms (REFs)
- Time frame for IRB approval (4-6 weeks)
DELEGATE SYSTEM

• Allows you to work on applications for your Principal Investigator
• PI must assign all team members as delegates
  • “Personalize”=> “Update My Delegates”
• Always sign in as delegate before working
REVIEW PROCESS

- HSO Staff Review
  - Administrative Screen
  - Staff Review / Application Analysis

- IRB Review
  - IRB _____/_____ _______
TYPES OF IRB REVIEW

- Full Board – greater than minimal risk
- Expedited Review – not more than minimal risk
- Exempt Status- 8 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
OFFICE HOURS

Monday, 2 PM - 4 PM, S108 Lindquist Center

Wednesday, 2 PM - 4 PM, 101 Hardin Library

Thursday, 10 AM - 12 PM, 101 Hardin Library
QUESTIONS?

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