IRB Overview

Sylvia Romo, IRB Manager

CPHS – IRB

- Committee for the Protection of Human Subjects
- Institutional Review Board
- Composition

Overview

- Mission: to protect the rights and welfare of human research participants
- Definition of research: systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge

Human Subjects

- An individual about whom an investigator, whether professional or student, conducting research obtains:
  - Data through intervention or interaction with the individual, or
  - Identifiable private information

Types of Review

- Exempt Research – Short application
  - Processed administratively
- Expedited Review
  - Reviewed by a committee member
- Full Committee Review
  - CPHS committees meet four times a month

Exempt Review Examples

- Retrospective chart review without identifiers
- Surveys/interviews/focus groups without sensitive questions
- Evaluation of educational program/course
- Use of already collected biological samples (collected for clinical purposes)
- Secondary analysis of already collected data

Expedited Review Examples

- Retrospective chart review with identifiers
- Surveys/interviews/focus groups with sensitive questions
- Collection of blood samples of limited volume
- Collection of biological samples for research purposes by noninvasive means

Full Board Examples

Clinical trial

- Randomized, double-blind, placebo
- Drug/Device
- When subjects are students, staff or residents
- Vulnerable populations (children, prisoners)
- International research

Submission for Initial Review

Required documents:

- Application
- Informed consent documents
- Protocol/Grant Cover Sheet
- Data Collection/Case Report Forms
- Letters of Support

Areas of IRB Focus

- Autonomy and respect for persons
- Equitable selection of subjects
- Risk versus benefit
- Recruitment methodology
- Consent process
- Privacy and confidentiality

Protocol Components

- Hypothesis/research question
- Background with references
- Subject population
- Recruitment methodology
- Procedures
- Sample size
- Analysis plan
- Security of data

Common Shortfalls

- Readability
- Research vs. Standard of Care
- Sample Size – High/Low
- Explain Tests/Scales/Tools
- Location, Environment

Informed Consent

- Consent is a process
- Document is a guideline
- Contains required elements and language
- Adult/parent/child
- Must be approved by CPHS
- Stamped version
- Signed by subject and research team

After IRB Approval

- Changes/Amendments
- Continuing Review (Annually)
- Protocol Deviations
- Serious Adverse Events
- Unanticipated Problems
- Data Safety Monitoring Reports

Question

CPHS Main Line: (713)500-6756 **CPHS@uth.tmc.edu**

iRIS Support: (713)500-7960 **IRIS@uth.tmc.edu**