UTHealth Houston

Human Subjects Research Overview
Committee for the Protection of Human Subjects

Sylvia Romo, Assistant Director of Compliance

Institutional Review Board – UTHealth Houston

Committee for the Protection of Human Subjects

- Memorial Hermann Health System
- Harris Health System
- Harris County Public Health
- Reciprocity Agreements (SMART IRB/UT System Reciprocity)

Committee for the Protection of Human Subjects

- Administrative Staff
- Members
- IRB Meetings

Overview

- Committee that reviews research involving human subjects
- Mission: To protect the rights, safety, and welfare of research participants
- Required for federally funded research in the US

Human Subjects

- Human subject means a living individual about whom an investigator (whether professional or student) conducting research:

  (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or

  (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

  FDA: 21 CFR § 50.3(g)

- Human subject means an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient.

What are the areas of IRB Focus?

Autonomy and respect for persons

- Consent process

Justice

- Equitable selection of subjects

Beneficence

- Minimize risk and maximize benefit

What research requires IRB Review?

- Any systematic investigation involving human subjects
- Data Collection through interaction or intervention
- Use of identifiable private information
- Clinical trials, surveys, interviews, behavioral health studies

Types of Review

- Exempt Research
  - Minimal Risk
  - Falls into specific exempt categories
  - Requires IRB determination
- Expedited Review
  - No more than minimal risk
  - Reviewed by IRB Member
- Full Committee Review
  - More than Minimal Risk
  - Vulnerable populations
  - Sensitive topics
- Non-Human Subjects Research
  - When determinations/letters are requested

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

Full Board Examples

- Clinical trial
- Randomized, double-blind, placebo
- Drug/Device
- Vulnerable populations (children, prisoners)
- Surveys/Focus Groups –Sensitive topic or questions

What is required for submission for IRB Review

All submissions are handled through iRIS –Integrated Research Information Software

https://iris.uth.tmc.edu/

- IRB Application
- Protocol
- Investigator Brochure/Package Inserts (Drug/Device Studies)
- Consent Documents
- Data Collection Forms/Case Report Forms
- Ancillary Reviews
- Letters of Support
- Human Subjects Education
- Guidance – CPHS Website and Templates https://www.uth.edu/cphs/

After IRB Approval -Investigator Responsibilities

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

Common Shortfalls

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

IRB Office

Anne Dougherty, MD
Institutional Official

Vanessa Fuller, BS-IRB Manager

Sujatha Sridhar, MBBS, MCE
Associate VP, Research Compliance

Laura Lincoln, BS – IRB Manager

Liz Gendel, PhD- Director
Research Compliance

Sylvia Romo, BSBM - Assistant
Director Research Compliance

IRB Office

IRB Panel A

Aleen George, MHA, MBA – Coordinator

IRB Panel B

Gabrielle Longo, BS –Coordinator

IRB Panel C

Chandni Chaudhari, MD – Coordinator

IRB Panel D

Alba Zeigler, BS, CPhT – Senior IRB Coordinator

Ryesha Cook MBA – Coordinator

Research Compliance Specialist

Meagan Olivares, CCRP

Reliance and Quality Improvement

Laura Baker, BS – Coordinator

Graduate Research Assistant

Adrick Harris, BS

Personnel Change Requests

CPHS Assistance

CPHS 713-500-7943
Email cphs@uth.tmc.edu

IRIS Support 713-500-7960

IRB Office Hours : Join the IRB Teams room IRB Office Hours to have your IRB and iRIS questions answered on Thursdays from 1 to 4 pm.