UTHealth Houston

Committee for the Protection of Human Subjects

7000 Fannin Street, Suite 1870
Houston, Texas 77030

IRB Overview

Sylvia Romo, Assistant Director, Compliance

CPHS – IRB

- Committee for the Protection of Human Subjects
  - Memorial Hermann Healthcare System
  - Harris Health System
  - Reciprocity
- Composition
  - Administrative Staff
  - Members
  - Meeting

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

IRB LEADERSHIP AND SUPPORT TEAM

Vanessa Fuller, BS
IRB Manager

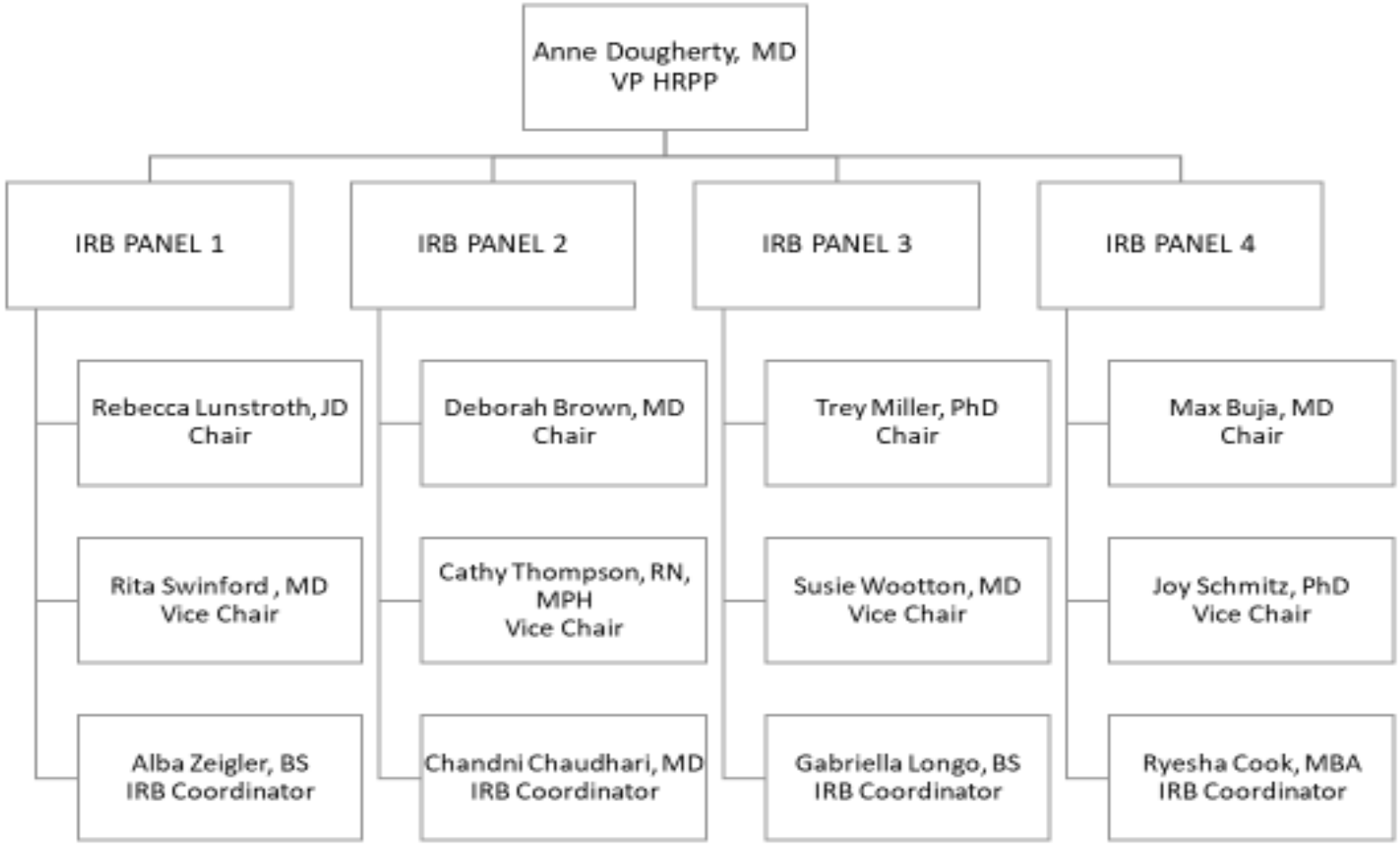
Laura K. Lincoln, BS
IRB Manager

Sylvia Romo, BSBM
Assistant Director, Research Compliance

Meagan Olivares, BS
IRB Reliance

Elizabeth Gendel, PhD
Director, Research Compliance

Barbara Legate, BS
iRIS Support



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.

Question

CPHS Main Line: (713)500-6756

CPHS@uth.tmc.edu

iRIS Support: (713)500-7960

IRIS@uth.tmc.edu