Regulatory Basics

Institutional Review Board
Research Requirements &
Common Audit Findings

Presentation by
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IRB Regulatory Coordinator
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IRB: Institutional Review Board

- Committee to review and approve human subjects research
- Overall protection of human research subjects
- Compliance with federal regulations
  - FDA
  - OHRP
  - HIPAA
- Compliance with institutional guidelines
UTHSC IRB

Responsible for overseeing research at:

- University of TN Health Science Center
- Le Bonheur Children’s Hospital
- Methodist Healthcare-Memphis Hospitals
- Regional One Health
- ULPS
Study Review Categories

I. Full Board
II. Expedited
III. Exempt
IV. NHSR
I. Full Board

• **Characteristics:**
  – Greater than minimal risk
  – Vulnerable populations
  – Invasive procedures
  – Require annual Continuing Reviews

• **Examples:**
  – Use of investigational drug, device, or biologic (Clinical Trials)
  – Research on illegal activities
  – Performance of biopsies to collect study specimens
II. Expedited

• **Characteristics:**
  – Use of Protected Health Information (PHI)
  – Minimal risk
  – Non-invasive procedures
  – Require annual Continuing Reviews

• **Examples:**
  – Retrospective Chart Reviews
  – Studies involving venipuncture on healthy adults
  – Studies involving audio or video recordings
  – Interventional studies using FDA approved drugs or devices
III. Exempt

• **Characteristics:**
  – De-identified information (No PHI)
  – Minimal Risk
  – No Continuing Reviews

• **Examples:**
  – Anonymous tests or surveys
  – Use of publically available or de-identified data/specimens
  – Use of existing data in which information is recorded without PHI
IV. Not Human Subjects Research (NHSR)

Human Subject*
A living individual about whom an investigator obtains
1) data through intervention or interaction
2) identifiable private information

Research*
A systematic investigation designed to develop or contribute
to generalizable knowledge.

Examples:
- Case Reports (5 or fewer subjects)
- De-identified tissue samples from deceased individuals

*45 CFR § 46.102
Exempt or NHSR?

Remember!

Let the IRB make the final determination!
IRB Research Requirements

Where do I begin?
UTHSC E-mail Address

• Don’t have one?
  – You will need to find a UT faculty/staff member to sponsor you
  – Sponsor must complete “UTHSC NetID Sponsored Request” form
CITI Training: UTHSC Group 3

Collaborative Institutional Training Initiative (CITI)

Must be completed every 3 years by all members of the key study personnel who are listed on the study application

Human Subjects Protection Training
— HIPAA and Privacy
— History and Ethics
— Informed Consent
— Vulnerable Subjects
Faculty Advisors

If you are a **student, resident, or fellow** and will be acting as the **Principal Investigator** in a study, you will need a faculty advisor.
iMedRIS Access

• All study applications are submitted through iMedRIS
Institutional Requirements
Methodist Le Bonheur Healthcare
Research Credentialing
Student Credentialing

- Students (UTHSC, UofM, etc.)
  - Job Description
  - Computer Access Forms
  - Confidentiality Agreement
  - CITI Training – Group 3
  - HIPAA Training
  - CV

Contact me to request forms!
Student Credentialing (cont.)

• Students are **NOT** allowed to interact with Le Bonheur patients.

• Students can **ONLY** assist in chart reviews.
Students on Rotation

• Students on rotation are fully credentialed and are allowed to interact with patients.

• However, once their rotation ends, if they want to continue to participate in MLH research, they must go through student credentialing.
Residents and Fellows

- Residents and Fellows are fully credentialed and allowed to interact with patients.
Clinical Affiliation Agreements

Covers students and/or faculty in specific departments

Examples include:

– UTHSC Nursing School (BSN, MSN, PhD)
– U of M School of Public Health
– UTHSC Clinical Pharmacy
Staff/Faculty Credentialing

✓ Not employed by MLH (i.e., UTHSC employee)

✓ Will be viewing medical records

✓ Will be interacting with patients

Contact Latashja Mosby at Latashja.Mosby@mlh.org
Children’s Foundation Research Institute
Research Requirements
CFRI/PCRU Advisory Board

- PI-Initiated
- Full Board
- Expedited studies with drug, device, or biologic
- Meets once a month
- Approval needed prior to full IRB approval
- Le Bonheur Children’s Hospital only
Departmental Forms

• Use of services outside your department

• Requires sign off by department director

• Examples:
  – Radiology
  – Laboratory
  – EEG/EMG
  – Pharmacy
Over-Age Forms

Needed if you plan to enroll subjects who are:

• Over 21 years of age
• Not current patients at Le Bonheur
• Undergoing an actual procedure

Exceptions
- Family studies
- Adults with chronic childhood diseases who are still being followed at Le Bonheur
UTHSC IRB / iMedRIS
Study Application Requirements
Key Study Personnel

• Who will participate in the conduct of the study?
  – Principal Investigator (PI)
  – Sub/Co-Investigators
  – Research Support Staff

• Study Contact
  – Always include Lisa Sentiff

• Faculty Advisor (if applicable)

• Designated Department Approval
  – Jon McCullers, MD

• Research Administrative Specialist (RAS)
  – Le Bonheur Children’s Hospital: Lisa Sentiff
Study Protocol

- Purpose
- Rationale
- Study Population
- Research Design
- Study Procedures
- Outcome Measures
Confidentiality and PHI

• What is PHI?
  – Protected Health Information
  – Information that can be used to identify an individual, which personally relates to their past, present, or future health

• How will PHI be:
  – Used and/or recorded?
  – Protected?
  – Stored?
  – Transferred to other sites?
HIPAA: Health Insurance Portability and Accountability Act of 1996

18 HIPAA Identifiers

- Names
- Geographic Locations
- Dates
- Telephone Numbers
- Fax Numbers
- E-mail Addresses
- SSNs
- MRNs
- Health Plan Beneficiary Numbers
- Account Numbers

- Certificate/License Numbers
- Vehicle Identifiers and Serial Numbers
- Device Identifiers and Serial Numbers
- URLs
- IP Addresses
- Biometric IDs
- Full face photos
- Any other unique ID (except for random codes)
HIPAA and PHI

• De-identified data:
  – removal of all 18 identifiers
    • Safe Harbor Method
    • Expert Determination

• Limited data set:
  – removal of 16 identifiers excluding:
    • Dates
    • Geographic locations (smaller than a state)
ON A SIDE NOTE…

Data Use Agreements (DUAs)

Required if the following criteria are met:

• identifiable data (PHI) will be shared with another entity for research purposes

• said entity is not covered by HIPAA language in consent form
Informed Consent

UTHSC Consent Form Templates

- Main
- Survey
- Repository
- Genetic Analysis

Required Elements of Consent

1) Research
2) Voluntary
3) Risks
4) Benefits
5) Alternatives to Treatment
6) Confidentiality
7) Compensation
8) Contact Information
Waiver of Informed Consent

Criteria
• Minimal risk
• Will not adversely affect the rights and welfare of the subjects
• Research cannot practicably be carried out without the waiver
• Additional relevant information will be provided to subjects

Most Common Example
• Retrospective chart review
Special Protections

- **Office for Human Research Protections (OHRP)**
  - 45 CFR 46 (Subparts B, C, & D)
    - Pregnant Women, Human Fetuses and Neonates
    - Prisoners
      - Children

- **Food and Drug Administration (FDA)**
  - 21 CFR 50 (Subpart D)
    - Children
Assent of Minors

Included in Main Consent Form

✓ 14-17 years of age
   Sign main signature page

✓ 8-13 years of age
   Sign “Short Form”
For more detailed information, please go to:

http://www.uthsc.edu/research/compliance/irb/
Common Audit Findings
12. CONSENT OF SUBJECT:
You have read or have had read to you a description of the research study as outlined above. The investigator or his/her representative has explained the study to you and has answered all the questions you have at this time. You knowingly and freely choose to participate in the study. A copy of this consent form will be given to you for your records.

Signature of Research Subject (18 years +) __________________________ Date __________ Time __________

Printed Name of Adult Research Subject __________________________

Assent of Minor (Ages 14-17) __________________________ Date __________ Time __________

Printed Name of Minor Research Subject __________________________

Signature of Legally Authorized Representative __________________________ Date __________ Time __________

Printed Name of Legally Authorized Representative __________________________

Relationship of Legally Authorized Representative __________________________

Signature of Person Obtaining Consent __________________________ Date __________ Time __________

Printed Name of Person Obtaining Consent __________________________

In my judgment, the subject or the legally authorized representative has voluntarily and knowingly given informed consent and possesses the legal capacity to give informed consent to participate in this research study.

Signature of Investigator __________________________ Date __________ Time __________
Consent Discussion Documentation

- Required by UTHSC IRB in addition to the Main Consent Form
- Must be signed and dated by the Person Obtaining Consent and the PI, if applicable

NOTE: This is different from Documentation of Consent
Delegation of Authority Log

• All key study personnel members must be listed

• Identifies who is responsible for performing which tasks throughout the study, such as:
  ✓ Obtain consent
  ✓ Perform physical exams
  ✓ Access medical records
  ✓ Dispense study drug
Licenses and CVs

- Required for Full Board and some Expedited studies

- A current copy of each must be retained for each of the study investigators

- Most common finding is that they are either missing, lapsed, or expired

- CVs should be updated every 3 years
References

UTHSC IRB
  •  http://www.uthsc.edu/research/compliance/irb/

Department of Health and Human Services (HHS.gov)
  •  45 CFR 46
  •  Health Information Privacy

Food and Drug Administration (FDA.gov)
  •  21 CFR 50
  •  Guidance for IRBs and Clinical Investigators