# Regulatory Basics

## Institutional Review Board Research Requirements & Common Audit Findings

**Presentation by**

**Lisa Sentiff, MPH, CCRP**

**IRB Regulatory Coordinator**

**Children's Foundation Research Institute**

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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

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# 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?


Let the IRB make the final determination!

# IRB Research Requirements

## Where do I begin?


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# 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

<u>Human Subjects Protection Training</u>

- HIPAA and Privacy
- History and Ethics
- Informed Consent
- Vulnerable Subjects


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# 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.

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# iMedRIS Access

- All study applications are submitted through iMedRIS


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# Institutional Requirements

## Methodist Le Bonheur Healthcare

## Research Credentialing

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# 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!

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# 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

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# 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

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## Research Requirements

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# 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


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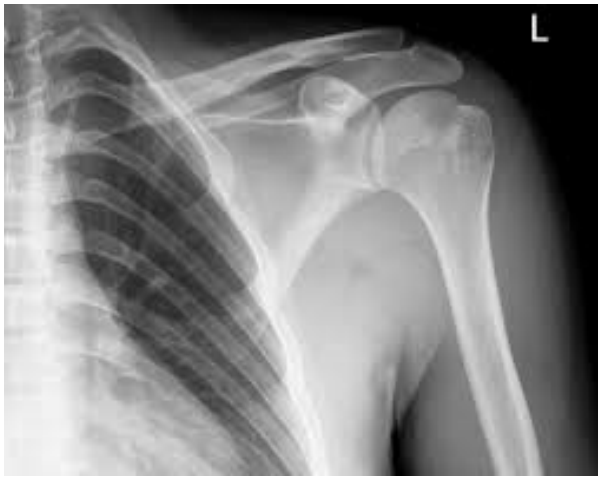
# Departmental Forms

- 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

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# 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)

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# 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)

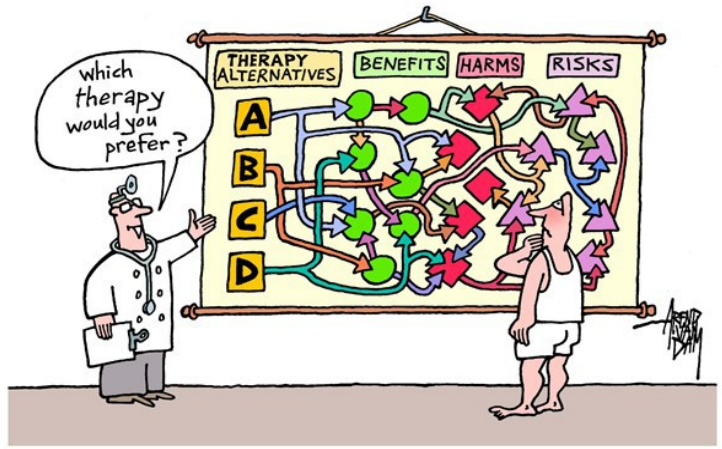
Required if the following criteria are met:

- 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




*informed consent*

**Required Elements of Consent**

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

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# 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

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# Assent of Minors

Included in Main Consent Form

✓ <u>14-17 years of age</u>

Sign main signature page


✓ <u>8-13 years of age</u>

Sign “Short Form”

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For more detailed information,

please go to:

http://www.uthsc.edu/research/compliance/irb/


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# Common Audit Findings

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# Consent Forms

## Signatures

- Even if POC and PI/I are the same, both signature lines must be signed

## IRB Approval dates

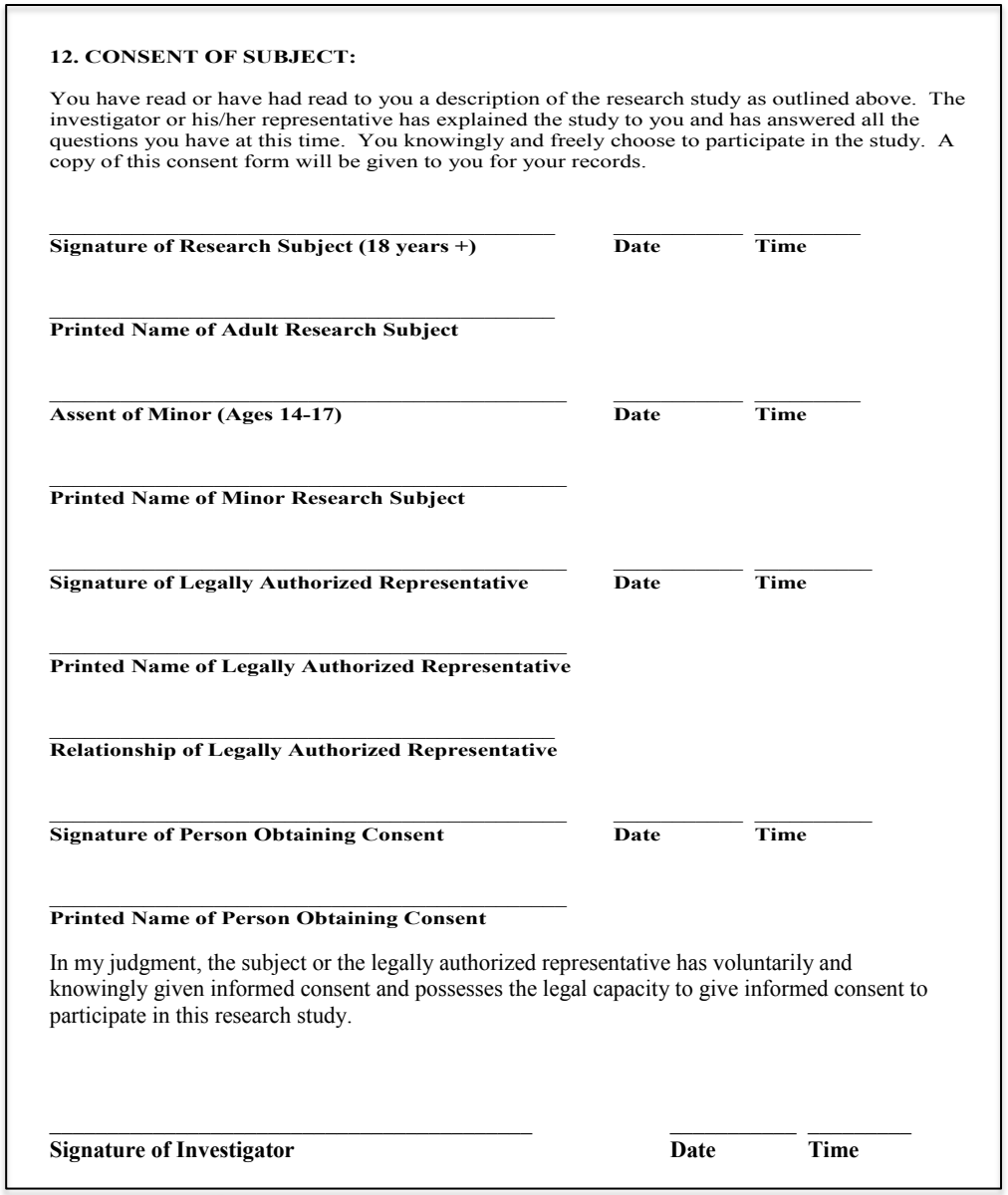
- Use most recent version

## Times

- AM vs PM
- PI/I must sign within 72 hours of subject

## Dates

- Everything signed must be dated



**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**

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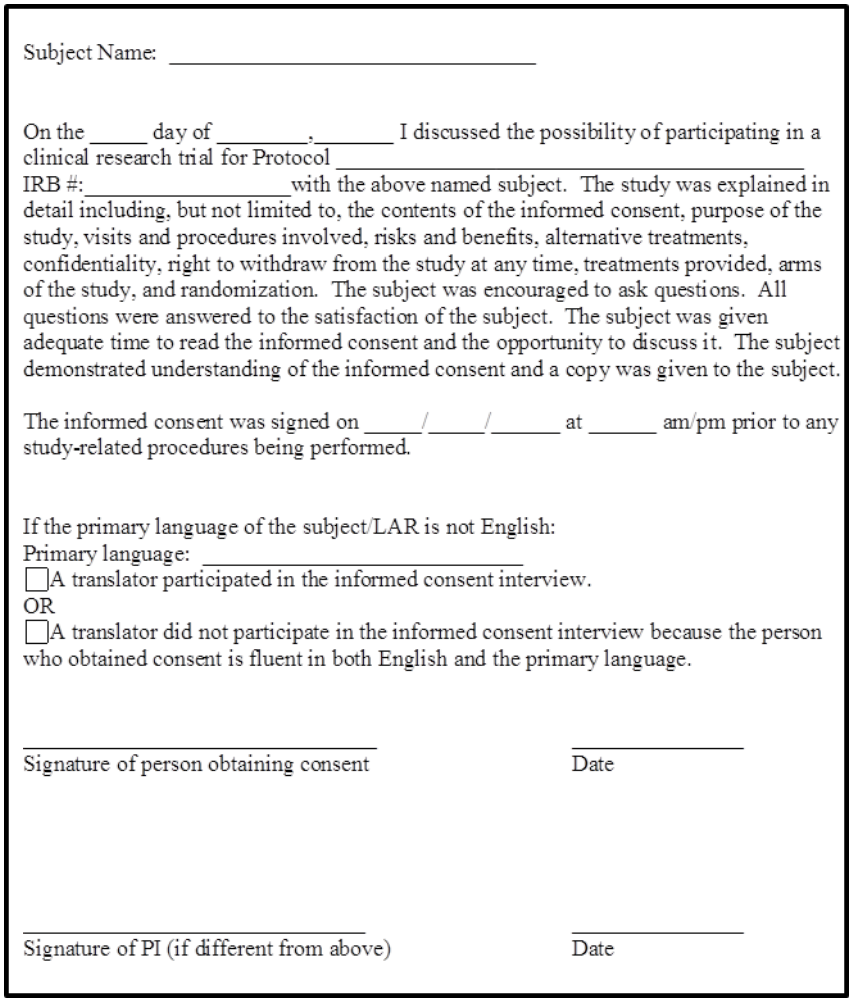
# Consent Discussion Documentation



Subject Name: _____

On the _____ day of _____,_____ I discussed the possibility of participating in a clinical research trial for Protocol _____ IRB #:_____with the above named subject. The study was explained in detail including, but not limited to, the contents of the informed consent, purpose of the study, visits and procedures involved, risks and benefits, alternative treatments, confidentiality, right to withdraw from the study at any time, treatments provided, arms of the study, and randomization. The subject was encouraged to ask questions. All questions were answered to the satisfaction of the subject. The subject was given adequate time to read the informed consent and the opportunity to discuss it. The subject demonstrated understanding of the informed consent and a copy was given to the subject.

The informed consent was signed on _____/_____/_____ at _____ am/pm prior to any study-related procedures being performed.

If the primary language of the subject/LAR is not English:
Primary language: _____
☐A translator participated in the informed consent interview.
OR
☐A translator did not participate in the informed consent interview because the person who obtained consent is fluent in both English and the primary language.

_____ _____
Signature of person obtaining consent Date

_____ _____
Signature of PI (if different from above) Date

- 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

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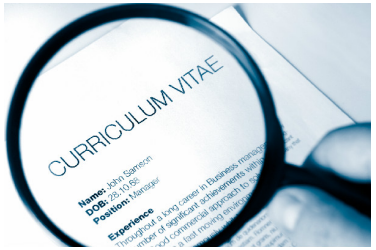
# Delegation of Authority Log

- 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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