

Human Subjects Research

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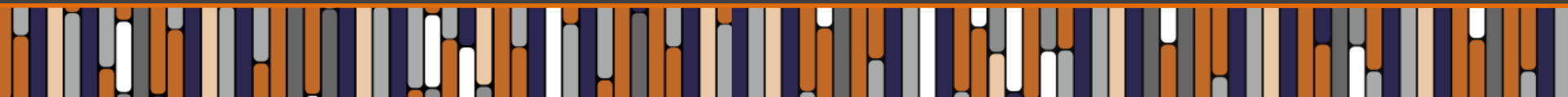
CPHS - IRB

- Committee for the Protection of Human Subjects
- Institutional Review Board
- Diverse individuals



Areas of Jurisdiction

- Research conducted by any UTHealth faculty, staff or student
 - MHHS
 - UT clinics
 - HCPC
 - Harris Health Systems/LBJ



Types of Review

- Full Committee Review
CPHS committees meet four times a month
- Expedited Review
Processed administratively but reviewed by a committee member
- Exempt Research – Short application
Processed administratively
- Reliance on another IRB



Submission for Initial Review

Required documents:

- Application
- Informed consent documents (if applicable)
- Protocol from sponsor (if applicable)
- Investigator brochure from sponsor (if applicable)
- Case report forms
- Recruitment material



Electronic Submission

- Electronic submission of protocols to the IRB
 - Initial submission
 - Change requests and amendments
 - Continuing reviews
 - Adverse Events, etc.
- Electronic routing and review by CPHS
- Notifications are electronic and available via e-mail and within iRIS



Electronic Submission, cont.

- System is web-based and available from any computer
- System is secured by UT-H ID's and passwords
- All Key Study Personnel will have access to protocols and to all related study correspondence and letters
- Approved, stamped informed consent documents are readily available in the system
- System has automatic reminders for continuing review deadlines



Informed Consent

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



Informed Consent (cont'd)

- Required language
- Sixth grade reading level
- Consent (over 18 years of age)
- Youth Assent (ages 7-17)
- Parental permission (under 18)
- Consent template



Human Subjects Education

UTHSCH policy (HOOP 23.11 Research Training) requires that all investigators participating in research involving human research subjects, human derived materials, or human derived data complete approved training on the protection of human research subjects regardless of the funding source for the research.

This includes:

- principal investigators
- study coordinators
- study nurses
- laboratory personnel
- non-key personnel

Course options:

- The CITI course offered by the University of Miami
(<https://www.citiprogram.org/default.asp?language=english>)



Routing Forms

- Research Conflict of Interest Certifications
 - Required for all PI's and Co-PI's on initial submissions
 - If a conflict is disclosed, refer to Conflict of Interest website



Protocol Registration Requirements

If the research study is:

- Clinical trial
- Investigator-initiated
- PI holds the IND/IDE
- Not registered by anyone else (sponsor)
- Planning publication in a peer-reviewed journal
- www.clinicaltrials.gov



Important Information

- iRIS Web Site: <http://iris.uth.tmc.edu>
- Documentation Web Site:
<http://www.uth.tmc.edu/orsc/irb/iRIS.html>
- iRIS assistance: 713-500-7960
- Office of Research Support Committees:
713-500-7943



Questions

