Human Subjects Research

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UTHealth
The University of Texas
Health Science Center at Houston
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
  - Harris County Psychiatric Center
  - 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
- NIH sample consent
- Protocol adapted from grant
- 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 for signature and COI
- 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-HID’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 guides the conversation
- Contains required elements/language
- Template on website
- Adults vs children
- Must be approved by CPHS
- Approval stamp
- Signed by subject and research team
Important Information

- iRIS Web Site: [http://iris.uth.tmc.edu](http://iris.uth.tmc.edu)
- Documentation Web Site: [http://www.uth.tmc.edu/orsc/irb/iRIS.html](http://www.uth.tmc.edu/orsc/irb/iRIS.html)
- iRIS assistance: 713-500-7960
- Office of Research Support Committees: 713-500-7943
Questions