Clinical Research

The NIH distinguishes 3 types of clinical research:

- Patient-oriented research
- Epidemiological and behavioral studies
- Outcomes and health services research

Clinical Research (source: NIH)

This type of research involves a particular person or group of people or uses materials from humans*. It can involve:

- Studies of mechanisms of human disease
- Studies of therapies or interventions for disease
- Clinical trials
- Studies to develop new technology related to disease

*This includes extracted human teeth!

Clinical Research

These types of studies examine the distribution of disease, the factors that affect health, and how people make health-related decisions.

Clinical Research (source: NIH)

These studies seek to identify the most effective and most efficient interventions, treatments, and services.
If your study can be categorized as clinical research by NIH, you will need to comply with the policies and procedures established by the government for Protection of Human Subjects!

What that means for you...

1) You will need to verify that ALL individuals who will be assisting with this research have completed the CITI training and that it is still valid (expires after 3 years). This includes, but is not limited to:
- Principal Investigators, Co-Investigators, Sub-Investigators
- Research Assistants/Associates
- Study Coordinators
- Dental Hygienists/Assistants
- Students
- Anyone involved in the study, especially if they will be interacting with subjects or samples (i.e., obtaining consent, collecting Protected Health Information (PHI), analyzing biological samples)


What that means for you...

2) You will need to apply for IRB approval
- During the application process, you will be able to decipher whether the study is exempt, expedited or full-board review. There will be different requirements for each type of IRB review and each study.
- When you submit to the IRB, you will need to include all study documents, including consent forms, protocols, marketing materials, case report forms, investigator brochures, etc.)

3) If required by the IRB, you will have to develop an informed consent form following the UTHSC template, which can be found at [http://www.uthsc.edu/research/research_compliance/IRB/consent.php](http://www.uthsc.edu/research/research_compliance/IRB/consent.php)

UTHSC does not use central IRBs. If any UTHSC faculty, staff, or student is working on a clinical research project, the UTHSC IRB must review and approve the study.

Any consent form used by UTHSC faculty, staff, or students, or in a UTHSC PI's study, MUST USE the UTHSC template.

What that means for you...

4) You (or your coordinator) should develop an “Investigator Notebook,” or research binder, that includes the following (at a minimum):
1. Copy of IRB- approved protocol
2. Copy of the IRB Outcome Letter
3. Study contract (if applicable) and sponsor contact information
4. CVs of all research team members (signed & dated within two years of study)
5. Contact information and role description for all research team members
6. Copy of IRB-approved consent/assent forms
7. Copy of all IRB-approved study documents
8. Study schedule
9. Master subject list – including all completed, screen fails, and withdrawn

What that means for you...

5) You (or the study coordinator) will have to securely maintain all research records and the Investigator Notebook throughout the study and for three years beyond study close-out.
6) You (or the designated person on your team) must manage and properly track all study data
7) You must track all adverse events (AEs) and communicate them to the proper individuals (i.e., IRB, study sponsor, FDA)
8) You (or the study coordinator) must submit all study changes to the IRB in a timely fashion and complete continuation and close-out forms.
**Consenting**

A few things to keep in mind

- Consent forms must be signed by subject or subject’s legal guardian/authorized representative. (NOTE: just because the person accompanies the subject DOES NOT mean that they are that individual’s legal guardian)
- Anyone who obtains consent (whether a resident or another faculty member) MUST BE listed in that specific study’s IRB application and MUST HAVE their CITI certification to obtain the consent.
- Subjects (legal guardians/authorized reps) must date and time their signature themselves.

**Case Report Forms (CRFs)**

A few things to keep in mind

- At a minimum, you should have:
  - A record/log of inclusion/exclusion criteria for each subject
  - A form for recording/tracking adverse events (even if you do not think that you will need one)
  - Product distribution log (if applicable)
  - Randomization chart (if applicable – record of to what product each subject was randomized, and if blind and products are coded, a code breaker)

**Master Subject Log**

It is necessary to keep a master log of all subjects, their study IDs, and their study status (complete, screen failure, withdrawn).

It is necessary to keep this master log separate from all subject charts and secured (whether in a locked file cabinet and/or a password protected electronic database).

**Access to Research Records**

When completing the IRB application, you will have to designate who, outside of the IRB, will have access to the research records.

Make sure to list anyone (including faculty/staff who are doing the analysis) who might need to see the records/CRFs to complete their work.

Keep in mind that the number of individuals with access to research records should be kept to a minimum. Create a system where the least amount have access.

**CITI Certification**

More details on CITI

- Collaborative Institutional Training Initiative (CITI)
  - www.citiprogram.org
  - Complete all modules for Group 3
  - Use UT NetID as username (non-UT users, use first initial of first name with full last name. Ex: jsmith)
  - Affilie with UTHSC- Memphis
  - Add employee number (if non-UT employee, type NOEPN)
  - Certification lasts 3 years
iMedRIS

- All investigators and some study staff should have access to iMedRIS, which is the electronic system used by the IRB to submit studies for approval.
- Once you have a UT NetID, log into iMedRIS (https://ris01.uthsc.edu). If this is your first time using iMedRIS, log back out immediately after logging in.
- Email Patricia Page (ppage@uthsc.edu) your name and department affiliation so she can give you full access.

IRB Fees

- The IRB has a fee to review studies that are industry sponsored:
  - Full Board Review = $2400
  - Expedited Review = $1200
  - Exempt = $500

*Please keep this in mind when preparing your study budget!

Contact

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