Practicum Involving Human Subjects Research

Overview
If your practicum project will involve human subjects research, you must seek Institutional Review Board (IRB) approval by the UTHealth Committee for Protection of Human Subjects (CPHS) prior to beginning your practicum.

Interaction with or analyzing information about people does not always constitute human subjects research, however. Many host organizations provide services to individuals or communities that do not meet the definition of research. In addition, not all research is human subjects research.

To help clarify these distinctions, CPHS provides the following definitions:

- **Research** is a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

- **Human subjects** is a living individual* about whom an investigator conducting research obtains data (including tissue, specimens, and cognitive phenomena) through intervention or interaction, whether identifiable or not, or private information.

- **Human subjects research** is defined as research involving human subjects, human derived materials, or human derived data. All human subjects research, funded and unfunded, must be reviewed and approved by the UTHealth CPHS before it is initiated if it falls in one of the following categories:

  1. Human subjects research conducted by any UTHealth employee (faculty, staff, administrative and professional), student, or resident in any facility/location (e.g. MHHS, HCPC, Thomas Street Clinic or LBJ General Hospital);

  2. Human subjects research conducted by non-UTHealth investigators that involves subjects/patients from any UTHealth-facility.

* UTHealth also requires IRB review for research involving deceased individuals.

CPHS provides additional definitions and examples here: [https://www.uth.edu/cphs/policies/requires-review.htm](https://www.uth.edu/cphs/policies/requires-review.htm)

Determining if the proposed activities constitutes human subjects research can be tricky. If you suspect your practicum involves human subjects research, discuss this possibility with your faculty mentor. You may also consult directly with CPHS. See the contact information and IRB office hours at the end of this guide. Have these conversations early in your practicum planning.

If any of your practicum activities requires IRB approval, you must obtain this approval before starting your practicum.
Practicum Students Working with UTHealth Faculty on Human Subjects Research

If your preceptor is a UTHealth faculty member and you are working on a study that already has IRB approval, the UTHealth faculty member may be able to add you to the study by submitting a change request through CPHS. If so, before beginning your practicum, you must wait for CPHS to approve you to conduct human subjects research on the project.

IRB Exemptions

Human subjects research that uses only publicly available data or de-identified data often qualifies for IRB exemption. Nevertheless, you must submit the study to CPHS, who will decide if the study is indeed exempt: neither you nor your faculty mentor can make the final determination.

Applying for IRB Review

To apply for IRB review and approval, submit information about the study on which you will be working through iRIS (Integrated Research Information System). For login instructions and more information about iRIS, see below.

iRIS login:  https://iris.uth.tmc.edu
Basic iRIS instructions:  https://www.uth.edu/cphs/for-researchers/basic-iris.htm
To register for a 2.5-hour iRIS course:  https://www.uth.edu/cphs/for-researchers/reg-iris-training.htm

Timelines for IRB approval depend on the type of human subjects data you will be working with (i.e. de-identified vs. identified), the location of the research, and whether your host organization has IRB approval for the research. Please note that CPHS review and approval can take several months. The Office of Public Health Practice advises that students needing IRB review and approval initiate the application at least one semester prior to enrolling in practicum.

Human Subjects Training

In addition to receiving IRB approval, students conducting human subjects research for practicum must complete Collaborative Institutional Training Initiative (CITI) training. CITI is a nationally and internationally recognized expert in research ethics, compliance, and professional education.

For step-by-step instructions to register for and complete the free online CITI course, refer to the Human Subjects and HIPPA Training on the practicum Orientation and Training Materials webpage.

CITI website:  https://about.citiprogram.org/en/homepage/
Registration Instructions:  https://sph.uth.edu/practicum/orientation-training-materials/

CITI training must be renewed every three years for UTHealth students, faculty, and staff engaged in human subjects research.
Committee for Protection of Human Subjects (CPHS)

Contacts:  https://www.uth.edu/cphs/contact-cphs.htm
Help Line:  713-500-7943

IRB Office Hours

Time:  Every Thursday 1:00 p.m.-4:00 p.m. CST
Location:  MSB B.64

IRB Office Hours are for all faculty, staff, and students involved with Human Subjects research. No appointment necessary. First come, first served. IRB Staff will be available to

• Provide guidance on developing GCP compliant protocols for human subjects research.
• Provide guidance for developing consent documents.
• Provide guidance and answer questions about the iRIS application system.
• Provide guidance and answer questions about the IRB reciprocity agreements including SMART IRB and working with commercial IRBs.