Does My Project Require Review by UTHealth’s Committee for Protection of Human Subjects (CPHS)?

START

Does your project include research activities?

Yes

Will your research involve human subjects or use of human-derived materials or data?

Yes

Will you be working on a protocol that has been approved by UTHealth’s IRB?

Yes

Will your project change the scope of the approved UTHealth protocol?

Yes

Ask UTHealth PI to submit an amendment to the protocol.

or

Submit a new iRIS application for your project.

Wait for IRB approval and complete CITI training.

No

Review by UTHealth CPHS is not required.

No

Yes

Submit a new iRIS application.

No

Submit a new iRIS application.

No

Submit a new iRIS application.

Yes

Does the external IRB have a reciprocity agreement with UTHealth?

Yes

Submit a new iRIS application and request permission to rely on the organization’s IRB.

No

Wait for IRB approval and complete CITI training.

Yes

Submit a new iRIS application.
**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 Committee for Protection of Human Subjects (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. Memorial Hospital Healthcare System, Harris County Psychiatric Hospital, Thomas Street Clinic, Shiner’s Hospital, LBJ General Hospital);
2. Human subject’s research conducted by non-UTHealth investigators that involves subjects/patients from any UTHealth-facility.

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

**Human subject** means 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.

For **descriptions and examples of activities that require review** by CPHS, see [https://www.uth.edu/cphs/policies/requires-review.htm](https://www.uth.edu/cphs/policies/requires-review.htm).

If you are unsure whether or not your project involves human subjects research, you may email a detailed description of your activities to CPHS (cphs@uth.tmc.edu). Alternatively, you may submit your proposed project through iRIS and select “requesting assistance in whether or not formal IRB review is appropriate” under question 8 of the iRIS application. A representative of the CPHS can help you determine if the described activities require further IRB review.

**IMPORTANT!** If your project involves human subjects research, you must receive approval from UTHealth’s IRB before beginning the research. If you are conducting your project with an organization external to UTHealth, you must receive approval from UTHealth’s IRB even if your site supervisor or your host organization has an approved protocol for the research. In some cases, UTHealth may rely on the external organization’s IRB. (See also reciprocity section below).

If you are working on research at an external organization, ask your site supervisor or preceptor about being added to the external site’s protocol. The external organization’s approval should be sought in addition to, not in place of, UTHealth’s IRB approval.
Change Requests/Amendments to Approved UTHealth Human Subjects Research Protocols

Changes in approved research, during the period for which CPHS approval has already been given, may not be initiated without CPHS review and approval except when necessary to eliminate apparent immediate hazards to the subject. The Principal Investigator (PI) must submit and receive approval from the CPHS before initiating any changes to a research study.

If your research activities will not change the previously approved protocol: Ask the UTHealth PI to add you to his/her approved protocol. To initiate the approval, the UTHealth PI must submit a change request in iRIS. The addition of new study personnel usually qualifies for expedited review, but you must wait for approval from CPHS before conducting the research.

Changes to the approved scope: If the activities for your project will extend beyond the what the UTHealth IRB approved for the existing protocol, the UTHealth PI may either submit a change request to amend his/her approved protocol or advise you to submit a separate iRIS application for your research activities.

For more information about change requests/amendments, please see https://www.uth.edu/cphs/policies/change-requests.htm.

IRB Reciprocity

IRB reciprocity: UTHealth may rely on IRB review of another organization or may serve as the IRB for another organization under a written IRB authorization agreement. These agreements are also called IRB reciprocity agreement or IRB reliance agreements. For a list of reliance agreements with other organizations, refer to the IRB Reciprocity guidance on CPHS’s website: https://www.uth.edu/cphs/irb-reciprocity/Reciprocity.htm.

Relying on Outside IRB: When UTHealth is the relying institution, the UTHealth PI must submit an application in iRIS to request for permission to rely on the outside IRB. For more information on this process see https://www.uth.edu/cphs/irb-reciprocity/RelyingInstitution.

UTHealth IRB as Reviewing IRB: When the UTHealth PI is the lead PI of a multi-site study or a collaborative study, UTHealth IRB may be willing and able to be the reviewing IRB. For more information on this process, see https://www.uth.edu/cphs/irb-reciprocity/ReviewingIRB.htm.
iRIS Applications
If you are proposing new human subjects research or if an amendment to an approved UTHealth protocol is not applicable, submit an application for IRB approval through iRIS (Integrated Research Information System).

   iRIS Login: https://iris.uth.tmc.edu

For assistance with submitting your iRIS application, please refer to the resources below.

   iRIS instructions: https://www.uth.edu/cphs/for-researchers/basic-iris.htm
   iRIS training: https://www.uth.edu/cphs/for-researchers/reg-iris-training.htm
   iRIS Helpline: 713-500-7960
   CPHS Helpline: 713-500-7943

IRB Review Process
For an overview of the UTHealth IRB review process, see https://www.uth.edu/cphs/policies/review-procedure.htm.

Human subjects research may qualify for an IRB exemption or expedited review; however, only CPHS can make this determination.

If CPHS determines that your human subjects research falls within an IRB exemption category, CPHS will send an approval of the exemption through iRIS. For more information about the IRB exemption categories and this process, see https://www.uth.edu/cphs/policies/exemptions.htm.

An expedited review consists of a review of the research by the IRB chair or by one or more reviewers designated by the chair. For more information about IRB expedited review, see https://www.uth.edu/cphs/policies/expedited.htm.

If you will be conducting human subjects research at an international site, you must allow additional time for the IRB review: these reviews can be extensive and require approval by a local ethics committee, or a local entity if there is no local ethics committee. For more information about the approval process for research at international sites, see https://www.uth.edu/cphs/policies/international.htm.

CITI Training
Students planning to conduct human subjects research must complete CITI (Collaborative Institutional Training Initiative Program) training in human subjects research every three years.

   CITI Login: https://about.citiprogram.org/en/homepage/
   Instructions to access the course: https://www.uth.edu/cphs/for-researchers/training.htm#CITI