

RESEARCH COMPLIANCE

UNIVERSITY OF TEXAS SCHOOL OF PUBLIC HEALTH

2017-2018



All research conducted by the faculty, students and staff of UTSPH including research projects and analyses of research data that are conducted as part of UTSPH courses, must be reviewed and approved or exempted by the appropriate Institutional committees *before* the research is initiated. At the University of Texas Health Science Center (UTHealth), these committees, which fall under the UTHealth Office of Research, monitor research compliance related to: Human Subjects Protection, Care and Use of Animals, and Environmental Health and Safety.

UTHealth Office of Research: <http://www.uthouston.edu/research/>

UTHealth Compliance Program: <http://www.uthouston.edu/compliance/>

It is the responsibility of the investigator (or course instructor) to ensure that a research project has received all necessary approvals prior to initiating a study, and to require all project staff and/or students to receive appropriate training before initiating any research related activities. It is also the investigator's responsibility to obtain approval for any additions or changes to the study, before they are implemented, as well as to maintain all necessary approvals through completion of the study.

This document provides UTSPH investigators with general information regarding the Institutional training that is available, and the oversight that is required for different types of research. In addition, general questions regarding training and oversight may be directed to Brooke Burns in the UTSPH Office of Academic Affairs and Student Services. However, investigators should visit the appropriate UTHealth website for the most up-to-date and complete information, and/or contact the appropriate programmatic official in the UTHealth Office of Research, to ensure that they have obtained all necessary training and approvals before initiating any research project.

Brooke Burns: 713-500-9072 or Brooke.Burns@uth.tmc.edu

Student Research: The information included in this document relates to students as well as faculty and staff. Additional information related specifically to student research is provided at the end of the document.

Human Subjects Protection

Committee for the Protection of Human Subjects (CPHS)

CPHS is the Institutional Review Board (IRB) for UTHealth. CPHS reviews proposed research as it applies to the individuals being asked to participate as research subjects in order to determine if adequate measures are in place to protect autonomy, safety, emotional health, and financial considerations.

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.

CPHS: <http://www.uthouston.edu/cphs/>

Most of the research conducted by UTSPH investigators will require review by CPHS. Examples of research that **does not** require CPHS review include:

Research Using Simulated Data: Research based solely on data obtained through computer simulations does not require CPHS review.

Research Using Published Literature: Research that is based entirely on published literature (e.g. systematic literature reviews) does not require CPHS review.

Exempt Status: Many research projects are exempt from CPHS review. However, the investigator **cannot** make the decision regarding exempt status. Studies that may be exempt must be submitted for review and determination of exempt status by CPHS. Examples of types of research that may qualify for exemption include:

Research Using Publicly Available Data: Research involving publicly available data (e.g. census data, labor statistics, data available online) must be submitted to CPHS in iRIS for determination of Exemption. Investigators should contact the CPHS at 713-500-7943 if they are not sure whether their data qualifies as “publicly available.”

Research Using Existing, De-identified Data: Research involving the use of existing, de-identified data sets must submit an application to CPHS in iRIS for determination of Exemption.

Expedited Review: Research involving existing data sets with the use of personal identifiers must be submitted for review by CPHS in iRIS. These studies may qualify for Expedited Review by CPHS.

Information on Exempt/Expedited Review: <http://www.uthouston.edu/cphs/policies/index.htm>

Human Subjects training: All individuals participating in research that involves human subjects must receive appropriate training before initiating any research activities, and must receive updated training as necessary.

Courses that satisfy the UTHealth requirement for education on the protection of human subjects are offered online by the Collaborative Institutional Training Initiative (CITI).

Information about CITI: <http://www.uthouston.edu/cphs/for-researchers/training.htm>

Link to CITI: <https://www.citiprogram.org/default.asp?language=english>

In addition to the above requirement, all principal investigators of sponsored projects must complete an online Investigator Briefing in the Responsible Conduct of Research. Further details on this requirement can be found at: <http://www.uthouston.edu/evpara/investigator-briefing.htm>

Applications: UT CPHS uses an online application called iRIS (Integrated Research Information System). All applications, including those for studies that may be exempt from CPHS review, must be submitted through iRIS.

Register for iRIS training: <http://www.uthouston.edu/cphs/for-researchers/reg-iris-training.htm>

Basic iRIS instructions: <http://www.uthouston.edu/cphs/for-researchers/basic-iris.htm>

Log in to iRIS: <https://iris.uth.tmc.edu/>

Care and Use of Animals

Center for Laboratory Animal Medicine and Care (CLAMC)

The CLAMC provides training related to the oversight, care and use of experimental animals, to ensure that the individuals involved in these activities are qualified to accomplish these tasks in a humane and scientifically acceptable manner.

CLAMC: <https://www.uth.edu/animal-research/>

Animal Welfare Committee (AWC)

All research using animal subjects or animal derived materials must be submitted to the AWC, the Institutional Animal Care and Use Committee, for the UTHealth. Faculty with approved animal use protocols must assure the AWC that personnel will be or are adequately trained. Training is provided through CLAMC.

AWC: <https://www.uth.edu/animal-research/awc.htm>

Environmental Health and Safety

Safety, Health, Environment and Risk Management (SHERM)

Training in basic laboratory safety as well as radiation, chemical and biosafety is provided by SHERM.

SHERM: <http://www.uth.edu/safety/>

Radiation Safety Committee

This Committee formulates and recommends policy for the use of radioactive materials and other sources of radiation. Research involving use of radioactive materials in humans must be reviewed by the Radiation Safety Committee.

Chemical Safety Committee

This Committee recommends policy for the use of chemicals that may be hazardous in the research, clinical and educational activities at UTHealth. Chemical Safety Committee approval must be obtained prior to using acutely toxic chemical agents, including those listed by the International Agency for Research on Cancer (IARC) or the National Toxicology Program (NTP) as suspected or confirmed carcinogens, or for which toxicological/epidemiological studies have indicated that the chemical has reproduction, acute, and or reactive hazard(s). In addition, any hazardous chemical that is used in such a way as to present the potential for an exposure above the Occupational Safety and Health Administration's Permissible Exposure Limits (PEL) or the American Conference of Governmental Industrial Hygienist's Threshold Limit Values (TLV), requires committee review.

Institutional Biosafety Committee

This Committee addresses ethical, scientific and regulatory issues related to infectious diseases and biological agents. Institutional Biosafety Committee approval must be obtained prior to using microbiological/infectious agents and/or recombinant DNA molecules in research.

Additional information about these Committees as well as application materials can be obtained at: <http://www.uthouston.edu/safety/manuals-and-forms.htm>

Student Research

Students as Personnel on UTHHealth Faculty Research Projects: Many UTSPH students participate as personnel in research being conducted by UTSPH or UTSPH faculty members. A student's involvement in such projects must be approved by all appropriate committees (CPHS, AWC, IBC, etc.). In general, students can be added as personnel to an existing approved protocol by submitting a change request to the appropriate committee.

Classroom Projects: Instructors who wish to include a research project or analysis of existing data as part of a course (e.g. to explore statistical methods or other methodological issues, etc.) should obtain CPHS approval for the class project. In general, applications for class projects involving contact with or analysis of data from human subjects should be submitted to CPHS (through iRIS) by the course instructor. Briefly, the application should include: the class objectives; the types of research activities that will be included in the course; a description of faculty oversight for the project; and an acknowledgement that any student activities that exceed the boundaries of the class would need to be submitted as individual projects (e.g. if a student wants to expand upon a classroom project, for instance, for use as a culminating experience). Students who wish to expand on a class project should contact CPHS to determine whether additional approvals will be required for their project. Questions regarding classroom projects should be directed to Cynthia Edmonds, Director, Committee for the Protection of Human Subjects (CPHS), at: Cynthia.L.Edmonds@uth.tmc.edu, or 713-500-7936.

Student Research: Many UTSPH students will engage in an independent research project as part of their academic program, such as the MPH written culminating experience, MS thesis, or PhD/DrPH dissertation. As with all UTSPH research projects, student projects must be reviewed by the appropriate Institutional committees before the research is initiated.

The IRB approval process for student projects is generally identical to that of faculty projects. However, for students who plan to undertake a project that falls within the scope of, or is closely-related to, an existing UTHHealth faculty member's CPHS-approved protocol, it may be possible for the study PI to obtain IRB approval of the student's project by submitting a personnel change request/protocol amendment to the existing, approved protocol in iRIS. Similarly, students may already be listed as personnel on the UTHHealth faculty member's study in question. In this case, the approval letter for the existing protocol or approval of an amendment to the existing protocol, can serve as the student's CPHS approval for the CE/thesis/dissertation project, as long as all of the work to be undertaken for the CE/thesis/dissertation is covered within the approved protocol.

Alternately, students needing IRB approval for their CE/thesis/dissertation who have not been added to a UTHealth faculty member's approved protocol in iRIS must obtain CPHS approval by submitting their own application to CPHS in iRIS. All student CE/thesis/dissertation projects needing IRB approval *must always* receive approval through the UTHealth CPHS, either by being added to an existing protocol with CPHS approval (as above), or by submitting an application for the student's own project in iRIS. When necessary, approval through another institution's IRB (i.e., Baylor IRB, MDACC IRB, etc.), should be obtained as well for the student's CE/thesis/dissertation proposal. Outside IRB approval may be required in addition to, but never in place of, the UT CPHS approval/exemption.

Students undertaking a written CE, thesis or dissertation project must complete all required training and obtain all necessary committee approvals before their project will be approved by the Assistant Dean of Academic Affairs and Student Services. It is the responsibility of the student and his/her research committee to determine which approvals are required, and to apply for, obtain and maintain all such approvals.

Students should visit the appropriate UTHealth website for the most current and complete information (see above), and/or contact the appropriate program official at UTHealth to ensure they have obtained the appropriate training and approvals needed before initiating their project. Brooke Burns in the Office of Academic Affairs and Student Services is available to help students determine which approvals may be required at Brooke.Burns@uth.tmc.edu. Students should visit the UTSPH Student Research pages at: <https://sph.uth.edu/research/student-research/> for detailed instructions on submitting the student CE, thesis, or dissertation proposal to the Office of Academic Affairs and Student Services, and to the UTHealth CPHS in iRIS.