RESEARCH COMPLIANCE

UNIVERSITY OF TEXAS SCHOOL OF PUBLIC HEALTH

2014-2015

All research conducted by the faculty, students and staff of the University of Texas School of Public Health (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 (UTHSC), these committees, which fall under the Office of Research, monitor research compliance related to: Human Subjects Protection, Care and Use of Animals and Environmental Health and Safety.

UTHSC Office of Research: http://www.uthouston.edu/research/

UTHSC Compliance Programs: 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 Ms. Rebecca Novak at the UTSPH Office of Research. However, investigators should visit the appropriate website for the most up-to-date and complete information, and/or contact the appropriate programmatic official in the UTHSC Office of Research, to ensure that they have obtained all necessary training and approvals before initiating any research project.

Rebecca Novak: x9055 or Rebecca.Novak@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)

The CPHS is the Institutional Review Board (IRB) for the UTHSC. 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.

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 Animals:*** Research that is exclusively conducted using animals or animal-derived materials does not require CPHS review. However, such research does require review by the Animal Welfare Committee (see below).

> ***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 quality 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 UTHSC 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: The UTHSC CPHS uses an online application. All applications, including those for studies that may be exempt from CPHS review, are submitted through the Integrated Research Information System, or 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: http://iris.uth.tmc.edu

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: http://www.uthouston.edu/animal-research/clamc.htm

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 UTHSC. Faculty with approved animal use protocols must assure the AWC that personnel will be or are adequately trained. Training is provided through CLAMC.

AWC: http://www.uthouston.edu/animal-research/index.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

Radiation Safety Committee approval must be obtained prior to the use of radioactive materials or other sources of radiation.

Chemical Safety Committee

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

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

Faculty Research: Many UTSPH students participate in research that is being conducted by UTSPH faculty. A student's involvement in such projects must be approved by all appropriate committees. In general, students can be added to an existing, approved protocol by submitting a change request to the appropriate committee.

Classroom Projects: Instructors who include a research project or analysis of existing research data for any purpose (e.g. to explore statistical methods or other methodological issues) as part of a course should obtain appropriate CPHS approvals. In general, applications for class projects that involve contact with, or analysis of data from human subjects should be submitted to CPHS (through iRIS), by the course instructor. Briefly, the application would include: the class objectives; types of research activities that will be included in the course; 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 where to expand a class project for use as a culminating experience). Students who wish to expand on a classroom project (e.g. for use in a written culminating experience) should contact CPHS to determine whether additional project approvals will be required. Questions regarding classroom projects should be directed to Cynthia Edmonds (Cynthia.L.Edmonds@uth.tmc.edu), Director of Research Support Services, UTHSC.

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

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. Ms. Rebecca Novak in the UTSPH is available to help students determine what approvals may be required for a specific project. However, the student should visit the appropriate website for the most up to date and complete information and/or contact the appropriate programmatic official in the UTHSC Office of Research to ensure that they have obtained the appropriate training and approvals before initiating their project. Students undertaking a written culminating experience, thesis or dissertation project must complete all required training and obtain all necessary committee approvals before their project will be approved by the UTSPH Associate Dean for Research.

In general, the approval processes for student projects are identical to those of faculty projects. However, if a student is conducting a project that falls under or is closely-related to an existing, UTHSC CPHS approved protocol, it may be possible for the study PI to obtain the appropriate approval for the student's work by submitting a change request or protocol amendment for the existing approved protocol.