The University of Memphis

POLICIES

RE7007 - Human Subjects Protection

Issued: February 14, 2017
Responsible Official: Vice President for Research
Responsible Office: Division of Research and Sponsored Programs

Policy Statement

At the University of Memphis, all human subjects research activities come under the purview and oversight of the Office of the Vice President for Research and the Institutional Review Board (IRB), irrespective of whether the research is funded or non-funded, minimal risk or more. The Human Subjects Protection policy applies to all University of Memphis faculty, staff, and students conducting human subjects research on or off-campus (domestic or international sites) as well as visitors conducting research at the University of Memphis.

Researchers, including the faculty advisors of student researchers, must successfully complete online human subjects protection training before submission to the IRB.

Human subjects protection is a collaborative effort by the researcher and the University of Memphis. The IRB is charged with the responsibility of protecting the rights and welfare of human subjects involved in research. The composition of the IRB and the number of members on the committee are in accordance with federal regulations. IRB members are appointed by the Vice-Provost for Research on the recommendation of the chairperson of the IRB. Members are appointed for renewable, three-year terms and include faculty with expertise in the various disciplines engaged in human subjects research on campus as well as community members.

In accordance with 45 CFR 46, the IRB is required to report all instances of non-compliance to the federal Office for Human Research Protections, Washington, DC. Additionally, non-compliance with this policy by faculty and staff members may result in one or more of the following:

- Censure;
- Removal from graduate faculty status;
- Suspension of research privileges at the University;

- Termination of employment

Non-compliance with this policy by students may jeopardize awarding of the degree being sought.

Purpose

This policy for the protection of human subjects is guided by ethical principles, federal law, and institutional standards. The guiding ethical principles are embodied in the Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research. Compliance with this policy provides protections for human subjects as mandated by applicable laws, regulations, and standards of local, state and federal government agencies concerning the protection of human subjects, including the U.S. Code of Federal Regulations (CFR):

- Title 45 CFR 46, Protection of Human Subjects, U.S. Department of Health and Human Services (DHSS), Office for Human Research Protections (OHRP) and
- Title 21 CFR 50, 56, 312, 600 and 812 of the Food and Drug Administration (FDA)

Definitions

Human Subject	A living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information. (Title 45 CFR 46.102(f)).
Research	A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. (Title 45 CFR 46.102(d)).
Exempt Review	Research activities involving human subjects that receive an exempt classification for review from the IRB are identified in 45 CFR 46.101(b)(1)-(6). The IRB chairperson or his/her designee has the sole authority for determining which UM research falls under this review classification.

Expedited Review	A review of research involving human subjects by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB in accordance with the requirements set forth in 45 CFR 46.110.
Full Board Review	Research that is determined by the IRB Chair or their designee that does not qualify for exempt nor expedited review must be reviewed by the full committee at a convened IRB meeting. Meetings dates and times are listed on the IRB webpage.

Procedures

Scope of Review

The IRB reviews research involving human subjects if one or more of the following apply:

* the research is sponsored by UM, regardless of the location of the project;

* the research is conducted by, or under the direction of, any staff, faculty, student, or other agent of UM in connection with his or her institutional responsibilities;

* the research is conducted by or under the direction of any employee or agent of UM using any property or facility of UM;

* the research involves the use of UM's non-public information to identify or contact human research subjects or prospective subjects.

Levels of Review

The IRB has the sole authority for determining level of review at the University.

Research activities involving human subjects that receive an **EXEMPT** classification for IRB review must be fully defined by one of the following categories:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices,

such as (a) research on regular and special education instructional strategies or(b) research on the effectiveness of or the comparison among instructional techniques, curricula or classroom management methods.

2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: a. information obtained is recorded in such a manner that subjects can be identified, directly or through identifiers linked to the subjects and b. any disclosure of the human subjects' responses outside the research could reasonably place the

subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability or reputation.

3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior that is not exempt under paragraph # 2 (above) if:

a. the human subjects are elected or appointed public officials or candidates for public office, or b. federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

4. Research involving the collection or study of existing data, documents, records, pathological specimens or diagnostic specimens, if these sources are publicly available or the information is recorded by the investigator in such a manner that the subjects cannot be identified directly or through identifiers linked to the subjects.

5. Research and demonstration projects which are conducted by or subject to the approval of (federal) department or agency heads and which are designed to study, evaluate or otherwise examine: (a) public benefit or service programs, (b) procedures for obtaining benefits or services under those programs, (c) possible changes in or alternatives to those programs or procedures or (d) possible changes in methods or levels of payment for benefits or services under those programs.

6. Taste and food quality evaluation and consumer acceptance studies, if: a. wholesome foods without additives are consumed or b. if a food is consumed that contains a food ingredient at or

below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U. S. Department of Agriculture.

Research classified in the **EXPEDITED** category poses no more than minimal risk to the subject and, for example, involves no more than:

* collection of hair, nail clippings, baby teeth or teeth in need of extraction;

* collection of excreta, sweat, saliva, placenta and amniotic fluid at delivery;

* non-invasive recording of data from subjects 18 years of age or older using routine clinical procedures (not including x-rays and microwaves);

* collection of blood samples of limited volume and frequency from subjects 18 years of age or older;

* collection of dental plaque via routine scaling of teeth using accepted techniques;

* voice recordings for research purposes (e.g., of speech defects);

* moderate exercise by healthy volunteers;

* study of existing data, records, or specimens;

* research where the researchers do not manipulate subjects' behavior and the research will not involve stress to subjects;

* research on drugs or devices for which an investigational new drug exemption or an investigational device exemption is not required;

	Research which is neither minimal nor expedited requires the review of the **FULL BOARD at a convened meeting**.
Responsibilities of the Researcher	Human subjects protection is a collaborative effort by the researcher and the institution. The researcher/principal investigator is responsible for: *submitting all the necessary documents in order to facilitate the IRB's review; *the compliance of all co-investigators, student investigators, and research associates with the IRB decisions, conditions, and requirements; *reporting to the IRB any changes to the research protocol (e.g., research design of the study, recruitment procedures); *requesting re-approval when contact with subjects will extend beyond the approval termination date; *reporting to the IRB chair any unanticipated adverse reactions or unanticipated events associated with the conduct of this research; *seeking clarification and advice from the IRB regarding ethical aspects of the research.
Submission Process	To submit an application for IRB consideration, go to http://www.memphis.edu/rsp/compliance/cayuse_irb.php to learn how to submit using Cayuse IRB online software.

FAQs

Whom do I contact for additional information?	Please consult the IRB at IRB@memphis.edu or visit the website at http://www.memphis.edu/rsp/compliance/index.php
What are the educational requirements associated with human subjects research?	Researchers, including the faculty advisors of student researchers, must successfully complete online human subjects protection training before submission to the IRB. Details are available online at

http://www.memphis.edu/rsp/compliance/index.php and www.citiprogram.org

Links

Title 45 CFR 46, Protection of Human Subjects, U.S. Department of Health and Human Services (DHSS), Office for Human Research Protections (OHRP)

http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html

Title 21 CFR 50, 56, 312, 600 and 812 of the Food and Drug Administration (FDA)

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm

Revision Dates

UM1742 -- revised February 14, 2017
UM1742 -- issued May 24, 2012
RE7007 supersedes UM1742

Subject Areas:

Academic	Finance	General	Human Resources	Information Technology	Research	Student Affairs
☒	☐	☒	☐	☐	☒	☐