Responsible Office: Office of Research and Grants
Effective Date: May 12, 2023

POLICY GOVERNING HUMAN SUBJECTS RESEARCH TRAINING

POLICY STATEMENT

Lipscomb University ("Lipscomb") requires that all faculty, staff, and students engaged in research involving Human Subjects successfully complete training appropriate to the type of research and activities being conducted.

PURPOSE

The purpose of this policy is to ensure that all researchers, whether or not such research is externally funded, have obtained appropriate regulatory and ethical training prior to the conduct of research or the performance of any research activities involving Human Subjects.

APPLICABILITY

This policy applies to any Lipscomb employee or student engaged in Human Subjects Research, whether or not the research or activities are performed on- or off-campus (including virtually).

DEFINITIONS

Capitalized terms that are used but not otherwise defined in this policy have the following meanings:

CFR means the Code of Federal Regulations.

Collaborative Institutional Training Initiative (*CITI* or *CITI Program*) is the virtual training provider currently utilized by Lipscomb to provide training in research, research conduct, and compliance.

Human Subject, as defined in 45 CFR § 46.102(e)(1), means a living individual about whom an investigator (whether professional or student) conducting research: (i) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

IRB means the Lipscomb Institutional Review Board, which is the committee that performs ethical review of proposed research involving Human Subjects.

Human Subjects Research involves a wide variety of research procedures, including, but not limited to, the collection of Human Subject data through survey mechanisms; direct or indirect observations; interventions; standardized tests from the fields of education, psychology or human performance; investigational drugs or devices; randomized clinical trials; research utilizing medical records; and/or research using existing pathological specimens, discarded tissue, or secretions.

Research, as defined in 45 CFR § 46.102(*l*), means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities. For purposes of this policy, the following activities are deemed not to be research:

(1) Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.

(2) Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).

(3) Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.

(4) Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

PROCEDURES

HUMAN SUBJECTS RESEARCH TRAINING

Human Subjects Research training courses are available at www.citiprogram.org. On the CITI Program website, click on "My Courses" and "Log In" if you already have an account, or "Register" an account in the system if you do not have an account. Select "Lipscomb University" as the Organization Affiliation.

Lipscomb provides the campus community with three CITI training courses in Human Subjects Research. Researchers (and faculty advisors, as appropriate) must earn a CITI Certificate of Completion in one course that is most closely aligned to the type of Research being conducted. The three available Human Subjects Research courses are as follows:

Option 1: Social-Behavioral-Education ("SBE") Human Subjects Research
Researchers shall take this course if the proposed Research focuses only on social, behavioral, or educational subjects and **DOES NOT** involve Research of physical health, mental health, biomedical topics, blood draws, investigational drugs or devices; randomized clinical trials; Research on medical records; or Research using existing pathological specimens, discarded tissue, or secretions.

Option 2: Health Sciences, Biomedical, or Pharmaceutical Human Subjects Research
Researchers shall take this course if the Research involves physical health, mental health, biomedical topics, blood draws, investigational drugs or devices; randomized clinical trials; Research on medical records; or Research using existing pathological specimens, discarded tissue, or secretions.

Option 3: Interdisciplinary-SBE and Health Sciences+
Researchers shall take this course if the Research focuses upon **a combination** of social, behavioral, or education subjects **and** involves physical health, mental health, biomedical topics, blood draws, investigational drugs or devices; randomized clinical trials; Research on medical records; or Research using existing pathological specimens, discarded tissue, or secretions. **The Interdisciplinary-SBE and Health Sciences+ course should be taken if there is doubt regarding the applicability of the other courses.**

REQUIRED AND SUPPLEMENTAL MODULES

Each training course contains both required and supplemental training modules. **All required modules must be successfully completed**. Furthermore, researchers **must take any and all supplemental modules directly related to the Research or activity(ies) being performed.** Failing to take appropriate supplemental modules may cause significant delays to the IRB review process. Supplemental modules may include, but are not limited to:

- Prisoners (ID: 8 or ID: 506)
- Children (ID: 9 or ID: 507)
- Pregnant women, fetuses, and neonates (ID: 10)
- International research (ID: 14081 or ID: 509 or ID: 971)
- Public elementary and secondary schools (ID: 805)
- Internet research (ID: 510)
- Non-English speakers (ID: 17260)
- Gender and sexuality diversity (ID: 16556)
- Undocumented status (ID: 16656)
- Critically ill (ID: 16592)
- Decisionally impaired (ID: 16610)
- Older adults (ID: 16502)
- Socially or economically disadvantaged (ID: 16539)
- Physical disabilities and impairments (ID: 16657)
- Students in research (ID: 1321)
- Workers and employees (ID: 483)
- Public health (ID: 17637, 17638, 17639, 17640)

In addition, a CITI Certificate of Completion **may be required** for one or more of the following courses, as specified for the applicable type of Research:

Supplemental Course:
Information Privacy and Security
This course is required if a Research study includes data from medical records or other health-related information.

Supplemental Course:
Good Clinical Practice Social/Behavioral Research Best Practices for Clinical Research
This course is required for any individual engaged in Research regulated by the U.S. Food and Drug Administration. This type of Research typically involves drug, device, or biologic agents or products. This course is *recommended* for any beginning researcher learning the steps involved in high-quality Research and participant safety, and may also be included in Research methodology courses.

Supplemental Course:
Responsible Conduct of Research ("RCR")
Completion of this course **does not** meet requirements for Human Subjects Research; however, completion of a Human Subjects Research course **and** RCR may be required in certain externally funded Research and sponsored programs. The Office of Research and Grants will notify all researchers if this course is required as a condition of any award.

Supplemental Course and In-Person Training:
RCR plus Eight Hours of Face-to-Face Training
Virtual **and** face-to-face training is required for certain categories of Research funded by the National Institutes of Health, and potentially other funding agencies. The Office of Research and Grants will notify all researchers if this course is required as a condition of any award.

CONFLICT

This policy is subject to applicable law. In the event of a conflict between the provisions of this policy and applicable law, including, without limitation, 45 CFR § 46, the provisions of applicable law shall control.

CONTACT

For additional information or questions regarding this policy, contact the Office of Research and Grants, which can be reached at 615-966-5907.

EFFECTIVE DATE

This policy was approved by the Office of the Provost on May 12, 2023.