IRB Training Requirements for All Researchers/Investigators Conducting Human Subjects Research

Question 1: Who needs to complete CITI training in order to conduct research?

Any researcher/investigator (faculty, students at all levels, and staff) involved in the collection of—or access to—data provided by human subjects must complete either the CITI research training course

- "Social & Behavioral Research Basic/Refresher"
- or
- "Biomedical Research Basic/Refresher"

depending on the research domain of the project.

Further, additional or alternate training may be required by the IRB upon assessment of research protocols submitted to the IRB for review.

• *Note:* These requirements also apply to collaborating researchers from other institutions, organizations, or agencies in the United States or in other nations.

Question 2: Who qualifies as a "researcher" or "investigator" required to complete CITI training?

For the purposes of training requirements, "researcher" and/or "investigator" refers to any person/individual who will be involved in the collection of the data from human participants or have access to data (including deidentified data) obtained from human subject research participants. This definition of "researcher/investigator" is broad, and includes Louisiana Tech's faculty, graduate students, undergraduate students, staff and any researcher from an institution or organizations other than Louisiana Tech University.

Question 3: Who qualifies as a "human subject" or "research participant?"

For the purpose of training requirements, a Human subject/participant is any individual (living or deceased) from whom a researcher/investigator will be collecting data in any manner, from but not limited to observation, interviews, surveys, and other methods that involve individuals responding to questions, performing tasks, or undergoing procedures. Additionally, a human subject/participant would also include the use of archival data that was previously collected from human subjects/participants.

Question 4: What CITI training(s) do researchers need to complete?

In general, researchers/investigators need to complete one of the following training courses based on the specific kind of human subjects' research they intend to conduct:

- Researchers/investigators must complete the "Biomedical Research Basic/Refresher" training if the research will collect data from human subjects that involves the collection of physiological information. Potential types of research in this area would include collecting health, fitness, biometric, sensory, etc. data; or involve physical contact with subjects or having subjects engage in physical activity. (Examples: Colleting individuals' body mass index information, performing a hearing test, or having subjects complete a cardiac stress test).
- Researchers/investigators must complete the "Social & Behavioral Research -Basic/Refresher" training if the research will collect data from human subjects that does not involve the collection of physiological information. Potential types of research in this area would include collecting psychological, sociological, economic, anthropology, business, etc. data. (Examples: Using surveys or focus groups to collect information on an individual consumer's behavior or observational research involving the researcher watching subjects engage in an activity, or collecting data via an online instrument).
- When the research contains <u>both</u> physiological and psychological elements, or if there is uncertainty about which training to complete, researchers should complete the "Biomedical Research Basic/Refresher training."

In some circumstances, other, specific basic/refresher trainings instead of biomedical or social & behavioral may be appropriate.

Note: Completing only the "responsible conduct of research" training courses is not sufficient to meet the training requirement essential to conduct human subjects research. Rather, researches/investigators <u>must complete</u> training which includes the words "basic/refresher" in the title (e.g., "Social & Behavioral Research - Basic/Refresher").

Question 5: How do researchers/investigators access CITI training?

Researchers/investigators domiciled in the United States may complete CITI training through Louisiana Tech University's CITI training platform (<u>https://about.citiprogram.org/</u>).

If you are not already a registered user, you must register with CITI by performing the following process:

• **Step 1:** Go to the CITI training platform online at <u>https://about.citiprogram.org/</u> to begin this process

- Step 2: Click on the blue "Log In" button located in the upper right-hand corner of the page to access the CITI system
- <u>Step 3:</u> Register under your name
- <u>Step 4:</u> Search "Louisiana Tech University" under "select your organization"
- <u>Step 5:</u> Confirm you are affiliated with Louisiana Tech University
- <u>Step 6:</u> Follow the registration and questionnaire prompts, including your primary research focus as identified previously in Question 3 (e.g., "Biomedical," "Social & Behavioral,"). Note: the CITI training courses that will be available to you are based on your responses to these questions.

After you have completed this process and are registered with CITI, you must next select the appropriate training course to complete. (See prior "Question 4" section to determine which CITI training course(s) you need to complete.)

If researchers domiciled outside of the United States are unable to complete CITT training through Louisiana Tech using the instructions provided above, the researcher should provide evidence of training from their institution or other appropriate training recognized by their local regulators to the IRB.

Question 6: When do researchers and/or investigators need to complete CITI training?

All researchers/investigators (as defined above) are required to include proof of current CITI training to the Louisiana Tech University Institutional Review Board (IRB) whenever submitting a research protocol for review. (For this process, "current CITI training" is defined as CITI training completed within three (3) years of the time the related IRB protocol is submitted for review).

To submit such proof of CITI training, researchers must email the related certificates (provided in .pdf format from CITI upon the completion of related training) to Tamira London IRB Administrative Coordinator (email: <u>tlondon@latech.edu</u>) along with the related research protocol materials required by the IRB for review and approve.

Most CITI training remains valid for 3 years from the completion of the related training, and all training certificates list the expiration date of a related training course. Expired training courses are not sufficient to meet the requirements established by the IRB, and evidence of current training must be provided with each research protocol submitted to the IRB for review.

• *Note:* The IRB does not maintain human subjects training records at this time; for this reason, *it is incumbent on each researcher/investigator to present proof of current training for each IRB protocol submitted for review.*