

**FREQUENTLY ASKED
QUESTIONS HUMAN
STUDIES RESEARCH
MANADATORY
EDUCATION**

1. Who must be educated in human subject protection?

All individuals who are “engaged” in research with human participants where Washington University (WU) is the Institutional Review Board (IRB) of Record.

2. What does “engaged” in research mean?

Engaged persons are those individuals who will have contact or interactions with research participants or identifiable private research data. These individuals should be listed as Study Team members on the HRPO application and protocol.

3. What education program will be accepted?

Only the CITI program will be accepted for Washington University faculty, students, and staff.

4. What about collaborators from other institutions?

Non-WU collaborators and consultants who are engaged in human research (as defined in Q.2) and under the auspices of another IRB do not need to provide proof of their human subjects education. However, HRPO reserves the right to require additional education.

5. Does this requirement apply to collaborators at foreign institutions?

Yes. If they are “engaged” in human research and under the auspices of another institution that has a Federal Wide Assurance (FWA), they do not need to provide proof of their human subjects education. If WU is the IRB of Record, these individuals will need to take the CITI training. If no FWA is available for the institution, HRPO reserves the right to require human subjects education training.

6. Do undergraduate students need to complete the education requirement?

Yes. Undergraduate students who are Project Directors or identified as members of the Study Team must complete the necessary education.

7. I am the Faculty Sponsor for a graduate student who will be conducting interviews for her Masters thesis. I won't be interacting with participants or see individually identified data. Why am I subject to this policy?

Faculty Sponsors are responsible for guiding students in the ethical conduct of research, including policies governing research with human participants and for ensuring that the student-researcher has sufficient training and experience to conduct the study. The Faculty Sponsor, therefore, must be well educated in human research requirements in order to fulfill these responsibilities.

8. Does this policy apply to my administrative support person who completes study paperwork?

Administrative staff who are “engaged” in human research must complete the necessary education. Examples of engagement:

- a. Dr. Smith who is a PI on a research study asks a house staff member to conduct a clinical exam on an individual who happens to be a research participant. The clinical examination is not part of Dr. Smith’s research protocol.
 - i. The house staff member is performing ordinary clinical duties and is not engaged in the research. She does not need to take the mandatory human studies education module.
- b. A photographer is asked to take a picture of a research participant. This picture will be included with the article being written that describes the results of the research.
 - i. The photographer is taking a picture as part of his normal duties, thus he is performing commercial services and is not engaged in the research. He does not need to take the human studies training module.
- c. Jane Smith, a WU undergrad working as a research assistant in a Psychology lab at Danforth campus, is asked to obtain informed consent from a research participant.
 - i. Jane Smith is engaged in the research. She needs to take the mandatory human studies education module.

- d. The intake worker at a local counseling services agency is asked to pass along a flyer advertising a research study to anyone that might be interested or that she feels may qualify for the study.
 - i. The intake worker is not engaged in the research. She does not need to take the human studies education module.
- e. A group of research participants are referred to a weight management clinic. Referral of these participants is part of the research protocol. Once referred, these research participants are treated as any other referral into the program.
 - i. Those assisting/instructing the research participants regarding weight management are not engaged in the research and do not need to take the human studies education module.
- f. Professor Jobs' secretary will transcribe notes concerning his research project.
 - i. The secretary is not engaged in the research and does not need to complete the mandatory human studies education modules.

9. Who are key personnel?

- a. Consistent with other Washington University policies, the WU Human Subjects Education Policy defines key personnel as “any individual responsible for the design, conduct, or reporting of research.”

10. Do all key personnel have to take the mandatory human studies education modules?

No. Only those key personnel that are “engaged in the research” must take the mandatory human studies education modules.

In the examples below, human subjects education is not mandatory as these individuals are not engaged in research activities:

- a. Professor Rose will receive de-identified research data once it has been collected. It is her job to analyze this data.
- b. Consultant Jones is called to provide guidance and expertise in designing the protocol. Dr. Ring will be the one who writes the protocol.
- c. Professor Reed will instruct research participants as he would anyone referred to him.

11. So, when are key personnel engaged in the research?

Key personnel are engaged in the research when they (i) intervene or interact with living individuals for research purposes; or (ii) obtain individually identifiable private information for research purposes [\[45 CFR 46.102\(d\),\(f\)\]](#).

In the following examples, the key personnel are engaged in the research:

- a. Statistician Clementine will design the statistical analysis procedures to be used in the research study and will then carry out these procedures once the data is received. This individual is involved in the design and execution of the research.
- b. Nurse Gold will provide information on the study, explain what is involved in the study, do an initial screening to see if the individual meets inclusion criteria, and consent all eligible participants.
- c. Consultant Crimes will provide expertise in the design of the protocol. Once approved, Dr. Crimes intends on conducting the research at her site in addition to providing PI Jones will guidance on protocol development.

12. How do students, post-docs and Non-WU employees obtain access to the CITI program?

To obtain a User ID# and password, contact your departmental office and ask for assistance. They will either provide this information or contact information for an individual in your department or school who has been designated to handle these requests.

Non-WU employees should contact their affiliate department at Washington University for assistance in obtaining a User ID# and password. They will either provide this information or contact information for an individual who has been designated to handle these requests.

13. Are non-WU employees required to take the new education program if they collaborate with WU researchers?

There are two types of non-Washington University employees. This includes individuals working in other countries.

GROUP 1 – Employees of outside institutions whose institutions have an IRB

This group is governed by an IRB operating under a Federal Wide Assurance. These individuals do not have to take the WU mandatory human studies training modules.

GROUP 2 – WU is the IRB of Record

These non-WU employees (including undergraduate students, post-docs and collaborators from foreign institutions) who collaborate on WU research are at institutions that do not have an IRB. WU is most concerned about those non-Washington University employees not governed by an IRB. In this instance, WU becomes the IRB of Record for these individuals. These individuals must take the WU mandatory human studies training modules.

14. What does IRB of Record mean?

- a. The IRB of Record is the IRB designated to review and approve your research.
- b. Scientific, ethical, and legal performance of the research.
- c. If you are on the medical school campus, select Biomedical Research Team. If you are an IRB member, select Biomedical IRB Member.
- d. If you are on the Danforth campus, select one of the two options marked Hilltop according to your department or school affiliation.

15. What if I am a researcher on Danforth and I collaborate with a medical school researcher?

- a. The modules you took to satisfy the behavioral research requirements will be accepted by the HRPO.

16. Do I need to take the CITI modules if I am listed as the PI on a training grant?

- a. If you are mentoring students conducting human subject research, you need to take the CITI modules.
- b. If you are listed as the PI on a training grant but you are not mentoring any students conducting human subject research you do not need to take the CITI modules. Grants and Contracts will have you sign an attestation form verifying that you are not conducting human subject research and that you are not mentoring any students conducting human subject research.

17. Do I need to take the CITI modules if I have a “Single Patient Emergency Treatment” application?

- a. Yes. You have 30 days after the date of approval to complete the required CITI modules.

18. What happens if an engaged member of the Study Team doesn’t complete the necessary education?

HRPO will not approve a request for a new or continuing project until the education requirement has been met by all engaged members of the study team.

19. My research is funded by an external sponsor. The G-bud system asks me to identify key personnel – NOT study team members. Are key personnel required to complete education in human subject protection?

It depends. Only key personnel, who are under the auspices of the WU IRB and are involved in the human research portion of the project have to comply with the education requirement. That means only those key personnel who are “engaged in human subject research” must complete the education requirement.