

Engagement, PI Eligibility, and Study Roles in Human Subjects Research: Ohio University IRB Guidance

Investigator Engagement:

The HHS regulations at 45 CFR part 46 use the term “investigator” to refer to an individual engaged in the conduct of human subjects research activities. How do you know if an individual should be listed as an investigator on an IRB protocol? Generally, whenever the individual will have any interaction with human research subjects or will access, view, or analyze private identifiable information about research subjects, they are considered to be engaged in the research and must be listed as an investigator.

Note: Funding agencies may have their own definition of study team members (i.e., “key personnel”) as it applies to grant or other funding applications.

The guidance in this document refers to research activities that meet the federal definition of research with human subjects.¹

Engagement:

Examples of activities that constitute research engagement and require an individual to be listed as an investigator include:

- Explaining or obtaining informed consent (this includes answering questions about research participation from prospective subjects)
- Obtaining identifiable private information about living individuals for research purposes
- Studying, interpreting, or analyzing identifiable private information or data for research purposes
- Interacting or intervening with or observing individuals to collect research data

Non-Engagement:

In some cases, when the interaction is occurring as part of an individual’s job duties, they may not be considered to be engaged in the research and would not need to be included as an investigator on the IRB protocol.

There are a few common scenarios where individuals, performing their job duties, may interact with research subjects or view private identifiable information, but would not be considered investigators. This may be true when an individual is providing a commercial

¹ <https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.102>

or professional service for only one part of the research protocol. Per OHRP guidance, the following three criteria must be met:

- the services performed do not merit professional recognition or publication privileges
- the services performed are typically performed by the individual/institution for non-research purposes
- the individual does not administer any study intervention being tested or evaluated under the protocol

An example of such professional job duties likely not constituting research engagement is the Ohio University Clinical & Translational Research Unit (CTRU). The job duties of these staff are to perform specialized, skilled activities (e.g., phlebotomist, nurse, DEXA operator, MRI operator, technician, etc.) to support biomedical research due to the absence of a hospital. When these individuals function within their regular work duties and their involvement in the research is limited to only those work responsibilities, without further contribution to the research, then they do not need to be listed on the IRB application. However, it is appropriate to describe their involvement in the protocol.

Examples: individuals in the following scenarios would likely not be considered investigators, so long as this is their only role in the research project:

- A professor forwarding a recruitment email from the study PI to students or colleagues, if the professor is not answering questions about the project and all inquiries are directed to the study investigators
- A physician providing a recruitment flyer to a patient who may qualify for a clinical trial, if the physician does not explain or obtain consent
- A phlebotomist who, as part of their regular job duties, draws blood from a research subject
- A transcriptionist who transcribes an interview recording as a professional service
- CTRU staff when providing a paid service to researchers as described above

Additional guidance from OHRP may be accessed here:

<https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-engagement-of-institutions/index.html>

Institutional Engagement:

An institution is considered engaged in a human subjects research project when its employees or agents are engaged, as described above. This is why Ohio University needs to know about your plans to be involved in research with human subjects when you are acting in your role as a faculty member, staff member, or student. This includes research that will be reviewed by an external IRB, in which case an IRB Authorization

Agreement will be needed.² However, in some unique cases, *you* may be engaged in human subjects research when Ohio University is not. For example, if an Ohio University faculty member, staff member, or student is engaged in research with human subjects *but not as an agent of Ohio University*, we would not consider the University to be engaged. Possible examples include:

- An Ohio University student working on a study conducted elsewhere, as part of an internship or volunteer position, and *not in their role as an Ohio University student* (e.g. not for course credit, degree requirement, thesis or dissertation research, etc.). Please note that under HCOM policy 7.11, currently enrolled medical students are *always* considered to be an agent of Ohio University when engaged in research and scholarly activities.
- An Ohio University staff member volunteering in their free time on a research project conducted outside of Ohio University that does not make use of any Ohio University equipment or resources.

If any sort of professional recognition or publication would identify the researcher as an Ohio University affiliate, Ohio University IRB review/deferral is likely to be needed.

If you are not sure whether an individual should be listed as an investigator on an IRB protocol, or whether Ohio University is engaged in the research, please contact the Research Compliance office for assistance.

Roles of Investigators on an Ohio University IRB Protocol:

Principal Investigator —The Principal Investigator (PI) has full responsibility for the oversight of a research study, including the design, development and implementation of the study plan. Only one person can serve as PI on the IRB study. The PI is fully responsible for the academic quality of the research and for ensuring compliance with the terms, conditions, and policies of the sponsor and Ohio University. The PI is the primary individual responsible for the implementation and oversight of the research protocol. The PI may delegate various responsibilities of day-to-day oversight and research methodology to a qualified co-investigator, but the PI maintains ultimate responsibility for the conduct of the study. PI responsibilities include:

- Day-to-day oversight of the research project and study personnel
- Ensuring that all study personnel are appropriately qualified and trained, including completion of any trainings required by Ohio University
- Awareness of, and compliance with, Ohio University policies and procedures and all applicable federal regulations governing the research, including requirements for periodic review and study close out

² For more information about Authorization Agreements, see <https://www.ohio.edu/research/compliance/irb-reliance>

- Protecting the rights and welfare of human research subjects
- Prompt reporting to the IRB of any adverse events, unanticipated problems, or other issues with the study conduct

At Ohio University, regular, salaried professors with at least a 50% appointment may serve as PI. This includes titles of professor or clinical professor (full, associate, and assistant). Additionally, regular, salaried staff with at least a 50% appointment and a title of director, associate director, or assistant director may serve as PI.

Graduate students who are currently active and have been enrolled at Ohio University for at least one semester in the last year may serve as PI. When the PI is a student, a regular faculty member must be listed in the advisor role in the IRB application.

The following positions may not serve as PI unless a formal request is made in writing and an exception granted by the Ohio University Vice President for Research and Creative Activity:

- emeritus professor
- lecturer/visiting lecturer
- instructor/adjunct instructor
- professor of practice, assistant/associate professor of practice
- adjunct professor; adjunct assistant/associate professor
- visiting professor; visiting assistant/associate professor
- research associate (unless permission was granted in the appointment letter)
- research scientist (unless permission was granted in the appointment letter)
- postdoctoral researchers (unless permission was granted in the appointment letter)
- research assistant
- undergraduate researchers

To request an exception for PI status, the candidate's dean, chair, or director should make a recommendation to the candidate's associate dean for research for approval of an exception. The college associate dean for research will email the candidate's CV and a statement of approval to the Office of Research Compliance (compliance@ohio.edu). The ORC will discuss the exception request with the Ohio University Vice President for Research and Creative Activity, record their decision, and notify the candidate and college associate dean for research.

Co-Investigator — the Co-I is an investigator working in partnership with the PI in the management, development and/or execution of the study. At times, the PI may delegate various responsibilities to the Co-I, but the PI always maintains overall responsibility and authority for the project.

Primary Contact — the primary contact (PC) serves as the primary contact with the IRB. Multiple team members can serve as PC. The PC may also have other roles on the study (e.g., PI, Co-I, Research Assistant).

Research Assistant — the research assistant works in a supportive role. They may interact with research subjects, collect or analyze data, and assist with writing results.

Advisor — if the PI is a student or post doc, a regular faculty member must serve as Advisor. The Advisor has the same responsibilities as the PI.