

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? Individuals who 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.

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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

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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 professional role

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