



Principal Investigator Eligibility, Faculty Advisors, and Research Personnel Requirements

Scope: The purpose of this guidance is to define individuals who have appropriate qualifications, sufficient authority, and institutional accountability to conduct ethical research and oversee the protection of human subjects in research at the University of Oregon. This guidance also addresses the role of faculty advisors, when appropriate, and other research personnel.

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I. Introduction

The Principal Investigator (PI) for a human subjects protocol must be the individual most qualified to oversee the conduct of the human subject research and is ultimately responsible for the design, conduct, execution, and/or reporting of the human subject research. Human subject research PIs do not need to be the same as the PI on a funded/sponsored award.

II. Principal Investigator Eligibility

Individuals as outlined below may be eligible to serve as Principal Investigator for human subject research protocols in which UO is engaged or for human subject research in which UO's IRB is otherwise determined to be the IRB of record.

- Faculty and other employees with a current UO appointment conducting research under their UO affiliation and in-line with their institutional responsibilities may serve as Principal Investigator. In some cases, RCS and/or the IRB may request verification of supervisory approval for the proposed research.
- Upon request and with appropriate qualifications, individuals with other institutional appointments, affiliations or engagements may be eligible to serve as PI if conducting work as part of their affiliation with the UO or with UO affiliated research. RCS and/or the IRB may require verification of department and/or divisional support of the individual and research.
- Students conducting research are eligible to act as Principal Investigator *only* when they are under the oversight of a Faculty Advisor (tenure related and non-tenure track faculty) meeting the qualifications of a Principal Investigator listed above.
- An individual who leaves the university but maintains a 0% or other small percentage appointment with the University of Oregon may remain as PI on a human subjects protocol for up to one year to complete the research or transition the research to a new PI or transfer to another institution.

III. Principal Investigator and/or Faculty Advisor Qualifications

In addition to the above eligibility requirements, a Principal Investigator and/or Faculty Advisor must demonstrate sufficient qualifications to conduct and/or oversee the design, conduct, execution, and/or reporting of the research involving human subjects. An individual's qualifications to serve as Principal Investigator and/or Faculty Advisor will be assessed based on the following:



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- Complete and current human subject protections training
- Adequate written description within the protocol materials detailing background and demonstrating appropriate experience, relevant training, and necessary clearances to ethically conduct the proposed research using the proposed methodology
- No known restrictions (internal or external to the institution) related to the oversight, engagement or conduct of human subject research
- Agreement to adhere to the Principal Investigator and Faculty Advisor Responsibilities, as well as all other institutional policies and requirements.

IV. Other Research Personnel

Any individuals interacting with participants or identifiable participant information for research purposes are considered engaged in the research and need to be listed as research personnel. If any research personnel are unaffiliated with the UO, see our [Collaboration in Research](#) guidance to ensure necessary collaborative agreements are in place.

V. Research Personnel Requirements

A. Research Personnel Form.

All protocols will need to establish a Research Personnel Form. This document is used to manage research personnel roles and training requirements. This form will need to be submitted at the time of initial review. Any changes to research personnel will require an amendment to the protocol. Amendment Applications will need to include an updated version of the Research Personnel Form with changes included. This form will also need to be submitted with continuation applications if the study requires continuing review.

B. Training Requirement.

All research personnel must maintain current human subject education certification. The University of Oregon subscribes to the online [Collaborative Institutional Training Initiative \(CITI\)](#) training through which the training requirement can be fulfilled. Alternatively, the UO will accept documentation of certification from NIH's Human Subject Training program. In some circumstances, RCS may accept alternative training with justification and demonstration of equivalency. Training must be completed every two years to maintain current training status. See our dedicated [Human Subject Research Education Requirement](#) webpage for more information about how to fulfill the training requirement.

C. Conflict of Interest in Human Subject Research Disclosure.

Each member of the research team will need to complete the [Conflict of Interest in Human Subject Research Form](#) to determine if any potential conflicts of interest exist between members of the research team and the research (NOTE: This form is not the same disclosure that is submitted for Financial Conflict of Interest related to a grant submission). The Principal Investigator is responsible for ensuring all members of the research team complete this form. **If no conflicts are identified, the investigator will need to keep a copy of the form for their records. The form only needs to be submitted with review materials when an individual identifies that they have a potential conflict.** RCS and/or the IRB will review the information and make a determination regarding the potential conflict and whether steps to mitigate the conflict are necessary.