UNIVERSITY OF OREGON | Research Compliance Services

INVESTIGATOR RESPONSIBILITIES

Scope: The purpose of this guidance is to outline the responsibilities assumed by a Principal Investigator when applying to conduct human subject research activities at the University of Oregon. When a student serves as Principal Investigator, the Faculty Advisor also assumes the Principal Investigator Responsibilities.

I. Introduction

When applying for approval to conduct human subject research at the University of Oregon, each application must be signed by a Principal Investigator who agrees to assume the responsibilities outlined in the Investigator Agreement section of the application. The responsibilities are standard across applications and are outlined in Section II as the Principal Investigator Responsibilities.

When conducting multi-site research for which the investigator requests a reliance arrangement, investigator responsibilities will change depending on whether the UO will assume responsibility as the reviewing IRB or whether IRB oversight is deferred to another institution. These are Principal Investigator Responsibilities for Multi-Site Research and are outlined in Section III.

II. Principal Investigator and Faculty Advisor Responsibilities

At the time of initial submission, an eligible Principal Investigator assumes responsibilities for the oversight and conduct of the study by signing the Investigator Agreement within the application. The PI agrees to assume these responsibilities while the protocol remains active and approved for human subject research activities.

When a student serves as Principal Investigator, a Faculty Advisor must also sign applications submitted to RCS and/or the IRB. When signing the application, the Faculty Advisor agrees to provide oversight for the conduct of the research and assumes the same Principal Investigator Responsibilities as outlined in the prior section. The Faculty Advisor is expected to support the student researcher with submissions to RCS and the IRB. This includes support the development of protocol materials, review of materials prior to submission, and preparing responses during the review process.

Investigator and Faculty Advisor Agreements and Principal Investigator Responsibilities

a) Conduct of the Research

1) I accept responsibility for the ethical conduct of this research and protection of participants as set forth in the Belmont Report, Declaration of Helsinki, the Nuremberg Code, the Common Rule, and the ethical principles of my discipline.

2) I accept responsibility for the conduct of this research ensuring this research is conducted according to:

   i) sound research design and methods;
   ii) the IRB approved protocol including the informed consent process;
   iii) the applicable terms of the grant, contract and/or signed funding agreements; and
   iv) applicable laws and regulations, including those for protecting the rights, safety, and welfare of human subjects.

3) I certify that I am or my faculty advisor is sufficiently qualified by education, training, and/or experience to assume responsibility for the proper conduct of this research. I accept responsibility for ensuring that members of this research team, including study staff and trainees, are appropriately qualified, trained and supervised.

4) I accept responsibility to personally conduct and/or directly supervise this research. I certify that I have sufficient time and resources to properly conduct and/or supervise this research for which I am responsible.

b) Ensuring and Maintaining Compliance

1) I will comply with relevant regulatory and institutional requirements, including those relating to conflicts of interest, responsible conduct of research and research misconduct.

2) I understand it is my responsibility to ensure that any research personnel, including myself, responsible for the design, conduct, and reporting of research declare any potential conflicts of interests related to the research and to maintain current records. I will ensure changes in conflicts of interest are promptly disclosed to the IRB.

3) I will ensure that informed consent is obtained as approved by the IRB and a copy is provided to participants, unless the IRB waives these requirements.

4) I will obtain initial IRB approval prior to implementing human subject research activities as well as prior approval for any amendments to this research.

5) I will conduct this research within the approval period issued by the IRB. I agree to submit a request for continuing review of this research at least 45 days in advance of the expiration date.

6) I will submit a closure report form prior to protocol expiration or within 45 days of completion of all activities involving human subjects or identifiable participant data.

7) I will maintain approval, as applicable, with collaborative entities including approvals from other countries or jurisdictions.

8) I will promptly report to the IRB (no later than seven days of discovery) any instances of noncompliance with the approved protocol or requirements of the IRB and any unanticipated problems.

9) I will assist in the facilitation of any monitoring and/or auditing of study activities and/or records as required by the IRB, funding entities, sponsors, and any federal and state regulatory agencies.

c) Investigator Records, Reports and Documentation

1) I will maintain research records, all protocol materials, and any other documents associated with this research (e.g., research plan, signed consent forms, and IRB correspondence).

2) I will maintain records for at least three years after this research ends, or for the length of time specified in applicable regulations or institutional or sponsor requirements, whichever is longer. I will take measures to prevent accidental or premature destruction of these documents.

3) I will ensure the safe and secure storage of this research data (whether in paper or electronic formats) and for protecting the confidentiality of the data in accordance with the approved protocol.

4) I will submit written reports to the IRB and permit inspection of the research records as required by the IRB.

III. Principal Investigator Responsibilities for Collaborative and Multi-Site Research

Collaborative and multi-site research may call for a reliance arrangement in which the UO IRB will serve as the single IRB or defers oversight to another IRB. With a reliance arrangement, additional investigator responsibilities are agreed to by the collaborating investigators. Below are the responsibilities for the UO and Site investigators depending on the reliance arrangement in place.

A. Investigator Responsibilities when UO IRB serves as the Reviewing IRB

When a Reliance Request is initiated, the UO Principal Investigator agrees to assume responsibility for the overall conduct of the study both locally and by relying sites. When submitting the site-specific materials in support of the Reliance Request, the Relying Site investigator agrees to uphold the responsibilities of the Relying Site Investigator.

1. UO Principal Investigator Responsibilities for Collaborative and Multi-Site Research

UO Principal Investigator Responsibilities for Collaborative and Multi-Site Research

a) As the overall PI for the study, the UO investigator is responsible for requesting the reliance arrangement for the UO IRB to serve as the IRB of record. This includes:

1) Requesting a pre-clearance letter of support from RCS prior to submitting for federal funding.
2) Facilitating execution of reliance arrangement in collaboration with RCS, the UO IRB, and relying sites.

b) The UO PI is responsible for securing IRB approval for the conduct of the research and maintaining current approval. This includes:

1) Submitting a protocol application and securing either an Exempt Determination from RCS or approval by the IRB prior to implementing human subject research activities.
2) Ensuring all sites are identified on the approved protocol and a Site Investigator is designated for each relying site. Ensuring executed reliance agreements are in place prior to a site engaging in human subject research activities.
3) Ensuring all research personnel engaged in the research at all sites are listed in the Research Personnel Form included in the IRB approved protocol. Ensuring all research personnel complete a Conflict of Interest forms and any forms identifying a conflict are included with the application for review by RCS and/or the IRB.
4) Developing a comprehensive Single IRB Plan included with the IRB protocol application.
5) Working with RCS during the review process to facilitate gathering information for all sites including basic contact information, local context surveys, and any other information required for review and approval of the protocol application.
6) Submitting and securing approval for any amendments to the research protocol and/or the reliance arrangement plan prior to implementing changes at any sites.
7) Submitting requests for continuing review or progress reports and ensuring continuous approval is secured while conducting human subject research activities.

c) The UO PI is responsible for overseeing the conduct of the research at all sites in compliance with the IRB approved protocol. This includes:

1) Fulfilling the obligations of the Principal Investigator Responsibilities as agreed to within the application submitted for protocol review to RCS and/or the UO IRB.
2) Ensuring all research personnel engaged in the research maintain current requisite training, are trained to conduct research according to the approved protocol and institutional policies.

3) Disseminating the currently approved protocol to all research sites and ensuring the currently approved protocol and materials, including the applicable consent and/or assent materials, are employed by the research team.

4) Implementing the reliance arrangement plan approved by the UO IRB.

5) Submitting reportable events that occur at any sites to the UO IRB and responding to any requirements resulting from the review of those event.

6) Providing and/or facilitating access to study records for all sites upon request from RCS, the UO IRB and/or regulatory agencies.

2. Relying Site Investigator Responsibilities for Collaborative and Multi-Site Research

Relying Site Investigator Responsibilities for Collaborative and Multi-Site Research

The Site Investigator is responsible for:

1) Providing information to the UO Principal Investigator, RCS, UO IRB, and federal regulators as requested during the protocol review and approval process and throughout the conduct of the research while the site is under the oversight of the reliance arrangement.

2) Conducting the research in accordance with the approved protocol and use the approved materials. Ensuring that the UO PI has secured approval for any changes prior to implementing any changes to the research activities.

3) Ensuring no individuals at the site engage in human subject research activities until documentation of an approved protocol listing those individuals is received.

4) Informing the UO Principal Investigator promptly of any reportable new events and supporting submission of the report to RCS and the UO IRB.

5) Ensuring any ancillary reviews and/or other institutional requirements pertaining to the conduct of this research are fulfilled prior to the implementation of human subject activities at the relying site.

B. Investigator Responsibilities when UO IRB defers IRB oversight to another IRB

When a Reliance Request is initiated, the UO Principal Investigator agrees to assume responsibility for the conduct of the research locally and agrees to adhere to the requirements of the reviewing IRB. The reviewing IRB may require additional responsibilities of the UO investigator.

UO Principal Investigator Responsibilities as a Relying Site

a) The UO Investigator is responsible for securing and maintaining a reliance arrangement prior to engaging in human subject research activities. This includes:

1) Submitting a reliance request to RCS and/or the UO IRB to initiate the reliance review and approval process for UO to rely on an external IRB.
2) Supporting the UO institutional review and approval by providing or facilitating access to protocol materials used by the relied upon site to secure approval.
3) Providing information to RCS, UO IRB and federal regulators as requested during the protocol review and approval process and throughout the conduct of the research while UO is relying on another IRB of record

b) The UO Investigator is responsible for the oversight of any research activities and study personnel at UO. This includes:

1) Conducting the research in accordance with the approved protocol and using the approved materials.
2) Ensuring that the lead PI has secured approval for any changes prior to implementing any changes to the research activities locally.
3) Fulfilling obligations as a site PI per the terms of the reliance arrangement.

c) The UO Investigator is responsible for ensuring local compliance with the IRB approved protocol and with UO institutional requirements. This includes:

1) Ensuring no individuals at the UO engaged in human subject research activities until documentation of an approved protocol listing those individuals is received.
2) Informing the lead PI promptly of any reportable new events and supporting submission of the report to the relied upon IRB. Ensuring RCS is notified of events to ensure RCS is positioned to support the local mitigation of the event and any requests to contribute to the review by the relied upon IRB.
3) Submitting any required progress reports and documentation of continued approval from the relied upon IRB to secure continued UO institutional approval for the conduct of the research locally.
4) Ensuring any ancillary reviews and/or other institutional requirements pertaining to the conduct of this research are fulfilled prior to the implementation of human subject activities at the relying site.