

Series 302 The Principal Investigator | Institutional Review Board

The Principle Investigator from Series 302 of the Standard Operating Procedures

I. The Role of the Principal Investigator

Studies involving human subjects require the utmost care. When a living person shares their bodies or information with a researcher to advance knowledge and scientific inquiry, that person is owed a strict duty of care by the research team. It is the role of the Principal Investigator to ensure that all facets of the study are completed in a manner that is consistent with that duty of care. Further, it is the role of the Principal Investigator to ensure that the study remains in compliance with all IRB-related requirements.

Prior to submitting a protocol in Quali Protocols, the individual designated as the Principal Investigator (PI) must ensure that they meet the requirements of who may serve as a PI as articulated in SOP-301.IV. and other relevant USU Policies.

In general, the following role statements with Utah State University permit someone serving in that role to also serve as a Principal Investigator:

- (Assistant, Associate) Professor
- Instructor (if the proposed research is on the subject of teaching or pedagogy)
- (Assistant, Associate) Librarian
- Extension (Assistant, Associate) Professor
- Research (Assistant, Associate) Professor
- (Assistant, Associate) Federal Research (FR) Professor
- Post-Doctoral Fellow that is *NOT* specifically Teaching (unless, as above, the research is on teaching or pedagogy)

II. Principal Investigator Responsibilities

In addition to the responsibilities articulated in SOP 301, Principal Investigators on human subjects research projects have a heightened obligation to fulfill their ethical obligations regarding the protection of human research participants. This includes the following:

1. Delegating only those responsibilities that are appropriate for delegation and maintaining appropriate oversight of all delegation decisions. While training new investigators is an important part of the teaching and research mission of Utah State University, when human participants are involved, adequate oversight is of the utmost importance. Delegation should be done with clear and understandable directives, and to research staff with adequate training and qualifications.
2. Maintaining appropriate oversight of the research study. The Principal Investigator should always be in a position to speak about or report on the status or activities of a research project. This includes ensuring that [USU Policy 588](#), regarding the storage and ownership of research data, is being closely adhered to.
3. Maintaining active human subjects research training, and devising systems to ensure that all research staff maintain active human subjects research training, during the life cycle of the protocol.
4. Creating, implementing, and overseeing a system to ensure that study-related documentation is being maintained consistent with the requirements in SOP-01(III).

5. Ensuring that the research staff are represented by agreements that are accurate as to their roles (i.e. that graduating students or transitioning faculty are covered by appropriate external researcher agreements once their affiliation with Utah State University has ended).
6. The timely transition of active protocols to a new Principal Investigator, when appropriate, and with ample time prior to the departure of the extant PI.
7. Delegating only those responsibilities that are appropriate for delegation, based on the training and qualifications of the researchers involved with the research study. Similarly, taking care to delegate those responsibilities that fall outside of the skills, training, and qualifications of the PI to an individual who possesses the relevant skills, training, and qualifications for a given research procedure.
8. Securing adequate resources available to safely conduct the research and ensure the well-being of the research participants prior to the initiation of a human subjects research protocol.
9. Developing a plan for maintaining records of research participant contacts, and ensuring that research participants are responded to in a prompt, thorough, and honest manner.
10. Ensuring that, at all times, the protocol is carried out in a manner that complies with all relevant regulatory requirements in each cognizant jurisdiction where the research is taking place, as well as the requirements put into place by all entities at Utah State University, including the IRB.

III. Alternative Qualification to Serve as Principal Investigator

In accordance with guidance from the Office for Human Research Protections, standards of accreditation from AAHRPP, and USU Policy 584, a Principal Investigator is an individual whose training, expertise, qualifications, and role with Utah State University inherently demonstrates that they are able to take full responsibility and oversight for research that involves human participants. Those roles, articulated in Section I above, may not fully capture all individuals who possess these requirements.

Alternative paths to serve as a PI are therefore established, in order to ensure that proposed human subjects research is being overseen by the individual best situated to ensure a strict duty of care to human participants involved in USU-based research projects. The following steps should be taken by an individual wishing to establish qualifications as a Principal Investigator *prior* to the initiation of a protocol in Quali Protocols:

1. The proposed Principal Investigator should prepare a summary of the details of the research they wish to oversee as PI.
2. A memorandum should be drawn up that specifies that the individual has met the standards outlined in this Procedure for serving as a PI. The Human Research Protections Office makes a template available for this purpose.
3. That memorandum should be provided to the individual's unit head (usually a Director or Department Head) and appropriate member of the office of the Dean or Vice President (usually an Associate Vice President or Associate Dean for Research), along with the summary outlined in section a), above.
4. The memorandum should be signed by those individuals and provided in the "Other Approvals & Documentation" section of the Quali Protocol submission.

Alternative qualifications will remain in force for the duration of the protocol for which it is sought, as well as (at the discretion of the unit and college-level administrator) the remainder of the academic year in which it has been submitted to the IRB. After that, it must be renewed by the individual seeking to establish qualifications as a PI.

IV. Withdrawal of Principal Investigator Privileges

When circumstances demonstrate that an individual who previously served as a PI is unfit to do so, the Institutional Review Board or Vice President for Research may withdraw an individual's status as a Principal Investigator of human subjects research projects. Examples of circumstances that may warrant withdrawal of PI status include:

- Research fraud or misconduct
- Serious or continuing noncompliance
- Failure to protect the rights, welfare, or well-being of research participants

- Inability to fulfill the responsibilities articulated in these SOPs

Withdrawals effectuated by the Institutional Review Board are not subject to appeal, and are usually for a definite duration of time. Particularly egregious violations, however, may result in the indefinite withdrawal of PI privileges.