

Investigator Guidance Series

University of Utah Institutional Review Board

INVESTIGATOR QUALIFICATIONS

Description

At the University of Utah, the IRB also acts as the ethical review board for University students, University staff, and other person(s) who are not appointed as either regular or research faculty by his/her department head. In this instance, the University student, University staff member, and other person(s) may act as a Principal Investigator with the mandate a faculty sponsor is provided. The faculty sponsor must be a person of appointment for either regular or research faculty by his/her department head (with the approval of the dean).

The University of Utah IRB has been designated as the ethical review board for Primary Children's Medical Center, Shriners's Hospitals for Children Intermountain, and the Veteran Affairs Salt Lake City Health Care System. Person(s) with workforce privileges similar or equivalent to that of an appointed regular or research faculty at the University of Utah may be designated as a Principal Investigator by the institution's research or other administrative department(s) with the authority to pronounce such responsibility.

Who Qualifies as a Principal Investigator?

A Principal Investigator (PI) must be faculty or have a faculty sponsor in order to submit to the University of Utah IRB. Detailed information can be found by referring to our Standard Operating Procedures.

At the University of Utah, a person appointed as either regular or research faculty by his/her department head (with approval of the dean) may be designated as Principal Investigator (PI). University faculty shall consist of the president, vice president, deans, directors of libraries, professors (including distinguished professors, presidential professors, and University professors), associate professors, assistant professors, instructors, librarians, associate librarians, assistant librarians, affiliate librarians, and auxiliary faculty (research, clinical, lecturer, visiting, adjunct) and emeritus appointments. *For a complete definition of University faculty see the Policy and Procedure Manual: Faculty Regulations-Chapter II. University Faculty, Section 9-2.*

The PI of the research study is ultimately responsible for assuring compliance with applicable University of Utah IRB policies and procedures, DHHS Federal Policy regulations, and FDA regulations; and for oversight of the conduct of the research study and the informed consent process (SOP 801). For a complete list of the general responsibilities of study investigators, please refer to IRB SOP 801.

Points to Consider When Designating a PI for a Study:

- Does the PI have the appropriate qualifications, experience, and facilities available to ensure that all aspects of the project and follow-up will be conducted rigorously and with due regard for the safety and well-being of the subjects?
- Are adequate procedures in place through which the researcher will monitor the project and report problems to the IRB?
- What is the investigator's past record with regard to approved research?

Who Qualifies as an Internal Co-Investigator?

Internal Co-Investigators are faculty or faculty-appointed individuals who are employed by the University of Utah. Co-Investigators are supervised by the Principal Investigator to perform critical trial-related procedures, and/or to make important trial-related decisions.

Co-Investigators should be able to answer in-depth questions about the study, among which include those concerning hypothesis, scope, methodology, anticipated outcome, and so forth.

Please contact the IRB Office at (801) 581-3655 or irb@hsc.utah.edu for additional guidance.

Investigator Guidance Series

University of Utah Institutional Review Board

Who Qualifies as an External Co-Investigator?

External Co-Investigators are faculty or faculty-appointed individuals who are not employed by the University of Utah, but may be responsible for conducting research at other institutions under the supervision of, or in collaboration with the PI.

Principal Investigator Qualification Chart

Professional Title/Designation	Principal Investigator	Internal Co-Investigator	External Co-Investigator	Requires a Faculty Sponsor
President and Academic Officers	X	X		
Vice-Presidents	X	X		
Deans	X	X		
Directors	X	X		
Professor	X	X		
Associate Professor	X	X		
Assistant Professor	X	X		
University of Utah Faculty	X	X		
Research	X	X		
Regular	X	X		
Auxiliary	X	X		
Clinical	X	X		
Visiting	X	X		
Adjunct	X	X		
Emeritus Appointments	X	X		
Instructor	X	X		
Lecturer	X	X		
Lecturer with rank of Professor	X	X		
Lecturer with Continuing Appointment	X	X		
Senior Lecturer	X	X		
Librarian	X	X		
Associate	X	X		
Assistant	X	X		
Affiliate	X	X		
Auxiliary	X	X		
Faculty or Faculty-Appointed individuals not employed by the University of Utah			X	
PI Unaffiliated with the University				X
Graduate Students*				X
Resident/Fellow				X
Other Students*				X
Staff				X
Other				X

*If students are involved in the study, a faculty member or other individual authorized to supervise graduate students must fulfill the appropriate advising responsibilities. The submitting department is obligated to assure compliance with this policy.

When is a Faculty Sponsor Required?

Students or University of Utah staff members who conduct research at the University of Utah must have a faculty sponsor for IRB submission.

By agreeing to act as the faculty sponsor on a research application, the sponsor must agree that the

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Investigator Guidance Series

University of Utah Institutional Review Board

student or guest investigator is knowledgeable about the regulations and policies governing research with human subjects and has sufficient training and experience to conduct this particular study in accord with the approved protocol. In addition, the sponsor agrees:

- to meet with the investigator on a regular basis to monitor study progress;
- to be available, personally, to supervise the investigator in solving problems should they arise during the course of the study; and,
- to notify the IRB of their replacement if they are unable to fulfill their role as faculty sponsor for any reason (e.g. sabbatical, etc.).

Points to Address

New Study Application:

1. **Section 1.1, Principal Investigator:** Enter the name of the designated PI for the study by clicking the “Select” button and searching for the individual in the “Select Person” list. If you are unable to search for this individual on the “Select Person” screen, it is likely that this individual is not currently registered in the ERICA system. This will need to be completed before this study can be approved. Please have the investigator register in ERICA by clicking the “ERICA” link at <http://www.research.utah.edu/irb/>, and following the login instructions on the screen. If this investigator does not currently have a University uNID, or needs assistance completing the registration process, please have them contact the IRB Executive Secretary at (801) 581-3655. **Please also ensure that all newly-registered investigators have completed the appropriate CITI Training modules.**

Protocol Summary:

1. **Title Page:** Please add the name and contact information of the PI, and all of the co-investigators (and Faculty Sponsor, if applicable) as per the IRB template.

Documents and Attachments:

1. **Current PI Scholarly Record (CV/Resume):** Attach a copy of the Principal Investigator’s (and Faculty Sponsor’s, if applicable) **Curriculum Vitae** (CV), resume, or other documentation that will demonstrate a scholarly record suitable for the study in question.

References & Links

University of Utah IRB SOP
301: Research Submission
Requirements

University of Utah IRB SOP
403: Initial Review-Criteria
for Approval

<http://www.research.utah.edu/irb/guidelines/sop.html>

University of Utah IRB SOP
601: Investigative Staff

University of Utah IRB SOP
801: IRB-Required
Investigator Actions

University of Utah Policy
and Procedure Manual:
Faculty Regulations

<http://www.admin.utah.edu/ppmanual/9-tbl.html>

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