



## INVESTIGATORS AND KEY STUDY PERSONNEL QUALIFICATIONS

### Description

Investigators and key study personnel conducting research at the University of Utah should be listed on the ERICA application and must complete required human subject research training. This guidance provides an overview of who qualifies as a principal investigator and who is considered key study personnel.

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### Who Qualifies as a Principal Investigator?

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A Principal Investigator (PI) who is responsible for research at the University of Utah or its affiliates must be faculty or have a faculty sponsor ~~in order to~~ submit a research application to the University of Utah IRB.

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Faculty at the University of Utah includes: **President and Academic Officers:** Vice-Presidents, Deans, Directors; **Professor:** Associate Professor, Assistant Professor; **University of Utah Faculty:** Research, Regular, Auxiliary, Clinical, Visiting, Adjunct; **Emeritus Appointments;** **Instructor;** **Lecturer:** Lecturer with rank of Professor, Lecturer with Continuing Appointment, Senior Lecturer; **Librarian:** Associate, Assistant, Affiliate, Auxiliary

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. The PI agrees to the general responsibilities of study investigators in the Statement of Assurance when submitting new study applications (please see the IRB page "[Who Can Submit an Application to the IRB?](#)" for the list of PI responsibilities).

#### 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 is the Responsible Investigator and the Site Principal Investigator (Site PI)?

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Because the University of Utah IRB may act as the IRB for sites outside of the University of Utah and its standard Affiliate Institutions (Primary Children's Hospital, Veterans Affairs SLC Health Care System, and Shriners' Hospitals for Children – Salt Lake City), it is necessary to identify the individual responsible for research at each participating site and the individual responsible for the overall conduct of the study. The ERICA application will ask for the person designated as:

- The Responsible Investigator - the person who has ultimate responsibility for the conduct of the study and ensuring the ERICA application is complete, accurate and current at all times; and
- The Site Principal Investigator (Site PI) - the person responsible for all research activities conducted at their study location. The Site PI can be the same person as the Responsible Investigator.

The Responsible Investigator should meet the qualifications of a Principal Investigator as described in this guidance. For additional information about the study personnel roles in the ERICA application, please see "[Study Personnel Roles in the ERICA application](#)" on the IRB website.

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**Who is a Sub-Investigator?**

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Sub-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.

Sub-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.

**When is a Faculty Sponsor Required?**

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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 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.).

**Who are key study personnel?**

Key study personnel are individuals engaged in the conduct of research activity, including investigators and research personnel who are directly involved in conducting research with study participants or who are directly involved in using study participants' identifiable private information during the research. All key study personnel should be listed on the ERICA application under site staff and sub-investigators if not already listed as a site contact person.

Key study personnel do not have to be affiliated with the University of Utah or one of its affiliate institutions.

Examples of key study personnel may include:

- Co-investigators
- Study coordinators
- Research nurses
- Research assistants
- Staff/clinical pharmacists involved in the direct enrollment of participants, or research protocol authorship
- Statisticians or consultants who contribute in a manner to qualify for authorship
- Collaborators
- Research support staff with access to private and identifiable private information, including audio or visual recordings

Some individuals may interact or have access to private identifiable information as part of their routine, paid employment. If involvement in research is limited to performing regular paid duties without contributing to the

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research enterprise, then these individuals are not considered key study personnel. Examples include, but are not limited to:

- Phlebotomist
- Radiology technician
- Staff nurse
- Staff pharmacist responsible for dispensing investigational drugs during their routine workday. The responsibilities include only the investigational drug preparation, dispensing and record documentation but not the direct enrollment of participants.
- Lead pharmacist responsible for the oversight of the investigational pharmacy policy and procedures, and investigational drug management (receipt, storage, dispensing).

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#### Points to Address

##### New Study Application:

**1. Contacts and Title page, question 1:** Enter the name of the Responsible Investigator. The Responsible Investigator can create, edit and submit all components of the application including participating site-level applications. Click the "Select" button and search for the individual in the "Select Person" list. If you are unable to search for this individual on the "Select Person" screen, this individual may not be registered in the ERICA system. Please have the investigator register in ERICA by clicking the "ERICA" link on the IRB website, and following the login instructions. If the investigator does not have a University uNID, or needs assistance completing the registration process, please contact the IRB Office at (801) 581-3655. **Please also ensure that all newly-registered University of Utah investigators have completed Human Subjects Research Training which is acceptable to the University of Utah IRB (see IRB website for more information).**

**2. Study Location and Sponsors page, question 1:** For each location entered in question 1, the Site Principal Investigator must be selected. Each study location will have the option to select the Site Principal Investigator. If the Site Principal Investigator is the same as the Responsible Investigator, check the appropriate box.

**3. Study Location and Sponsors page, question 1, Addition of a Site:** On the pop-open page for each site, key study personnel should be listed under question 3 or 4 as a site contact person, site staff, or sub-investigators.

##### 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

<http://irb.utah.edu/guidelines/irb-sops.php>

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**INSTITUTIONAL REVIEW BOARD**  
THE UNIVERSITY OF UTAH

**Investigator Guidance Series**

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

<http://irb.utah.edu/guidelines/irb-sops.php>

University of Utah Policy 6-  
300: The University Faculty-  
Categories and Ranks ~~and~~  
Procedure Manual: Faculty  
Regulations

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

<https://regulations.utah.edu/academics/6-300.php>

Who Can Submit an  
Application to the IRB?

<http://irb.utah.edu/submit-application/new-studies/who-can-submit.php>

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