

Institutional Review Board Training Series: Roles & Responsibilities of a Principal Investigator



UtahStateUniversity

April 13, 2026

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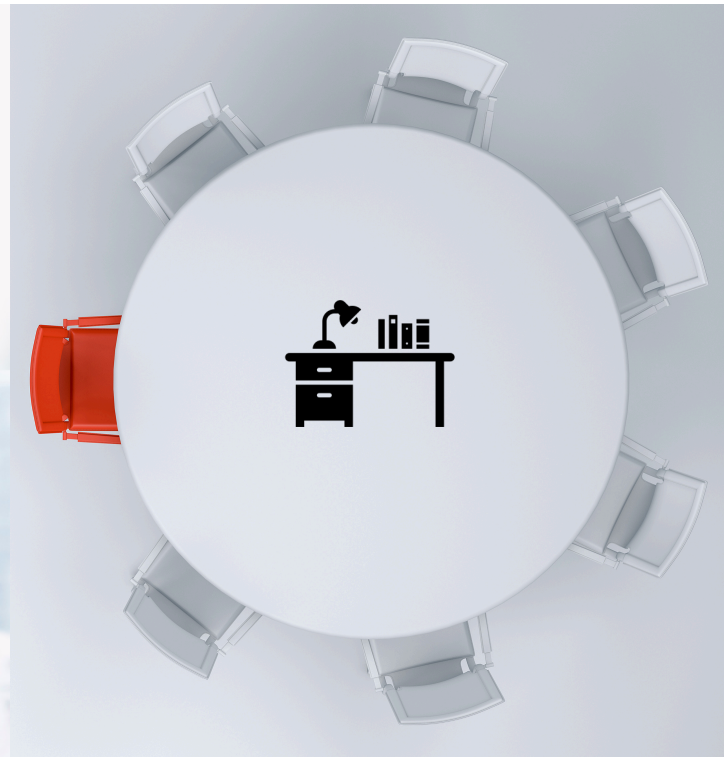
Executive Director of Human Research Protections

Learning Objectives

By the end of this session, attendees will:

- Understand the core regulatory and ethical roles the Principal Investigator (PI) fulfills
- Identify primary responsibilities across the study lifecycle
- Recognize compliance risks common to studies at USU
- Apply expectations from USU's Human Research Protection Program to current and future studies

The Institutional Review Board



The Human Research Protection Program

VP for Research

Responsible for overseeing all aspects of USU's Human Subjects Research portfolio & ensuring appropriate access to resources for a well-functioning Human Research Protection Program (HRPP)



Human Research Protections Office

Manages the day-to-day aspects of implementing and overseeing the HRPP, including:

- Researcher training
- Coordination with COI, IBC, ICOI, SPO processes
- Receiving complaints, concerns, and questions from research participants

The IRB

Reviews all proposed human subjects research at Utah State University according to:

- Established ethical standards,
- Policies & procedures, and
- Best practices

Researchers

Responsible for carrying out and overseeing research with human participants in a manner that:

- Complies with the terms of IRB's review,
- Ensures adequate resources and training for the safe conduct of the research, and
- Takes proactive steps to ensure the health, safety, and well-being of research participants

Why This Matters

Researchers are the most impactful component of Utah State University's Human Research Protection Program.

Research participants entrust their data, their experiences, and sometimes their safety to the research team. As a result, the PI has a strict duty of care toward them as they participate in knowledge creation led by the PI.

We all have a shared goal in protecting the rights and welfare of research participants.



Who Can Be a PI?

Every research institution must decide who can serve as a Principal Investigator. At USU, a PI for Human Subjects Research is someone:

- The institution has delegated research responsibility to via a formalized role statement
- Someone with oversight authority
- Someone with appropriate institutional access to resources necessary to safety carrying out research

Those responsibilities and resource allocations are not attributed to students, and so students cannot serve as a PI.

What is a PI's Core Role?

A Principal Investigator is responsible for **all aspects of the study.**

A Principal Investigator is responsible for **compliance with all IRB requirements.**

A principal investigator makes decisions with **the protection of research participants** at the forefront of their decisionmaking.

Delegation is allowed, but **accountability is not transferrable.**

Principal Investigator Operational Responsibilities

The Project Lifecycle



Before A Study Begins

Principal Investigators are responsible for the following:

- Ensuring IRB approval, exemption, or reliance is in place
- That the study team is fully trained – not just CITI
- That the approved protocol represents the reality of the study plan
- That the PI has the ability to oversee all aspects of the study



Before A Study Begins – Practical Questions

- Have I factored my student's timeline into account when helping them consider a project?
- Have I trained or verified the training for all relevant study procedures – beyond CITI Training?
- Does the protocol reflect the reality of how my student/lab works, or did I say what I thought would be easiest to get through the IRB?
- Are things structured in such a way that I can readily access any information I need to answer questions about the conduct of this study?

While a Study is Ongoing

Principal Investigators are responsible for the following:

- Ensuring the terms of IRB approval are being adhered to
- Maintaining oversight of the study team
- Ensuring compliance with all non-IRB requirements (DMP, sponsor review requirements, deliverables, budgets)
- Communicating with the IRB as needed.



While a Study is Ongoing – Practical Questions

- Am I knowledgeable about what my approved protocol says?
- How, in what ways, and at what frequency do I need to monitor the study to ensure I am maintaining appropriate oversight?
- What changes might I need to make to the protocol for a better participant experience?
- I am surprised by something that happened or that I learned – should I communicate with the IRB/

Modifications

Principal Investigators must monitor their studies in a manner that permits them to identify a needed change.

This includes changes in:

- Recruitment
- Study Procedures
- Data collection instruments
- Informed consent documents
- Informed consent processes



Reporting Responsibilities

Principal Investigators must promptly report or directly oversee the prompt reporting to the IRB of:

- Deviations
- Adverse Events
- Information regarding new or increased risks
- Unexpected issues
- Closures, cancellations, and completions



When the Study Expiration or Continuation Date is Approaching

Principal Investigators have defined responsibilities for projects as a study winds down. These differ based on the type of IRB approval you are working under.

- Full Board: Renew **Annually**
- Expedited: Renew **at your stated end date**
- Exempt: Expires **at your stated end date** or 5 years
- Reliance: Expires when the project expires at the Reviewing Institution



What to do if my study expires...

But what if I can close it?



So how do I know if I can close it out?



irb.usu.edu/closures

What would happen if I keep going...?

Series 800: Noncompliance

801 Noncompliance

When any Utah State University employee, student, or affiliate receives information related to Noncompliance and those activities appear to be related to research being conducted by USU personnel or under USU's purview

802 IRB Review of Noncompliance

The convened Utah State University Institutional Review Board shall, based on the findings provided by the investigative team and materials provided by the investigator(s), make the final determination of whether the allegations of noncompliance constitut...

Principal Investigator Operational Responsibilities

Practical Tips



Practical Tips for PIs

- Be supportive, AND realistic
- Start Qualtrics, RedCAP, Box projects & add collaborators
- Centralize study communication
- “Show me”
- Monitor often, but especially at first
- Delegate, but apply expertise as well
- Conduct your own audit
- Coordinate dissertation and thesis committee needs

Principal Investigator Responsibilities

Where Does It Most Often Go Wrong?



Common Mistakes

- Poor team oversight, especially re: CITI Training Expirations
- Expired protocols
- Not filing amendments
- Not being able to produce information about the study
- Poor planning for study timeline

Practical Tips to Avoid Common Mistakes

- Set calendar reminders; automatic revocation of access
- Close or replace protocols on time.
- Conduct your own audit of your protocol. Pick one protocol heading, and check to see if that's what's happening in your project.
- Any response that begins with "My student..." Stop. Fix whatever gap prevents you from speaking about the study status.
- Give yourselves plenty of time for study completion. If you can't give yourself padded time, reconsider whether that study is appropriate at this juncture.

Principal Investigator Responsibilities

Case Studies





Resources

- Utah State University Policy [4103.6](#): *Protection of Human Participants in Research*
- Utah State University Policy [4100](#): *Research*
- Standard Operating Procedure [301](#): *Researcher Responsibilities*
- Standard Operating Procedure [302](#): *The Principal Investigator*
- USU School of Graduate Studies [Handbook](#)
- USU Policy [4002](#): *Academic Freedom and Professional Responsibility*
- Link to close out [Expedited & Convened IRB](#) protocols (post-expiration)
- Link to close out [Exempt](#) protocols (post-expiration)

Q & A

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Thank You!

Please use the feedback link on our home page (or scan this QR code) to request topics for Fall 2026 IRB trainings.

