



# CU IRB and Me:

**UNDERGRADUATE RESEARCH,  
PERSONNEL MODIFICATIONS**

# Agenda

- Undergraduate research
- Personnel Modification eForm
- CITI webinars
- IRB website
- Revised guidance documents
- Q & A



# Undergraduate Research

# Undergraduate Research

## Requirements for Undergraduate Researchers

- Undergraduate students may not serve as PI for a research study
- A qualified faculty investigator must oversee the work
- Can be added to research studies where they are serving as key research personnel, including Greater than Minimal Risk studies
- Students/learners who conduct the following research activities should be added to the protocol:
  - Interact/intervene with human subjects, AND/OR
  - Recruit, obtain informed consent (documented or verbal), AND/OR
  - Access, use, generate, or analyze PHI or identifiable information
- There is no requirement for a student or learner to be added to a QI project or NHSR project
- Undergraduate Researchers do not need to complete a Conflict of Interest (COI) Disclosure
- Complete CITI training
- Provide a dated (ex. MM-DD-YYYY) resume

# Undergraduate Research

## **What does constitute research when undergraduate students are involved?**

- A systematic investigation conducted by a student with intent to present the results of the investigation outside of the confines of the institution does constitute human subject research
- An investigation conducted to meet educational requirements with no intent to present the results of the investigation outside of the organization but is then re-analyzed in order to prove or disprove a hypothesis does constitute human subject research

# Undergraduate Research

What **does not** constitute research when undergraduate students are involved?

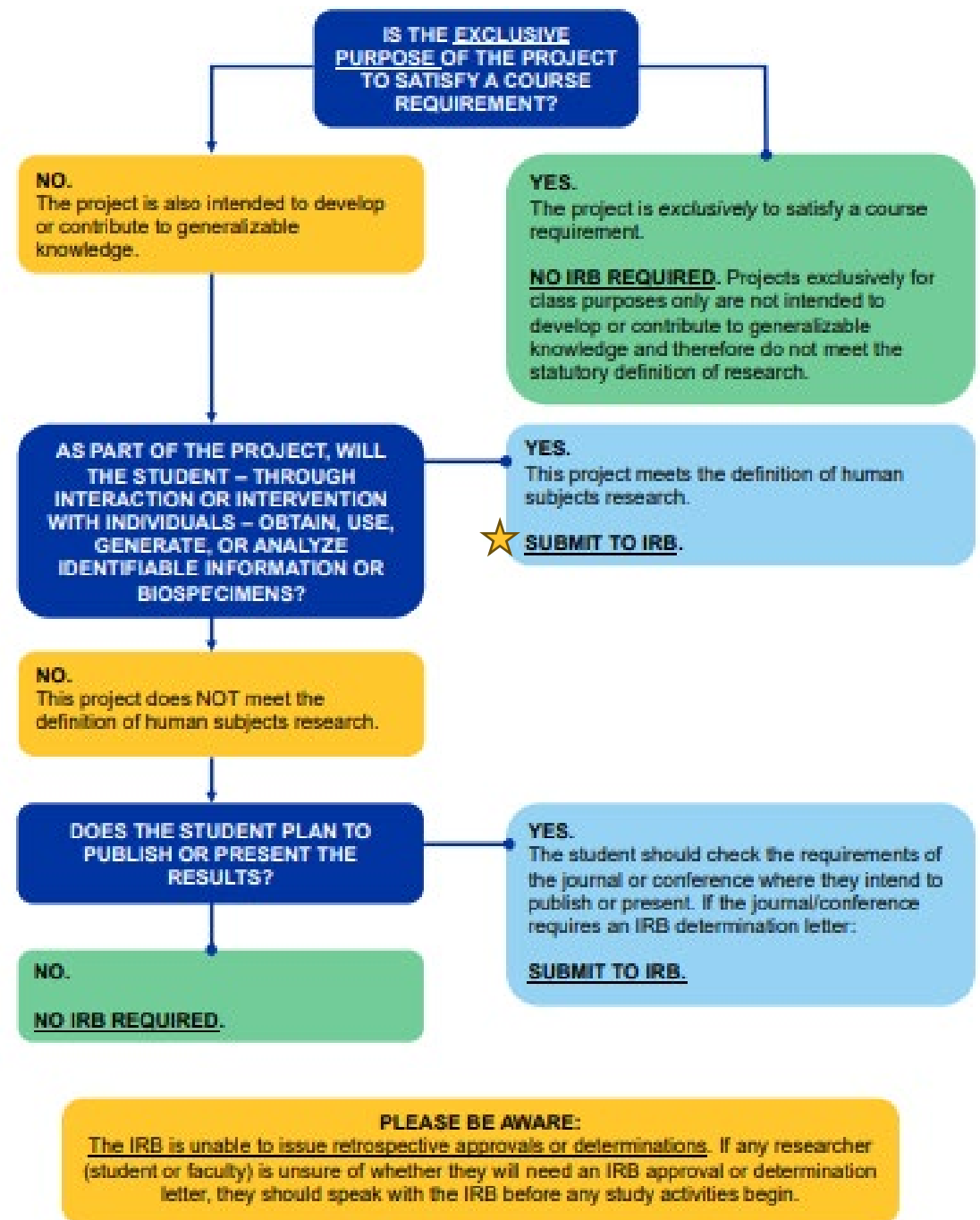
- Student projects:
  - A systematic investigation conducted by a student that involves living individuals but is performed solely to meet educational requirements of a single academic course **is not considered human subject research** providing the results of the investigation are presented only within the confines of the classroom or similar forum and to the students, their instructors, parents/family members, or a limited number of other invited guests. This does not include presentation in a student research fair or forum, where the public are invited or have easy access.
- Undergraduate students may present the results of a classroom project without meeting the definition of human subjects research if the presentation is also a classroom assignment

# Flowchart for Student Projects

## Does a Student Project Need to be Submitted to the IRB?

This flowchart is located on the IRB website.

★ Reminder: Undergraduate students are not permitted to be the Principal Investigator for human subjects research.



# Undergraduate Students as Research Participants

- Students (for example, undergraduates, graduate students, medical students, residents, fellows, doctoral students) may be recruited for research participation
- A student may not be required to participate in research without a comparable non-research alternative offered as a course requirement
- Students (individuals or groups) should not be selected solely on the basis of convenience when they would not otherwise be appropriate for inclusion
- Recruitment of students taking classes from the PI or other study personnel is strongly discouraged. When such recruitment is scientifically justified and important to the conduct of the research, there must be additional safeguards in place to reduce the risk of undue influence or coercion.

# Undergraduate Students as Research Participants (cont.)

- A student's decision about research participation may not affect grades or other such assessments of opportunities for the student
- Attention must be paid by the investigator to the risks to the student's privacy, since the classroom situation may make it difficult to keep an individual's participation confidential
- Use of student education records for research must comply with the requirements of the Family Educational and Rights Privacy Act (FERPA) at 34 CFR 99.
- Research involving surveys with students in elementary and secondary schools that receive funding from the Department of Education must also comply with the Protection of Pupil Rights Amendment (PPRA) at 34 CFR 98



# Personnel Modification eForm

# New: Personnel Modification eForm

- Only to be used for adding and/or removing study team personnel on approved protocols
- Makes personnel changes easier for study teams to submit and for IRB Office provide quicker reviews
- Cannot be used for Principal Investigator designation changes or updating documents (e.g., protocol document, consent form) – a Modifications submission is required for these types of changes

# New: Personnel Modification eForm

## Submitting a Personnel Modification request

- 1. Navigate to the Master Record for the study
- 2. Select **Personnel Modification** from the dropdown menu
- 3. Click **Add**

Type	Submission Number	Investigator Submitted On Date	Determination Date	
<a href="#">Modifications</a>	2044492-02	N/A	In Development	N/A
<a href="#">Initial Application</a>	2044492-01	N/A	Approved	10-Feb

Submissions

Dropdown menu options:

- Personnel Modification
- Annual, Continuing, or Project Termination
- Closure
- Prompt Reporting Event
- Admin Submission

Buttons: Add, Delete

# New: Personnel Modification eForm

## Submitting a Personnel Modification request

4. Click **NEW – Personnel Modification** under Document/Form

**Personnel Modification**      Submission Number: 2044492-03    Created on: 22-Apr-2026    Status: In Development

Document/Form <a href="#">Add</a>	Type	Status	<input type="button" value="Submit"/>
<b>NEW - Personnel Modification</b>	Application	Incomplete	(Mandatory Form)

[Show Existing Protocol Attachments](#)

# New: Personnel Modification eForm

## Submitting a Personnel Modification request

5. Complete the Personnel Modification form by adding new study team members (highlighted in yellow; click the yellow plus sign and add a Start Date) and/or removing existing study team members (highlighted in green; add an End Date)

### PERSONNEL

Personnel - Review + (Add Personnel - Review)



Personnel - Review

**\* Investigator Name and School or Department**

Administration, InfoEd

**Department** Pharmacology & Neuroscience - Omaha

**COI** ?

**Principal Investigator**



**\* Start Date**

27-Jan-2026

**End Date**

**\* Role**

**Certifications**

Certification	Begin	End
-	-	-

**\* Are you a student, resident, or fellow?**

Yes  No

Click [HERE](#) to learn what documentation/training is required of personnel

For Faculty/Students, click [HERE](#) to learn what personnel are required to be listed on this form.



Personnel - Review

**\* Investigator Name and School or Department**

Seiffert, Rosa

**Department** Research Compliance Office

**COI** ✓

**Principal Investigator**



**\* Start Date**

27-Jan-2026

**End Date**

**\* Role**

**Certifications**

Certification	Begin	End
CITI Health Information Privacy and Security (HIPS) for Clinical Investigators	04-May-2022	03-May-2025
CITI Responsible Conduct of Research Course	17-Sep-2024	17-Sep-2028

**\* Are you a student, resident, or fellow?**

Yes  No


Click [HERE](#) to learn what documentation/training is required of personnel

For Faculty/Students, click [HERE](#) to learn what personnel are required to be listed on this form.

# New: Personnel Modification eForm

## Submitting a Personnel Modification request

6. Scroll to the top of the form
7. Check the **Complete** box in the right corner
8. Click **Submit**



The screenshot shows a blue header bar with four white buttons: "Save", "Submit", "Complete", and an unchecked checkbox. The "Submit" button is highlighted in yellow. Below the buttons, the text "Updated By: Nancy McCormick @ 22-Apr-2026 08:59:18 AM" is displayed in white.

Save Submit Complete

Updated By: Nancy McCormick @ 22-Apr-2026 08:59:18 AM



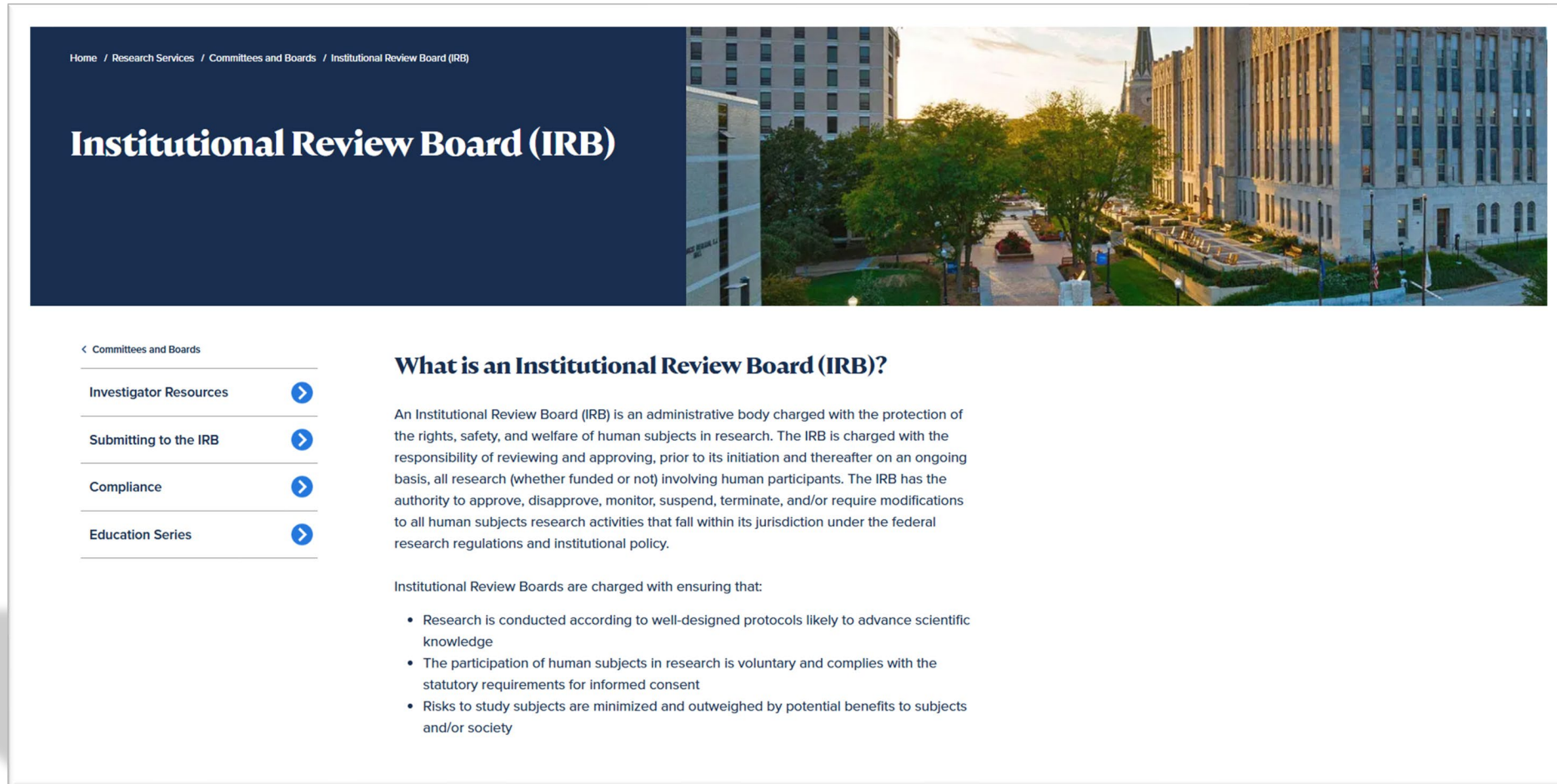
# Resources

# CITI Webinars

## **Available webinars relevant to today's topics**

- Working with Your IRB (ID: 317832)
- Data Management and Security for Student Researchers: An Overview (ID:317857)
- The Importance of Mentorship in Biomedical and Behavioral Research (ID:317742)

# CU IRB Website



Home / Research Services / Committees and Boards / Institutional Review Board (IRB)

## Institutional Review Board (IRB)

< Committees and Boards

- Investigator Resources >
- Submitting to the IRB >
- Compliance >
- Education Series >

### What is an Institutional Review Board (IRB)?

An Institutional Review Board (IRB) is an administrative body charged with the protection of the rights, safety, and welfare of human subjects in research. The IRB is charged with the responsibility of reviewing and approving, prior to its initiation and thereafter on an ongoing basis, all research (whether funded or not) involving human participants. The IRB has the authority to approve, disapprove, monitor, suspend, terminate, and/or require modifications to all human subjects research activities that fall within its jurisdiction under the federal research regulations and institutional policy.

Institutional Review Boards are charged with ensuring that:

- Research is conducted according to well-designed protocols likely to advance scientific knowledge
- The participation of human subjects in research is voluntary and complies with the statutory requirements for informed consent
- Risks to study subjects are minimized and outweighed by potential benefits to subjects and/or society

# Revised Guidance Documents

## Templates

- Revised Informed Consent Template
- Revised Parent/Guardian Permission Template
- Revised Assent for Ages 7-12 Template
- Revised Assent for Ages 13-18 Template

*\*\* The Senior IRB Administrators will return submissions if these documents are not on the most updated template*

- Revised HIPAA authorization
- Protocol Template
- NHSR/QI Proposal Template **\*NEW\***
- Checklist: Does my Project Require IRB Review?

# Help us help you

## Our goals

- Provide meaningful education and guidance to the research community
- Support researchers for the lifetime of their studies

### IRB Booking Page



### Suggestions for future CU IRB and Me sessions





Next CU IRB and Me Session:  
**Open Office Hour**  
on 17-Jun-26 at 12 PM (Central)



# Q & A



*Thank you.*

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