Creighton UNIVERSITY

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?

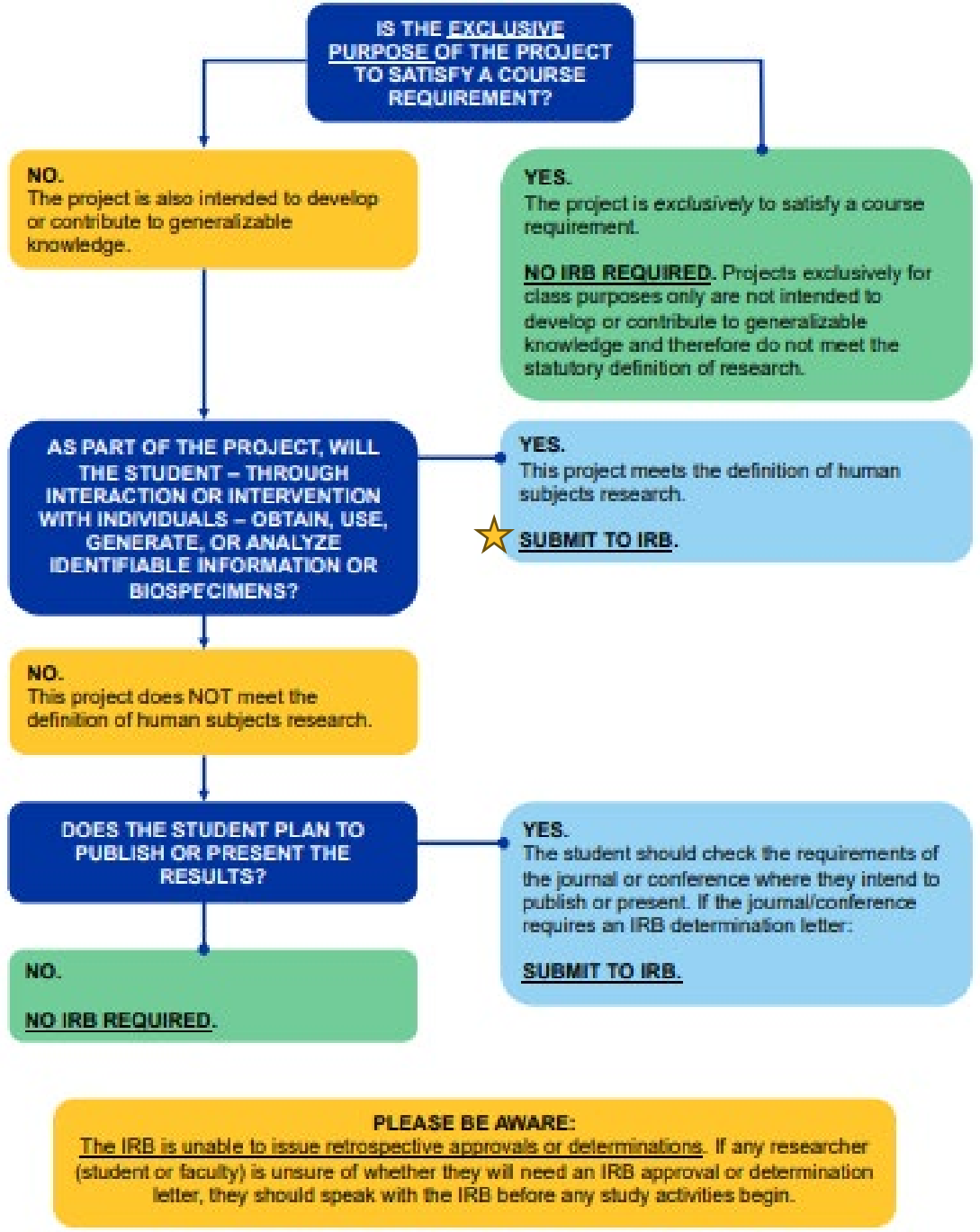
- Student projects:
  - A systematic investigation conducted by a student that involves living individuals but is performed solely to meet educational requirements of a single academic course ***is not considered human subject research*** providing the results of the investigation are presented only 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

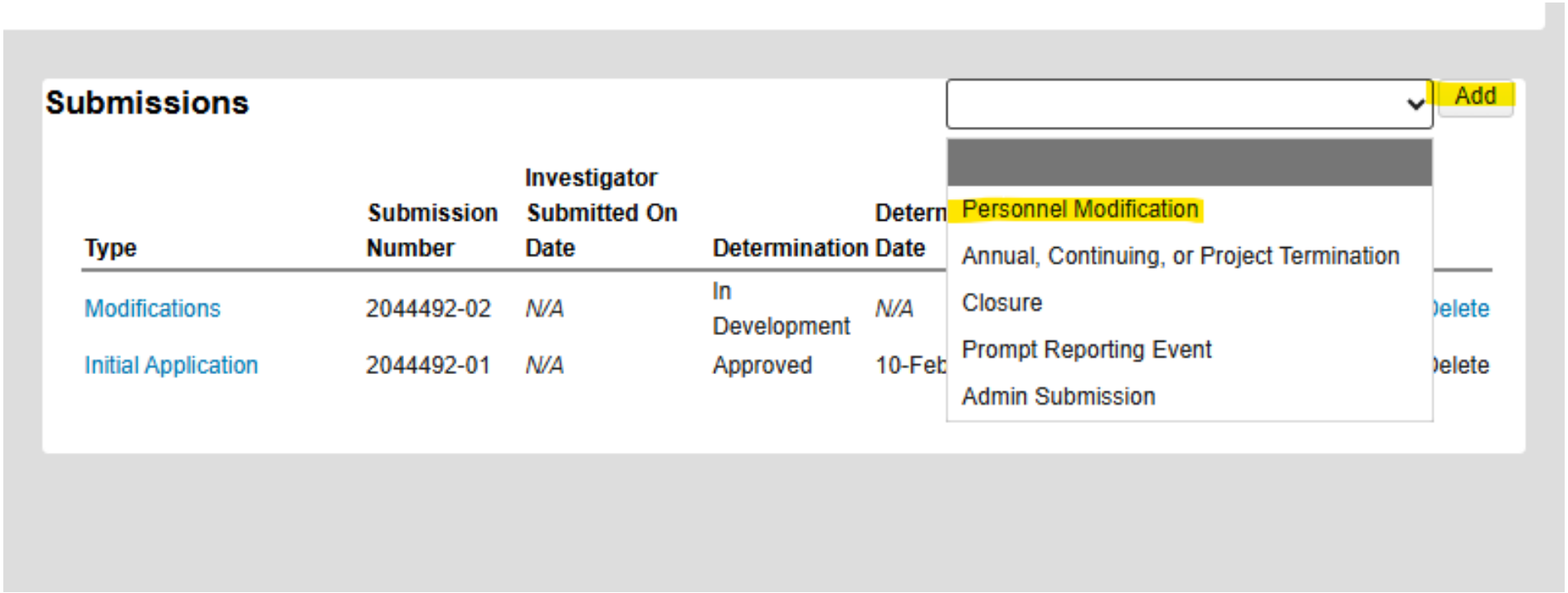
New: Personnel Modification eForm

- 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

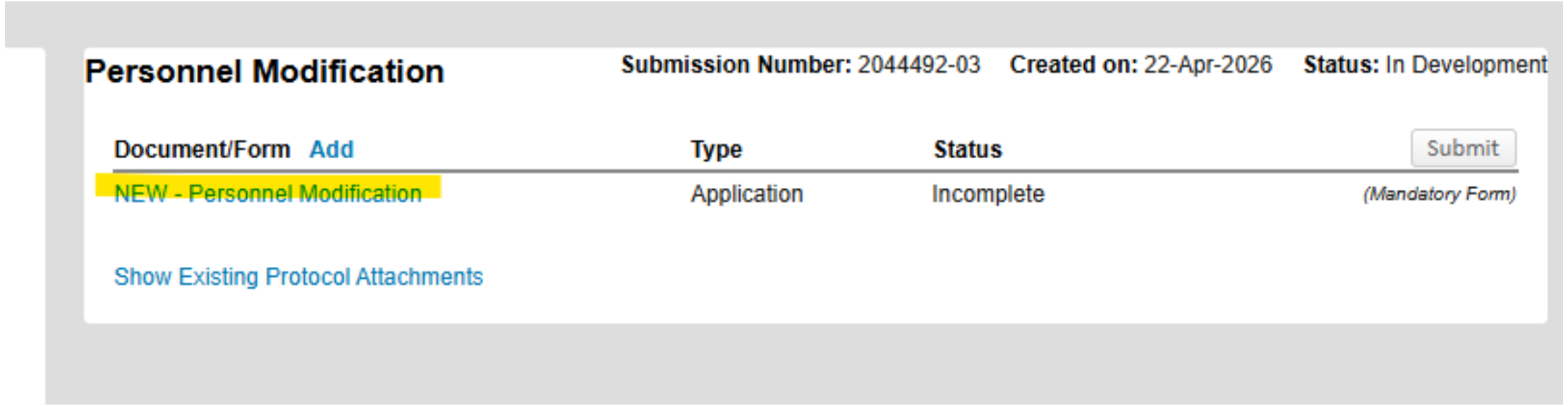
1. Navigate to the Master Record for the study
2. Select **Personnel Modification** from the dropdown menu
3. Click **Add**



New: Personnel Modification eForm

Submitting a Personnel Modification request

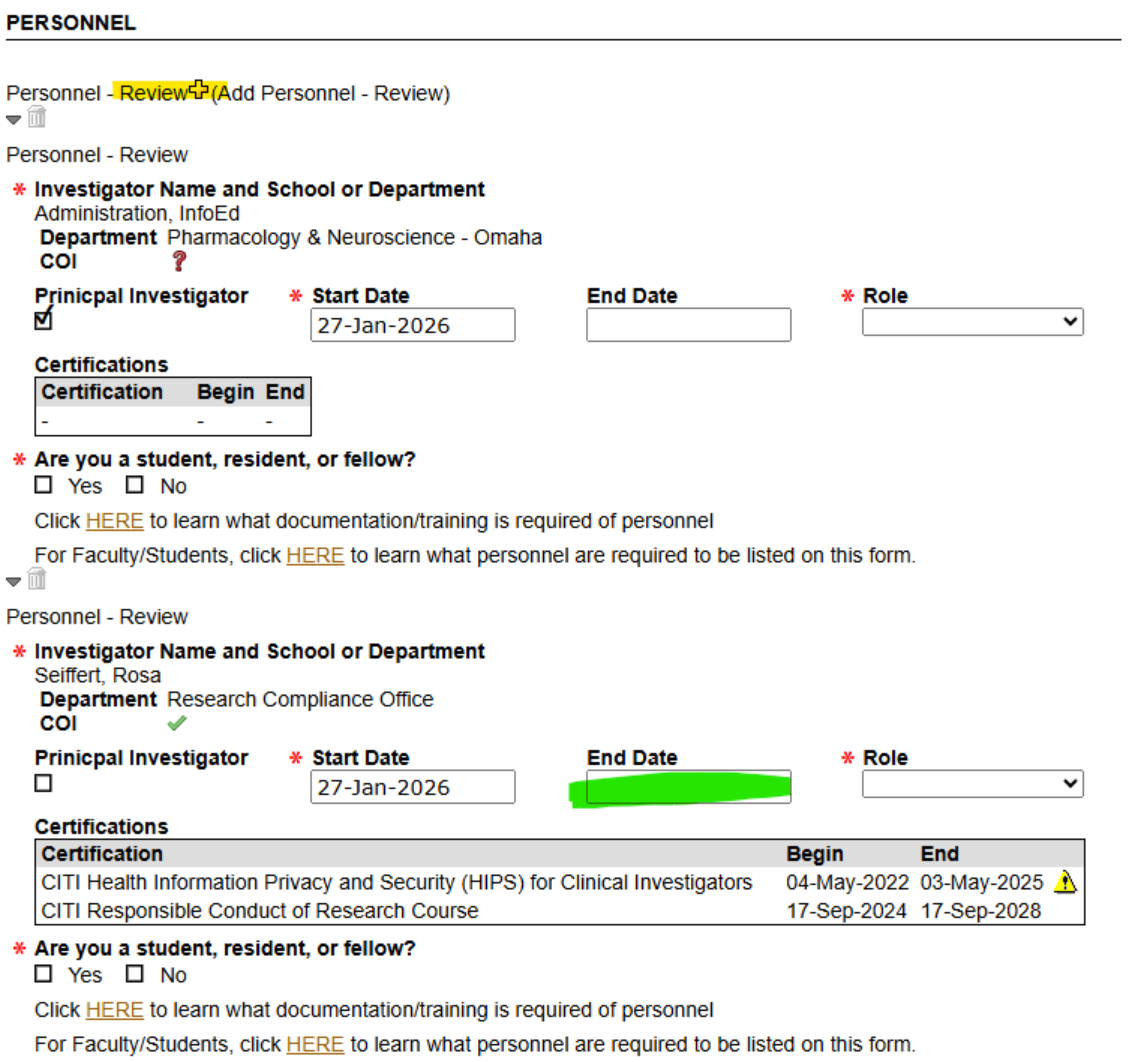
4. Click **NEW – Personnel Modification** under Document/Form



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

Prinicpal 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

Prinicpal 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

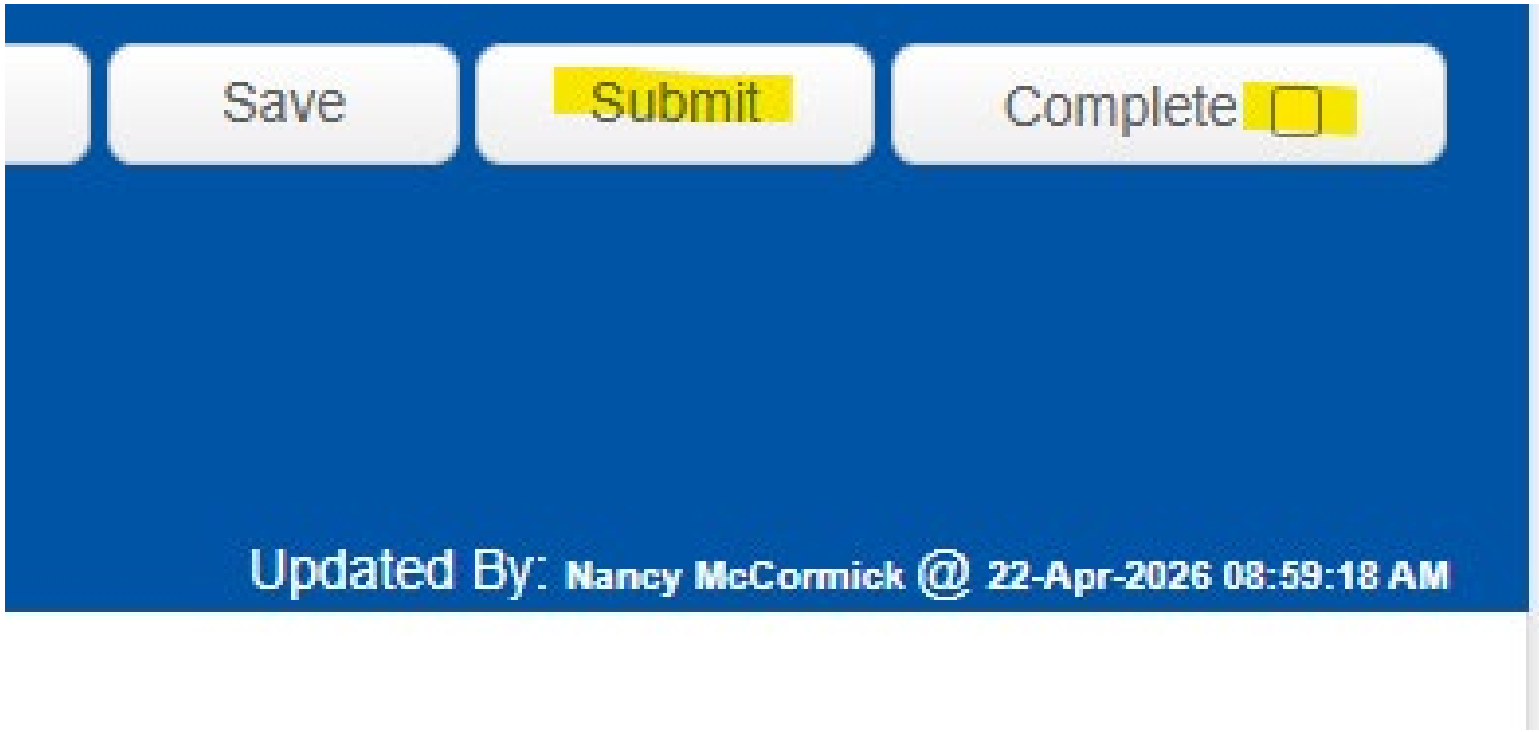
Click HERE to learn what documentation/training is required of personnel

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**



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

https://www.creighton.edu/research-services/committees-and-boards/institutional-review-board-irb

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?

https://www.creighton.edu/research-services/committees-and-boards/institutional-review-board-irb/investigator-resources

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

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Thank you.

IRB Office | 402.280.2126 | IRB@creighton.edu