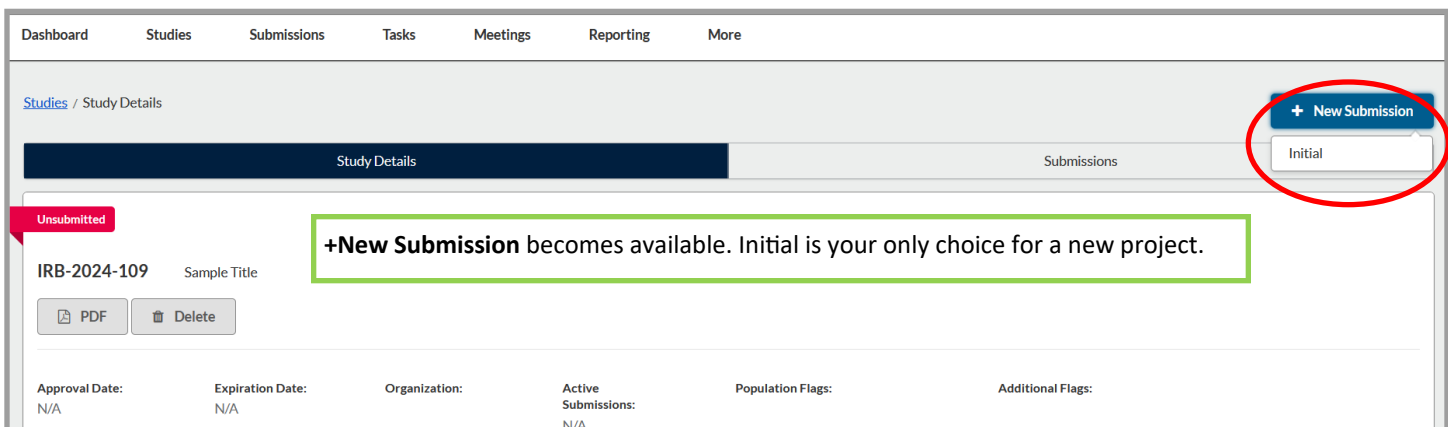
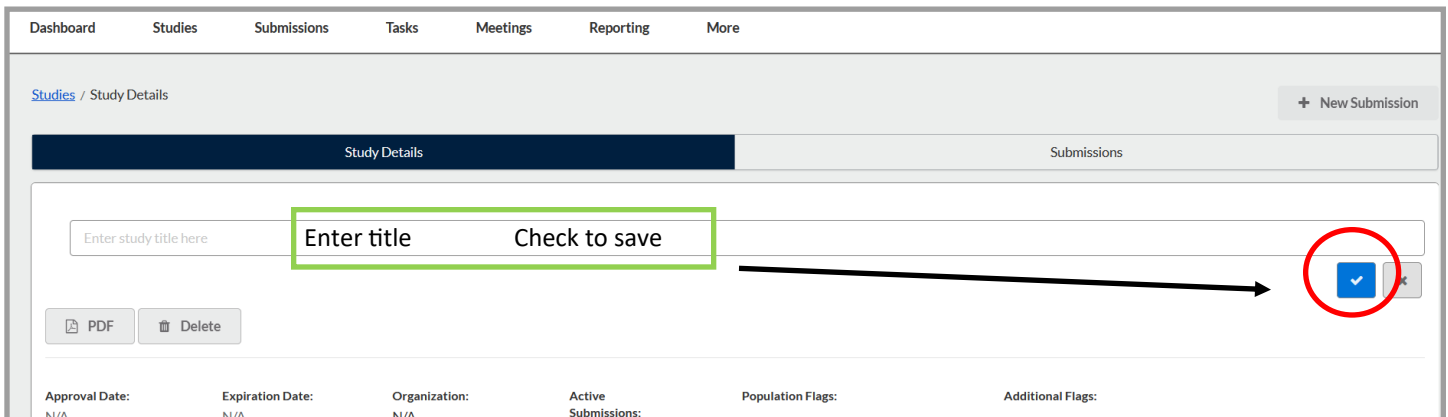
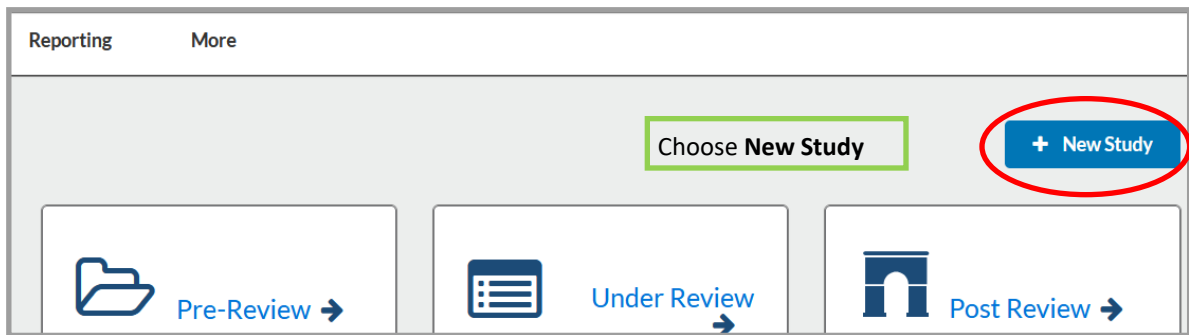
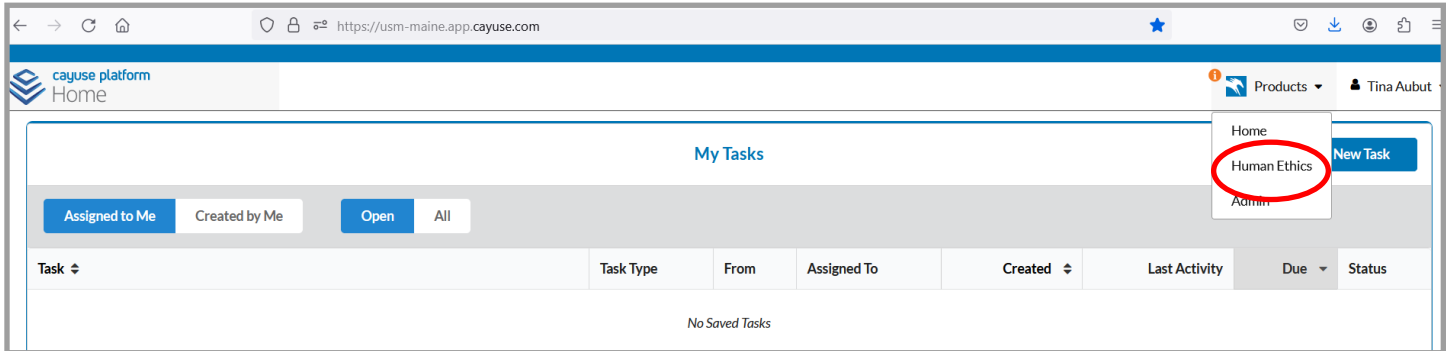


Request for Determination of Human Subject Research

After logging in, select **Human Ethics** from the Products drop-down.



Dashboard Studies Submissions Tasks Meetings Reporting More

Studies / Study Details / Submission Details

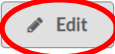
1 **In-Draft**
Submission is with researchers

2 **Awaiting Authorization**
Submission is awaiting certification or approval

3 **Pre-Review**
Submission is being prepared for review

Unsubmitted

Initial
IRB-2024-109 - Sample Title

 PDF Delete

The person creating the submission is automatically the Primary Contact (PC).
Click on **Assign PI (Principal Investigator)** (or Edit button).

PI:	Current Analyst: N/A	Decision: N/A	Policy: Post-2018 Rule	Required Tasks: Assign PI Assign PC Complete Submission
Review Type: N/A	Review Board: N/A	Meeting Date: N/A		

Approvals Task History Attachments

Dashboard Studies Submissions Tasks Meetings Reporting More

IRB NUMBER: IRB-2024-109

Sample Title - Initial

CREATE PDF COMPARE SAVE

Sections <

Getting Started

Read through **Getting Started**
Then click **Yes** that you have read the information.
The other sections will begin to appear based on your responses.

About Cayuse Human Ethics

Cayuse Human Ethics (HE) is an interactive web application. As you answer questions, more sections will appear. Therefore not all numbered sections may appear. You do not have to finish the sections to proceed to the next section.

Additional information has been added throughout the form for guidance and assistance. Please read through each section.

For more information about the IRB submission Process, IRB Tracking, and Cayuse HE Tasks, please refer to the in-app help (the orange question mark near the bottom right) or contact the IRB Office: Office of Research Integrity and Outreach (ORIO) at: usmorio@maine.edu or 207-780-4517

Submit protocol for review at least thirty (30) days prior to starting data collection.

[EMI Collaborative Boards](#)

IORG#: IORG 1507
Federalwide Assurance
IRB 1953, U of S
IRB 11534, U of S

Dashboard Studies Submissions Tasks Meetings Reporting More

IRB NUMBER: IRB-2024-109

Sample Title - Initial

Sections <

Getting Started ✓

Project Personnel

Basic Information

Attachments

Throughout the submission, you will be required to provide the following, as applicable:

- CV or Resume for all research staff
- Human Subject Research training for all research staff
- Interview/Focus Group Questions
- Questionnaires/Surveys
- Recruitment Materials (e.g., flyers, email text, verbal scripts)
- Letters of Agreement/Cooperation from organizations
- Consent Forms
- Assent Forms/Parental Permission
- Methods section of your thesis or dissertation proposal
- Grants/Sub-contract
- Other files associated with the project

I have read the information above and I am ready to begin my submission.

Yes

In the scenario below, checking off Student triggers adding a Faculty Sponsor for this project. Which behind the scene is a Co-Principal Investigator (PI). Use the arrows instead of the browser navigation and SAVE your work.

Dashboard Studies Submissions Tasks Meetings Reporting More

IRB NUMBER: IRB-2024-109
Sample Title - Initial

CREATE PDF COMPARE SAVE

Sections
Getting Started ✓
Project Personnel
Basic Information
Attachments

Project Personnel

* What kind of affiliation does the Principal Investigator have with USM?

Student
* Undergraduate Student
 Graduate Student
 Staff
 Faculty
 External to USM

* Name of USM Department or External Organization

Muskie School of Public Service

Click "Find People" to add the **Principal Investigator**. POP-UP: type in part of a name, click find icon.

If you are not finding someone, they may not have had a profile set up.

Cayuse User ID Request: <https://forms.gle/SUUNKEmL2EE3AKEW7>

IRB NUMBER: IRB-2024-109
Sample Title - Initial

CREATE PDF COMPARE SAVE

Note: If you cannot find a person in the people finder, please contact the IRB Office immediately.

* Principal Investigator
The person listed as the PI will be required certify submissions before they are sent to the IRB for review. They will also have edit access to this study, can create follow-on submissions after Initial approval, and will be included in study communications. The PI will be required certify submissions before they are sent to the IRB for review

FIND PEOPLE

* Primary Contact
Any people listed as the Primary Contact will be required certify submissions before they are sent to the IRB for review. They will also have edit access to this study, can create follow-on submissions after Initial approval, and will be included in study communications. The PI will be required certify submissions before they are sent to the IRB for review

FIND PEOPLE

Name
Tina Aubert

* Faculty Sponsor
If the PI is a Student, the Faculty Sponsor will be required certify submissions before they are sent to the IRB for review. They will also have edit access to this study, can create follow-on submissions after Initial approval, and will be included in study communications. The PI will be required certify submissions before they are sent to the IRB for review

FIND PEOPLE

Co-Investigator
Any people listed as the Co-Investigator will be required certify submissions before they are sent to the IRB for review. They will also have edit access to this study, can create follow-on submissions after Initial approval, and will be included in study communications. The PI will be required certify submissions before they are sent to the IRB for review

FIND PEOPLE

PRINCIPAL INVESTIGATOR

Aubert

Name	Organization	Email	Phone
Tina Aubert	Research Integrity	tina.aubert@maine.edu	

Type in part of the name, click the magnifying glass symbol, then the plus sign next to the name you want. Then Save.

Selected Records
* Select a single record.

CANCEL SAVE

You may add more than one Co-PI. However, all the Co-PI(s) and Faculty Advisor are also **required to certify submissions before they are sent to the IRB for review**. As the protocol goes through a review, it may be sent back with questions. Each PI will need to certify each time it is returned to the IRB. Other Personnel do not need to Certify the submission.

This guide shows the process for a **request for human subject research** projects. It is recommended that the student notify their Faculty Advisor when a draft is complete **BEFORE** Complete Submission and Certify the submission.

Dashboard Studies Submissions Tasks Meetings Reporting More

Initial - USM Preview Only

Sections <

Getting Started ✓

Project Personnel

Basic Information

Attachments ✓

*** Is this Human Subject Research?**

If no, only the Determination for Human Subject Research form will display.
If yes, attach resume and training will display.
If No or Student Classroom Project, choose "Request for Determination of Human Subject Research" under Basic Information.

Yes
 No
 Faculty Led Student Classroom Project

Faculty Led Student Classroom Project will ask to upload the Faculty Principal Investigator's CITI training, CV, and Course Syllabus.

Conflict of Interest. If any are marked as Yes it will ask to explain and to pick a name of the person with the conflict.

Getting Started ✓

Project Personnel

Basic Information

NR NHR Not Research o...

Attachments ✓

*** Conflict of Interest**

NOTE: If you answer Yes to any of the questions below and are faculty or staff for USM, you may be required to file a Conflict of Interest disclosure statement and complete Conflict of Interest CITI training. View the FCOI information on the USM website [here](#).

*** Do any of the involved Investigators or their immediate family have consulting arrangements, management responsibilities or equity holdings in the sponsoring company, vendor(s), provider(s) of goods, or subcontractor(s)?**

Yes
 No

*** Do any Investigators or their immediate family have any financial relationship with the sponsoring company, including the receipt of honoraria, income, or stock/stock options as payment?**

Yes
 No

*** Is any Investigator(s) a member of an advisory board with the Sponsoring company?**

Yes
 No

*** Do any investigators receive gift funds from the Sponsoring company?**

Yes
 No

*** Do any investigators or their immediate family have an ownership or royalty interest in any intellectual property utilized in this protocol?**

Yes
 No

If any of the above are yes, please explain.

Getting Started ✓

Project Personnel

Basic Information

Attachments

Basic Information

*** Study Site(s)**

List all sites/locations involved with this project.

B I U S **☰ ☰** **🔗 🖼️**

Initial - USM Preview Only

Sections <

- Getting Started ✓
- Project Personnel
- Basic Information
- Attachments ✓

Collaboration Information

* **External Sites**
 Will any research activities occur at any External Sites in the United States? This would include locations other than where you are employed as long as they are within the United States.
 Yes
 No

* **External Collaborators**
 Will any External Collaborators be conducting research activities?
 Yes
 No

* **International Sites**
 Will any research activities occur at non-US sites?
 Yes
 No

Depending on your answers to Collaborative Information, additional questions may appear. Example on next images.

Sections <

- Getting Started ✓
- Project Personnel ✓
- Basic Information ✓
- Study Design ✓
- Study Selection ✓
- Study Procedures ✓
- Study Products ✓
- International Resea... ✓
- Participant Protect... ✓
- HIPAA ✓
- Data & Safety Moni... ✓
- Attachments ✓

Collaboration Information

* **External Sites**
 Will any research activities occur at any External Sites in the United States? This would include sites not affiliated with this institution or that have their own IRB.
 Yes
 No

* **IRB Oversight Arrangements**
 Indicate how IRB oversight is organized for this study.
 Study involving more than 1 site where each site will conduct their own IRB review
 Study involving more than 1 site where this site is the **Reviewing IRB** (IRB of Record) for other sites
 Study involving more than 1 site where this site is **Relying** on an External IRB
 Multi-site study (multiple US sites participating in a research study using the same protocol) where this site is the **Reviewing IRB** (IRB of Record) for all sites
 Multi-site study (multiple US sites participating in a research study using the same protocol) where this site is **Relying** on an External IRB

* **External Collaborators**
 Will any External Collaborators be conducting research activities?
 Yes
 No
 If any External Collaborators are engaged in research activities on behalf of an Institution, the answer to External Sites above should probably be Yes as well.

External Collaborator Information

* **Name and Affiliation of all External Collaborators**
 List all External Collaborators, the institution they are affiliated with (if any), and their duties in the study.

Collaborators

Sections <

- Getting Started ✓
- Project Personnel ✓
- Basic Information ✓
- Study Design ✓
- Study Selection ✓
- Study Procedures ✓
- Study Products ✓
- International Resea... ←
- Participant Protect... ✓
- HIPAA ✓

Training Documentation for External Collaborators
 Upload any required training documentation for External Collaborators.
 ATTACH
 sample attachment.docx | ✕

Reliance Agreements
 Upload all applicable reliance agreements for any External Collaborators or US External Sites (Individual Investigator Agreements (IIA), IRB Authorization Agreements (IAA), MOUs, etc.).
 ATTACH

* **International Sites**
 Will any research activities occur at non-US sites?
 Yes
 No

International Research has an additional section.

Once a Yes/No is chosen above, the type of project will appear. For this example, Research Study.

Sections <

- Getting Started ✓
- Project Personnel
- Basic Information
- NR NHSR Not Research o...
- Attachments ✓

* **Project Type**
 What type of project is this submission for?

Research Study
 Request for Determination of Human Subject Research: Activities Without a Plan to Conduct Research (Case Report, Quality Improvement project, Public Health project, Pilot Project) **OR** Research in which this Institution is Not Engaged
 Select this option if **either** are true:

- You are not sure if your project requires IRB oversight.
- You need a formal determination from the IRB on if the project requires IRB oversight.

118 Determination/Future Human Research
 Select this option if **BOTH** are true:

- This research project will involve or may involve human subjects in the future, but future protocol development must take place first.
- You need documentation of IRB review in order to release your grant funds.

Clinical Trial
 Single Patient, Treatment Use, Continued Access Drug/Device Study
 Emergency (or Compassionate) Use of Investigational Drug or Device

Sections

- Getting Started ✓
- Project Personnel ✓
- Basic Information ✓
- Study Design ✓
- Study Selection ✓
- Study Procedures ✓

Study Dates

Please provide the intended study start and end dates.
Consider: start date should be about 30 days after submission to the IRB.

* Start Date

* End Date

Sections

- Getting Started ✓
- Project Personnel
- Basic Information
- Attachments ✓

None/In Kind/Internal funding from the principal investigator's organization
 Other External Funding: Private non-profit, Foundations, State Funding, etc
 US Government: Federally funded
 Industry Sponsored: funding from a company, usually for-profit, specific to the advancement of your type of research
 International/Non US

* Funding

* Name the Funder(s):

If your funding entity is not in the list, please name them here.

Sections

- Getting Started ✓
- Project Personnel
- Basic Information
- Attachments ✓

* Title of Grant (if different from protocol title):

* Period of funding:

* Amount of funding:

* Attach grant materials, contracts, or agreements with the funding source.
 -Word or pdf copies are best. Links, such as Google or SharePoint, cannot be accessed by external reviewers.

Attachments ✓

If applicable, USM Research Service Center Award Notification Number(s):

National Science Foundation (NSF) proposals and National Institutes of Health (NIH) with direct costs greater than \$500,000 must attach a Data Management Plan in the Attachment section

-Word or pdf copies are best. Links, such as Google or SharePoint, cannot be accessed by external reviewers.

End of Basic Information Section

Sections <

Getting Started ✓

Project Personnel

Basic Information

NR NHSR Not Research o...

Attachments ✓

NR NHSR Not Research or Not Human Subject Research

Request for Human Subject Research Determination

* What is the purpose of the activity?

B I U S ☰ ☷ ☹

Project Personnel

Basic Information

NR NHSR Not Research o...

Attachments ✓

* What are the activities being conducted?

B I U S ☰ ☷ ☹

Sections <

Getting Started ✓

Project Personnel

Basic Information

NR NHSR Not Research o...

Attachments ✓

* Included Populations

Please indicate any population(s) that will knowingly be enrolled. Check all that apply.

- Adults (18 years of age or older)
- Fetuses
- Pregnant Women
- Neonates (birth to less than 1 month)
- Children (including infants from birth to less than 1 month determined to be viable)
- Prisoners
- Cognitively Impaired Adults
- Other Vulnerable Populations
Please describe.

- De-identified data only
- None of the above
Please explain.

* Justification of Vulnerable Populations

Necessity of Inclusion and any Special Arrangements

B I U S ☰ ☷ ☹

Getting Started ✓

Project Personnel

Basic Information

NR NHSR Not Research o...

Attachments ✓

* Who is the intended audience?

-How will the results be shared, with whom, and in what form?

B I U S ☰ ☷ ☹

Sections <

Getting Started ✓

Project Personnel

Basic Information

NR NHSR Not Research o...

Attachments ✓

* If there is a Business Associate Agreement (BAA), with which healthcare provider?

* Are you using Maine Integrated Youth Health Survey (MIYHS) data?

Yes
 No

* Has this been reviewed by another IRB?

Yes
 No

Sections <

Getting Started ✓

Project Personnel

Basic Information

NR NHSR Not Research o...

Attachments ✓

* Are you requesting a determination in order to fulfill W-9 form requirements?

Incentive/payment to participants

Yes
 No

Yes response will show additional questions.

* W-9 ↙

Who will be responsible for obtaining, securing, and disbursing compensation?

If participants were required to complete a W-9 form, how would it negatively impact your study?

How will you be compensating your study participants?

What is the total amount of compensation per participant?

Sections <

Getting Started ✓

Project Personnel

Basic Information

NR NHSR Not Research o...

Attachments ✓

On how many separate occasions throughout the study will a participant receive compensation?

How will you ensure a participant does not obtain more than \$600 in a calendar year resulting from participation?

How will compensation to participants be distributed?

Where will compensation be stored until it is dispersed?

What security provisions will be in place to prevent theft?

Sections	<
Getting Started	✓
Project Personnel	
Basic Information	
NR NHR Not Research o...	
Attachments	✓

*** Is the Activity Non-research?**

§46.102 (l) (1-3)

*** Is the activity scholarly or journalistic?**
- Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.
 Yes
 No

*** Is the activity a public health surveillance activity?**
-Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).
 Yes
 No

*** Is the activity a collection and analysis of information for a criminal justice agency?**
-Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.
 Yes
 No

Getting Started	✓
Project Personnel	
Basic Information	
NR NHR Not Research o...	
Attachments	✓

*** Does the project meet definition of "Research"?**

As defined by 45 CFR 46, **research** is "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."

*** Is the activity an investigation?**
-Investigation means a searching inquiry for ascertaining facts or a detailed or careful examination.
 Yes
 No

*** Is the activity systematic?**
-Systematic means having or involving a system, method, or plan. (including the selection of subjects, decisions about what observations to record, and an interview process)
 Yes
 No

*** Is the activity designed to develop or contribute to knowledge?**
-Designed means done with purpose or intent. Develop means to elaborate or expand in detail. Contribute means to be an important factor in. Knowledge means truth, facts, or information.
 Yes
 No

*** Is the knowledge generalizable?**
-Generalizable means relevant beyond the population or program from which it was collected, or universally applied/accepted, to other contexts or situations.
 Yes
 No

Sections	<
Getting Started	✓
Project Personnel	
Basic Information	
NR NHR Not Research o...	
Attachments	✓

*** If the project is research, does it meet the definition of "Human Subject" research?**

As defined by 45 CFR 46, a human subject is "a living individual, about whom an investigator (whether professional or student) conducting research: (1) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens, or (2) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens."

*** Does the research involve obtaining information (or biospecimens) about a living individual?**
-About means the information concerns the individual whose information is collected; the focus of the investigation is the opinions, characteristics, or behavior of the individual.
-Biospecimen means material such as urine, blood, tissues, cells, DNA, RNA, and proteins.
 Yes
 No

*** Does the project involve interaction or intervention with individuals?**
-Interaction includes communication or interpersonal contact between investigator and participant.
-Intervention includes both physical procedures by which information or biospecimens are gathered and manipulation of the participant or the participant's environment that are performed for research purposes (for example, having participant listen to music and then having them perform memory tasks in order to investigate the effect of music on memory).
 Yes
 No

NR NHR Not Research o...	
Attachments	✓

*** Does the project involve obtaining, using, studying, analyzing, or generating private information?**
Private information means information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record).
Consider: If the project only involves data and/or specimens that were pre-existing, or collected for some purpose other than this project, consider the original source of the data/specimens, how they are provided to investigators, if the data/specimens are identifiable in any way to investigators, etc.
 Yes
 No

*** Does the research involve obtaining, using, studying, analyzing, or generating identifiable biospecimens?**
Identifiable biospecimens means the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.
 Yes
 No

Sections

- Getting Started ✓
- Project Personnel
- Basic Information
- NR NHSR Not Research o...
- HIPAA**
- Attachments ✓

HIPAA

- The Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule applies to projects where Protected Health Information (PHI) is being obtained, used, or released/ disclosed by a [Covered Entity](#) for the purposes of Research.
- Even if your project is Not Human Subject Research, you may still have requirements under HIPAA if PHI is being obtained, used, or released/disclosed by a [Covered Entity](#).
- Protected Health Information (PHI) = health information + one or more of the [18 identifiers](#)

• Does this project involve obtaining, using, or releasing/disclosing identifiable PHI by a Covered Entity?

Yes
 No

Attach recruitment material(s), questionnaires or surveys, grant/funding materials, and consent language document(s), etc.

-Word or pdf copies are best. Links, such as Google or SharePoint cannot be accessed by external reviewers.

ATTACH

Project Personnel

Basic Information

NR NHSR Not Research o...

Please include any additional information you would like to provide.

B I U S ☰ ☷ ↻

Once each section has a checkmark, the COMPLETE SUBMISSION will appear. Click on COMPLETE SUBMISSION.

Attachments ✓

Attach any consent, as

ATTACH

Routing Send to PI for certification? ✓

COMPLETE SUBMISSION ▶

SUBMISSION ROUTING

Are you sure you want to continue?

⊗ CANCEL ✓ CONFIRM

Harker, Liam.PDF x

Clicking on **Submission Details** in the upper left corner of the page will get you back to the certification page.

Dashboard

Studies

◀ SUBMISSION DETAILS

Awaiting Certification

Initial
IRB-2023-16 - Test Research Project in Cayuse

[View](#) [PDF](#) [Delete](#)

Routing: [Return](#) [Certify](#)

PI: **Current Analyst:** **Decision:** **Policy:** **Required Tasks:**
Time/Asstet N/A N/A Post-2018 Rule N/A

Review Type: **Review Board:** **Meeting Date:**
N/A N/A N/A

Approvals **Task History** **Attachments**

Research Team


Name	Role	Result	Date
Time/Asstet	Principal Investigator	Pending Certification	

A pop-up will appear to confirm certification before it is routed to the next CO-PI or Faculty to certify.

Time/Asstet Principal Investigator Pending Certification

When all certification routing is done, it goes into the queue of an ORIO analyst for next steps.

Certify



I confirm that I have the proper training, expertise and resources to conduct this study. I understand and accept my responsibilities as the Principal Investigator and Primary Contact for this study. I confirm that I have no significant financial conflict of interest in this project or have disclosed a conflict per institutional policies and federal requirements. I confirm that the information provided in this application is true, complete, and accurate to the best of my knowledge; that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties; and agree to accept responsibility for the oversight and scientific conduct of the project.

[Cancel](#) [Confirm](#)