

NAVIGATING E-PROTOCOL FOR USM STUDENTS

For assistance please contact

Office of Research Integrity and Outreach (ORIO)

usmoiro@maine.edu

207-780-4517 (please leave a voicemail message)

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ORIO'S HOME PAGE: [HTTPS://USM.MAINE.EDU/ORIO](https://usm.maine.edu/orio)

usm.maine.edu/orio

TODAY'S HOURS
SEPTEMBER 18, 2020
Office Hours
8-4:30

CONTACT +

Home

About Us

People

Location & Hours


Research Compliance -

Human Subjects

Animal Use

OFFICE OF RESEARCH INTEGRITY AND OUTREACH

ORIO is responsible for ensuring compliance with applicable federal, state and local laws, regulations in research, and other covered activities before work begins. [Learn more.](#)



Collaborative Institutional Review Board


We have two registered Collaborative Boards for Human Subject and Biomedical Research, which are available for reviewing external protocols.

[Learn More](#)

Human Research Protection Program

HRPP ensures the protection of the rights and welfare of persons participating in human subject research conducted at or affiliated with USM.

[Get Started](#)



Either/Or link

Human Research Protection Program (HRPP)

For the purpose of this presentation, the focus will be on **eProtocol** submissions.

Choose “Human Subject Research” for step by step guidance.

Human Research Protection Program (HRPP)

The University of Southern Maine (USM) Human Research Protection Program (HRPP) ensures the protection of the rights and welfare of persons participating in human subject research conducted at or affiliated with USM.

HRPP Guidance and Resources

FORMS

[Human Subject Research](#) - new protocol steps

- [eProtocol login](#)

[Request for Determination of Research Involving Human Subjects](#)

[USM Faculty Led - Student Classroom Research Project](#)

[USM Undergraduate Social Work Student](#) - individual or small group course research project

If you are not sure your project is Human Subject Research, you may submit a request for determination of Human Subject Research.

IRB Submission Process and eProtocol Resources

Thirty (30) days prior to starting data collection: [Checklist](#)

- [Complete the required CITI training](#)
- Request an eProtocol User ID
- Review the IRB Guidance
- Log into eProtocol
- Create a protocol
- Answer the questions
- Upload attachments
- Submit the form

Students, Faculty, Staff, and External CITI training requirements:

Associate with the **University of Maine System**.

Choose one course, as applicable:

- “Social and Behavioral Research - Basic/Refresher”
or
- “Biomedical Research - Basic/Refresher”
- [Visual Guides available](#)



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All research staff must have an **eProtocol UserID** in order to add them to your protocol. This includes Faculty Advisor for student research.

- After [requesting a UserID](#), ORIO staff review the submission then create the ID.
- You will receive automatic email with a link to set your password. (check your spam mail for the email if you don't see it).
- You will have **24 hours** to set your new password.
- FireFox or Safari browsers works best with eProtocol. Allow pop-ups in your browser settings.
- Contact usmorio@maine.edu if you have any issues logging in to eProtocol.

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 - Create a protocol
 - Answer the questions
 - Upload attachments
 - Submit the form
- [General Guidance](#)
 - [Definitions](#)
 - [Recruitment](#)
 - [Role and Responsibility of Faculty Advisor](#)
 - [Informed Consent/Parental Permission and Child Assent](#)
 - [Sensitive Information/Special Subject Populations](#)
 - [Online Survey Platforms](#)
 - [Data Storage and Security Standards](#)
 - [Health Insurance and Portability Act \(HIPAA\)](#)
 - [Data Use Agreements \(DUA\)](#)
 - [Business Use Agreements \(BUA\)](#)

IRB Submission Process and eProtocol Resources

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[Steps to submitting Human Subject Research](#)

- When you [log into eProtocol](#), you will be on your Investigator home page
- Click “[create protocol](#)” button
- Type in your “Study Title” (you can change this later) then Check “[IRB Form](#)”
- Most of your profile information will fill in automatically as Principal Investigator. Then click “[create](#)” button. You can add/edit [Personnel](#).
- Fill in your CITI training information
- Add other [Personnel](#) and Faculty Advisor by clicking the binoculars to search for them. Fill in their CITI training dates as well.

IRB Submission Process and eProtocol Resources

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 - **Answer the questions**
 - **Upload attachments**
 - Submit the form
- Do not hit the back button on the browser!
Use the “next” and “previous” buttons.
 - Answer the questions. If something is not applicable, explain why (Not just NA)
 - All research personnel and Faculty Advisor’s **CV/Resume** MUST be in the attachment section.
 - Other common attachments:
 - Recruitment materials: scripts, email, poster, social media ads
 - Questions: survey or interview
 - Letter(s) of cooperation with a research location
 - Any other information that would assist the IRB in making a decision

IRB Submission Process and eProtocol Resources

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- [Answer the questions](#)
- [Upload attachments](#)
- **Obligations/Submit the form**

1	Protocol Information
3	Obligations
	Return Notes
2	Check For Completeness
4 FA	Submit Form

- Check for Completeness is on the left blue navigation bar. This will take you to any incomplete section.
- Obligations section is also on the left blue navigation bar. Read what you are agreeing to, check off Principal Investigator, then hit Submit Form
- Student protocols go into the queue of the Faculty Advisor listed in Personnel. The Faculty Advisor (FA) will review, click off their Obligations then Submit Form.
* TIP: Tell your FA you have submitted.
- The protocol will then receive an initial review by ORIO staff for completeness. It may be returned with instructions for additional documents or clarifications. Once accepted, the protocol is sent on to be assigned to a reviewer.

Tips for completing sections of eProtocol:

Subject Checklist

- Check all that apply
- Check intended subjects for research; not who may be incidental in the subject pool.

Study Location

- Where will the research take place aka research site?
- Don't forget to answer the four (4) questions at the bottom of the page!
- Attachment section should have letter of cooperation with the site (if not USM).
 - If using your place of employment, you must separate yourself as employee and approach as a student.
- If recruiting from other UMS campuses, ORIO will submit your protocol for review to the other UMS campuses.

General Checklist

- Check all that apply

Funding

- Leave blank if no funding
- Provide enough information for clarity i.e.
 - Department Funds
 - Undergraduate Research Opportunity Program (UROP) funding

Protocol Information has several subsection

Application type checklist:

- Exempt [Categories](#)
- Expedited/Full Board [Categories](#)

Exempt research are human subjects studies that present no greater than minimal risk to subjects and do not have to be reviewed by an IRB Board member. A qualified staff member can review.

Tips for completing sections of eProtocol:

Exempt/Expedited: Choose which subcategory best fits your research. Otherwise, it becomes Full Board.

Summary:

- You may edit your title here.
- All board members are provided your summary after approval.
- Estimate start/end date. Research **MUST** be approved before you may start to collect data.
- Briefly describe procedures. There will be another section where you can provide more detail.

Recruitment:

- Remember to upload [recruitment materials](#) into the attachment section before submitting: scripts, flyers, emails, social media ads, etc

Procedures to Maintain Confidentiality:

- Types of data will you work with: (Check all that apply)
- Please refer to [Anonymous and De-Identified Data](#) (pdf) for an explanation of the differences in data types.
 - **Identifiable**: You can see, talk to, or communicate directly with the person
 - **Anonymous**: You have no way of knowing who responded
 - **De-identified or Coded**: You received a data set that was once identifiable; however, you did not receive any of the identifiable information

Confidentiality tip: For an online survey intended to be anonymous; however, they are willing to be available for further questions or contact for an incentive you are offering, you can create a second survey to collect their contact information. Program the survey's submit button to go to the next survey. Explain in the primary survey, they can provide contact information without being linked to their responses.

Tips for completing sections of eProtocol:

Consent Information

- **Consent/Parental Permission** checklist of essential parts of a consent form, types of consent, and useful templates can be found [here](#).
Don't forget the [mandatory statement](#)
 - If you are conducting retrospective research and are requesting a Waiver of Consent, upload a document explaining your request instead of the consent form.
 - **IMPORTANT:** After uploading each consent document, click on the title of the document and answer the applicable questions. (Assent section as well)
-
- Tip: Online surveys must have the consent information in the beginning of the survey giving the choice to proceed or not.
 - In the Consent Type drop-down choose Waiver of Documentation, which means no signature.

The screenshot shows the 'Informed Consent' section of the eProtocol interface. It includes a form with fields for Title, Consent Type, and Consent Document. A red box labeled 'Upload' points to the Consent Document field. Below the form, a table lists the uploaded documents. A red box labeled 'Click on Title' points to the title 'My Informed Consent form' in the table. Below the table, there are two sections of questions. A red box labeled 'Answer Questions' points to the first question: 'Will informed consent of research subjects be obtained from all participants?' The second question is 'Who will obtain subject's consent? (Check all that apply)' with four checkboxes for Principal Investigator, Co-Investigator, Other research staff, and Other (specify).

Informed Consent

Title *

Consent Type *

Consent Document * ☒ Attachment tina aubut HIPS citiC

Choose type of consent, answer the questions, if applicable attach by clicking the Add button.

Informed Consent

	Title	Consent Type	At
<input type="checkbox"/>	My Informed Consent form	Informed Consent	09/

Will informed consent of research subjects be obtained from all participants?

Answer Questions

Who will obtain subject's consent? (Check all that apply)

☐ Principal Investigator

☐ Co-Investigator

☐ Other research staff

☐ Other (specify)

Tips for completing sections of eProtocol:

Assent is for children under the age of 18.

- ORIO does not provide assent templates because of the varied comprehension over age ranges.
- Write the Assent statement to the level of understanding of the intended research subjects.
- Children do have the right to refuse participation even with parental consent.
- **IMPORTANT:** After uploading each consent document, click on the title of the document and answer the applicable questions. (see previous slide)

Risks and Benefits

- Expedited protocols will fill out both sections. Exempt fill out only Risks. Put some earnest thought into risks.

HIPAA

- If you checked off HIPAA under General Checklist, this section will be filled out.
- **IMPORTANT:** For HIPAA Waiver/Alteration, click the Add button at the bottom of the page for **additional questions**.

Potential Conflict of Interest

- Expedited protocols will fill out this section.

Attachments

- READ THE LIST OF RELEVANT DOCUMENTS TO UPLOAD
- Missing attachments is the most common reason for a protocol to be returned.

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