IRB Member Guide for eProtocol Review

Office of Research Integrity and Outreach
University of Southern Maine
Protocol

Please review the information below before you log-in.

If you would like to submit a research activity involving human subjects to the USM Institutional Review Board (IRB) for the Protection of Human Subjects for review please use the e-Protocol Management System (e-Protocol is currently compatible with Firefox and Internet Explorer).

If you have any questions or would like to request assistance please contact the Office of Research Integrity and Outreach (ORIO) at: usmorio@usm.maine.edu or 207-780-4517, we are happy to help!

NOTE: All research activities involving human subjects must receive review and approval BEFORE they are initiated. Approval is documented formally, on signed letterhead. Email notification should not be construed as approval.

1. Do you have a username and password? If not, you'll need to request one. In order for research staff to be listed on the protocol they must request a username and password as well.

2. e-Protocol is currently compatible with Firefox and Internet Explorer only. You will also need to disable pop-up blockers in order to use the system.

3. Make sure your CITI training is up to date (completed in the last 4 years); you will be asked for this information in the system. If you have not completed CITI training or need to update your training please visit the USM IRB Training website.

4. Make use of the resources, USM IRB guidance documents, and templates listed in the dashboard at the bottom of the Investigator home screen and also found throughout the form.

5. Familiarize yourself with the exempt categories, you will be asked to provide a preliminary determination regarding whether or not your project may qualify for exempt status.

6. If you don't think your project qualifies for exempt status you will be asked if your project falls into one of the listed expedited review categories. If you don't think your project fits into one or more of the expedited categories then you may proceed with the application and the proper review category will be determined by IRB staff.

7. Pay close attention to what each question is specifically asking; answers should be succinct and written in plain language.

8. Please remember that you are able to save your work, leave, and enter the system as you would like.

9. If a question is not applicable to your project state: "n/a".

10. Please be sure you attach all relevant attachments before you submit (e.g., consent, assent, and parental permission documents, measures, funding application, letters of support etc.).

11. Check for completeness before submitting, the system will let you know if information is missing.

12. When you're ready to submit be sure that you have properly submitted your application: Submit Form.
The protocol will be listed under the type of submission (e.g., New)
This is where you will write your questions and comments. Click on the ID number to see the research protocol.
The research protocol will open in a new browser window.
This is the research protocol. Use the Next and Previous buttons to view the protocol pages.

If you want to print the protocol, click on Print View to generate a PDF of the research protocol.
After you have read the research protocol you can minimize your browser (recommended) or close the protocol to access the questions/comments page.
At this point you can either 1) send comment/suggestions to the PI or 2) recommend the protocol for approval.

To send comments and questions to the PI, click on the Write Comment(s) button.
To write comments:
1) Choose the protocol section the question relates to
2) Type one comment or question
3) Choose the necessity of the response (at least one comment must be necessary for approval)
4) Click the Save button or Save and Add Comment Button if including more comments or questions
When you have written all comments and questions submit the comments to the ORIO by clicking on the Submit to IRB button.
If you don’t have any comments or questions for the PI you can recommend the protocol for approval after completing the checklist.
Complete the reviewer checklist and supply comments if necessary.

| Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result (achieved from research interventions). |
|---|---|---|
| Yes | No | N/A | Comments |

| Risks to subjects are minimized by using procedures that are consistent with sound research design and which do not unnecessarily expose subjects to risk. |
|---|---|---|
| Yes | No | N/A | Comments |

| When possible, risks to subjects are minimized by using procedures already being performed on the participants for diagnostic or treatment purposes. |
|---|---|---|
| Yes | No | N/A | Comments |
After completing the checklist you can recommend the protocol for approval.
If you have comments regarding your approval (e.g., think it falls into expedited category #7) you can leave them in the Approval Notes section. If you have any side comments for the ORIO, you can leave them in the Notes to IRB section.

Choose the adequate approval option for the protocol. The options listed will vary depending on submission type.

1) Choose here

2) Click here
Note the successful submission of your recommendation for approval (or submission of comments to the PI) under Protocol Event.
Note the successful submission of your recommendation for approval (or submission of comments to the PI) under Protocol Event.
Review the responses to your comments here. To view any changes to the research protocol click on the ID.

You can now:
1) Send additional comments or questions to the PI by clicking on the Write Comment(s) button or
2) Complete the checklist and recommend the protocol for approval.
If you submitted comments or questions to the PI, you will receive email notification when they have sent responses. You will need to log back into eProtocol to view the responses.
Thank you for your review!

Contact ORIO with any questions:
usmirb@usm.maine.edu
(207) 780-4517