Protocol Amendment
Quick Guide

How to submit a protocol amendment to the IRB using the e-Protocol Management System
Welcome to the University of Southern Maine's Office of Research Integrity and Outreach (ORIO)!

We are responsible for the oversight of the:

- Human Research Protection Program (HRPP)
- Institutional Review Board (IRB)
- Institutional Animal Care and Use Committee (IACUC)
- Institutional Biosafety Committee (IBC)
- Responsible Conduct of Research (RCR)
- Export Control Regulations (ECR)
- Administration of the Financial Conflicts of Interest (FCOI)

The links to the right will guide you through the IRB, IACUC and IEC submission processes. There are also links for helpful resources as well as the mandatory trainings.

NEWS & EVENTS

Give us your feedback
POSTED SEPTEMBER 7, 2012
The Office of Research Integrity and Outreach (ORIO) has created an anonymous questionnaire on a new survey software tool as a means of gathering information from the UMaine community about ORIO operations.

Recent changes in Federal Regulations regarding Financial Conflicts of Interest (FCOI)
POSTED AUGUST 17, 2012
Recent changes in Federal Regulations regarding Financial Conflicts of Interest (FCOI) in research

RESOURCES

e-Protocol Management System

Click Here

4/19/13
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 IRPP 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.

13. Keep an eye on your email, you will receive notifications from the system but you will need to log in to the system to take action.
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<thead>
<tr>
<th>Option</th>
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<tbody>
<tr>
<td>Open in View Mode</td>
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<tr>
<td>Protocol Details</td>
</tr>
<tr>
<td>Start Amendment</td>
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<tr>
<td>Start Final Report Form</td>
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<td>Start Report Form</td>
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<td>Start Protocol Deviation Form</td>
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1) select this option

2) click OK
Changes to an approved protocol must be reviewed and approved by the IRB before being implemented.

1. Summarize and explain the proposed changes to the protocol in lay terms.

Proceed to the appropriate section(s) and make your changes. Make necessary changes to study documents (e.g., measures, consent forms), when applicable.

2. Indicate Level of Risk involved with the changes proposed. (If level of risk has changed, please update the section ‘Risks’ in the protocol information.)

   - Increased
   - No Change
   - Decreased

3. Describe any Other Changes

List of Sections (including questions) and study documents that have been changed/added.
Make all changes to protocol – include new attachments.
Obligations

Obligations of the Principal Investigator are:

Modifications - Changes in any aspect of the study (for example, project design, procedures, consent forms, advertising materials, additional key personnel or subject population) will be submitted to the IRB for approval before instituting the changes.

Consent Forms - All subjects will be given a copy of the signed consent form. Investigators will be required to retain signed consent documents for 3 years after completion of study.

Training - Human subject training will be completed by all key personnel.

Adverse Events - All adverse events occurring in the course of the protocol will be reported to the IRB as soon as possible, but not later than ten (10) working days.

Continuing Review - IRB Protocol Report Forms will be submitted annually at least 60 days before expiration of protocol.

Completion Report - The IRB will be notified when the study is complete. To do this, complete the IRB Protocol Report Form and select "Final Report."

The Faculty Advisor attests that (s)he has read the protocol submitted for IRB review, has read the Role and Responsibilities of the Faculty Advisor; USM IRB Guidance, and agrees to provide appropriate education and supervision of the student investigator. In the case of student protocols, the faculty supervisor and the student share responsibility for adherence to policies.

The Principal Investigator has read and accept(s) responsibility for the study, including adherence to DHHS, FDA, and USM policies regarding protections of the rights and welfare of human subjects participating in this study.
Do you want to submit the IRB Protocol 13-04-198 (Webster)?

Click Yes

Note successful submission.