Protocol Amendment
Quick Guide

How to submit a protocol amendment to the IRB using the e-Protocol Management System

4/19/13 updated 1.30.2018
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.

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.

Location & Hours

Research Compliance

Human Subjects

Animal Use

Biosafety

Click Either

Get Started
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.

- I am not sure my research project is human subject research
- I am conducting human subject research
- I am an Undergraduate Social Work Student (SWO) Conducting Research

I am a USM Faculty Member

- I am conducting my own research, however not sure it is considered human subject research
- I am conducting my own human subject research
- I am conducting a class research project
- I am a mentor/faculty advisor for student research (pdf)

I am a USM IRB Board Member

I am external to USM and want my research reviewed by USM’s IRB

I am external to USM and want to recruit USM students, faculty, and/or staff for my research (pdf)

I am a USM staff and wish to conduct a survey or other fact gathering on campus

What is "CITI" training?

Additional Resources
OFFICE OF RESEARCH INTEGRITY AND OUTREACH

IRB Submission Process and e-Protocol Resources

Step 4: Log into e-Protocol. After you receive a User ID and temporary password you can now log into the online submission system, e-Protocol. Please make sure to read the information listed on the e-Protocol login page https://usm.keyusa.net/.

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

Submit protocol for review at least thirty (30) days prior to starting data collection.
<table>
<thead>
<tr>
<th>Protocols (In Preparation / Submitted)</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>NEW</td>
<td>7</td>
</tr>
</tbody>
</table>

Currently there are no Submitted protocols to process.

<table>
<thead>
<tr>
<th>AMENDMENT</th>
<th>5</th>
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</thead>
</table>

Currently there are no Amendment protocols.

<table>
<thead>
<tr>
<th>CONTINUING REVIEW</th>
<th>5</th>
</tr>
</thead>
</table>

Currently there are no Continuing Review protocols.

<table>
<thead>
<tr>
<th>REPORT</th>
<th>5</th>
</tr>
</thead>
</table>

Currently there are no Report forms.

<table>
<thead>
<tr>
<th>DEVATION</th>
<th>5</th>
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</table>

Currently there are no Deviation forms for review.

<table>
<thead>
<tr>
<th>FINAL REPORT</th>
<th>5</th>
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Currently there are no Final Report forms.

### Approved Protocols

<table>
<thead>
<tr>
<th>Protocol ID</th>
<th>Principal Investigator</th>
<th>Approval Date</th>
<th>Last Approval Date</th>
<th>Expiration Date</th>
<th>Review Decision</th>
<th>Form Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>13-44-198</td>
<td>Casey Webster</td>
<td>04/19/2013</td>
<td>04/19/2013</td>
<td>N/A</td>
<td>Expedited Review</td>
<td>AMENDMENT</td>
</tr>
</tbody>
</table>

Currently there are no Non-Active Protocols.
1) select this option

2) click OK
Revision/Amendment
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.

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

3. 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

4. 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 study 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 90 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 [she] 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 protection of the rights and welfare of human subjects participating in this study.
Click here – Submit Form
Do you want to submit the IRB Protocol 13-04-198 (Webster)?

Click Yes
Thank you for submitting the Protocol 13-04-198.

### IRB

**Protocols (In Preparation / Submitted)**

<table>
<thead>
<tr>
<th>Protocol ID</th>
<th>Principal Investigator</th>
<th>Protocol Event</th>
<th>Status/Comments</th>
<th>Panel</th>
<th>Meeting Date</th>
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<tr>
<td>13-04-198</td>
<td>Casey Webster</td>
<td>SUBMITTED TO IRB</td>
<td>SUBMITTED</td>
<td>USM IRB</td>
<td></td>
</tr>
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</table>

**Continuing Review**

Currently there are no Continuing Review protocols.

**Report**

Currently there are no Report forms.

**Deviation**

Currently there are no Deviation forms for review.

**Final Report**

Currently there are no Final Report forms.

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**Non-Active Protocols**

Note successful submission.