Final Report
Quick Guide

How to submit a protocol final report 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 snap survey software as a means of gathering information from the UMS 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
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@usmmaine.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 HSPD 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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<td>Protocol ID</td>
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<td>-------------</td>
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<td>12-04-199</td>
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<td>Currently there are no Non Active Protocols.</td>
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Click on protocol #
2) Click OK

1) Select this option:
- Open in View Mode
- Protocol Details
- Start Amendment
- Start Final Report Form
- Start Report Form
- Start Protocol Deviation Form
Obligation of the Protocol Director - Final Report

- You may close a human subject research protocol approved by the IRB at any point prior to its continuing review date.
- Submit within 30 days of the completion of the study.
- Should not be submitted until after the final site visit by the sponsor (industry sponsored projects).
- Should not be submitted if the funding is still open (an open funding account requires a current IRB approval).
- Investigators must inform study participants of any significant new knowledge obtained during the course of the research that may affect their future health.

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<tr>
<td><strong>Yes</strong></td>
<td><strong>No</strong></td>
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<tr>
<td>Is this study closed to enrollment?</td>
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<tr>
<td>Have all participants completed all research-related interventions?</td>
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<tr>
<td>Have all participants completed all research-related follow-up?</td>
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<tr>
<td>Has the University data analysis been completed?</td>
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<tr>
<td>Has your sponsored project (funding) been closed?</td>
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<tr>
<td>If this is a multi-site study and University is the coordinating institution or the University investigator is the lead investigator, is the study closed at all participating sites?</td>
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1) Answer these questions

2) Click continue
Final Report Form

Instructions:
You must complete all questions. Enter "NA" or "none as needed."

1. Confirm
   - Yes
   - No
   a. Is the study closed to enrollment?
   b. Have all participants completed all research-related interventions?
   c. Have all the participants completed all research-related follow-up?
   d. Has the University of Southern Maine data analysis been completed?
   e. Has your sponsored project (funding) been closed?
   f. If this is a multi-site study and outside of the coordinating institution or the University of Southern Maine investigator is the lead investigator, is the study closed at all participating sites?

2. Number of participants enrolled since the beginning of the study.
   (enrolled includes all participants who signed a consent form, whether they were later deemed ineligible)

3. Provide a summary of withdrawals from the research (both participant and investigator initiated) since the beginning of the study. Include the number and reasons for withdrawal.

4. Number of participants lost to follow-up since the beginning of the study.

5. If any new or unanticipated risks were identified from this study, provide a summary of the risks identified.

6. If any participant experienced unanticipated harms or injuries, provide a summary of the harms experienced.
Final Report Form

Instructions:
You must complete all questions. Enter N/A or none as needed.

1. Confirm

   a. [ ] Is the study closed to enrollment?
   b. [ ] Have all participants completed all research-related interventions?
   c. [ ] Have all the participants completed all research-related follow-up?
   d. [ ] Has the University of Southern Maine data analysis been completed?
   e. [ ] Has your sponsored project (funding) been closed?
   f. [ ] If this is a multi-site study, University of Southern Maine is the coordinating institution or the University of Southern Maine investigator is the lead investigator, is the study closed at all participating sites?

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4. Number of participants lost to follow-up since the beginning of the study.

5. If any new or unanticipated risks were identified from this study, provide a summary of the risks identified.

6. If any participant experienced unanticipated harms or injuries, provide a summary of the harms experienced.
Do you want to submit the IRB Protocol 13-04-198 (Webster)?

Click Yes

**IRB**

**Protocols (In Preparation / Submitted)**

**NEW**
Currently there are no Submitted protocols to process.

**AMENDMENT**
Currently there are no Amendment protocols.

**CONTINUING REVIEW**
Currently there are no Continuing Review protocols.

**REPORT**
Currently there are no Report forms.

**DEVIAION**
Currently there are no Deviation forms for review.

**FINAL REPORT**

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<th>Status/Comments</th>
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<td>Casey Webster</td>
<td>SUBMITTED TO IRB</td>
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<td>USM/IRB</td>
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**Approved Protocols**

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<th>Approval Date</th>
<th>Last Approval Date</th>
<th>Expiration Date</th>
<th>Review Decision</th>
<th>Form Type</th>
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<td>13-04-198</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>
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Note successful submission