

Office of Research Integrity and Outreach (ORIO)
University of Southern Maine
e-Protocol FAQ's

Below please find a list of e-Protocol FAQ's. If your questions are not answered here or if you experience any difficulty using the system, please feel free to contact us directly. We can be reached via email at usmorio@maine.edu or by phone at 207-780-4517. We are happy to help!

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1. When should I use e-Protocol?

- All research involving human subjects conducted by any employee or agent of USM (faculty, staff, students, etc.) must receive IRB review and approval prior to implementation. If you have a NEW protocol you would like to submit for IRB review you should use e-Protocol. If you need to take action on an existing protocol (file a revision or amendment, file for continuing review, close the project, report an adverse event etc.) this should be done using the paper based system. If you have any questions about whether or not you should be using e-Protocol please contact ORIO staff for guidance.

2. How do I get started?

- Before you can access the e-protocol system you will need a username and password. To request a username and password you will need to complete the "Request for e-Protocol ID" form on the ORIO website found [here](#). Your request will be reviewed in a timely fashion. You will be notified via the email address indicated on the form of your e-Protocol username and password.
<https://usm.maine.edu/orio/request-e-protocol-user-id>
- Please review the [exemption categories \(46.101 \(b\) 1-6\)](#), you will be asked to make a preliminary determination regarding whether your project may qualify for exempt status. If you feel that your project qualifies for exempt status you should indicate this by checking the box on the "General Checklist" entitled "Study eligible for Exempt review."
<https://usm.maine.edu/sites/default/files/orio/exemption%20categories%207.18.12.pdf>
- Make sure your CITI training is up to date, (completed in the last 4 years) you will be asked for this information when you log-in to e-protocol. If you have not completed CITI training or need to update your training go [here](#). You will have to input the CITI training information for all research staff each time you submit a new protocol. We advise you to keep training records for easy reference however, if you don't know if or when a person completed CITI training you can contact ORIO to find out.
<https://usm.maine.edu/orio/irb-training>

3. How do I access the e-Protocol site?

- The log-in page for e-Protocol can be found here: <https://usm.keyusa.net/>. If you submit to the IRB on a regular basis you may want to bookmark this page in your browser. **Please be advised that e-Protocol is currently compatible with Firefox and Internet Explorer only. You will also need to disable pop-up blockers within your browser.**
- Please review the information listed on the log-in screen before logging into the system.
- When you log-in, on your dashboard you will see a section at the bottom of the page named "Information Resources" here you will find useful resources, including ones that are referenced throughout the application. Here you will also find an "Investigator User Guide" please print this out and refer to it as needed when using the system.

4. How do I create a NEW protocol in e-protocol?

- When a protocol is created for the first time, it is considered a NEW form.
- Please refer to the "Investigator User Guide" on the dashboard under "Information Resources" for further instruction.

5. As Principal Investigator (PI), how can I give my research staff the ability to view and make edits to my protocol?

- In order to list a person as research staff on a protocol they must have an e-protocol username and password as well. If they do not have one, they'll need to request one at <https://usm.keyusa.net/>
- All research staff (listed on the protocol) with the exception of "other personnel" have the ability to view and edit the protocol when it is not held by IRB staff. Only the PI has privileges such as - 'Create', 'Submit', 'Clone', 'Delete' and 'Respond to Comments'.
- Once each staff person has their user name and password, the PI will add them by clicking on the binoculars to search for each person by last name.
- **It is helpful to disable pop-up blockers on your web browser.** Sometimes, sections pop-up behind the main page.

6. I'm being asked to answer questions that aren't relevant to my project; do I need to answer these questions?

- The application form is designed to capture information on a wide range of differing projects. If you feel that a section of the application is not applicable to your project please indicate- "n/a" It's important that you write something in this section, if you don't the system will recognize your application as incomplete and won't allow you to submit.

7. How do I request a waiver for Informed Consent and Assent in e-Protocol?

- Protocol Information section form #14; choose **Waiver of Consent** from the drop down menu, insert *Waiver of Consent* as the title, answer the questions, and then click save. You can follow the same procedure for the assent section (form #15); however, the assent section will be disabled if you did not indicate that you will be working with minors in the Population Checklist section.

8. I am not able to answer Question 7 regarding compensation under Protocol Information; what's wrong?

- General Checklist section the Compensation/incentives is not checked. The system recognizes that you are not compensating participants and therefore does not require you to answer those corresponding questions. You can go back to the General Checklist and check the corresponding box. You should then be able to answer the questions.

9. The e-Protocol will not submit, now what?

- Check on the Obligation section that terms have been agreed to by clicking the checkbox.

10. I've submitted my application to the Institutional Review Board (IRB), now what?

- Once you successfully submit your application to the IRB, ORIO will receive notification from the system that a new protocol has been submitted. ORIO staff will review the submitted application for completeness. During this review ORIO staff will check to see that you have attached all necessary documents, for example: letters of support from research sites, the funding application, a copy of all recruitment materials, consent/assent/permission documents, copies of all measures etc.
If it's determined during this review that your submission is not complete or more information is needed, your protocol will be returned to you and you will be notified via email.

11. I've received email notification that my protocol has been returned, now what?

- You will need to log-in to the system to access your protocol, at that time you will see the return notes affiliated with your project. Please address these comments and re-submit your protocol.
- The student advisor may also receive an email. Page 23-25 of the user guide will provide details.
- To view comments, click on Comments Received under Protocol Event section.

12. I've received email notification that the Institutional Review Board (IRB) has reviewed my protocol and has requested clarification or additional information, now what?

- You will need to log-in to the system to access your protocol, at that time you will see the reviewer comments affiliated with the protocol. Please respond to these comments and (provide additional information and/or clarify existing language) in the protocol and/or attach the requested items and re-submit your protocol to the IRB.
- Once the submission is deemed complete, the faculty advisor will not receive any further requests to re-submit.

13. How do I check the status of my protocol?

- To check on the status of a protocol please log-in to the system. You will see a listing of your protocol submissions, the protocol event field and the status field will indicate the status of your protocol.

14. How do I access my approval letter and other approved study documents?

- Once approved, these documents should be listed in the attachments section of the relevant protocol. In your study, please use only the approved consent/assent/permission form(s) with the USM IRB approval dates in the header (when applicable). If these documents are not available your study may not yet be approved. Approval is documented explicitly in writing; an email should not be construed as approval. If you are unsure whether or not your project has been approved please contact the ORIO.

15. How do I take action on an approved protocol- submit a revision or amendment, submit for continuing review, report a protocol deviation, file a report, or close my protocol?

- **Definition of Form Types:**
 - *Amendment: After a protocol form is approved, if there are any revisions or amendments to the protocol, an Amendment must be submitted. Please note: You need to request prior approval of all revisions and amendments from the IRB BEFORE implementation.*
 - *Continuing Review: For an approved protocol, Continuing Review should be submitted before its expiration, ideally 60 days prior to the expiration date and no less than 30 days prior to the expiration date. If you are unsure whether or not your project continues to involve human subjects, and therefore requires continuing review, please contact the ORIO for guidance.*
<https://usm.maine.edu/orio/hrpp-definitions>
 - *Protocol Deviation: In the case of an incident of deviation, violation or participant non-compliance during research, a Protocol Deviation should be submitted, notifying the IRB of the incident. If you are unsure whether an incident should be classified as a protocol deviation please contact the ORIO for guidance.*
 - *Report: In the case of adverse events, unanticipated problems, or new information that may pose risks to subjects or others and alter the risks, benefits, or alternatives available to subjects, a Report should be submitted to the IRB for review. If you are unsure whether or not you should file a Report please contact the ORIO for guidance.*
 - *Adverse events: adverse events encompass both physical and psychological harms and can be defined as any untoward or unfavorable medical occurrence in a*

human subject, including any abnormal sign, symptom, or disease, temporally associated with the subjects participation in the research, whether or not considered related to the subjects participation in the research.

- *Unanticipated Problem: unanticipated problems, in general, include any incident, experience, or outcome that meet all of the following criteria: 1) unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB- approved research protocol and consent document(s); and (b) the characteristics of the subject population being studied; 2) related or possibly related to participation in the research(possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research) ; and 3) suggests that the research places subjects or others at a greater risk of harm than was previously known or recognized.*
 - *Final Report: At the conclusion of the research, when the activity no longer involves [human subjects](#), a Final Report should be filed for review. This is the final document submitted for a protocol. If you are unsure whether or not your project continues to involve human subjects please contact the ORIO for guidance. <https://usm.maine.edu/orio/hrpp-definitions>*
1. Point to "Investigator" on the top menu and click "Approved Protocols." You can also find the list of approved protocols on your dashboard in the "Approved Protocols" section.
 2. Click on the "Protocol ID." "Approved Protocol Decision" popup is displayed with various options.
 3. Select the desired form creation option and click "OK". The selected form is created and displayed in a new window.
 4. Please refer to the "Investigator User Guide" on the dashboard under "Information Resources" for further instruction.

16. How do I clone a protocol?

- Instead of creating a NEW protocol, you can clone an existing protocol if there are little or no modifications.
- Please refer to the "Investigator User Guide" on the dashboard under "Information Resources" for further instruction.

17. How do I delete a protocol?

- Please refer to the "Investigator User Guide" on the dashboard under "Information Resources" for further instruction.

18. How do I delete a deviation entered by mistake?

- The PI needs to delete the deviation. Check the Delete Protocol button and then check the box for the associated deviation. Then you can click the delete button up at the top right.

19. Can I print a copy of the protocol?

- Yes. When you're logged into the system, and after you have created a protocol you should see a "Print View" option listed on the left hand side of the protocol. You need to be viewing the protocol you want to print for this to work, you can't print from the dashboard. Select what you want printed and hit the "ok" button. The system will generate a pdf of your protocol that you can save and print.

20. Don't see an answer to your question?

- Please visit our Contact Us page located here: <http://usm.maine.edu/orio/contact-us> and submit your question. We will reply to you with a response as soon as possible. You may also reach us by phone at (207) 780-4517.