Submitting a Modification (MOD) in eIRB+

Go to the main page for eIRB+ and log-in.

1. Once in the system you will be brought to your inbox.
2. Once the page populates, select “My Studies” in the middle of the page and then search by STU#.

3. Once you have filtered, select the study, which will then take you to the main page of the study.

4. On the left side of the page toward the bottom select “Create Modification/CR; or Close”. If you do not see this option, that means there is currently a modification under review. You must wait until the current modification is complete.

5. Once in the submission select “Modification”.

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7. You will then also select the scope of the modification. (You may select one scope or both if they both apply to the submission).

- When selecting “study team member information”, please ensure that all personnel have current human subjects training.
- If the modification is a PI change, select “Other parts of the site”

8. Then select continue. Once you select continue you will not be able to go back and change the type of submission or scope of the modification.

Modification Information
9. The beginning of the next page states Modification Information and you will be asked questions regarding the status of the study and what modification is being requested. There will be 2 questions where there are pre-populated selections, and then a 3rd question where you will state the exact nature of the modification.
   a) Question 1: Select which of the following criteria are applicable for the current enrollment for the study.

   1. Study enrollment status:
   - No subjects have been enrolled to date
   - Subjects are currently enrolled
   - Study is permanently closed to enrollment
   - All subjects have completed all study-related interventions
   - Collection of private identifiable information is complete

   b) Question 2: Select who should be informed of the requested change. (determine what is applicable based on the revision, i.e. changes in Study Team Members, with the exception of the PI, would not require notifying subjects, but a major consent form change would be applicable to notify current subjects.)

   2. Notification of subjects: (check all that apply)
   - Current subjects will be notified of these changes (provide a plan of how you will notify subjects in section 3 below)
   - Former subjects will be notified of these changes (provide a plan of how you will notify subjects in section 3 below)
   - No subjects will be notified (provide a reason why subjects will not be notified in section 3 below)

   c) Question 3: In the top section of the box provide a description of the exact modification that is being requested, so the IRB coordinator can reference this when generating the approval letter. Always reference a version date or number, if available or applicable, in your description of study documents. Then if necessary, make a space and provide a more detailed description of the changes being made or the rational for them, including any reference to summary of changes documents.

   Example: Other Parts of Study Modification.
10. If the modification was for "Other Parts of the Study" then when you select Continue you will then be taken to the main page of the study application and allowed to navigate through to make the necessary updates. You can find more tips on the IRB website: https://www.irb.northwestern.edu/modifications-2/

11. If the modification was for “Study Team Member Information” then you will be taken directly to that page of the study application and then you can make the necessary updates. Once completed you will select Finish and then will be taken to the main page of the submission.

12. Once on the main page for the submission, you can then notify the PI to submit using the template language described at the end of the “COMPLETING A NEW STUDY SUBMISSION IN EIRB+” section. (If you have Proxy permission for the study, you will then also be able to submit and do not have to notify the PI.)

13. Type in a message to notify the PI that the submission is complete and ready to submit and select OK.

14. The submission process is complete and an email will be sent to the PI to submit.

15. If a modification for internal study team personnel has been submitted, you will receive
automatic approval via an IRB comment and you will not receive an approval letter.

Hello Dr. Pereira,

The submission is complete and ready to submit. Thank you.