Submitting a Modification/Continuing Review (External IRB)

1. Go to the main page for [eIRB+](#) and login.

2. Once in the system you will be routed to your inbox.

3. You will then select “My Studies” and then search for the study in which you would like to submit a modification or continuing review.

4. Once the study populates select the name and you will then be directed to the main page of the overall “Study” application for the External IRB study.
5. Once on the main page, you will then need to navigate to the “Site” record.

6. As you are redirected to the “Site” submission, on the left side of the page you will then select “Create Modification” on the left side of the page under “My Current Actions”.
7. You will then be routed to be “Modification” page of the submission and there will be 2 questions in which you will need to respond.
   a. **Question 1:** What is the purpose of this submission? *(Please note the only option will be “modification”).* Once it is selected, the second question will appear.
   b. **Question 2:** Modification scope in which you will select one or both options. *(Please note by selecting only “Study Team and Research Location Information”, you will not have access to any other parts of the “Site” application).*
      i. Study team and research location information
      ii. Other parts of the site

8. Once you have provided a response to all questions, select continue located at the top or bottom of the right side of the page.

9. The next page of the application should be the “Modification Information” page, in which there are 3 questions.
   a. **Question 1:** Study enrollment status in which you will need to select from the available options.
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:** Notification of subjects, this question is only required if the submission includes materials that will need to be provided to current or former participants.

2. Notification of subjects: (check all that apply)

- [ ] Current subjects will be notified of these changes
- [ ] Former subjects will be notified of these changes

c. **Question 3:** Provide a brief summary or rationale regarding the submission. *(For example: Request to add Kevin Smith to the study team member list and Newly revised protocol dated 10-04-2018 Version 4).*
10. Once you have provided a response to all questions, select continue located at the top or bottom of the right side of the page.

11. NOTE: If your modification request or continuing review includes new or updated documents, upload the documents following the chart on the final page of this guidance.

12. You will then be redirected to the “Site” application where you will then make the requested modifications. (For example: When making a change to the “Study Team” member list, you will be taken directly to the “Study Team Member” page and then you will make the requested edits).
13. If you are making an update to the “Study Team Member” list and the requested person is not listed, then they are not registered in the system and will need to go to https://irb.northwestern.edu/eirb and complete the “New User” steps as listed.

14. Once you have finished making the requested changes, you will be taken to the final page of the “Site” application, in which you will select “Finish” to continue.
15. You will then be redirected to the main page of the modification page.

16. Select “Notify the PI to submit”. (If applicable and if you receive an error message, make sure that the RSS indicates “Completed” before notifying the PI to submit)

17. If submitting a continuing review, navigate to the STUDY record “STU00XXXXXX”
18. Click on “Edit Study”
19. Navigate to the “External IRB” page
20. Update the response to **Statement 6: Last day of approval period**: to the new expiration date.
21. Using the chart on the final page of this guide, update all applicable documents in the STUDY record
22. The application process is complete and an email will be sent to the PI to submit. Once the PI submits, the modification submission will be routed to the Northwestern IRB for administrative review. **(Please note submit functionality only occurs on the “Site” submission).**
### Where to upload documents for External IRB Studies: Study vs. Site Submissions in eIRB+

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