

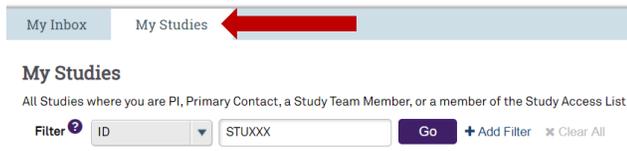
Submitting a Modification (MOD) in eIRB+

Go to the [main page](#) for eIRB+ and log-in.

1. Once in the system you will be brought to your inbox.
- 2.



3. Once the page populates, select "My Studies" in the middle of the page and then search by STU#.



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

My Current Actions

- View Study
- Printer Version
- View Differences
- Create Mod/CR, or Close**
- Report New Information
- Assign Primary Contact
- Add Comment
- Manage Study Access
- Update RSS

Activity	Author	Activity Date
Modification STU00210196-MOD0003 Opened	Broccoli, Rose	11/6/2020 8:32 AM
Continuing Review STU00210196-MODCR0001 review complete: Approved	Graham, Sheila	9/30/2020 7:15 PM
Modification STU00210196-MODCR0001 review complete: Approved	Graham, Sheila	9/30/2020 7:15 PM
Continuing Review STU00210196-MODCR0001 Opened	Broccoli, Rose	9/1/2020 8:39 AM
Modification STU00210196-MODCR0001 Opened	Broccoli, Rose	9/1/2020 8:39 AM
45-Day CR Deadline Reminder Sent	Administrator, System	9/1/2020 1:00 AM
60-Day CR Deadline Reminder Sent	Administrator, System	8/17/2020 1:00 AM

5. 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.

Modification / Continuing Review / Study Closure

6. Once in the submission select "Modification".

* What is the purpose of this submission? (Select Continuing Review to close a study)

- Continuing Review
- Modification**
- Modification and Continuing Review

[Clear](#)

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).

Modification scope:

- Study team and research location information
 Other parts of the site

- 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.**

Continue »

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 rationale for them, including any reference to summary of changes documents.

Example: Other Parts of Study Modification.

3. * Please provide a brief summary and rationale for the modifications, including any plan to notify participants of changes (if applicable).

If there are updates to the IB (Investigator Brochure), please indicate if the updated IB:
a. affects the risk-to-benefit ratio of the study thereby requiring a change to the study documents;
b. affects alternatives available to study participants; and/or
c. represents new information that should be provided to participants.

I4V-MC-JAHO (d) Protocol dated May 11 2020
 Clinical Protocol Amendment (d) Tracked Changes

18-167 Main Consent 10-21-2020 (tracked changes)
 -Subjects will be informed of this change as it may effect the study visit schedule.
 Subjects will be re-consented at their next visits.

myTransfer2 User Guide External Partners dated August 28 2019
 -guide for using secure file transfer system
 Updated Data Security Plan version 10-06-2020

Example: Study Team Member Information

Request to add Jane Smith to the study team member list.

Continue »

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.

Study Team Members

1. Internal Personnel

Identify each additional person involved in the design, conduct, or reporting of the research: ?

+ Add					
	Name	Roles	Involved in Consent	E-mail	Phone
<input type="checkbox"/> Update	Daniel	Co-Investigator	no		
<input type="checkbox"/> Update	Jeanne	Study Team Member	yes		NU
<input type="checkbox"/> Update	Noreen	Study Team Member	yes		Northwestern University Medical School
<input type="checkbox"/> Update	Kim	Study Team Member	yes		Northwestern University Medical School

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.**

History Project Contacts Documents Sites

Filter ² Activity Enter text to search for Go + Add Filter ✕ Clear All

Activity	Author	Activity Date
Submitted	Perera, Minoli	12/14/2018 4:12 PM
This amendment was automatically approved because it involves a minor update to the Study Team. ←		
PI Notified to Submit	Kupczyk, Magda	12/14/2018 3:57 PM

Hello Dr. Perera,
The submission is complete and ready to submit.
Thank you,