

## Submitting a Modification/Continuing Review (External IRB)

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

As of Thursday, May 3, 2018, the Conflicts of Interest (COI) tab is now viewable for all users and projects in eIRB. Information about the conflict of interest process can be found at: <https://www.northwestern.edu> questions regarding conflict of interest to [NUCOI@Northwestern.edu](mailto:NUCOI@Northwestern.edu).

At the time of continuing review, all actively enrolling studies will be required to conform to the new consent form template. We **strongly recommend** you submit a combination MOD/CR instead of a separate CR. reflect the revisions being made, please amend your current consent form document to incorporate the new template changes instead of pasting your current consent form language into the new template document.

NetID:

Password:

Remember me

After signing in to this site, you are bound by the terms and conditions set forth when you received your account.

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.

**My Studies**

All Studies where you are PI, Primary Contact, a Study Team Member, or a member of the Study Access List.

Filter

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.

My Inbox   My Studies   My Reviews   In Review   Archived   New Information Reports   User Info

### My Studies

All Studies where you are PI, Primary Contact, a Study Team Member, or a member of the Study Access List.

Filter <sup>?</sup> Name  Go + Add Filter x Clear All

ID	Name	Date Created	Date Modified	State	Full Study Title
STU00206922	External IRB Test Study	2/12/2018 3:24 PM	2/12/2018 3:24 PM	External IRB	External IRB Test Study

1 items   page 1 of 1   10 / page

5. Once on the main page, you will then need to navigate to the “Site” record.

**External IRB**

Initial approval:  
Approval end:  
Last updated: 2/12/2018 3:24 PM

**Edit Study**

**STU00206922: External IRB Test Study**

Lead principal investigator: Marcella Oliver

Local site: [IRBSITE00000024](#)

External IRB → Closed

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”.

## My Current Actions

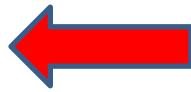
View Site

Printer Version

View Differences

Create Modification

Report New Information



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.

Continue >>
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).

3. \* Please provide a brief summary and rationale for the modifications:

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.

Continue >>

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.

**Pre-Submission**  
Last updated: 10/11/2018 3:42 PM

**IRBSITE00000024-MOD0001: Modification #1 for Site for External IRB Test Study**  
Principal investigator: Marcella Oliver  
Submission type: Modification  
Primary contact: Marcella Oliver

IRB office: IRB Office  
IRB coordinator:  
Regulatory authority:  
Site: IRBSITE00000024  
Study: STU00206922

**Next Steps**

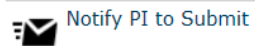
- Edit Modification
- Printer Version
- View Differences
- Submit
- Assign Coordinator
- Add Comment
- Add Private Comment
- Discard
- Notify PI to Submit

History | Contacts | Documents | Reviews | Snapshots

Filter: Activity [dropdown] Enter text to search for [input] Go + Add Filter x Clear All

No data to display.

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”

**Pre-Submission**

Last updated: 10/11/2018 3:42 PM

**Next Steps**

Edit Modification

Printer Version

View Differences

Submit

Assign Coordinator

Add Comment


Add Private Comment

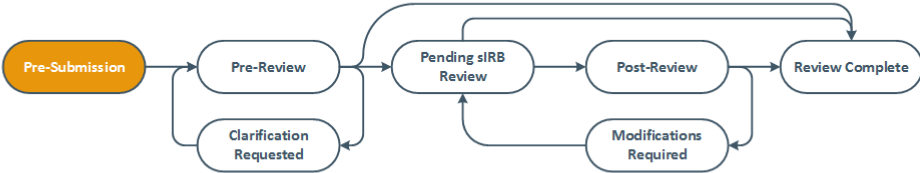
Discard

Notify PI to Submit

IRBSITE00000024-MOD0001: Modification #1 for Site for External IRB Test Study

Principal investigator: Marcella Oliver  
 Submission type: Modification  
 Primary contact: Marcella Oliver

IRB office: IRB Office  
 IRB coordinator:  
 Regulatory authority:  
 Site: IRBSITE00000024  
 S:  STU00206922



```

graph LR
    A([Pre-Submission]) --> B([Pre-Review])
    B --> C([Pending sIRB Review])
    B --> D([Clarification Requested])
    D --> B
    C --> E([Post-Review])
    C --> F([Review Complete])
    E --> G([Modifications Required])
    G --> C
    F --> B
  
```

History | Contacts | Documents | Reviews | Snapshots

Filter: Activity [Enter text to search for] Go + Add Filter x Clear All

No data to display.

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+

Study Document	eIRB+ Location	Submission Page
Protocol	Study Submission ("STU")	Basic Information
Local Protocol Addendum	Site Submission ("IRBSITE" a.k.a. "Site")	Site-Specific Documents
Consent Form(s) w/ NU-specific language	Site Submission ("IRBSITE" a.k.a. "Site")	Site-Specific Documents
Consent Form Template(s)	Study Submission ("STU")	Study-Related Documents for non-NU Research Sites
Investigator Brochure	Study Submission ("STU")	Drugs
Package Insert	Study Submission ("STU")	Drugs
Device Manual	Study Submission ("STU")	Devices
Recruitment Material (Overall Study)	Study Submission ("STU")	Study-Related Documents for non-NU Research Sites
Recruitment Material (Northwestern Site)	Site Submission ("IRBSITE" a.k.a. "Site")	Site-Specific Documents
Questionnaires (Overall Study)	Study Submission ("STU")	Study-Related Documents for non-NU Research Sites
Questionnaires (Northwestern Site)	Site Submission ("IRBSITE" a.k.a. "Site")	Site-Specific Documents
External IRB Approval Letter (Initial Site Approval)	Study Submission ("STU")	External IRB
External IRB Approval Letters (Post-Initial Approval)	Site Submission ("IRBSITE" a.k.a. "Site")	Site-Specific Documents
Institutional Authorization Agreement	Site Submission ("IRBSITE" a.k.a. "Site")	Site-Specific Documents