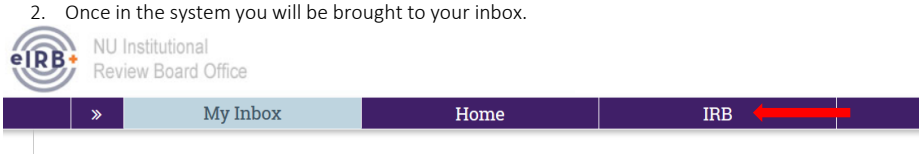
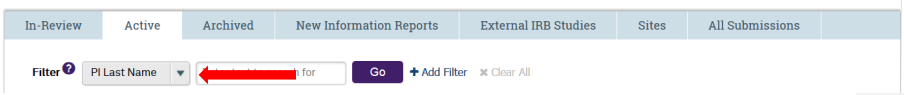
Submitting a Continuing Review + Modification (CR-MOD) in eIRB+

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

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

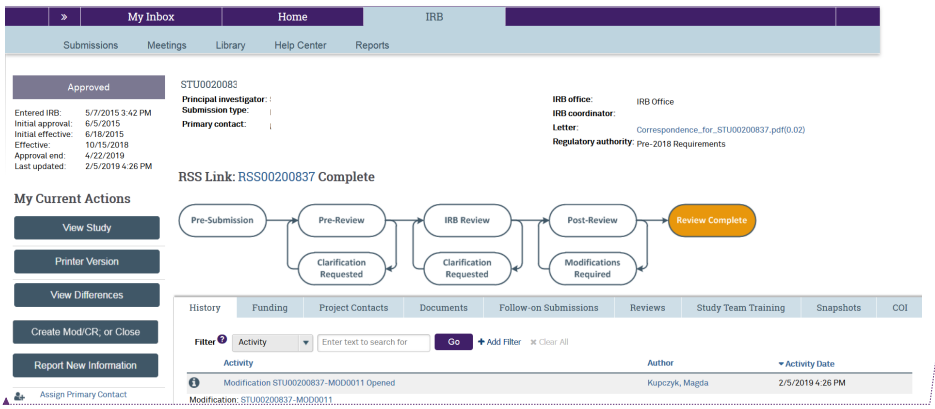


3. On the left side of the page toward the top select "IRB".



4. Once the page populates, select "Active" in the middle of the page and then filter for the study using the criteria available.

5. Once you have filtered, select the study, which will then take you to the main page of the study. (Update the screenshot because it no longer looks like this one.



6. Before starting the Continuing Review submission, you will want to click on the "Study Team Training" tab of the main study page and scan the list for expired personnel training. If CITI

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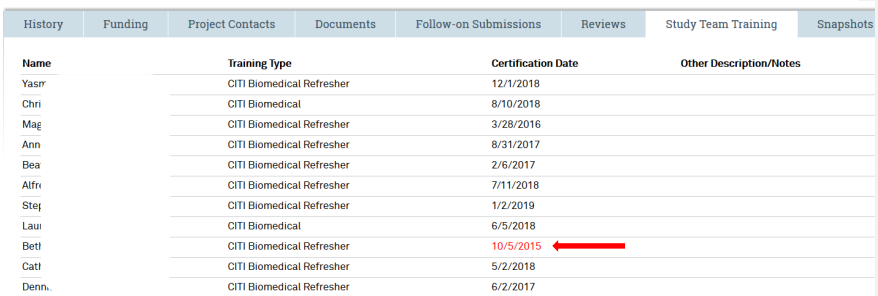
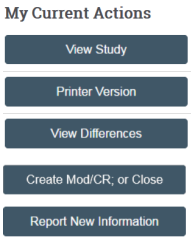
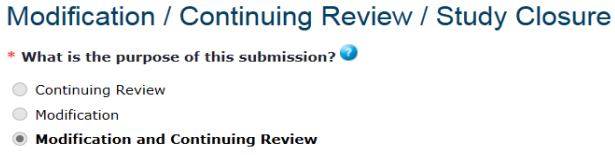
training date is expired (in red), you will want to notify the personnel to update their CITI training and send their email irbtraining@northwestern.edu as soon as possible. The IRB will not re-approve a study if personnel has expired training on file.



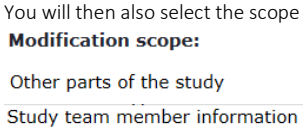
7. On the left side of the page toward the bottom select “Create Modification/CR; or Close”.



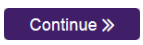
8. Once in the submission select “Modification and Continuing Review”.



9. You will then also select the scope of the modification.



10. Then select continue.

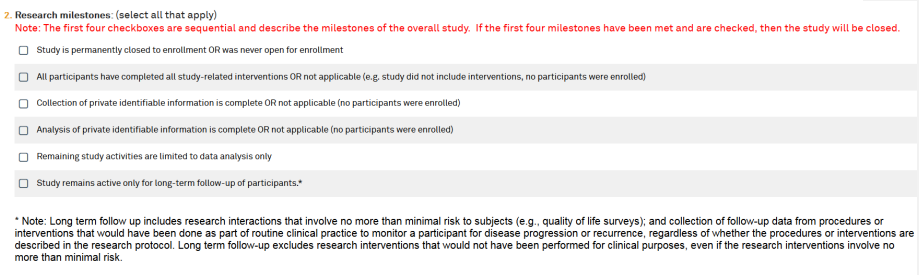


11. The beginning of the page states **Continuing Review/Study Closure Information** and there are 4 questions in total to respond to and then a section to upload any pertinent documents for the

continuing review.

a) **Question 1:** This question request information for the total number of subjects enrolled at this site and then study-wide. Subjects enrolled refers to the total number of subjects who consented minus screen failures. Even if the study is only conducted at this site please include the overall enrollment number listed in the above question. You will also need to indicate the number of subjects enrolled since the last continuing review if this is not the initial CR for the study.

b) **Question 2:** The next question will request information for the current status of the study, which should be confirmed with the study coordinator or main contact for the study. Select all that apply. (Update the screenshot because it now includes a box and language to acknowledge closure when the study is being closed. In addition, the language associated with the red note has changed also.)



c) **Question 3:** Select all that apply on the lists that are applicable for the study.

3. **Check the items that are true since the last IRB continuing review for all sites involved in the study. For each item left unchecked, include a corresponding explanation or supporting document in section 4 below:**

- ☐ NO subjects experienced unexpected harm (that wasn't previously reported to the IRB).
- ☐ Anticipated adverse events have NOT taken place with greater frequency or severity than expected.
- ☐ NO subjects have withdrawn from the study after initial screening procedures, if any.
- ☐ There have been NO unreported unanticipated problems involving risks to subjects or others.
- ☐ There have been NO complaints about the study.
- ☐ There have been NO publications in the literature relevant to risks or potential benefits that would indicate a need to modify any part of the study.
- ☐ There have been NO interim findings.
- ☐ There have been NO multi-center trial reports.
- ☐ There have been NO data safety monitoring reports.
- ☐ There have been NO regulatory actions that could affect safety and risk assessments (e.g. FDA drug recall).
- ☐ There has been NO other relevant information regarding this study, especially information about Biomedical risks including box warnings or ANY updated package inserts, IBs, or device reports.
- ☐ In the opinion of the Principal Investigator, the risks and potential benefits are unchanged.
- ☐ There have been NO modifications to the study that have not been submitted to or approved by the IRB.
- ☐ All problems that require prompt reporting to the IRB have been submitted.

d) Under number 4 you are requested to upload any supporting documents, which may include DMC letters not previously submitted, publications, etc. including any additional information about subject withdrawals.

4. Attach supporting documents: (for each item left unchecked above, include an explanation or a document from an external source)

Name
There are no items to display

12. Once all the questions are completed select "Continue".

4. **Attach supporting documents**: (For each item left unchecked, include an explanation or document. You may upload supporting documents explaining other situations even if all boxes are checked, such as a reason why there have not been any DSMB reports.)

+ Add

Name
There are no items to display

13. The beginning of the next page states **Modification Information** and will ask questions regarding the status of the study and what modification is being requested. There will be 2 questions where there are pre-populated selections 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. (Only make a selection if this is applicable to the revision, i.e. changes in Study Team Members, with the exception of the PI. would not have any items selected)

2. **Notification of subjects:** (check all that apply)
   - ☐ Current subjects will be notified of these changes
   - ☐ Former subjects will be notified of these changes

This needs to be updated. There are now three available options.

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. 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.

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

Example: Other Parts of Study Modification.

Because of the IRB's added language related to IB submissions, it may be ideal to supplement the language in the description used to follow the three IB related items above.

3. * **Summarize the modifications:**

Investigator Brochure Ninth Edition dated August 14, 2014, Protocol Amendment 3 dated September 30, 2014, Updated Main Informed Consent dated January 7, 2015 and New Open Label Consent form added dated January 7, 2015.

Please see summary of changes documents for both the investigator brochure and the protocol for modifications.

The informed consent changes include changing the study drug name "GS-6624" to "simtuzumab" throughout the consent form, explanation of "clinical events" and the information regarding the open label phase being added, in which a new consent form is now also being submitted.

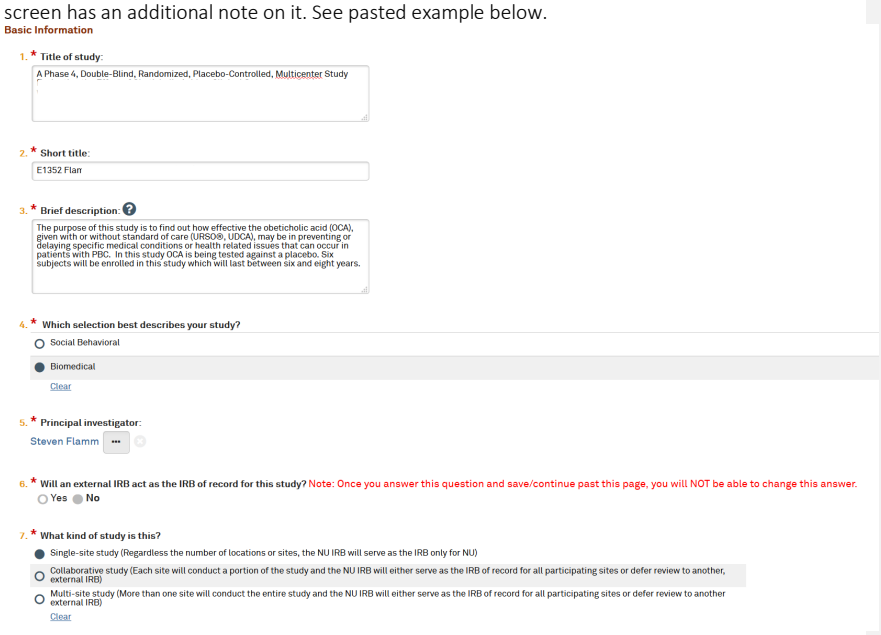
Example: Study Team Member Information

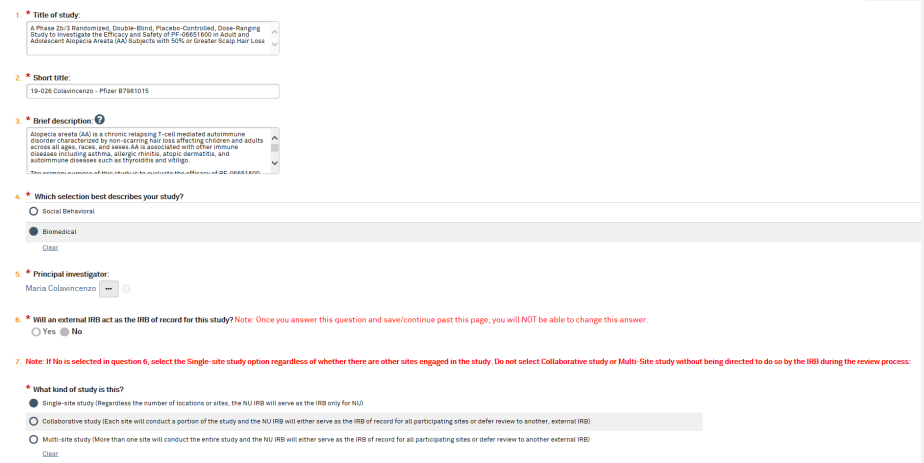
3. * **Summarize the modifications:**

Request to add Julie the study team member list.

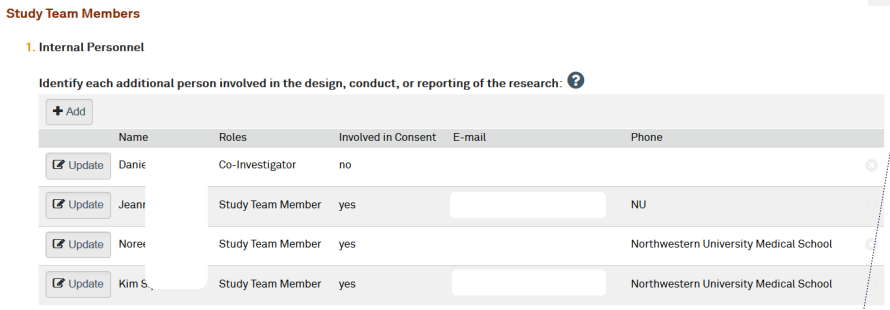
14. If the modification was for "Other Parts of the Study" then when you select **Continue** you will then be taken to the main page of the study application and allowed to navigate through to make

the necessary updates. (The screenshot used to populate this needs to be updated because this screen has an additional note on it. See pasted example below.

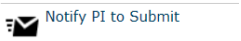




15. If the modification was for "Study Team Member Information" then you will be taken directly to that page of the study application and then you can make the necessary updates. Once completed you will select **Finish** and then will be taken to the main page of the submission.



16. 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.)



17. Type in a message to notify the PI that the submission is complete and ready to submit and select OK.
18. The submission process is complete and an email will be sent to the PI to submit.

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