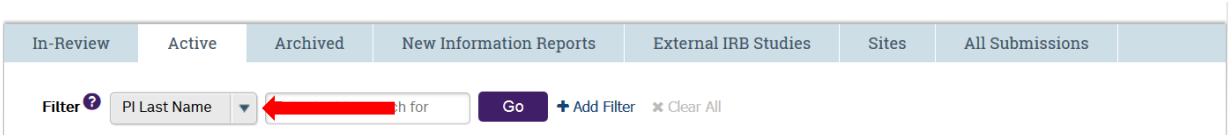
Submitting a Termination in eIRB+

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

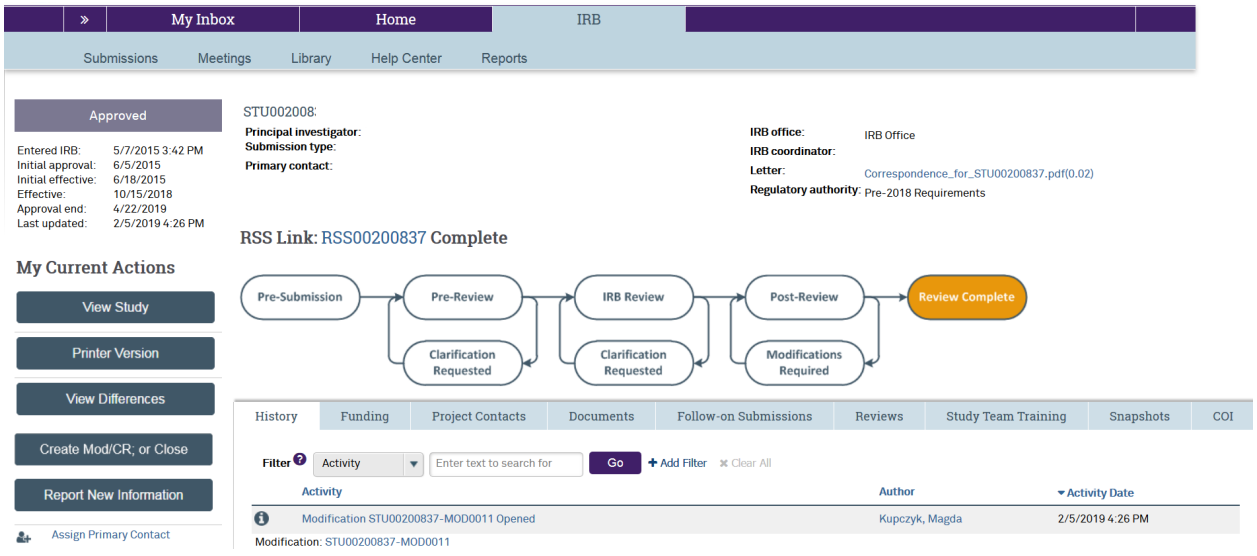
2. Once in the system you will be brought to your inbox.

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

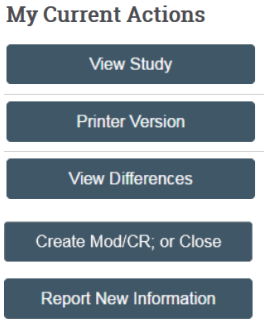


4. Once the page populates, select “Active” in the middle of the page and then filter for the study using the criteria available.

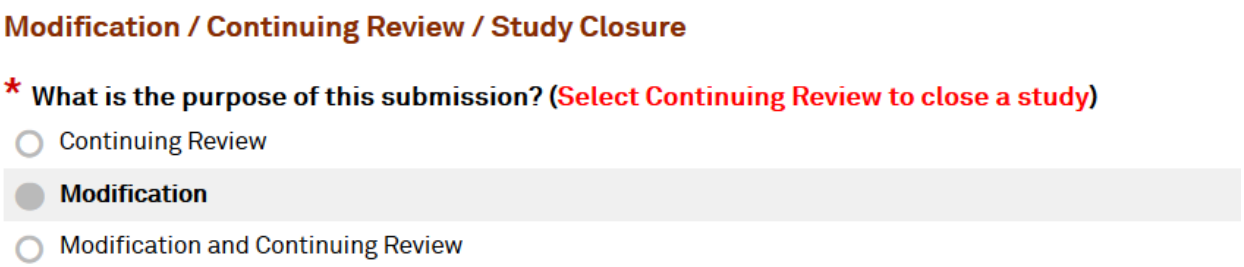
5. Once you have filtered, select the study, which will then take you to the main page of the study.



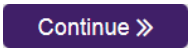
6. On the left side of the page toward the bottom select “Create Modification/CR; or Close”.



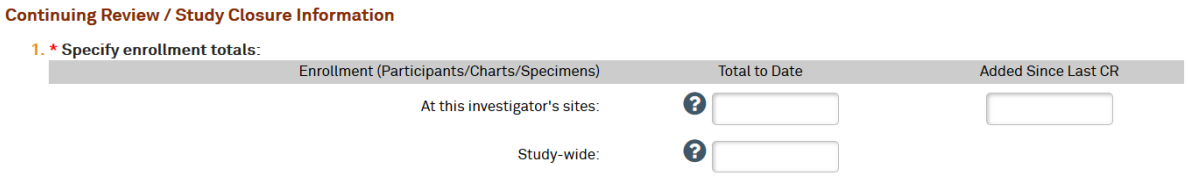
7. Once in the submission select “Continuing Review”.



8. Then select continue.



9. 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, which should be confirmed with the study coordinator. 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 also be confirmed with the study coordinator or main contact for the study. Select all that apply**. (Since this is a termination the first 4 choices should be applicable)**

2. **Research milestones**: (select all that apply)
Note: The first four checkboxes are sequential and describe the milestones of the overall study. If the first four milestones have been met and are checked, then the study will be closed.

- ☐ Study is permanently closed to enrollment OR was never open for enrollment
- ☐ All participants have completed all study-related interventions OR not applicable (e.g. study did not include interventions, no participants were enrolled)
- ☐ Collection of private identifiable information is complete OR not applicable (no participants were enrolled)
- ☐ Analysis of private identifiable information is complete OR not applicable (no participants were enrolled)
- ☐ Remaining study activities are limited to data analysis only
- ☐ Study remains active only for long-term follow-up of participants.*

* Note: Long term follow up includes research interactions that involve no more than minimal risk to subjects (e.g., quality of life surveys); and collection of follow-up data from procedures or interventions that would have been done as part of routine clinical practice to monitor a participant for disease progression or recurrence, regardless of whether the procedures or interventions are described in the research protocol. Long term follow-up excludes research interventions that would not have been performed for clinical purposes, even if the research interventions involve no more than minimal risk.

* **I acknowledge that this study will be closed:** ☑ 

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 Sponsor Close-out letters or reports, DMC letters not previously submitted, publications, etc. including any additional information about subject withdrawals.

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

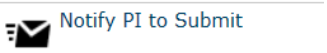
Name
There are no items to display

10. Once all the questions are completed select “Continue”.

Continue »

11. You will be taken to the Final Page of the submission and then select **Finish** and you 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. (If you have Proxy permission for the study, you will then also be able to submit.) **(Make sure that the RSS**

indicates "Completed" before notifying the PI to submit)



13. Type in a message to notify the PI that the submission is complete and ready to submit using the template language described at the end of the "COMPLETING A NEW STUDY SUBMISSION IN EIRB+" section and select **OK**.
14. The submission process is complete and an email will be sent to the PI to submit.