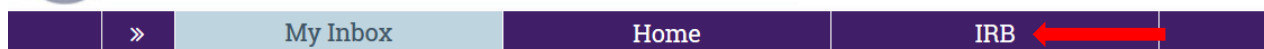


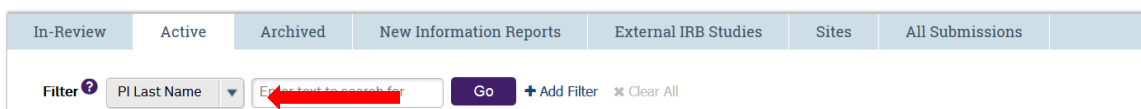
1. Go to the main page for eIRB+ and log-in.



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.

Approved

Entered IRB: 5/7/2015 3:42 PM
 Initial approval: 6/5/2015
 Initial effective: 6/19/2015
 Effective: 10/15/2018
 Approval end: 4/22/2019
 Last updated: 2/5/2019 4:26 PM

STU00200837: El352 Flamm - Intercept 747-302 (OCA)
Principal investigator: Steven Flamm
Submission type: Initial Study
Primary contact: Magda Kupczyk

IRB office: IRB Office
IRB coordinator: Michelle Brown
Letter: Correspondence_for_STU00200837.pdf(0.02)
Regulatory authority: Pre-2018 Requirements

RSS Link: RSS00200837 Complete

My Current Actions

- View Study
- Printer Version
- View Differences
- Create Mod/CR, or Close
- Report New Information
- Assign Primary Contact

Flowchart: Pre-Submission → Pre-Review → IRB Review → Post-Review → Review Complete. Clarification Requested loops back from Pre-Review, IRB Review, and Post-Review.

History: Funding, Project Contacts, Documents, Follow-on Submissions, Reviews, Study Team Training, Snapshots, COI

Filter: Activity (dropdown), Enter text to search for, Go, + Add Filter, ✕ Clear All

Activity	Author	Activity Date
Modification STU00200837-MOD0011 Opened	Kupczyk, Magda	2/5/2019 4:26 PM

Modification: STU00200837-MOD0011

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 training date is expired (in red), you will want to notify the personnel to update their CITI training and as soon as possible. CITI training is now linked to eIRB and should automatically populate in eIRB as you complete it on the CITI website. The IRB will not re-approve a study if personnel has expired training on file.

History	Funding	Project Contacts	Documents	Follow-on Submissions	Reviews	Study Team Training	Snapshots
Name	Training Type	Certification Date	Other Description/Notes				
Yasmeen Ali	CITI Biomedical Refresher	12/1/2018					
Christina Clarke	CITI Biomedical	8/10/2018					
Magda Kupczyk	CITI Biomedical Refresher	3/28/2016					
Anne Laumann	CITI Biomedical Refresher	8/31/2017					
Beatrice Nardone	CITI Biomedical Refresher	2/6/2017					
Alfred Rademaker	CITI Biomedical Refresher	7/11/2018					
Stephanie Rangel	CITI Biomedical Refresher	1/2/2019					
Lauren Sadowsky	CITI Biomedical	6/5/2018					
Bethanee Schlosser	CITI Biomedical Refresher	10/5/2014					
Catherine Stika	CITI Biomedical Refresher	5/2/2018					
Dennis West	CITI Biomedical Refresher	6/2/2017					

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

My Current Actions

View Study

Printer Version

View Differences

Create Mod/CR; or Close

Report New Information

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

Modification / Continuing Review / Study Closure

* What is the purpose of this submission? ?

- ☒ Continuing Review
☐ Modification
☐ Modification and Continuing Review

9. Then select continue.

Continue »

10. The beginning of the page states **Continuing Review/Study Closure Information** and there are 3 questions in total to respond to and then a section to upload any pertinent documents for the continuing review.

- a) **Question 1:** This question requests information for the total number of subjects enrolled at this site should be confirmed with the study coordinator. If the study is multi-site, check with the sponsor/monitor for study-wide enrollment “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.

Continuing Review / Study Closure Information

1. * Specify enrollment totals:

Enrollment (Participants/Charts/Specimens)	Total to Date	Added Since Last CR
At this investigator's sites:	<input type="text"/>	<input type="text"/>
Study-wide:	<input type="text"/>	

- 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. D
- c) Note that if you endorse “all subjects have completed all study-related interventions,” the IRB will not re-stamp the ICF(s), as they assume there is no longer a need for consenting and/or re-consenting
- a. Check with the study team to ensure that a re-stamped ICF is not needed. If the study team believes re-consent may still be necessary, this will need to be explicitly requested from the IRB

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.

- d) **Question 3:** Select all that apply 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.

- e) Under number 4 you are requested to upload any supporting documents, which may include DSMB/C 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

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

Continue »

12. You will be taken to the Final Page of the submission. Select **Finish** and you will be taken to the main page of the submission.
13. Once on the main page for the submission, you can then notify the PI to submit. (If you have submission rights for the study, you will then also be able to submit.) **(Make sure that the RSS indicates “Completed” before notifying the PI to submit)**



Notify PI to Submit

14. 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**.
15. The submission process is complete and an email will be sent to the PI to submit.