ENORY UNIVERSITY Institutional Review Board

Research Administration

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Preparing for the Transition

PI Transfers

Objectives

- Cover actions required when a PI leaves Emory
- Review non-IRB considerations
- Highlight Resources for both onboarding and departures
- Modifications to add external personnel





What are the options? It depends.

The following scenarios require action:



The research at Emory will end and the PI will continue the study at another other institution



The PI will remain engaged in research (with the other institution) after leaving Emory and the research continues locally



The PI will take the study grant with them to the new institution

Required Documentation

Signature

- If the PI is leaving Emory, the IRB requires completion of the PI <u>Transition Form</u>, which can be submitted via logged comment, email, etc.
- The form will prompt for critical details related to the departure

EMORY IRB PI TRANSITION FORM

Instructions: Only needed with a PI leaving or coming to Emory AND 1) taking or bringing IRB approved studies to/from the other instution, or 2) Will remain engaged in research (with the other institution) to be able to continue the study at Emory/Other Institution or 3) if they are taking/bringing the study grant with them. Make sure to submit this form 30 to 45 days before the PI is leaving or coming to Emory.

PI Name:	Effective Date of Move:	
Name of Institution I am Leaving:	Name of Institution I am Moving To:	

List Below The Affected Studies:

				This study will end at Emory or	My research activities after I leave Emory/Other institution
IRB Number	Study Title	Current Status of Study	Actively Federally Funded?	other institution after I leave	Emory/Other institution

PI Transition Form



When should a study be closed at Emory?

- Human Subjects Research activities have ended at Emory
- There is not a qualified co-Investigator at Emory that can assume responsibilities as the PI

Transfer PI Oversight?

- Is there a qualified investigator that has the time and expertise to assume the role at Emory?
- Investigators that move to an Adjunct Faculty position cannot remain PI on a study at Emory

Opening the Study at the New Institution (while keeping open at Emory)



Work with the Emory IRB Reliance Team to determine what, if any, steps are required for work to begin at the **new** institution.



It may be easier for Emory to take on the role of reviewing IRB for both institutions but **don't** assume!

Other Team Member Departures

 If ANY member of your study team stops being an Emory employee or student but plans to still work on the study (at Emory or their new institution) please alert the IRB analyst. The IRB will need to determine if a reliance agreement is needed.

New PI joining Emory?

- Encourage new faculty to reach out to the IRB early! A member of the Education and QA team is happy to assist them with locating <u>resources</u>, determining next steps, etc.
- If research will continue at the new PI's former institution and they want to continue the research at Emory, contact Julie Martin (Reliance Team Lead) to talk about a potential reliance agreement.

 Faculty Onboarding Guide: https://med.emory.edu/about/_files/pdfs/som_faculty_ guide_july2021.pdf



Submitting the PI-Change Modification in eIRB

- *Important* At the start of the Modification smartform, select "Other parts of the study" and not "Study team member information." This is the only way to edit the first page of the smartform, where the PI is listed.
 - If you are changing the PI and other team members, select **both** options ("Study team member information" and "Other parts of the study").
 - In the Modification summary, please indicate if any new study staff are NOT affiliated with Emory.
- Remember: also update the PI name in **protocol**, and (*if applicable*) the consent form(s).



IMPORTANT!

- If you need to add an unaffiliated person under "Local" study team members, using a sponsored account, <u>alert the analyst</u>.
 - Note it in the Modification summary and log a comment in the Modification History.
 - An unaffiliated team member *may* require a reliance agreement.



Emory IRB's role in the process

- Our staff will communicate internally when a PI modification is submitted for the first study.
- Having the details from the PI transition form avoids redundant requests for information and streamlines the review process.
- If additional action is required based on details provided in the PI transition form, IRB staff will be in contact.

Non-IRB Considerations

- Data Use Agreements (DUA) or Material Transfer Agreements (MTA) may be required:
 - Reach out to Office of Technology Transfer, or may be handled automatically by OSP if there will be a subaward or grant transfer
- Award <u>Close-outs</u> and/or <u>transfers</u>:

- Reach out to the Office of Sponsored Programs to determine what is needed
- Central <u>guidance</u> for faculty leaving Emory.
 - Work with your Department to determine whether any additional action is required, beyond what is detailed above.

Contact Us

- General Inquiries: IRB@emory.edu
- Study-specific inquiries: You may contact <u>your study analyst</u> directly.

