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New Streamlined Process to Add External Collaborators & Other Updates

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Topics to Discuss

- When will Emory provide oversight for external collaborators?
- What is the process for adding external collaborators?
- Important reminders and updates
- Review of information on our website
Who are external collaborators?

- Researchers **not affiliated with Emory, CHOA, or Grady** who conduct any portion of the Emory protocol

- Does not include external collaborators who are conducting their own secondary data analysis
When may Emory provide review for an external collaborator?

- The collaborator is engaged in human subjects research
- The research is not exempt
- The study is federally funded and use of a single IRB is required
- The collaborator is not from an institution with an IRB
- The collaborator is from an Atlanta CTSA institution with who we have an overarching agreement for IRB reliance.

Contact IRB.reliance@emory.edu for other scenarios
External collaborators should not be added to a protocol so they can do a secondary analysis of the study data/specimens.
This would require a new submission!
What should be in the protocol?

- External collaborators (other than students working on the study over the summer) should be listed on the cover page of the protocol along with a description of who is serving as the reviewing IRB.

  **Example:** “Emory will serve as the reviewing IRB for this collaborator.” or “This collaborator’s local IRB will review.”

- Add detail to the multi-site research section of the protocol that describes what the external collaborators are doing. (Except for summer students assisting with the study for experience.)
How to Add an External Collaborator

1. Review the guidance on the Collaborative Research Page of the IRB website.
2. Determine if the collaborator is engaged in HSR – use our Engagement Determination Checklist.
3. Send an email to irb.reliance@emory.edu with the information requested on our website.
4. The reliance team will respond to your email with questions and will provide the reliance documents once completed.
5. Once you receive the reliance documents, submit a modification and upload the reliance documents in the external team member section.
Important Points to Remember

► Once reliance is executed, we need updated documentation from the local IRB (if any) each time further external staff are added.

► If a collaborator is affiliated with another institution, please DO NOT get an Emory sponsored account to add as Emory study staff in our smartform. They must be added under “External Team Member Information.”

Of note: The IRB now searches the Emory online directory for all staff additions to try to catch these situations.
Reminders for External IRB Submissions

- Always review the guidance posted on our website
- Use the documents posted on our website
- Confirm the following before you submit to the Emory IRB
  - You have provided all of the required documents
  - there are NO changes to Emory’s required language in the ICF (injury option in eCTS, cost option 2 as default)
  - All study team members have current CITI training for the study
  - All ancillary reviews are completed and documentation is uploaded

- If any of the submission requirements are not met, we will withdraw the study so you can continue to work on it. Do not submit back until ALL requirements are met.
- Do not submit to the reviewing IRB until the Emory IRB issues signoff!!
Updates

- We will be updating the external consent checklist and our consent form templates posted on our website.
- Injury options are changing to just two:
  - industry funded studies
  - non-industry funded studies
- Cost options are changing to just two:
  - If the study has billables, use option 2 as a default
  - If OCR determines option 3 is correct, provide documentation
Planning on Submitting a Federal Grant?

If the study will include researchers from other institutions, please reach out to the reliance team early in the planning process at irb.reliance@emory.edu.

The Emory IRB charges for single IRB review. You may need to include fees in your budget.

Are you submitting an SBIR/STTR grant? Reach out to the reliance team early in the process to discuss.

The Emory IRB has a choice about whether to serve as the reviewing IRB for multi-site research. Please do not assume we will be the reviewing IRB without discussing with the reliance team.
Tour of the Collaborative Research section of the Emory IRB website:

- Guidance for adding external collaborators
- External IRB submission requirements
- Emory as the sIRB
Thank you!
Any Questions?

IRB.reliance@emory.edu