



# EMORY UNIVERSITY

## Institutional Review Board

### Research Administration

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# Adding External Collaborators to Emory IRB Submissions

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# Topics to Discuss

- ▶ Who are external collaborators?
- ▶ When will Emory provide oversight for external collaborators?
- ▶ What is the process for adding external collaborators?
- ▶ Important points to remember

# Who are external collaborators?

Researchers **not affiliated with Emory** who conduct any portion of the Emory protocol such as:

- analyzing identifiable samples/data
- obtaining consent
- conducting interventions/procedures
- collecting data
- is prime awardee of a federal grant

<https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-engagement-of-institutions/index.html>



# 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](mailto:IRB.reliance@emory.edu) for other scenarios

# How may Emory provide review for an external collaborator?

An  
institutional  
reliance  
agreement

For institutions that will receive a federal subaward or who routinely conduct research

An  
individual  
investigator  
agreement

For researchers not affiliated with any institution, or whose institutions does not routinely conduct research (e.g., an independent consultant or a community health clinic)

## Special Note

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 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.”

- ▶ Other areas may need to reflect the external collaboration, especially if non-Emory sites are involved.



# How to Add an External Collaborator

Complete the *External Team Member List* found at [https://irb.emory.edu/\\_includes/documents/sections/external-study-team-member-list-template.docx](https://irb.emory.edu/_includes/documents/sections/external-study-team-member-list-template.docx)

Create a MOD selecting a scope of "Study Staff" (also check "Other Parts of the Study" if smartform or document revisions needed)

Upload the completed *External Team Member List* under "Local Study Staff," Question #2, "External Team Member Information"

If the collaborator does not have a local IRB, ensure they complete any necessary Emory CITI training and upload the certificates.

# External Team Member List

Name	Name of Institution/Or ganization	Status at Institution (Faculty, Student, etc.)	Role on Study (Co-Investigator, Study Coordinator, Data Entry, etc.)	Email Address	Financial Interest? * (Y/N)	<p><b>Specific research activities conducted by this person:</b></p> <ul style="list-style-type: none"> <li>• Prime awardee of federal grant or contract</li> <li>• Obtains informed consent</li> <li>• Conducts research interventions/procedures with participants (includes surveys, interviews, manipulating environment and observing or recording private behavior)</li> <li>• Has access to/analyzes identifiable data</li> <li>• Performs protocol specific services that merit professional recognition, publication privileges</li> </ul>

# Important Points to Remember

- ▶ If your collaborator is affiliated with a research institution, they must reach out to their local IRB to see if they require a local submission.

At Emory, we require an “XIRB” submission for administrative review when Emory staff is engaged in a collaborative study under another IRB’s review.

- ▶ If unsure whether your collaborator is “engaged” in human subjects research, their local IRB must make the determination (if no local IRB, Emory IRB will determine).

# Important Points to Remember

- ▶ Please be very clear and exact about the research activities of your collaborator in the External Team Member List.

The more information we have, the easier the process will flow.

- ▶ Data identifiability is based on the 18 HIPAA identifiers. If any of the 18 HIPAA identifiers are included, the data is treated as potentially identifiable.

For example, all elements of date except year alone make data identifiable.

# 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.

Thank you!  
Any Questions?

[IRB.reliance@emory.edu](mailto:IRB.reliance@emory.edu)

