

# Reliance Process – What will change, what won't after Insight

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# Agenda

- ▶ What will change after Insight?
- ▶ What will stay the same?
- ▶ What are the External IRB requirements?



# What will change?

- External IRB studies will need to be submitted using a Cede Protocol type.
- There will not be logged comments in Insight.
- When you receive approval from the external IRB, you will email the approval letter and stamped consent forms to the reliance team instead of attach them in a logged comment.
- There will not be “pSites” in Insight for relying sites that will enroll participants. Documents for participating sites will go in their attachments section.



# What will stay the same?

- ▶ If you are submitting a federal grant that will fund multiple sites to conduct human subjects research, you still need to meet with the reliance team to discuss whether Emory can serve as the single IRB.
- ▶ You will need to include single IRB fees in your budget submitted with your grant.
- ▶ The guidance for when Emory will be the single IRB, when Emory will review for external collaborators and what is needed for external IRB submissions will all stay the same.



# Adding External Collaborators



# Website Guidance

<https://irb.emory.edu/guidance/research-types/collaborative.html>

The screenshot shows the Emory University IRB website. The navigation bar at the top includes links for ABOUT, GUIDANCE (highlighted with a red box), FORMS AND TEMPLATES, RESOURCES, MEMBERS, and PARTICIPANTS. The main content area is titled "Guidance" and includes a description: "Access current guidelines, policies, and other information needed to complete your tasks and projects." Below this is a "BROWSE GUIDANCE" section. To the right, there are four columns of links. The first column, "Reportable Information", includes "Getting Started" with links like "Does My Project Need IRB Review?", "IRB Review Types", "Study Submission Guidance", "eIRB Page-level Help", "Consent Toolkit", and "Participant Facing Materials". The second column, "Revised Common Rule", includes "Research Types" with links like "Clinical Trial Studies", "Collaborative Research/Single IRBs/Reliance Agreements" (highlighted with a red box), "Food and Drug Administration", "International Research", "Sponsor Investigator Studies", and "Sociobehavioral Research/Minimal Risk Studies". The third column, "COVID-19", includes "Other Guidance" with links like "Treating a Patient", "FDA Unapproved Device", "Federal Policy", "Protection of Human Subjects (Common Rule)", "Office for Human Research Protections (OHRP)", "Health Insurance Portability and Accountability Act (HIPAA)", and "US Department of Health and Human Services (HHS)".

**Guidance**

Access current guidelines, policies, and other information needed to complete your tasks and projects.

**BROWSE GUIDANCE**

**Reportable Information**

**Getting Started**

- Does My Project Need IRB Review?
- IRB Review Types
- Study Submission Guidance
- eIRB Page-level Help
- Consent Toolkit
- Participant Facing Materials

**Revised Common Rule**

**Research Types**

- Clinical Trial Studies
- Collaborative Research/Single IRBs/Reliance Agreements
- Food and Drug Administration
- International Research
- Sponsor Investigator Studies
- Sociobehavioral Research/Minimal Risk Studies

**COVID-19**

**Other Guidance**

- Treating a Patient
- FDA Unapproved Device
- Federal Policy
- Protection of Human Subjects (Common Rule)
- Office for Human Research Protections (OHRP)
- Health Insurance Portability and Accountability Act (HIPAA)
- US Department of Health and Human Services (HHS)

# 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 CTSI institution with who we have an overarching agreement for IRB reliance.

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



## Special Note

External collaborators cannot be added to a protocol so they can do a secondary analysis of the study data/specimens.

**Secondary data analysis requires a new submission!**



# How to Add External Collaborators

Complete Engagement Guidance Checklist found at  
[https://irb.emory.edu/\\_includes/documents/sections/guidance-engagement-determination-checklist.docx](https://irb.emory.edu/_includes/documents/sections/guidance-engagement-determination-checklist.docx)

If engaged in HSR, complete the External Study Team Member list and email to [IRB.reliance@emory.edu](mailto:IRB.reliance@emory.edu) along with the following information

- Name of external collaborator and home institution (if applicable)
- Description of specific research activities
- Time period that external collaborator is expected to conduct research
- Link to the study in eIRB
- Copy the analyst assigned to your study



# What Happens Next?

- ▶ An IRB Reliance Specialist will review the information and determine what type of reliance, if any, is required and contact you with any questions
- ▶ A reliance packet will be created and sent to the appropriate entity, either the institution or the individual (if no IRB is available)
- ▶ Please note, your collaborator needs to reach out to their home institution to see what steps are needed on that end for reliance to be completed
- ▶ The Reliance Analyst will email you with the completed documents and instructions to now submit a MOD to add the external collaborator



# When will Emory review for external “sites”?

- ▶ When Emory is the prime awardee of a federal grant
- ▶ When there are 5 or less domestic sites enrolling participants
- ▶ When the Emory PI has a strong coordinator or project manager who can facilitate the communication and onboarding of sites in a timely manner.
- ▶ When the PI has budgeted for single IRB fees.



# Review of the sIRB Process



The PI meets with reliance team when planning federal grant that will fund a multi-site research study



Once the study team receives the NOA, they submit to the Emory IRB.



The Emory IRB reviews the protocol and all study-wide documents including any site-specific materials for Emory including the consent.



All sites will insert their institution's language for cost, in case of injury, etc. into the approved master consent form.



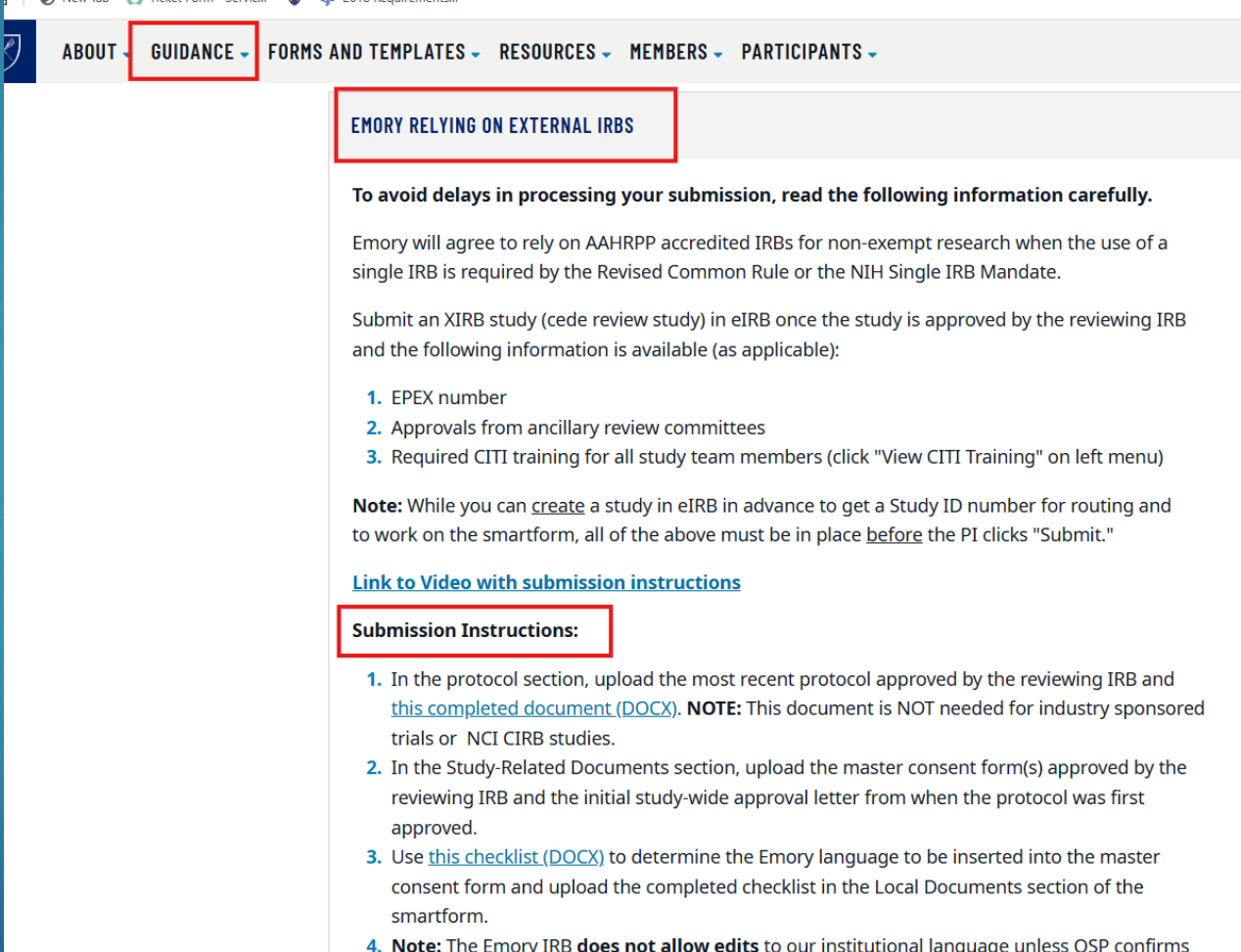
Participating sites are submitted to the Emory IRB as they complete the reliance documents and their site-specific consents.



# External IRB Process



# Submission Instructions - <https://irb.emory.edu/guidance/research-types/collaborative.html>



The screenshot displays the Emory IRB website's navigation and content. The top navigation bar includes links for ABOUT, GUIDANCE, FORMS AND TEMPLATES, RESOURCES, MEMBERS, and PARTICIPANTS. The GUIDANCE link is highlighted with a red box. Below the navigation bar, a sub-header 'EMORY RELYING ON EXTERNAL IRBS' is also highlighted with a red box. The main content area provides instructions on how to submit a study for review, including a list of required documents and a link to a video with submission instructions. A red box highlights the 'Submission Instructions:' section, which contains a numbered list of steps for submitting a study.

ABOUT GUIDANCE FORMS AND TEMPLATES RESOURCES MEMBERS PARTICIPANTS

## EMORY RELYING ON EXTERNAL IRBS

**To avoid delays in processing your submission, read the following information carefully.**

Emory will agree to rely on AAHRPP accredited IRBs for non-exempt research when the use of a single IRB is required by the Revised Common Rule or the NIH Single IRB Mandate.

Submit an XIRB study (cede review study) in eIRB once the study is approved by the reviewing IRB and the following information is available (as applicable):

1. EPEX number
2. Approvals from ancillary review committees
3. Required CITI training for all study team members (click "View CITI Training" on left menu)

**Note:** While you can create a study in eIRB in advance to get a Study ID number for routing and to work on the smartform, all of the above must be in place before the PI clicks "Submit."

[Link to Video with submission instructions](#)

### Submission Instructions:

1. In the protocol section, upload the most recent protocol approved by the reviewing IRB and [this completed document \(DOCX\)](#). **NOTE:** This document is NOT needed for industry sponsored trials or NCI CIRB studies.
2. In the Study-Related Documents section, upload the master consent form(s) approved by the reviewing IRB and the initial study-wide approval letter from when the protocol was first approved.
3. Use [this checklist \(DOCX\)](#) to determine the Emory language to be inserted into the master consent form and upload the completed checklist in the Local Documents section of the smartform.
4. **Note:** The Emory IRB **does not allow edits** to our institutional language unless OSP confirms



# Emory's Local Context Review



## Review

We review the submission, documents, confirm all institutional requirements are met



## Institutional Signoff


We issue institutional signoff



## Submit to External IRB

You may submit to the reviewing IRB



- 
- ▶ Emory's cost, in case of injury, HIPAA language **REPLACE** sponsor's language in approved master consent forms
  - ▶ Emory's cost and in case of injury options are determined by other departments, given to Emory IRB

Sponsors  
May Not  
Edit  
Emory's  
Language



# Institutional Sign-Off

Once local context review is complete,  
we sign the reliance document.

We issue institutional sign off

The study team submits to sIRB (w/ICFs,  
LCR form, external consent checklist)

# After You Have IRB Approval

Provide the approval letter and approved consent forms to the reliance team

We will update the status of the study

Review website for latest requirements for submitting CRs, Modifications, RNIs



# Thank you!

## Questions?

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

IRB Webinar Feedback Survey

