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

JULIE T. MARTIN, RN, MED, CIP

ASSISTANT DIRECTOR, EMORY UNIVERSITY IRB

BETH POPLASKI, CIP

SR. RELIANCE RESEARCH PROTOCOL ANALYST

Agenda

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

What will change?

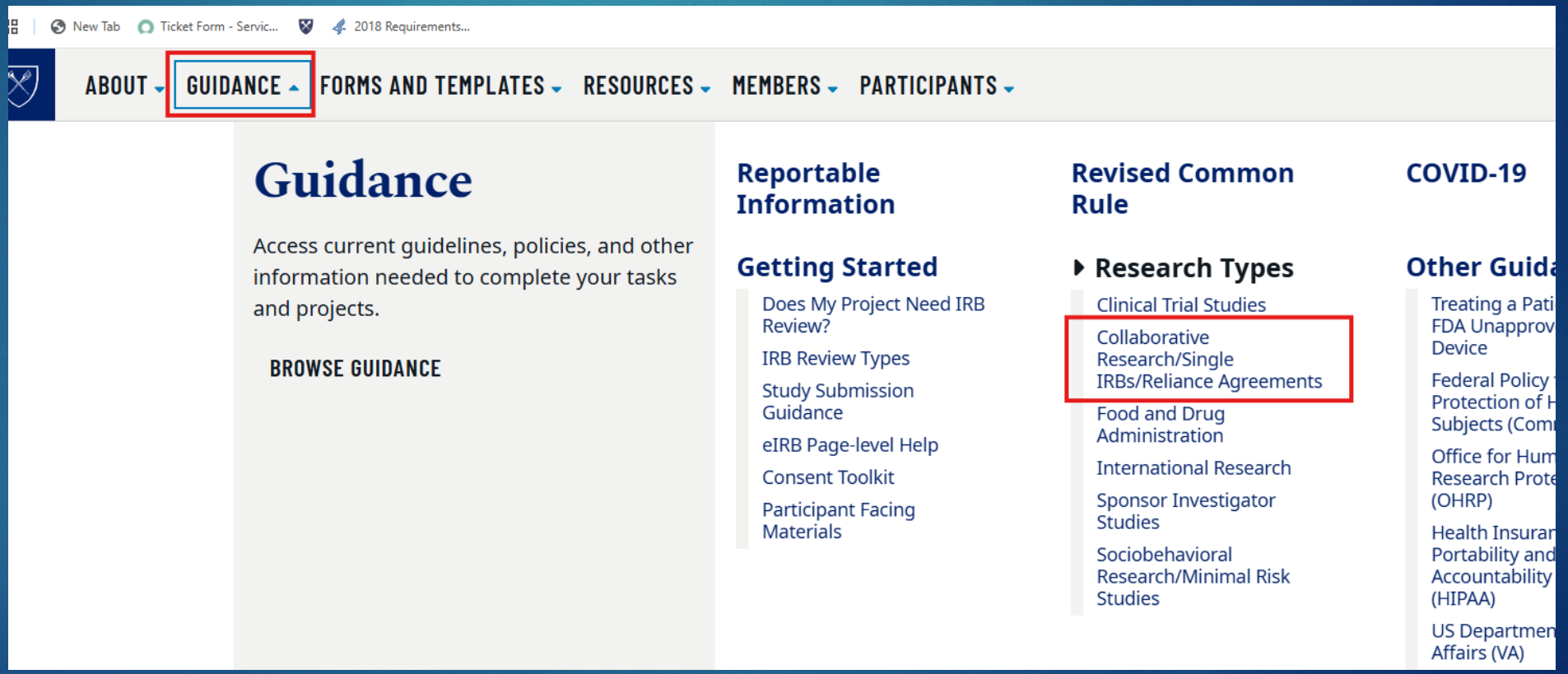
- External IRB studies will need to be submitted using a Cede Protocol type.
- There will not be logged comments in Insight.
- When you receive approval from the external IRB, you will email the approval letter and stamped consent forms to the reliance team instead of attach them in a logged comment.
- 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



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 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

If engaged in HSR, complete the External Study Team Member list and email to 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.

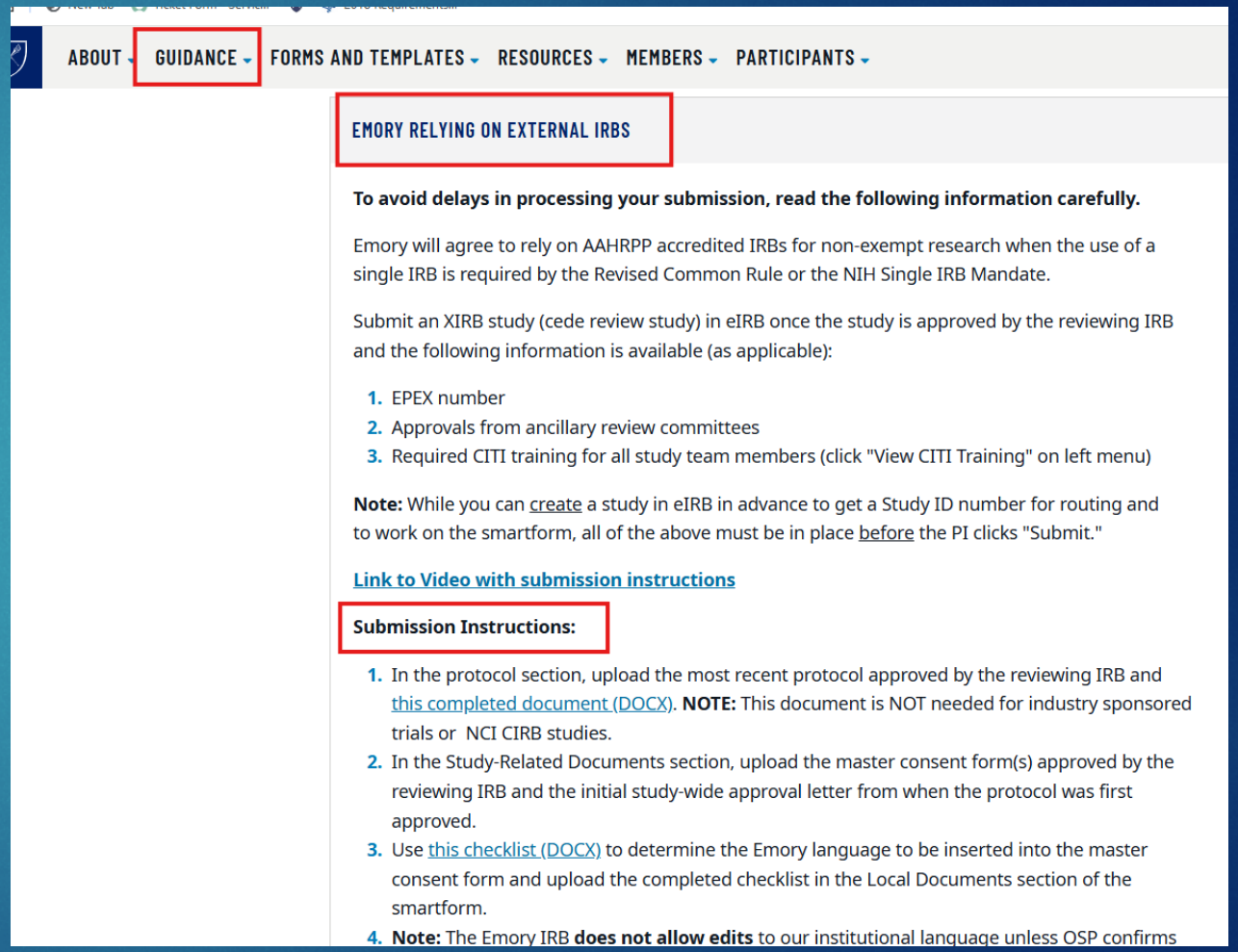
The Emory IRB reviews the protocol and all study-wide documents including any site-specific materials for Emory including the consent.

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



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

Sponsors May Not Edit Emory's Language

- 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

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

IRB Webinar Feedback Survey