



EMORY UNIVERSITY

Institutional Review Board

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Plan for Emory as the Single IRB and External IRB Requirements

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Topics for Today

- ▶ What is a Single IRB?
- ▶ Why is Reliance Required?
- ▶ What Has The Emory IRB Been Doing So Far?
- ▶ What Will Change?
- ▶ External Collaborators
- ▶ What is Needed for External IRB Submissions?
- ▶ How to Handle Sponsor Changes to ICFs



Plan for Emory to
be the sIRB

What is an sIRB?

A single IRB is the IRB that provides oversight for all participating sites within the U.S. that are engaged in non-exempt human subjects research.

At Emory, we use this term when the Emory IRB is the reviewing IRB for other sites that will enroll participants and have their own consent forms.

Why do we Have Reliance?

- ▶ The goals of using a single IRB for multi-site research are:
 - ❖ To streamline the ethical review of research
 - ❖ Have consistency amongst sites
 - ❖ Allow the sIRB to see ALL reportable events occurring in the study


Regulatory Requirements for sIRB

NIH Single IRB Mandate

- January 25, 2018
- NIH-funded Multi-site studies conducting same protocol
- Only U.S. sites
- Does **not** apply to career development, research training or fellowship awards
- Applies even to non-NIH funded studies if the NIH is a site

Cooperative Research Component of Revised Common Rule

1. January 20, 2020
2. Federally-funded cooperative research studies involving more than one institution
3. Only U.S. sites
4. Does **not** apply to studies that have been approved by any IRB prior to January 20, 2020 or where funding agency determined sIRB not appropriate



FDA Requirement is Coming

- ▶ In September 2022, the FDA announced their proposal to require use of a single IRB for FDA-regulated cooperative research conducted in the U.S.
- ▶ This will expand the single IRB requirement to pharma studies that are currently not subject to the other two requirements.

What Have We Been Doing?

- ▶ Emory has been providing oversight to external collaborators who are working with an Emory study team at a partner site or performing just a portion of the research such as data analysis.
- ▶ We have served as an sIRB on a very limited basis for a few studies that had just a few external sites.



What Will Change?

- ▶ **We don't have all details finalized**, still looking at best way to recover fees to do this work, as it increases administrative burden.
- ▶ Planning to serve as an sIRB for
 - Multi-site studies where use of an sIRB is required
 - Emory PI is lead PI
 - U.S. sites only
 - 5 or less sites

Once Plans are Finalized...

- ▶ We will communicate it to the Emory research community
- ▶ Will conduct webinars to provide guidance/education
- ▶ Post sIRB guidance and materials on our website

External Collaborators

To prevent delays...

- ▶ Notify external collaborators to contact their IRBs early
 - ❖ Does their local IRB consider them engaged in human subjects research?
 - ❖ What do they need to do to request reliance?
- ▶ Complete the External Study Team Member template, upload in external study team member section of smart form
- ▶ Include in the protocol a description of the external collaborator's role in the research
- ▶ Do Not add external collaborators to local study team member section- Disregard this text in eIRB "this may include non-Emory persons with sponsored eIRB accounts."

External IRB Process

Emory's Local Context Review



Review

We review smart form, documents, confirm all institutional requirements are met



Institutional Signoff

We issue institutional signoff



Submit to External IRB

You may submit to the reviewing IRB

November 2021 - New Streamlined External IRB Process

- ▶ Submit to Emory once everything is in place
 - ▶ EPEX number
 - ▶ Confirmation of in case of injury option
 - ▶ Study-wide approval letter, approved master consent
 - ▶ Approvals from Ancillary Reviews (radiation, biosafety, COI, etc.)
 - ▶ Current CITI training for all study team members
- ▶ Blasted by IRB and webinar in November 2021

Include in the Submission:

1. Study-wide approval letter, most recent approved protocol and master ICFs
2. For studies NOT going to WCG or Advarra- this completed document
3. External IRB Consent Checklist - mark applicable language, use default cost option 2
4. Emory's site-specific consent(s) –(Create by inserting required language into the approved master consent form(s) using **TRACKED CHANGES**).

- ▶ 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

Log a comment with the sIRB approval letter and approved consent forms for your site

We will move the study to an active state

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

Thank you!

Questions?

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