When Emory Relies on External IRBs

WHAT YOU NEED TO KNOW

JULIE T. MARTIN, RN, MED, CIP

ASSISTANT DIRECTOR, EMORY UNIVERSITY IRB

November 2021 - New Streamlined External IRB Process

▶ Submit to Emory once everything is in place
  ▶ EPEX number
  ▶ Confirmation of cost and in case of injury options
  ▶ Study-wide approval letter and approved master consent from reviewing IRB
  ▶ Completed external IRB consent checklist and Emory's tracked consents
  ▶ Approvals from Ancillary Reviews (radiation, biosafety, COI, etc.)
  ▶ Current CITI training for all study team members

▶ Blasted by IRB and webinar in November 2021

Why the change?

- External IRB submissions were in eIRB in some cases for up to a year while…
  - Information became outdated (master consent forms, Emory language inserted into consents, CITI training, etc.)
  - There was inefficient use of resources to keep following up on pending items

What do I need for my Emory IRB Submission?

- ▶ Always review current guidance on website
- ▶ Include the following (as applicable to the study):
  - ▶ Study-wide approval letter and **CURRENT** approved master consent from reviewing IRB
  - ▶ Completed Form A (WCG or Advarra) **or** Supplement to Protocol (all other IRBs)
  - ▶ Documentation of Cost and In Case of Injury options
  - ▶ Documentation of completed ancillary reviews (PRMC, radiation and biosafety, COI, etc.)
  - ▶ Completed external IRB consent checklist (use version posted on IRB website)
  - ▶ Emory-specific consent form with tracked changes (based on master consent)

Emory's Local Context Review

Review

We review smart form and documents only to 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 and In Case of Injury options **REPLACE** sponsor's language that is in approved master consent forms

- Emory's Cost and In Case of Injury options are determined by other departments, given to Emory IRB

- Emory's options are consistent with executed clinical trial agreements and reimbursement analysis

Sponsors May Not Edit Emory's Language

Submit these to the Reviewing IRB:

The consent forms reviewed by Emory IRB

The external IRB consent checklist reviewed by the Emory IRB

Documentation of Emory's Institutional Signoff

After You Have External IRB Approval

Log a comment with the external IRB approval letter for your site

Include approved, stamped consent forms

We will move the study to an "Active" state

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

Questions You Might Be Asking

Q: If I must wait to submit in eIRB until cost and In Case of Injury options are confirmed, won't that delay my approval?

A: No, you cannot begin research without an executed contract or confirmation of these options. Correct language is needed in your consent form.

Q: If the sponsor is using Advarra, can I still submit to WCG IRB?

A: No. Use the IRB the sponsor is using for other sites. Include the study-wide approval letter and approved master consent in eIRB.

Q: What if the sponsor wants to review the consent forms before I submit to the reviewing IRB?

A: You can route the consent forms to the sponsor as a courtesy once you have inserted Emory's language (per the external IRB consent checklist), with the understanding that sponsors may not edit our institutional language. You should not route to sponsor AFTER we issue signoff.

Q: If I must wait for institutional signoff before I submit to the reviewing IRB, won't that delay my approval?

A: No. The reviewing IRB would need to wait for our sign-off before approving your site regardless. You can submit to the reviewing IRB as soon as you receive signoff. Your consent forms will not need to be sent back to us for further review and there is no post-approval hold.

Don't Forget

Review current guidance on our website before submitting

If the submission includes everything outlined on our website, we should be able to issue signoff quickly

We strive to improve efficiency and processes and welcome your feedback

Thank you!
Any Questions?