Emory IRB Single IRB (sIRB)Plan and Process

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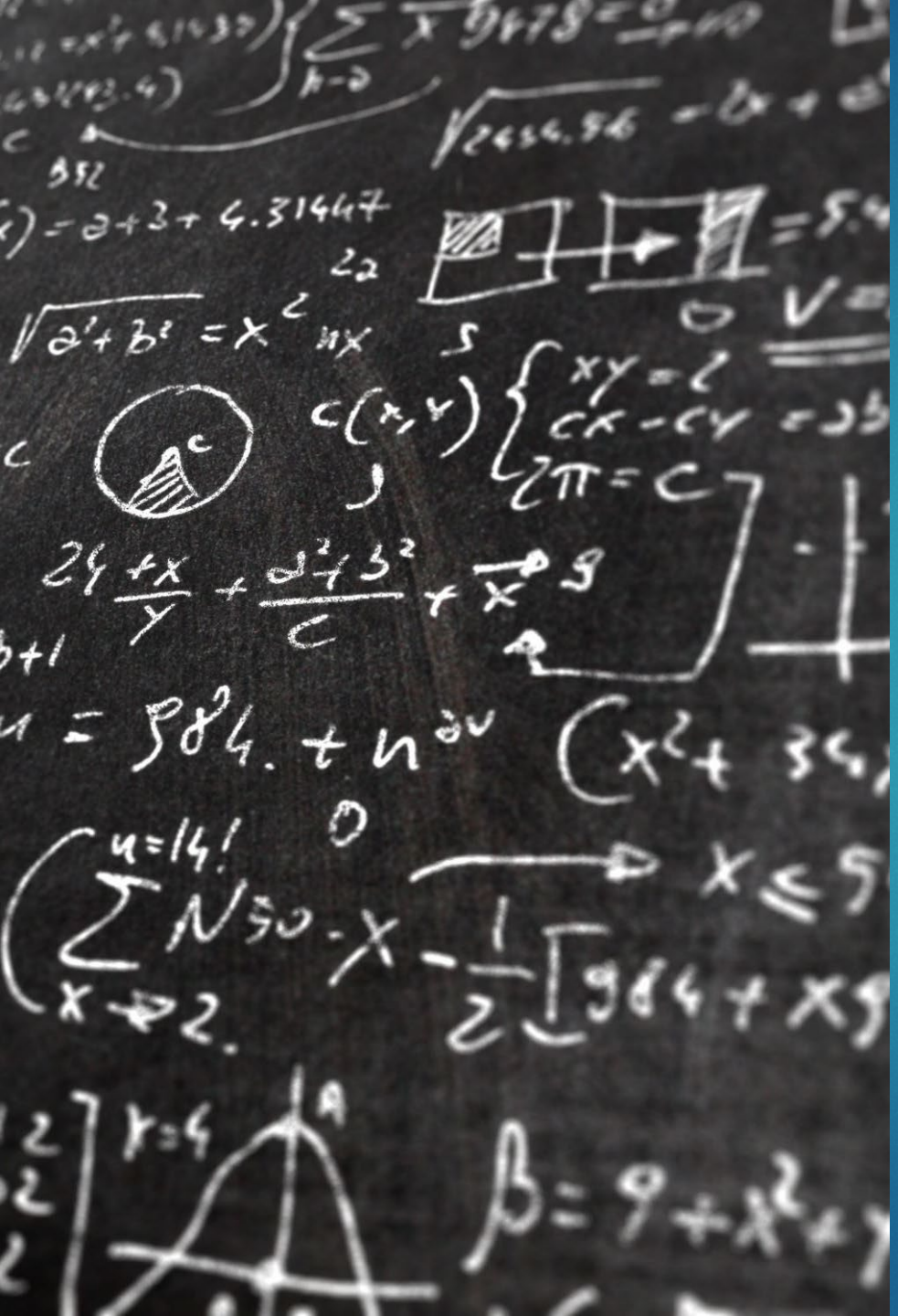
Agenda

- What is a Single IRB (sIRB)?
- Why is Reliance Required?
- Challenges/Solutions
- What is Process When Emory is the sIRB?
- What is Local Context?



What is an sIRB?

- A single IRB is the IRB that provides oversight for all of the 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 (materials, determinations)
  - 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
- Applies to non-NIH funded studies if the NIH is a site

Cooperative Research Component of Revised Common Rule

- January 20, 2020
- Federally-funded cooperative research studies involving more than one institution
- Only U.S. sites
- 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.

Challenges and Solutions

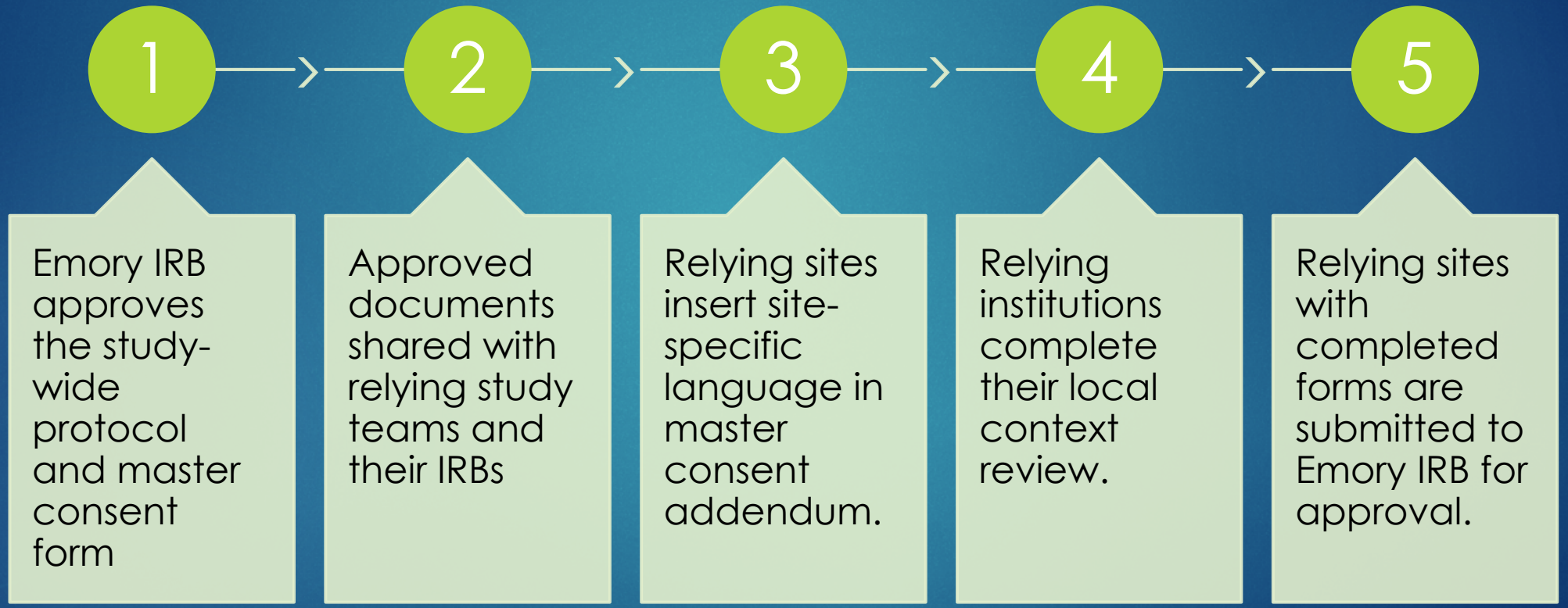
- Historically, reliance agreements took months to execute
- IRBs have varying degrees of experience with reliance
- NIH no longer requires sIRB plan w/grant applications

- SMART IRB Master Agreement
- SMART IRB Harmonization Efforts, Webinars

Emory IRB as an sIRB

- Multi-site studies where use of an sIRB is required
- Emory PI is lead PI/prime awardee
- U.S. sites only
- 5 or less sites

Reliance Process



Step 1: Consult with Reliance Team

- If applying for a federal grant and want Emory to serve as the sIRB, contact the reliance team early.
- Whether Emory or another IRB is the sIRB, be sure to add sIRB review fees to the grant budget.
- Provide complete information about the procedures that will be conducted and the sties that will participate in the study.
- Send email to irb.reliance@emory.edu to request to meet with the reliance team to review the specifics of the study and sites.

Step 2: Submit to the Emory IRB

- Emory study team will submit study-wide materials to the Emory IRB for approval (as applicable to the study)
  - Protocol
  - Master consent form(s)
  - Investigator Brochure
  - Surveys/questionnaires
  - Recruitment materials

Step 3: Addition of Sites

The Emory study team provides instructions to relying sites. Relying sites will need to submit to their local IRBs to request reliance, so they will need to begin the process as soon as they are provided the Emory IRB approval documents.

It is the responsibility of the Emory study team to follow up with relying sites for completion of the required documents. (site-specific consent form addendum, reliance document, local context review form)

Once all of the required documents are completed for each pSite, the pSite submission is reviewed by the Emory IRB.

What does the IRB need to consider when approving a pSite?

- Do all study team members have current CITI training?
- Do any have COIs? If yes, is there a management plan?
- Does consent include site's required language (e.g. cost, in case of injury, HIPAA authorization as applicable)?
- Does relying institution have any concerns about study?
- Is there info from ancillary reviews to consider?
- Are there local laws or institutional policies applicable to the research?

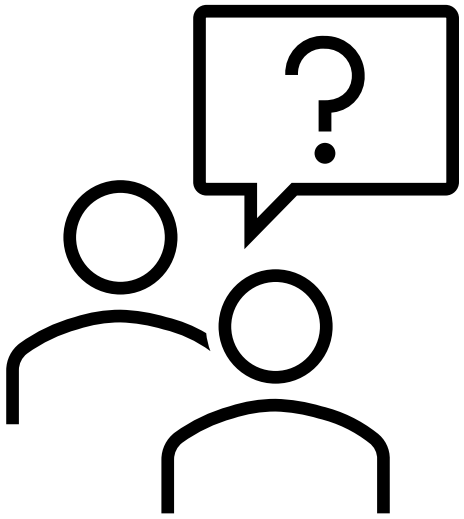
Post-Approval

Once the site's documents have been reviewed, the pSite can be approved.

Each pSite receives an IRB approval letter and stamped consent form.

The Emory study team is responsible for submitting CRs, modifications and RNIs to the Emory IRB on behalf of all study teams

Study staff changes will be tracked by the local IRBs.



Question?

Irb.reliance@emory.edu