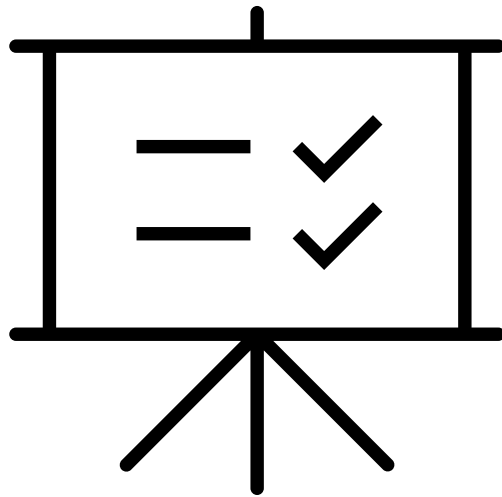


IRB Updates

- ASK RCRA - 5/12/2026
- REBECCA ROUSSELLE, BA, CIP AND SHARA KARLEBACH, WHNP-BC, CIP

Agenda



- Brief Overview of the Emory IRB Role
- Other Events
- Single IRB/Reliance
- Review of Guidance
- Tips for a timely review
- Research Navigation Resources

The IRB Committees & Staff



Biomedical Committee: 5 panels, convenes weekly

Sociobehavioral: 1 panel, convenes infrequently

Dedicated SAE/UP/Non-Compliance panel: meets monthly

Around 80 members

Around 22 full-time staff

Regulations: “Common Rule”

The regulations that govern all *federally-funded* human subjects research

Main elements:

- Definitions: Define IRB’s scope
- Informed consent
- IRB approval criteria and process

Emory incorporates Common Rule into Policies for *all* research

Regulations: FDA

Applicable to *FDA-regulated clinical investigations*

Definitions and scope differ from Common Rule

- **Even deidentified specimens** are “human subjects”
- No exemptions
- Differences between Drugs and Devices



Compliance Activities

Other Events: The IRB is tasked with reviewing “Other Events” reported on Human Research projects. These events can include safety and/or compliance matters.

Not-for-cause reviews: The IRB take steps to proactively review projects after approval. This can include record reviews on site or remote assessments. This is not meant to be punitive but more of an opportunity to see how the study is progressing.

For-cause reviews: If there are concerns about the conduct of a study, the IRB will conduct a review to assess compliance and corroborate concerns. This can also include CAPA monitoring, which may also be done in collaboration with Clinical Trials Audit and Compliance.

Collaborative Compliance

RCRA & EMORY IRB JOINT AUDITS

Typically, these are done for the following:

- Problems involving both potential human subject noncompliance and research misconduct.
- Complex cases that need interpretation of overlapping rules.

EMORY IRB AND OTHER GROUPS

- Children's Healthcare of Atlanta
- Atlanta VAMC
- Institutions under Reliance

IRB Compliance Reminders

If you are alerted to an FDA inspection, tell the IRB along with the following:

- Principal Investigator (PI)/Research Coordinator
- Sponsor
- The Research Integrity Office at researchcompliance@emory.edu.

* Notify RCRA immediately if the reason for the inspection is "directed" (i.e., for cause), or an FDA Inspector arrives at your site unannounced. See additional guidance, [here](#).

Secure your sensitive data! Please only store and/or share using [vetted platforms](#) as approved by the IRB. Also, if someone leaves the study team, remove their access!

Single IRB Requirements

Required for certain multisite studies

Emory uses commercial IRBs for most *industry-sponsored multisite trials*

Use of single IRB *required* for federally-funded multisite studies

Take-home message: Use our website, and plan ahead with the IRB

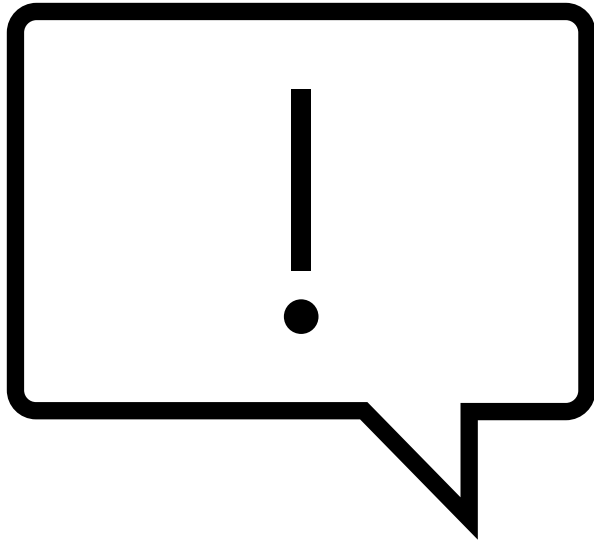
Reliance Process

Don't submit to the reviewing IRB until Emory IRB issues signoff



Anytime Emory will collaborate with someone external to Emory (including a small business) **talk to us before** submitting the grant application; we won't review for other sites in many cases without charging Single IRB fees.

Those will need to make it into the budget!



Insight Reminders

- ❖ Continuing Reviews can't be submitted if there is an AME in process (we're asking Insight to change this)
- ❖ Ancillary Reviews are auto-triggered via *Study Details* form
- ❖ No "PI Proxy" role - PI must sign off every time something is submitted (even when responding to requested changes)
- ❖ Communication – no option to post general comments to the IRB analyst (e.g. asking for updates or clarifications) - instead, Submitter/PI responds to comments on specific forms, or use email

Insight Reminders

- ❑ All studies have Expiration Dates now, even when no Continuing Review is required; require “Expedited Check-Ins” instead
- ❑ Study Staff updates: only needed at Continuing Review or Expedited Check-in (unless required by third party, e.g. VA)
- ❑ Assigned IRB analyst now changes with each follow-on submission (AME, CR...)
- ❑ No *Detailed Protocol* for studies that are limited to:
 - Secondary Data Analysis
 - Chart reviews
 - Exempt research

Note: We do want to see the *multisite* protocol for studies where Emory is a participating site

Insight Updates



Check expiration dates. Submit Continuing Review or Check-In 45+ days before expiration. **Coming 5/22: Studies will be closed** after they have been expired for more than 90 days with no CR submission. (Not CEDE submissions)



Get migration amendments done ASAP! The deadline is end of June

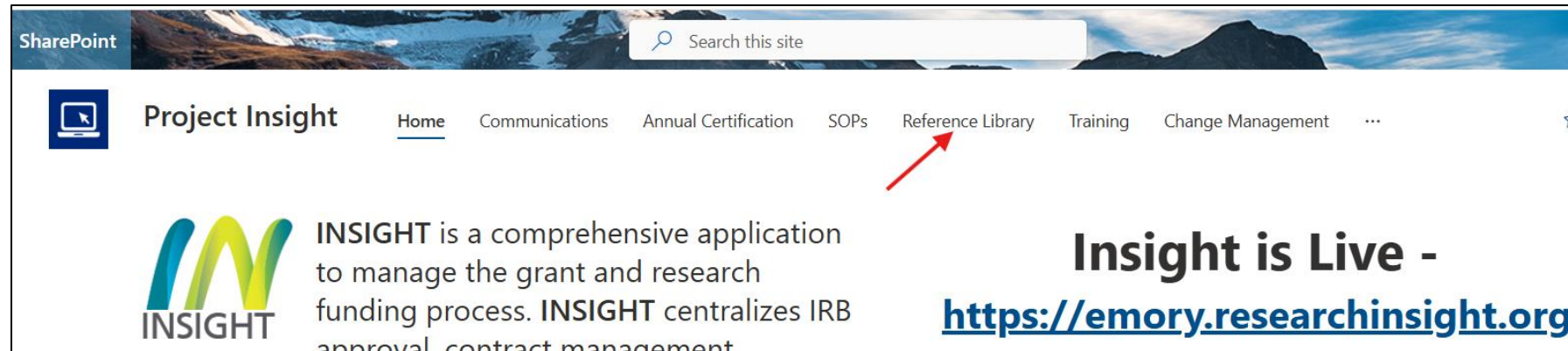


Refer to historic records in eIRB while it's still available...

Insight System Job Aids/Videos

General Information on Insight

- To stay informed about the Insight project across all of Research Administration: [the Insight SharePoint page](#)



SharePoint

Search this site

Project Insight

Home Communications Annual Certification SOPs **Reference Library** Training Change Management ...

INSIGHT INSIGHT is a comprehensive application to manage the grant and research funding process. INSIGHT centralizes IRB approval, contract management

Insight is Live -
<https://emory.researchinsight.org>

IRB Guidance

The “guidance” tab

ABOUT ▾ **GUIDANCE ▾** FORMS AND TEMPLATES ▾ RESOURCES ▾ MEMBERS ▾ PARTICIPANTS ▾

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**
- Insight System 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 with an FDA Unapproved Drug or Device
- Federal Policy for the Protection of Human Subjects (Common Rule)
- Office for Human Research Protections (OHRP)
- Health Insurance Portability and Accountability Act of 1996 (HIPAA)
- US Department of Veteran Affairs (VA)
- PHI Identifiers (PDF)
- Belmont Report
- Council for International Organizations of Medical Sciences (CIOMS)
- Declaration of Helsinki (World Medical Association)
- ICH Guideline for Good Clinical Practice (GCP)

The “forms and templates” tab

The image shows a navigation menu with the following items: ABOUT, GUIDANCE, FORMS AND TEMPLATES, RESOURCES, MEMBERS, PARTICIPANTS. The 'FORMS AND TEMPLATES' item is highlighted with a red box. Below the menu, there are four main sections: 'Forms and Templates' (with a sub-link 'BROWSE FORMS AND TEMPLATES'), 'Protocol Templates' (with a sub-link 'Food and Drug Administration'), 'Consent Toolkit' (with sub-links 'Instructions and Guidance' and 'Short Forms'), and 'Waivers' (with sub-links 'Waiver of Consent', 'Waiver of Documentation of Consent', 'Waiver or Alteration of HIPAA', 'Waiver of Assent', 'Waiver of Parental Permission', and 'Frequently Asked Questions'). The 'Consent Toolkit' and 'Protocol Templates' items are also highlighted with red boxes.

ABOUT ▾ GUIDANCE ▾ **FORMS AND TEMPLATES ▾** RESOURCES ▾ MEMBERS ▾ PARTICIPANTS ▾

Forms and Templates

Find the documents you need to support your research efforts.

BROWSE FORMS AND TEMPLATES

Protocol Templates

Food and Drug Administration

Consent Toolkit

- Instructions and Guidance
- Short Forms

Other

Waivers

- Waiver of Consent
- Waiver of Documentation of Consent
- Waiver or Alteration of HIPAA
- Waiver of Assent
- Waiver of Parental Permission
- Frequently Asked Questions

Avoid these pitfalls...

Not using current consent form & protocol templates

Removing/altering template language in the above documents

Submitting conflicting information to the IRB (# enrolled, time in study, procedures, risks, compensation, etc.)

Lack of clarity around research-specific procedures and those being done regardless of whether participant joins study (research vs. usual care)

Adding new grant/collaborators to existing studies for secondary analyses - requires a separate IRB submission

Adding staff using the External Staff option. **Please do not use this.** Instead, upload external team member list. *Note:* Reach out to the reliance team before adding external collaborators.

What to do when you have questions

1. Review guidance on our website: <https://irb.emory.edu/>
2. Review Insight training materials:
<https://emory.sharepoint.com/sites/Insight/SitePages/Reference-Library.aspx>
3. If your question is about an **existing** submission, email the analyst screening it. You can see the analyst name on the right panel. You can find contact information by hovering on name. Please refrain from contacting the Reviewer since they are busy faculty. Contact the IRB instead.
<https://irb.emory.edu/about/contact/index.html>
4. If your question is about a **future** IRB submission or a **general** question, email our listserv at IRB@emory.edu.
5. If your question is about **reliance**, email the reliance team at irb.reliance@emory.edu.

