

IRB Updates

- IRB WEBINAR- 5/14/2026

URGENT ACTION REQUIRED

Anticipated May 22nd: Insight will automatically close all Emory-reviewed studies that have been expired for 90 days unless there is a Continuing Review/Check-In *submitted*. REMINDER: Only Emory-reviewed studies that have been expired for 90 days will close out starting 5/22. If your CR/Expedited Check-In overdue by less than 90 days, it will not close out.

Note: Exempt studies will automatically be moved to Inactive/Closed as of the expiration date.

As noted in past newsletters, this functionality had been disabled since the system transition, until data fixes were complete. The closure cannot be reversed.

What you need to do for studies under your responsibility (i.e. you are PI or are responsible for IRB submissions): Review your Insight studies' expiration dates in the Humans module. To do this, click "Search" on your main Humans dashboard to see a list of all studies you're associated with. Sort by expiration date (including under the *Active-Exempt* tab). Submit a Continuing Review/Check-In, at least 45 days before expiration if possible.

If there is already a CR or Check-in submitted for your study, the study will not close out.

Insight Continued

Remember: also, budget time to fill in the new Insight forms as part of the CR/Check-In, if you haven't already done a migration amendment.

For Cede Review (external IRB) studies: provide your renewal information from the reviewing IRB, per instructions [here](#), but these will not move to Lapsed/Closed at this time.

Please make sure someone from your team reviews all messages that come from the IRB!

The IRB has included details on critical updates in the following ways:

- Website updates (Insight System Help)
- Insight newsletters for the past several months
- Webinars
- Email Blasts
- Outreach presentations

Frequently asked questions

Will my study close out if I've already submitted a Continuing Review or Check-In?	No
What if the PI is no longer at Emory?	The system will automatically close the study, so you just can let that happen.
Can the study be reopened?	No, you would need to do a new submission
What if my PI cannot sign off in time?	As long as the CR/Check-In is submitted, the study will not close while pending PI sign-off.
What if I want to close a study?	You will use the Continuing Review/Check-In submission to close the study. The first question asks for study status.
If my study didn't require Continuing Review, but it expired, is that noncompliance?	No, we are not treating that as noncompliance at this time. The Check-In process is aimed at cleaning up inactive studies (that the PI neglected to close out). It also reminds study teams about ongoing responsibilities.

Insight Updates



Check expiration dates. Submit Continuing Review or Check-In 45+ days before expiration.



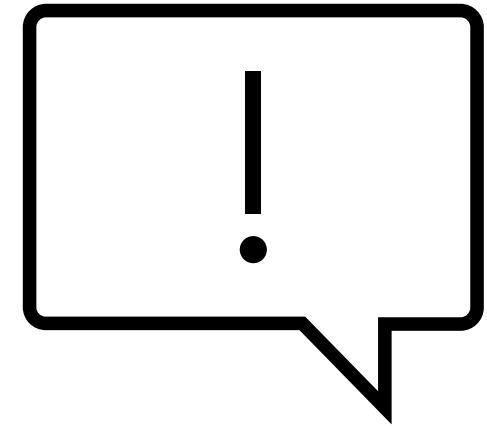
Get migration amendments done ASAP! The deadline is end of June



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

Insight Basic Reminders

- ❖ Continuing Reviews can't be submitted if there is an AME in process so consider the expiration date when submitting AMEs (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 Basic 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)



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

IRB Guidance

Finding Updated Information

The IRB updates
the website
frequently

It is critical that
study teams
review the
relevant sections

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, and PARTICIPANTS. The 'FORMS AND TEMPLATES' item is highlighted with a red box. Below the menu, there are four main sections: 'Forms and Templates', 'Protocol Templates', 'Consent Toolkit', and 'Waivers'. The 'Forms and Templates' section includes a description and a 'BROWSE FORMS AND TEMPLATES' button. The 'Protocol Templates' section includes 'Food and Drug Administration'. The 'Consent Toolkit' section includes 'Instructions and Guidance' and 'Short Forms'. The 'Waivers' section includes a list of waiver types: '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 'Other' section is also present.

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

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's 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.

