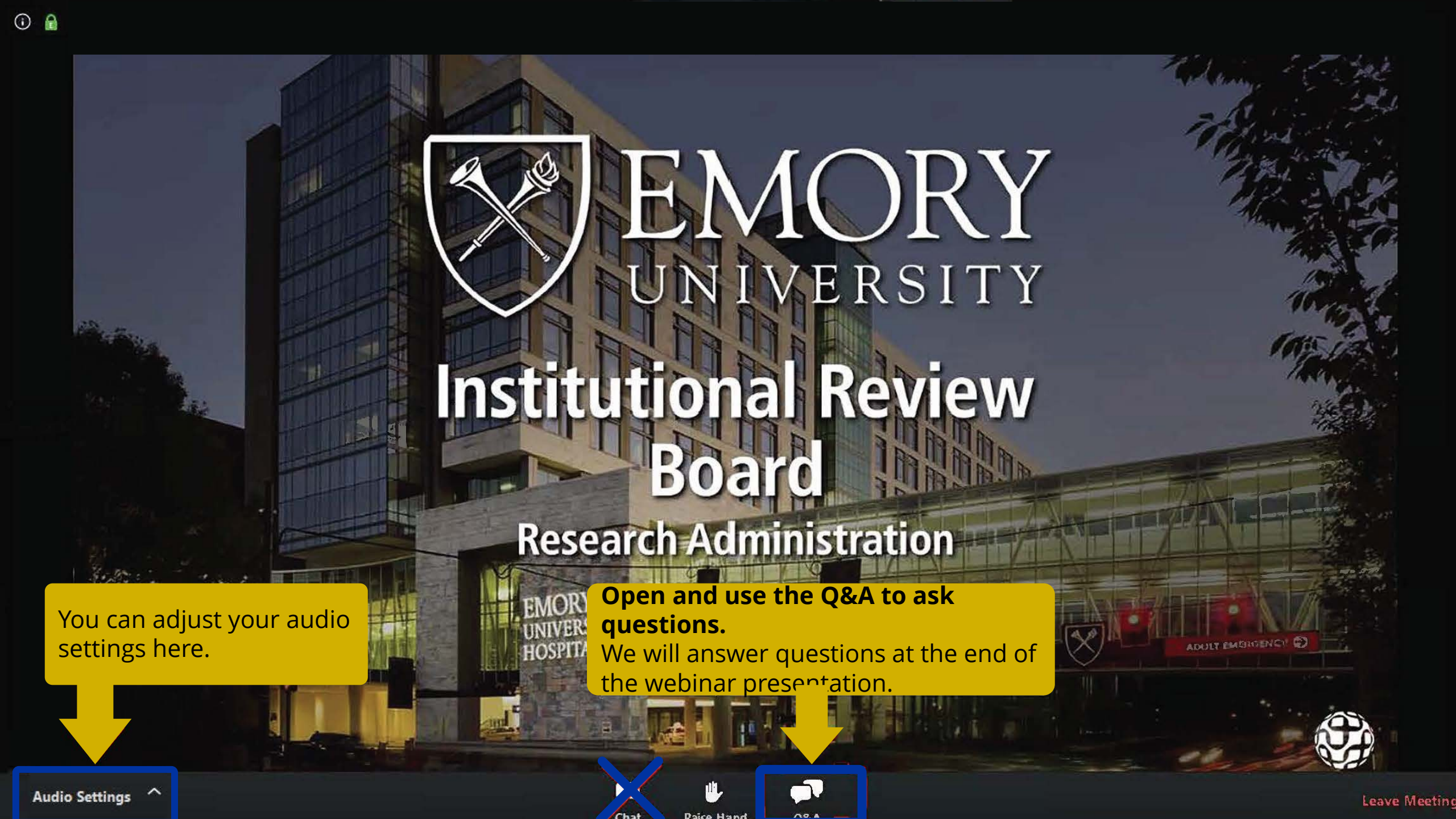
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We will answer questions at the end of the webinar presentation.
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Secondary Analyses, Substudies, and IRB Review

...and other important updates

Emory IRB Webinar
September 10, 2026

Primary analyses vs. Secondary analyses

Primary analyses vs. Secondary analyses

EXAMPLE SCENARIO

Study "Effects of Exposure to Second Hand Smoke on Nose Hair Length and Political Views" started in 2009.

The protocol listed two specific aims, various data and specimen collection details, and an estimated completion of 2019.

As of 2026, the study is still Active.

The study had transitioned to the "Revised Common Rule" in 2020, so no longer required Continuing Review.

The study team would still periodically add new study team members.

In Insight, the study now requires "Expedited Check-Ins" so the PI submitted one.

The IRB analyst for the Check-In wondered, "why is this study still open," and asked the study team.

"We think the data from this study is still useful for further analyses, and it's an easy way for our students to do human subjects research, by doing data analysis projects."

Primary analyses vs. Secondary analyses

The IRB's Job (i.e. why that started a dialog with the PI):

1. **Ensure all human research activities are reviewed and approved at all times**

2. **Evaluate proposals in terms of Approval Criteria:**
   - **Risks are minimized**
   - **Risks are reasonable in relation to benefits and/or to the importance of knowledge gained**
   - **Equitable selection of participants**
   - **Informed Consent**
   - **Adequate data safety monitoring**
   - **Privacy and Confidentiality protections**
   - **Vulnerable participants are protected**

3. **Help ensure that funded agreements align with an IRB-approved protocol**

Primary analyses vs. Secondary analyses …or substudies

What the IRB Needs to Do the Job

- Well-defined protocols and consents
- Protocol updates if those defined aims, methods, and other plans will change in any way
- New protocols for most new work
- Clarity about what is happening now, vs what happened in the past

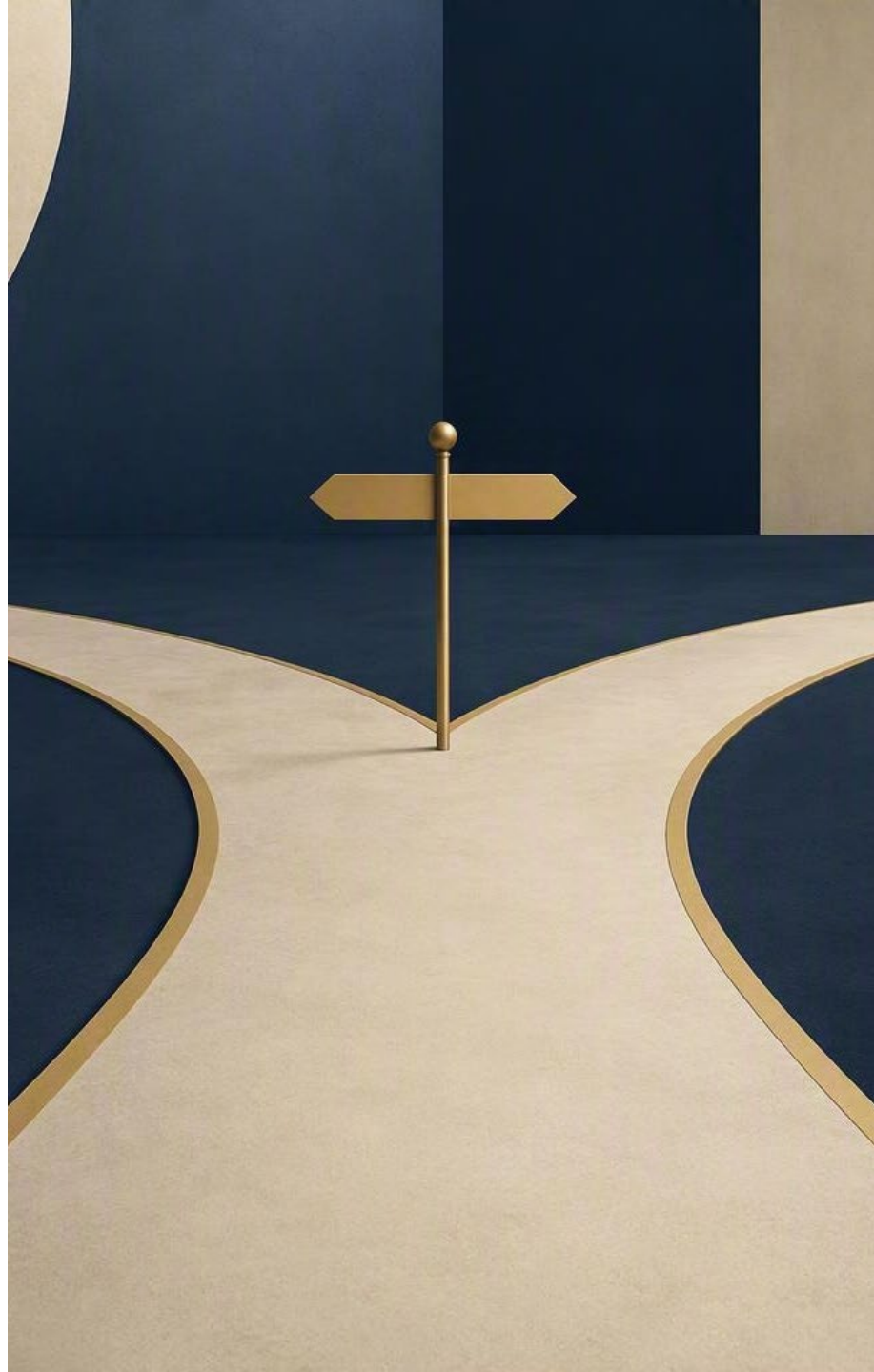
Amendment or New Submission?

Three questions…

01 Do the proposed changes alter the research hypothesis, purpose, or aims?

02 How substantially do the procedures and methods change?

03 Will new regulations or oversight apply?
E.g. FDA, Federal Funding, Reliance, etc.



When an amendment starts to work against you

An overly long protocol

Layer enough changes onto one document and it grows past the point where a reviewer can hold it together.

Internal inconsistencies

Older aims/methods/inclusion criteria/data plans and newer ones sit side by side, contradicting each other in ways that are easy to miss.

Content no longer relevant

Information and documents that applied to the original design must stay in the file but obscure the current ones.

The result can be confusing to reviewers. In some cases a new protocol — current and consistent — is easier to review and faster to approve.

AMENDMENT MAY SUFFICE

The basic research question remains intact

- The original study aims and objectives are not complete already
- The hypotheses are generally unchanged
- Study purpose and aims still hold
- The work builds on the same question it started with

NEW PROTOCOL MAY BE WARRANTED

The focus or research question has changed

- A new direction, even one built on knowledge from the existing study
- Purpose or aims not fully aligned
- Reviewers would be assessing a different question
- Different PI, new grant

- **Or,** the original protocol is a repository or registry

The good news about Secondary Analyses!

Secondary Analysis protocols no longer require Protocol attachments in most cases!

Review of a new SDA submission is often **more efficient** than the IRB weighing whether an amendment is appropriate! Especially for older, migrated studies that may need other updates.

Data from older, concluded studies CAN STILL BE RETAINED – just not used until a new IRB approval is in place for secondary analyses (assuming consent language allows).

Take home message: Check with the IRB when in doubt, and close out studies when they are done.

Sharing and Caring

Alert **Sharing data or specimens with others for their own research aims must be handled carefully**	**Outside of Emory:** **Data or Material Use/Transfer Agreements and reliance agreements may be needed**	**All:** **Other investigator should have own IRB submission *unless* you can provide data/specimens with no HIPAA identifiers and you are not collaborating scientifically**

Other Important Updates and Reminders…

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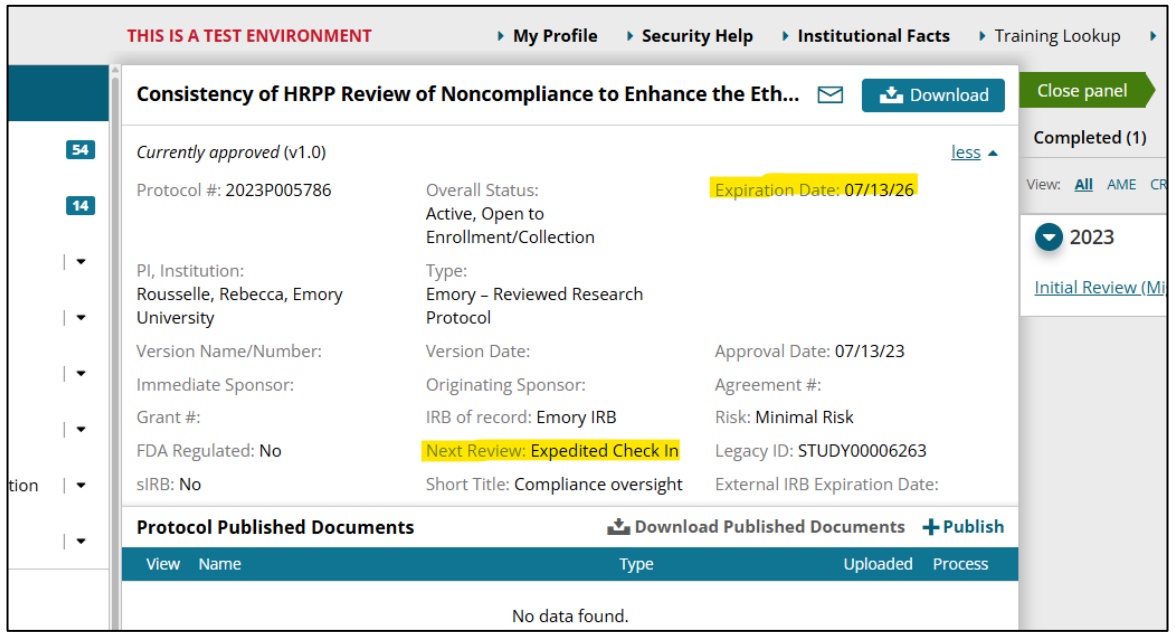
Everything Expires in Insight

But not in the same way…



If your "Next Review" is "Expedited Check-In" (or "Exempt Check-In")…

- **You do NOT have to stop activities if your study Lapses, but you need to submit an Expedited Check-in!**
- Do not let your studies go "Inactive."
- You CAN let Exempt studies go Inactive; keeping it Active is optional.
- **See our instructions for Expedited Check-Ins** on our Insight Help page! There is a trick to them.

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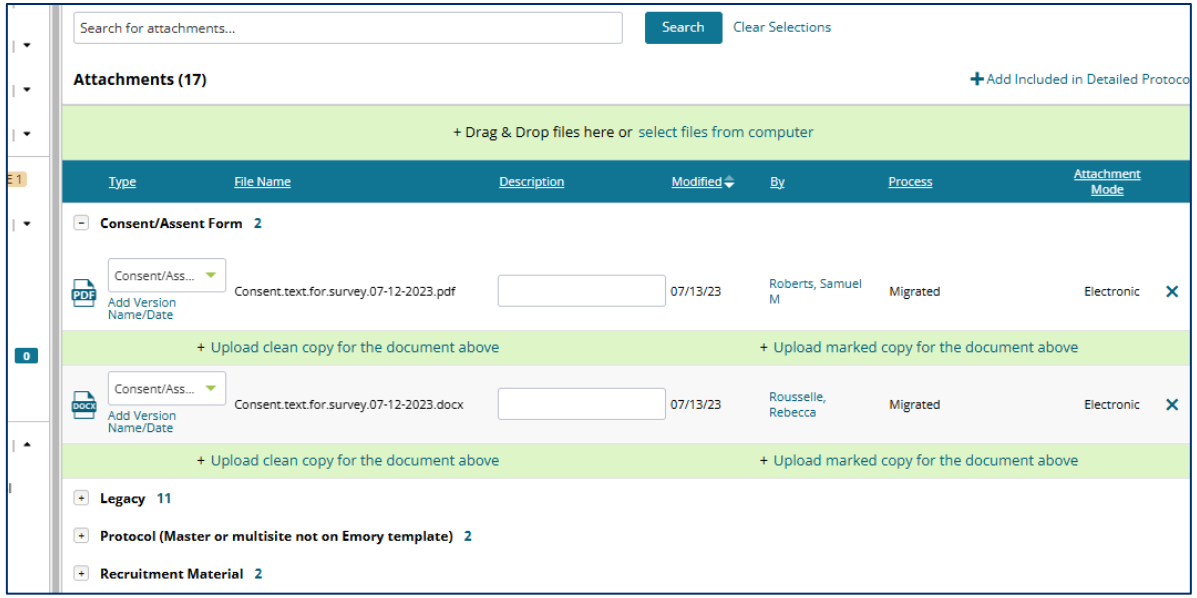
Level Up: How to Submit Revised Attachments

We recognize that Insight's "Attachments" version management be confusing. We created guidance with step-by-step instructions and screenshots to help you. You can find the guidance and other important information under the "Guidance" tab's "Insight System Help" section.



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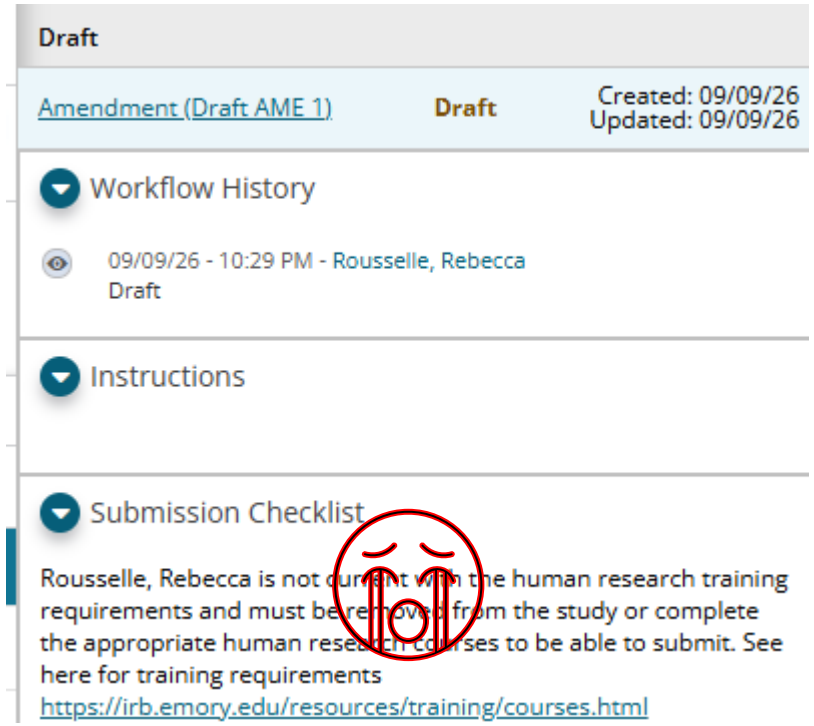
CITI Training Not Showing Up in Insight?

Reminder: Emory IRB no longer requires real-time study team updates for approved studies. PI's are responsible for ensuring all of their team members have all required training.

(Exceptions: person needs to work in Insight, person is external to Emory, or third-party requires it.)

When you need to add someone on the Staff form (e.g. at initial review), follow the step-by-step **CITI troubleshooting instructions** in the "CITI Training" section – please check them out before submitting a ticket, to save time!



Migration Amendments: Act Now and Save!

…yourself time when you actually have to do an urgent Amendment or Continuing Review

If you have not already done so, **submit your "Migration Amendments" as soon as possible** for any studies that were first approved in eIRB.

eIRB will be archived soon, and it will be easier for you to do your Amendment while you still have access to eIRB. Insight is now the official record for all Active studies.

When completing migration Amendments, you **must** use the instructions under "Insight System Help," in the "Amendments" section.

International Research: People's Republic of China (PRC) and "PIPL" Review

Start Early

If you are planning to do research in the PRC, or with individuals in the PRC (including simple survey studies), reach out very early to the Office of Ethics and Compliance to discuss how your plan can be compliant with China's PIPL privacy regulations.

There May Be Costs

Emory is working on guidance for this area, but for now it starts with a conversation. OEC and OGC will likely review study plans and contracts. They may need to seek outside counsel. **Note:** the study team or department may need to budget for outside counsel review.

Collaboration is Key… for Collaborative Research

If your research will involve any external collaborators:

To avoid getting in a pickle, review our Collaborative Research webpage when planning to work with external collaborators. Reach out to the reliance team early to discuss.

Why?

- You may need to include single IRB review fees in budget submitted with your grant application.
- You may not realize reliance is required for multisite fed-funded research
- For SBIR/STTR grants, the company that is the prime awardee must have IRB approval even if they are not conducting any research activities. Emory can provide this review but will charge the grant the sIRB review fees. The fees need to be in your budget.

Last but not Least: Office Hours start Sept 16!

Wednesdays from **11:00AM-12:00PM** (via Zoom) with **no appointments required** for general IRB and Insight questions

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Please let us know what you think of this webinar!

Questions? Comments?

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