



# EMORY UNIVERSITY

## Institutional Review Board

### Research Administration

You can adjust your audio settings here.

**Open and use the Q&A to ask questions.**  
We will answer questions at the end of the webinar presentation.

Audio Settings ^

Chat

Raise Hand

Q&A

Leave Meeting



# The Student Research Roadmap: IRB Basics and Thesis/Dissertation Submission

Emory IRB Webinar October 8, 2026



# Agenda

- Emory IRB Overview
- Guidance on IRB Submission & Review Process
- Issues encountered with International research
- Final tips & takeaways



# IRB's Role



Guides researchers through regulatory process and promotes compliance



Provides balance to scientific bias: includes non-scientists and unaffiliated persons



Has authority to disapprove or halt research



Acts as HIPAA Privacy Board for research at Emory University and Emory Healthcare

# Human Subjects Research Regulations



Regulatory language governing HSR in Federal agencies

- National Science Foundation, Defense, Agriculture, Energy, Education, USAID, etc.

DHHS Title 45 CFR Part 46 Subpart A

- Subparts B-D: Additional Protections
- Subpart E: IRB Registration

FDA Title 21 CFR 50 & 56

HIPAA, Public Law 104-191

# How the IRB Staff Help

**Answer questions,  
make suggestions**

**Guide through the  
regulations**

**Provide triaging  
analysis (do you  
really need IRB  
review/approval?)**

**Conduct preliminary  
analysis, spot issues,  
support IRB  
members**

**Coordinate IRB  
meetings and  
correspondence with  
researchers**

**Education & Quality  
Assurance**



Where can I get help if the website resources aren't enough?

# ASK THE IRB STAFF!

We'd love to help you!

- Email our listserv [irb@emory.edu](mailto:irb@emory.edu)
- Website [www.irb.emory.edu](http://www.irb.emory.edu)
- IRB Office Hours – Every Wednesday, 11-12 over Zoom:  
<https://emory.zoom.us/j/93067072857?from=addon>



# Go to the authoritative source

- Emory College of Arts & Sciences and Laney GS faculty advisors may not know all the ins and outs of the IRB process
- IRB staff tend the IRB listserv all day M-F – aim to reply within 24 business hours

IRB Office Hours – Every Wednesday, 11-12 over Zoom (\*\*subject to change): <https://emory.zoom.us/j/93067072857?from=addon>

- If you don't get a satisfactory response within 1-2 business days, email the Director or Assistant Director

[Rebecca.rousselle@emory.edu](mailto:Rebecca.rousselle@emory.edu)

[ccorkra@emory.edu](mailto:ccorkra@emory.edu)

# IRB Triage Questions We Ask in This Order



## Triage Pyramid

### Full Board

All other studies must be reviewed at a convened meeting of the IRB where quorum is present

### Expedited

Only if IRB determines that study poses no more than minimal risk AND all study procedures fit one or more categories in a special list published in the Federal Register

➤ E.g., surveys, questionnaires, focus groups, noninvasive biological samples

### Exempt

- PI must submit study proposal via Insight for this determination
- Informed Consent usually must be obtained; HIPAA may still apply
- Exempt categories can be found at [45 CFR 46.104](#)
- The IRB is the only unit authorized to make this determination
- Exempt determination is valid indefinitely unless changes in project affect the analysis. PI must request clarification from IRB (submit an “amendment” in Insight)

### Not “Research” with “Human Subjects”

1. PI *can* make this determination without the IRB.
2. PI can complete : [Non-Human Subject Research Determination Form](#) .
3. PI is encouraged to consult IRB in making this decision if unsure (email request to [irb@emory.edu](mailto:irb@emory.edu)).

**Is it “research”?** Term of art defined at 45 CFR Section 46.102(l): *Research* means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. **Does it involve “human subjects”?** Term of art defined at 45 CFR Section 46.102(e)(1): *Human subject* means a living individual about whom an investigator (whether professional or student) conducting research: (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

# Research or Not?



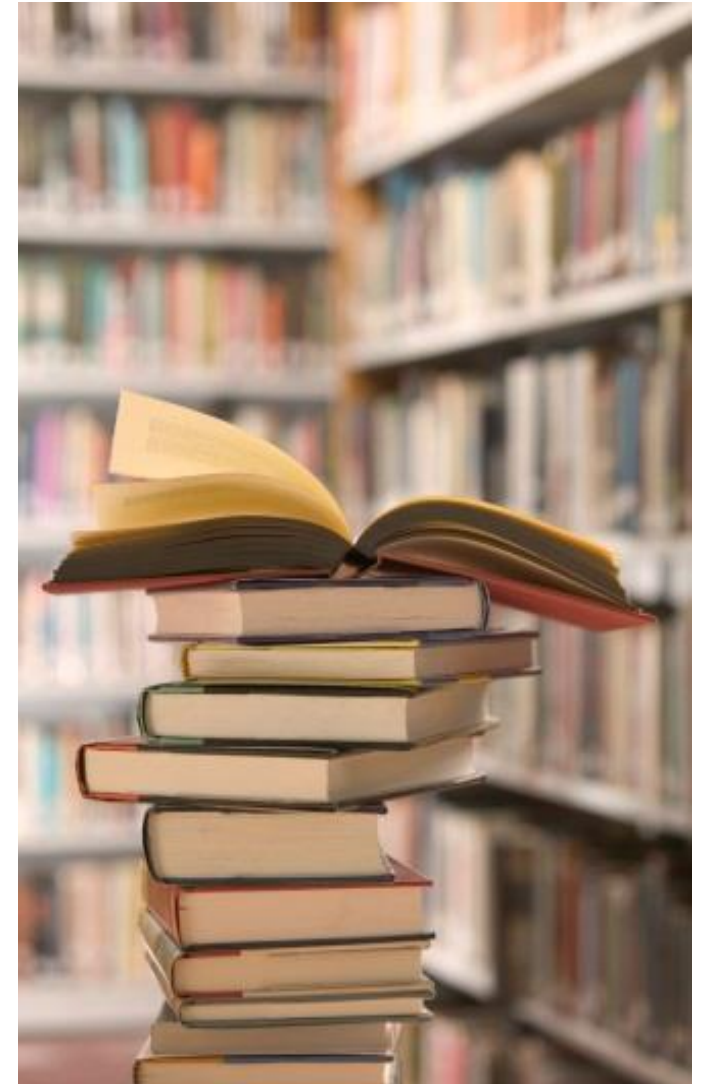
**Generalizable knowledge** is information **gathered to draw general conclusions beyond the study population**. The researcher approaches the project with the intention of extrapolating from the chosen sample to generate knowledge about that larger reference group.

By contrast, **non-research** projects gather information about a chosen sample to **describe a local phenomenon**, or draw conclusions that are intended to be used for **the benefit of that local sample alone**.

# “Research” or Not?

## Not “Research”

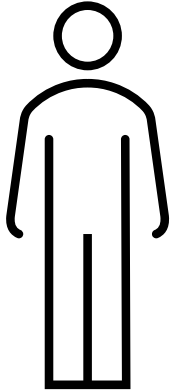
- Some education activities
- Most oral history projects
- Quality improvement/assurance, program assessments
- <6 case reports or case series
- Most public health practice
- But... **it always depends.**



**Research** (45 CFR Section 46.102(d)): a systematic investigation designed to develop or contribute to generalizable knowledge.

# “Human Subjects” or Not?

**A living individual about whom an investigator conducting research obtains data through intervention or interaction with individuals or obtains identifiable private information**



## Examples of Identifiers

- Date of birth
- Mailing address
- Telephone #
- Email
- SSN
- Biometric identifiers, including fingerprints and voiceprints.
- **List of 18 Identifiers**

About a living person (at time of collection)

Intervention/interaction – in person, phone, internet

Identifiers

Private vs public

- 45 CFR 46.102(F)

# What is “Exempt”

Most common types of exempt research:

- Normal Educational Practices and Settings
- Surveys, interviews and focus groups of adults
- Public observation of adults and of children (but only if investigators do not intervene at all)
- Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject, that is brief in duration, harmless, painless, not physically invasive, not likely to have a significant impact on the subjects and the investigator has no reason to think subjects will find the interventions offensive or embarrassing.

# What is “expeditable”?

Non-exempt HSR that is:

- Minimal risk AND
- Fits one or more federal register categories

## OHRP Expedited Review Categories

Most common expeditable research:

- Medical record reviews
- Blood, urine, hair, saliva samples
- Non-invasive biometric measurements
- Research on group characteristics or behaviors (perception, cognition, motivation, identity, language, cultural beliefs or practices)

\*\*\* More than minimal risk research goes to full board meeting.

EMORY UNIVERSITY

# Sociobehavioral Research Projects



- While projects in this field are often examinations of quite unique places and cultures, the work is usually done to gain knowledge about human behavior more generally, to generalize to a larger theory, or to contribute to the academic field. While many of these projects may meet the exempt review criteria, they usually require at least an initial IRB submission
- Sociobehavioral research is a gray area.
  - Some are like a case study (not “research”)
  - Some explicitly develops generalizable knowledge (“research”)
  - Does My Study Need IRB Review?
    - If still unsure, ask the IRB for help!

# Publishing

*I want to publish, so it's research, right?*

- One can publish works that meet and do not meet the IRB-specific definition of “research.”
- Publishing is simply sharing information with an external audience.
- You can request a Non-Human Subject Research determination confirmation, which can be provided to publishers and journals to satisfy IRB clearance requirements.

## Non-Human Subject Research determination form

- If not research, publication should not attempt to generalize conclusions or make recommendations.



# So, you need to submit to the IRB for your honors or Grad thesis or dissertation:



Q: When should I submit my project to the IRB for review?

A: *Submit as early as you can, especially if planning international research.*

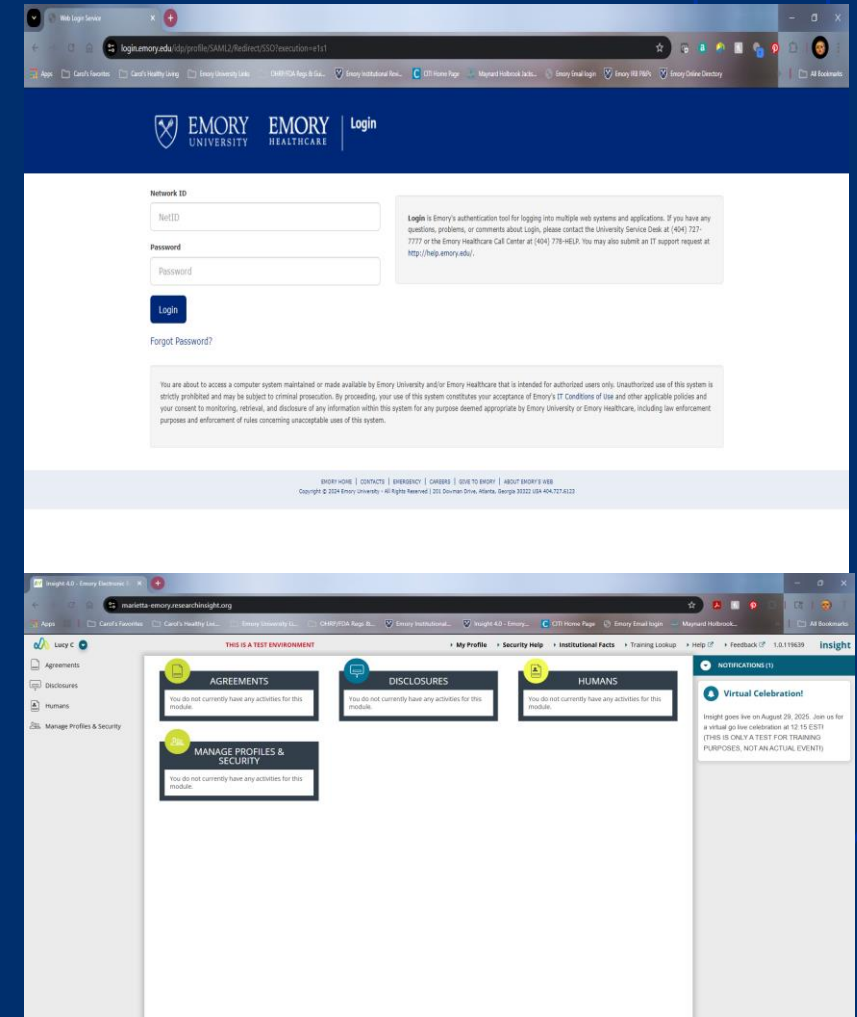
Q: How long does the IRB process generally take from writing to approval? Emory Target Turnaround Times

A: *It depends:*

- On the quality of the initial submission and if you have used the required template documents;
- Responsiveness of the principal investigator/study team to IRB requests for more information or changes and vice-versa;
- Whether local research ethics review/oversight is available or required.

# Activate your Insight Account

- Login to INSIGHT:  
<https://login.emory.edu/idp/profile/oidc/authorize?execution=e1s2>
- Users with an Emory or Emory Healthcare NetID can log into INSIGHT using their NetID and password.
- IRB submissions will use the HUMANS Module
- Complete Brainier INSIGHT Training:  
<http://leo.cc.emory.edu/>
- More information related to training in INSIGHT:  
<https://emory.sharepoint.com/sites/Insight/SitePages/Insight.aspx?csf=1&web=1&e=fqn6cV>



# CITI Training:

- **Both** the faculty PI and Student must have valid CITI certification prior to review of the study. Approval of project will be delayed without valid CITI
- **<https://irb.emory.edu/resources/training/courses.html>**
  - scroll down to see the specific course you will need to take based on your study area and activities.
- Use this link below to login to CITI program:  
**[Log into the CITI Training Program \(Emory Login Required\)](#)**
- Refer to this link if having CITI difficulty in Insight:  
**[CITI troubleshooting guidance](#)**

# So, you need to submit to the IRB:

What should I submit to the IRB for review? Will be uploaded in **Attachments form** in Insight:

☐ **Lay Summary** (entered directly into Study Overview form)

☐ **Detailed Research Protocol** **YOU ARE REQUIRED TO USE THIS DOCUMENT if you are conducting Non-exempt human subjects research.**

☐ **Data Collection Instruments** – Surveys, Interview or Focus Group Discussion Guides, Observation Recording Forms.

☐ **Recruitment Materials** – participant facing materials to garner interest in study participation, e.g. flyers, emails, social media (may not need if your study meets the exempt review criteria)

<https://irb.emory.edu/guidance/getting-started/study-submission.html>

☐ **Informed Consent or Assent Forms**

[https://irb.emory.edu/\\_includes/documents/sections/saasshb\\_consent\\_template.docx](https://irb.emory.edu/_includes/documents/sections/saasshb_consent_template.docx)

☐ **Site permission letters** (if applicable)

# How to get through the IRB process quickly & smoothly

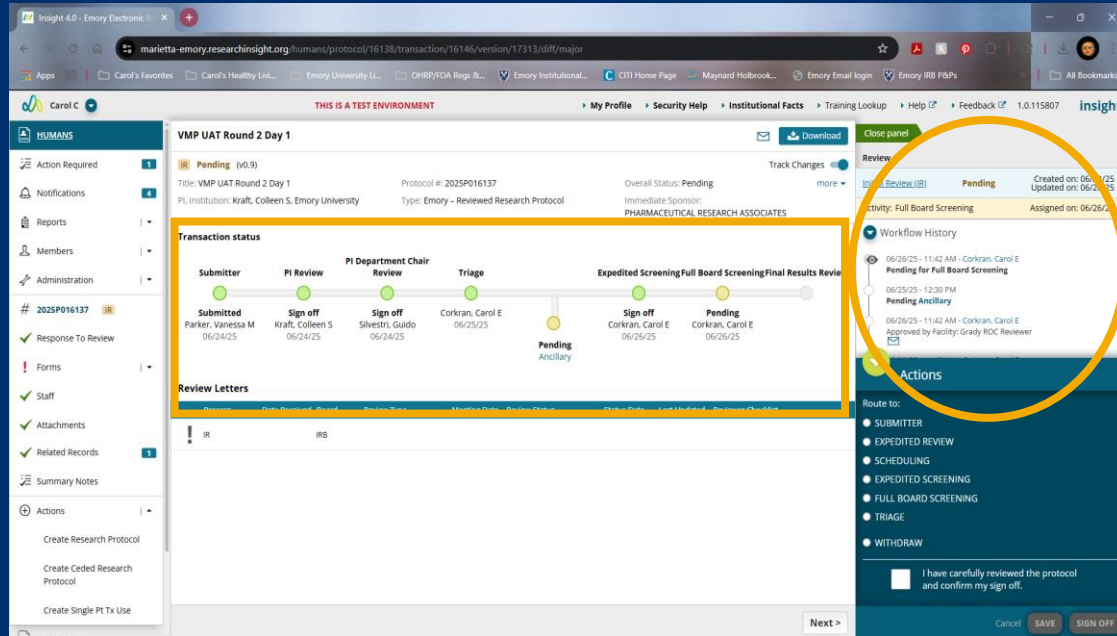
## In INSIGHT smartform

- Please always use our Insight Help webpage with detailed instructions:  
<https://irb.emory.edu/forms/insight/how-to.html>
- INSIGHT training is available at <http://leo.cc.emory.edu/> - In Brainier – If you don't already have access, you may need to request
- Create Research Protocol [Insight Job Aid - Creating a Research Protocol](#)
- Ensure that both the **“Title of Study”** and include the prefix below that applies:
  - **“Undergrad\_Honors Thesis:** [your full study title goes here]
  - **e.g. MPH/Doctoral Thesis/Dissertation:** [your full study title goes here]
- Answer the questions in the Study Overview form.
- The forms include branching logic based on how you respond and should lead to complete the required forms accurately.
  - If your study routes to the Exempt review categories, you will not need to provide a detailed protocol document in the Attachments form.
  - If your study routes to the Expedited review categories, you will need to provide a detailed protocol document in the Attachments form.



# How to get through the IRB process quickly & smoothly

## In INSIGHT Workspace



1. List your Faculty Advisor/Mentor as the Principal Investigator (PI) to properly route for Department Review. Student accounts are not linked with academic departments, thus have no PI Department Chair to review.
2. Ensure that your faculty advisor-Principal Investigator has clicked the submit button! They will need to sign-off each time the study is resubmitted after making changes.
3. Look for email notifications from Insight that let you know if action is required by you and your faculty advisor
4. Reply to the changes requested as promptly as you can.
5. To see where your study is in the process there are two views, the Transaction Status “subway map” or “Workflow History” that provides a more granular view of the “subway map”

# Insight: Initial Review Submission Workspace

Administration

# 2025P016137 IR

Response To Review

Forms

Initial Questionnaire

Study Overview

Study Funding Sources

PHARMACEUTICAL RESEARCH ASSOCIATES [CORP]

Intervention

Data Security

Study Subject Areas

Study Details

Clinical Trials Registration

Study Population

Research Locations

Recruitment

Compensation

Informed Consent

Data Collection Tools

Study Agents: Drugs, Biologics, Dietary Supplements

Overview of Study Agents: Drugs, Biologics, Others

Emergency Kit

THIS IS A TEST ENVIRONMENT

My Profile Security Help Institutional Facts Training Lookup Help Feedback 1.0.115807 insight

VMP UAT Round 2 Day 1

IR Pending (v0.9)

Title: VMP UAT Round 2 Day 1

Protocol #: 2025P016137

Overall Status: Pending

PI, Institution: Kraft, Colleen S, Emory University

Type: Emory - Reviewed Research Protocol

Immediate Sponsor: PHARMACEUTICAL RESEARCH ASSOCIATES

Originating Sponsor: RECURSION

Agreement #: 2025A026915

Grant #: 00142020

IRB of record: Emory IRB

sIRB: No

Short Title: VMP UAT Round 2 Day 1

Transaction status

Submitter PI Review PI Department Chair Review Triage Expedited Screening Full Board Screening Final Results Review

Submitted Sign off Sign off Corkran, Carol E Pending Ancillary Sign off Pending

Parker, Vanessa M 06/24/25 Kraft, Colleen S 06/24/25 Silvestri, Guido 06/24/25 Corkran, Carol E 06/25/25 Corkran, Carol E 06/26/25 Corkran, Carol E 06/26/25

Review Letters

| Process | Date Received | Board | Review Type | Meeting Date | Review Status | Status Date | Last Updated | Reviewer Checklist |
|---------|---------------|-------|-------------|--------------|---------------|-------------|--------------|--------------------|
| IR      |               | IRB   |             |              |               |             |              |                    |

Next >

Close panel

Review

Initial Review (IR) Pending Created on: 06/24/25 Updated on: 06/26/25

Activity: Full Board Screening Assigned on: 06/26/25

Workflow History

06/26/25 - 11:42 AM - Corkran, Carol E Pending for Full Board Screening

06/25/25 - 12:30 PM Pending Ancillary

06/26/25 - 11:42 AM - Corkran, Carol E Approved by Facility: Grady ROC Reviewer

Actions

Route to:

SUBMITTER EXPEDITED REVIEW SCHEDULING EXPEDITED SCREENING FULL BOARD SCREENING TRIAGE WITHDRAW

☐ I have carefully reviewed the protocol and confirm my sign off.

Cancel SAVE SIGN OFF

# Emory IRB Considerations when reviewing International Research



Is there local research ethics oversight available in country? Home institution? What are the local requirements?

If there is no local research ethics review board or oversight in country, you will need to provide a Letter of Cultural Context:

- This letter cannot be written by the principal investigator. The writer must be familiar with the culture, customs and norms of the setting and able to vouch for the appropriateness of the study activities and/or consenting process as well as the ability of the research team to carry out all study activities.
- The letter may come from the following persons as long as they qualify as described above:
  - An advisor
  - Advisory board member
  - A dissertation committee member
  - Emory University faculty member.
- The letter should contain the contact information of the writer (e.g. on letterhead)

# Emory IRB Considerations when reviewing International Research (link)



- Is there local research ethics oversight available in country? Home institution? What are the local requirements?
- Local laws & regulations
- Emory researchers hiring & training local contractors, enumerators, interviewers, translators, what do we need to be concerned with regarding IRB oversight? HSR Protections Training? Internet availability/reliability, training available in language needed, other options?
- Local Research Context – Research Procedures & Informed Consent processes are culturally appropriate
- Is the international research receiving U.S. federal funding?



# Emory IRB Considerations when reviewing International Research



- **Informed Consent** – in addition to ensuring the elements of Informed Consent are met, we also consider the following issues:
  - Disclosure of information to individuals who may be unfamiliar with and distrustful of the concepts:
    - Differences in societal and cultural norms;
    - Differences in role of women in society;
    - Differences in the role of family and community in the consent process;
    - Multiple local languages; and
    - Literacy Level

# Emory IRB Considerations when reviewing International Research



- Informed consent documents must be in a language appropriate to the location of the research, and understandable to proposed participants – Language & grade-level
- Informed consent translations will need to be reviewed in English by Emory's IRB and a translated version will need to be submitted to Emory's IRB as well after initial IRB approval.
- The translation may be done by a certified translator (certification will need to be provided along with the translated documents to the IRB) OR a back-translation can be done (one person translates documents into the language and a different person translates the translation back into English and verifies none of the content/meaning was lost during initial translation)
- More info about Local Research Context; Research Conducted at Non-Emory sites can be found in Ch 16 of our Policies & Procedures:
- **Emory IRB Policies & Procedures**

# Local Laws & Regulations

Privacy Laws may differ from country to country and are definitely something to be mindful of when designing your research studies. ***Additional review by outside counsel may be needed leading to further delay in beginning research activities.***

- For Example:
- In the European Union they have the General Data Protection Regulations (**GDPR**)
- **In People's Republic of China – PIPL 2021**

**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 data management & safety 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 obtain outside counsel. **Note:** the study team or department may need to budget for outside counsel review



| International Guidelines Resources                                                                                              |                                                                                                                                                                                                                                                                                                              |
|---------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| The Council for International Organizations of Medical Sciences (CIOMS)                                                         | <a href="https://cioms.ch/wp-content/uploads/2017/01/WEB-CIOMS-EthicalGuidelines.pdf">https://cioms.ch/wp-content/uploads/2017/01/WEB-CIOMS-EthicalGuidelines.pdf</a><br><a href="https://cioms.ch/shop/product-category/free-publications/">https://cioms.ch/shop/product-category/free-publications/</a>   |
| The Nuffield Council on Bioethics Report (2002, follow-up 2005)                                                                 | <a href="http://www.nuffieldbioethics.org/research-developing-countries">http://www.nuffieldbioethics.org/research-developing-countries</a> and<br><a href="http://www.nuffieldbioethics.org/research-developing-countries-follow">http://www.nuffieldbioethics.org/research-developing-countries-follow</a> |
| WHO’s Good Clinical Practice Guideline                                                                                          | <a href="http://whqlibdoc.who.int/publications/2005/924159392X_eng.pdf">http://whqlibdoc.who.int/publications/2005/924159392X_eng.pdf</a>                                                                                                                                                                    |
| The International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) | <a href="#">Available in English.</a>                                                                                                                                                                                                                                                                        |
| WHO Operational Guidelines for Ethics Committees that Review Biomedical Research                                                | <a href="http://www.who.int/tdr/publications/training-guideline-publications/operational-guidelines-ethics-biomedical-research/en/">http://www.who.int/tdr/publications/training-guideline-publications/operational-guidelines-ethics-biomedical-research/en/</a>                                            |
| U.S. Office for Human Research Protections (OHRP)                                                                               | <a href="#">International Compilation of Human Research Standards</a><br><a href="#">Listing of Social and Behavioral Research Standards</a>                                                                                                                                                                 |

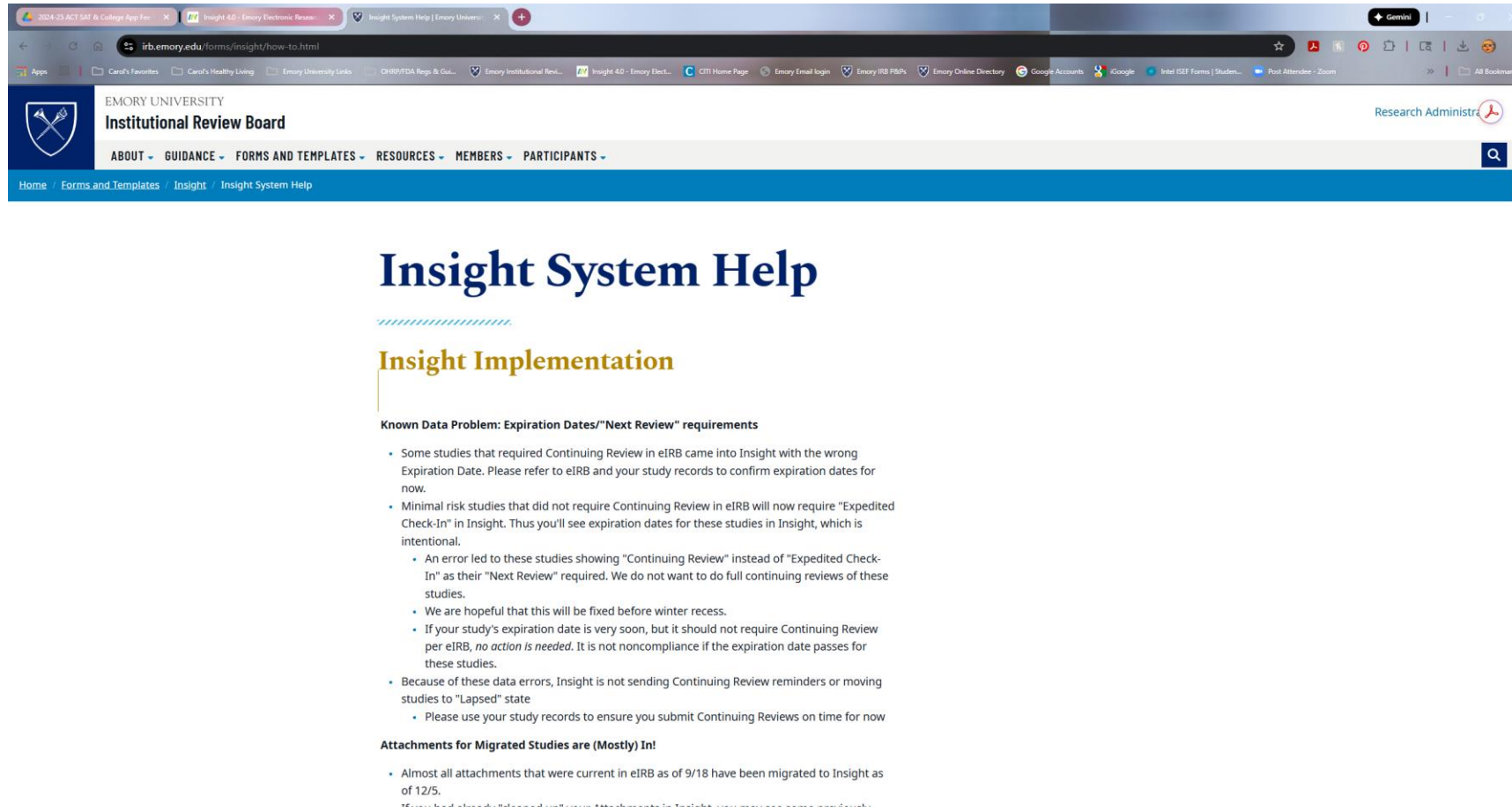
# INSIGHT – known issues as of 09/25/2026:



- **Student Study Team Members**

- Some students do not have active profiles in Insight, thus can't be added to study teams or create submissions. If the student previously held work-study job that was terminated, their profiles may show as inactive. Please contact me immediately if you are experiencing this issue.
- Emory IT is working to fix the root cause. In the meantime, reminder that the IRB no longer requires real-time study staff updates. (Exceptions: when a third-party requires it, or for external personnel.) Emory users with Inactive Insight accounts can start working on studies once they've completed all required training and (if applicable) credentialing.

# [HTTPS://IRB.EMORY.EDU/FORMS/INSIGHT/HOW-TO.HTML](https://irb.emory.edu/forms/insight/how-to.html)



EMORY UNIVERSITY  
Institutional Review Board

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

Home / Forms and Templates / Insight / Insight System Help

## Insight System Help

### Insight Implementation

**Known Data Problem: Expiration Dates/"Next Review" requirements**

- Some studies that required Continuing Review in eIRB came into Insight with the wrong Expiration Date. Please refer to eIRB and your study records to confirm expiration dates for now.
- Minimal risk studies that did not require Continuing Review in eIRB will now require "Expedited Check-In" in Insight. Thus you'll see expiration dates for these studies in Insight, which is intentional.
  - An error led to these studies showing "Continuing Review" instead of "Expedited Check-In" as their "Next Review" required. We do not want to do full continuing reviews of these studies.
  - We are hopeful that this will be fixed before winter recess.
  - If your study's expiration date is very soon, but it should not require Continuing Review per eIRB, *no action is needed*. It is not noncompliance if the expiration date passes for these studies.
- Because of these data errors, Insight is not sending Continuing Review reminders or moving studies to "Lapsed" state
  - Please use your study records to ensure you submit Continuing Reviews on time for now

**Attachments for Migrated Studies are (Mostly) In!**

- Almost all attachments that were current in eIRB as of 9/18 have been migrated to Insight as of 12/5.

<https://emory.sharepoint.com/sites/Insight>

2024-25 ACT SAT & College App Fee x Insight 4.0 - Emory Electronic Research x Project Insight - Home x

emory.sharepoint.com/sites/Insight/

Apps Carol's Favorites Carol's Healthy Living Emory University Links OHRP/FDA Regs & Gui... Emory Institutional Rev... Insight 4.0 - Emory Elect... CITI Home Page Emory Email login Emory IRB P&Ps Emory Online Directory Google Accounts iGoogle Intel ISEF Forms | Studen... Post Attendee - Zoom All Bookmarks

SharePoint Search this site

Project Insight Home Communications Annual Certification SOPs Reference Library Training Change Management Insight Demos Our Team FAQ's Not following



INSIGHT is a comprehensive application to manage the grant and research funding process. INSIGHT centralizes IRB approval, contract management, regulatory compliance, study budgeting, and financial management into a single application.

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

**Strategy Library - Reporting Tool**  
**Strategy Library - Job Aid**

**Need assistance?**

[Open an Insight Support Ticket](#)

**Need virtual, how-to help?**

**Call (470) 819-5067**

**Humans (IRB) Submissions Announcement! October 1st**

All studies have now migrated from eIRB into Insight, except for about 96 studies that were left off, and IT is working hard to migrate those.

**NOTE:** Attachments (documents uploaded in eIRB submissions) are NOT YET ACCURATE for migrated studies. They should be present in about a week. **Please** refer to your eIRB studies for the current approved documents (e.g. protocols, consent forms), and use those for amendments in Insight.

Please find information here on working with migrated studies including migration amendments, and for updates on the remaining 96 studies: <https://irb.emory.edu/forms/eirb/how-to.html>. If you have an urgent amendment or continuing review submission request for one of those studies, please email [irb@emory.edu](mailto:irb@emory.edu) directly.

Please also see here for Insight training record troubleshooting: <https://irb.emory.edu/resources/training/courses.html>

**Standard Operating Procedures (SOPs) are available [here](#).**

**Insight Training is available! [Click here and select Learning Management](#).**



# Thank you!

- Emory IRB Listserv: [IRB@emory.edu](mailto:IRB@emory.edu)
- (404) 712-0720
- [www.irb.emory.edu](http://www.irb.emory.edu)
- IRB Staff Directory:  
<https://irb.emory.edu/about/contact/research-analysts.html>
- Rebecca Rousselle, BA, CIP, IRB Director
  - 404-712-0785 or [rebecca.rousselle@emory.edu](mailto:rebecca.rousselle@emory.edu)
- Carol Corkran, MPH, CIP, Assistant Director
  - 404-712-8545 or [ccorkra@emory.edu](mailto:ccorkra@emory.edu)

Please let us know what you think  
of this webinar!

Questions?  
Comments?

**IRB Webinar Feedback Survey**

