



# 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



Emory University is introducing a **fully integrated research administration package**, Insight. Insight is a cloud-based system unifying distributed and complex organizational processes into one highly integrated system to enable compliance, efficiency, and transparency. Insight takes the complexity out of the process.

**Features and benefits:** Optimization and standardization of research processes to:

Reduce  
redundancy across  
the enterprise














Enhance patient  
safety and billing  
compliance

Transparent, real-  
time data and  
reporting

Integration with  
other enterprise-  
wide systems



# Phase I: Where to go now?

Submit	Current	June 20th 2025!
IRB		  Humans
Grant, Contract, CDA, MTA Agreements	    Minuet	  Agreements
Disclosures	 	  Disclosures





PeopleSoft




EMORY  
UNIVERSITY

Office of the Senior  
Vice President for Research

# Insight Home Dashboard

 **Heather S** 

Dashboard

Logout 


Disclosures

Humans

Manage Profiles & Security

Administration

[My Profile](#) [Security Help](#) [Institutional Facts](#) [Training Lookup](#)



### AGREEMENTS

8 ACTIVITIES FOR REVIEW

[2009A017241](#): ICA2  
Assigned: 04/04/25


[2025A031197](#): COI  
Assigned: 03/31/25

[2025A030452](#): Initial Review  
Assigned: 03/21/25

[2025A030993](#): COI  
Assigned: 03/21/25

[2025A030940](#): ICA1  
Assigned: 03/19/25


[See all](#)



### DISCLOSURES


1 ACTIVITY FOR REVIEW

[121](#): Annual Disclosure form required - Shin...  
Assigned: 03/23/25



### HUMANS

You do not currently have any activities for this module.



### MANAGE PROFILES & SECURITY

You do not currently have any activities for this module.



## AGREEMENTS

Action Required

8

Search By

All Agreements/Proposals

## Shinn Testing School Workflow

PI: Shinn, Heather (P6094497)

Institution: Emory University

Organization: 912500

OII Contact: example@example-researchinsight.org

SSO access to  
Insight w/  
Network login

# Get to Know your PPID

- Unique identifier to everyone at Emory.
- Issues with Insight, you will be asked for your PPID.

Demographics: Shinn, Heather (P6094497)

For updates to Associated Organization or Security, navigate to the appropriate pages on the left.

First Name: Heather

Middle Name:

Last Name: Shinn

Primary Email: heather.shinn@emory.edu

User Name: P6094497

Display Name: Shinn, Heather

Domain Status: Active

Title:

Office Address:

City:

State:

Office/Team Type: Select...

Office Location:

Office Phone:

Mobile Phone:

Postal Code:

Degrees:

Select...

## HUMANS

Action Required

0

Notifications

6

Reports

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Create Research Protocol

## Humans Protocols 12

Search by Protocol #, Protocol Title, or PI name

Search

Advanced (0) Clear Selections

Title Protocol # PI Name Overall Status Last Modified Expiration Date Institution

### 2025P000089 Testing Related Records

Lyon, Ksenia Emory - Reviewed Research Protocol Expiration Date: 03/21/26

### 2025P000088 Testing for Research Week

Kraft, Colleen ID: P1257710 Emory - Reviewed Research Expiration Date: 03/20/26

Draft AME 1

Draft AA 1

colleen.kraft@emory.edu

Phone: (01) 678-778-5492

Organization: Emory > Emory University > School of Medicine > Pathology > SOM: Pathology: Admin

Last Modified: 03/21/25

Last Modified: 03/21/25

Testing

Kraft, Colleen

Emory - Reviewed Research

Expiration Date: N/A

Left Panel flags for submitter what is still required with Red Explanation Point

Submission Checklist keeps a running list of what the submission needs and will direct submitter to missing documentation.

The screenshot shows a sidebar panel titled 'HUMANS' with a user icon. Below the title, it says 'In Progress' next to an 'IR' label. A list of items follows: 'Forms' with a red exclamation mark icon, 'Staff' with a red exclamation mark icon, 'Attachments' with a green checkmark icon, 'Related Records' with a green checkmark icon and a blue box containing the number '0', and 'Summary Notes' with a list icon.

The screenshot shows a 'Submission Checklist' panel. At the top, there is a 'Close panel' button and a 'Draft' status label. Below this, the 'Initial Review (IR)' status is shown as 'Draft'. The panel contains a list of instructions for the submitter, including filling out fields like 'Title', 'Short Title', and 'Please provide a lay summary that follows our guidelines here'. It also lists requirements for research specimen repositories and research data registries. The panel ends with a 'Cancel' button and a 'CREATE PROTOCOL' button.

# Insight Humans Module (IRB)





# Humans Module Quick Wins

CITI Training will be integrated with Study Staff and submitter will no longer have to wait for approval.



Streamlined exemption process.



Some submissions will no longer require Protocol attachments.

Insight 4.0 - Emory Electronic R...

marietta-emory.researchinsight.org/humans/protocols

Heather S

HUMANS

Action Required0

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Create Research Protocol

Create Ceded Research Protocol

Create Single Pt Tx Use

Agreements

Disclosures

Manage Profiles & Security

Administration

Humans Protocols11

Search by Protocol #, Protocol Title, or PI name

Search

Advanced (0)

Clear Selections

View: ActiveInactiveActive, ExemptClosed, Exempt

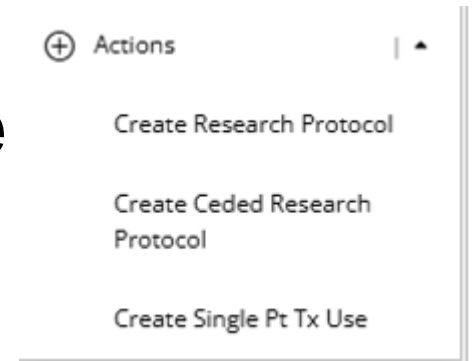
Title	Protocol #	PI Name	Overall Status	Last Modified	Expiration Date	Institution
2025P000088 Testing for Research WeekActive, Open to Enrollment/Col						
Kraft, Colleen		Emory - Reviewed Research Protocol	Expiration Date: 03/20/26			
TestingIn Pr						
Kraft, Colleen		Emory - Reviewed Research Protocol	Expiration Date: N/A			
IR	Draft	Draft	Last Modified: 03/18/25			
2025P000065 Testing Cede WorkflowSubmitted, Cede						
Kraft, Colleen		Externally - Reviewed Research Protocol	Expiration Date: N/A			
CEDE	Submitted	PI Review	Last Modified: 03/17/25			
2025P000052 Testing Ancillary Name: "Specialty: PRMC/Winship"Sub						
Kraft, Colleen		Emory - Reviewed Research Protocol	Expiration Date: N/A			
IR	Submitted	Triage	Last Modified: 03/17/25			
2025P000063 Mark "IsAdminApprove" to YES for the Drug or Device that gets added in a form when the transaction is approvedSub						
Lyoni, Ksenia		Emory - Reviewed Research Protocol	Expiration Date: N/A			
IR	Submitted	PI Review	Last Modified: 03/17/25			
2025P000051 Testing Ancillary Name: "Specialty: PRMC (stem cell)"Sub						
Kraft, Colleen		Emory - reviewed research Protocol	Expiration Date: N/A			
IR	Submitted	PI Review	Last Modified: 03/07/25			
2025P000050 Testing: Ancillary Name: "Device: CHOA"Sub						
Kraft, Colleen		Emory - Reviewed Research Protocol	Expiration Date: N/A			

Click Search

Insight Humans Landing Page

# Humans Module – Protocol Types

- **Research Protocol (IR)** – Standard, new IRB protocol
- **Ceded Research Protocol** - External IRB
- **Single Pt Tx Use** – For certain single-patient uses of unapproved drugs/devices.
- **Protocol Nomenclature**  
– 2025PXXXXXX



Legacy Protocol # will live  
in Insight.

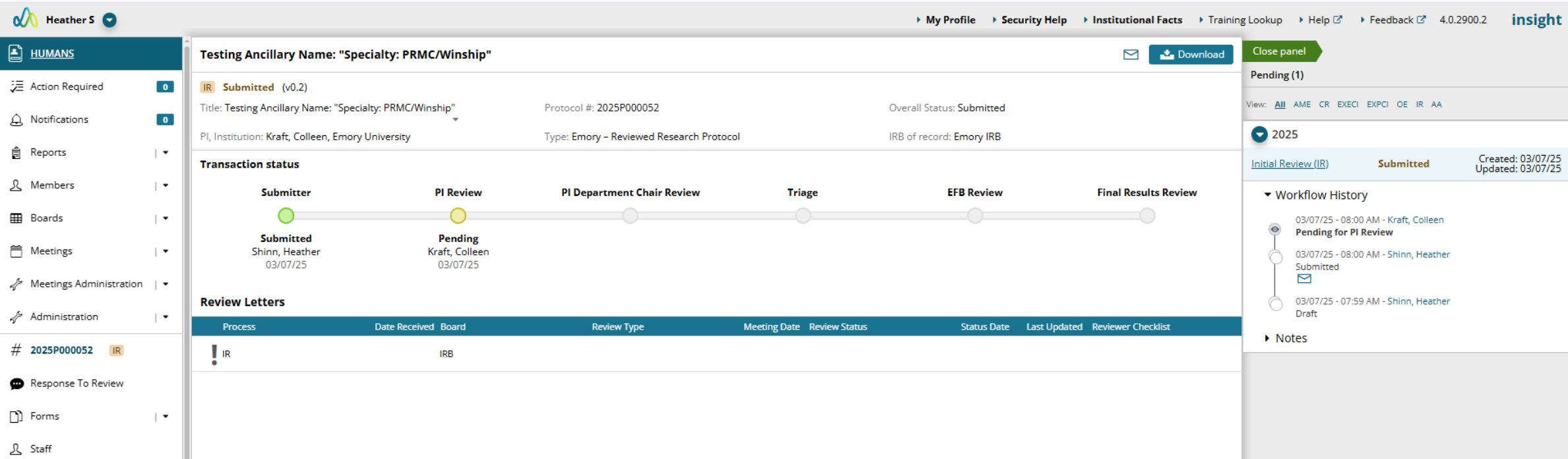
# IRB Forms

- IRB Forms have been built into Insight.
- There are a base set of forms that will trigger.
- There are additional forms that may trigger based on how questions are answered in the protocol.

Forms <span>+ Add New Form</span>			
	Last Modified	Modified By	Process
Initial Questionnaire			
<a href="#">Study Overview</a>	03/21/25	Shinn, Heather	IR
Study Funding Sources			
<a href="#">MERCK AND COMPANY [Corporate]</a>	03/21/25	Shinn, Heather	IR
Intervention			
<a href="#">Health Data and Security</a>	03/21/25	Shinn, Heather	IR
<a href="#">Study Subject Areas</a>	03/21/25		IR
<a href="#">Conflicts of Interest</a>	03/21/25		IR
<a href="#">Study Details</a>	03/21/25		IR
<a href="#">Clinical Trials Registration</a>	03/21/25		IR
<a href="#">Study Population</a>	03/21/25		IR
<a href="#">Research Locations</a>	03/21/25		IR
<a href="#">Recruitment</a>	03/21/25		IR
<a href="#">Compensation</a>	03/21/25		IR
<a href="#">Informed Consent</a>	03/21/25		IR
<a href="#">Data Privacy, Confidentiality, and Sharing</a>	03/21/25		IR
<a href="#">Data Collection Tools</a>	03/21/25		IR
Secondary Use of Data and/or Specimens			
<a href="#">Secondary Use of Data and/or Specimens</a>	03/21/25		IR

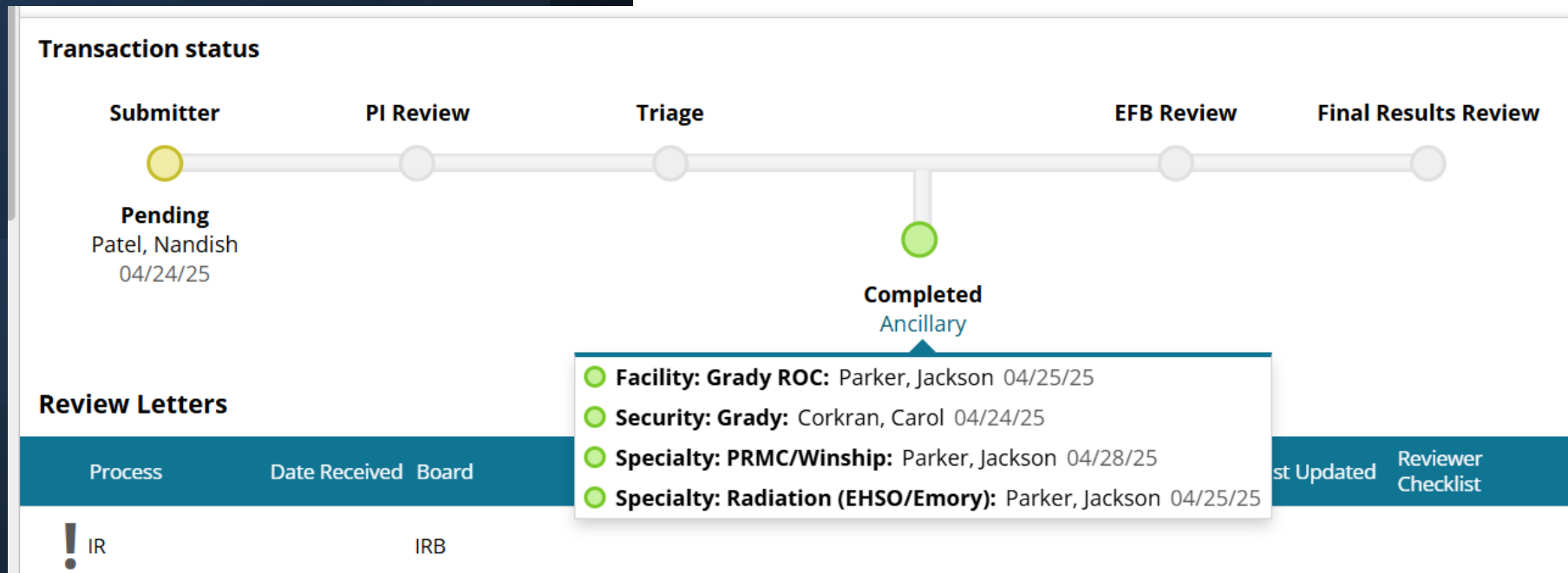


# Subway Map for Workflow Tracking



# Ancillary Reviews

- Ancillaries are built in Insight, same as current state.
- Insight will trigger an activity via workflow to the assigned ancillary reviewer(s). The ancillary reviewer will then do the review in Insight and take an action.
  - Radiation Safety, Biosafety, PRMC, COI, etc.
- Study will not be approved until ancillary reviews are completed.



Insight 4.0 - Emory Electronic R...

marietta-emory.researchinsight.org/humans/protocol/210/transaction/302/version/1238/forms/11120

Heather S

My ProfileSecurity HelpInstitutional FactsTraining LookupHelpFeedback4.0.2900.2

HUMANS

Action Required0

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In ProgressIR

Forms

Initial Questionnaire

Study Overview

Study Funding Sources

Add Study Funding Sources

Intervention

Health Data and Security

Study Subject Areas

Conflicts of Interest

Study Details

Clinical Trials Registration

Study Population

Research Locations

Recruitment

Compensation

Informed Consent

Data Privacy Confidentiality

Protocol InfoFormsStaffAttachmentsRelated Records

Testing Related Records

IR Draft (v0.1)

Title: Testing Related RecordsOverall Status: In ProgressType: Emory - Reviewed Research Protocol

IRB of record: Emory IRB

Sponsor/Funding

Instructions

Select fund type etc etc

Search Insight Agreements for the funding proposal (pending or awarded) supporting the research below

No funding proposal in Insight Agreements

NONE - There is no external sponsor/funding, institutional award or sundry funds supporting this research

Agreement #Project IDPI NameShinn, Heather (P6094497)SearchClear Selections

Agreement #	Grant #	PI Name	Record Type	Sponsor	Project Period
<div><div></div><div>2025A030774</div></div>		Shinn, Heather	Grant & Cooperative Agreement	MERCK AND COMPANY	03/27/25 - 06/03/26
<div><div></div><div>2025A030626</div></div>		Shinn, Heather	Grant & Cooperative Agreement	MERCK AND COMPANY	03/27/25 - 06/03/26
<div><div></div><div>2025A030537</div></div>		Shinn, Heather	Grant & Cooperative Agreement	MERCK AND COMPANY	03/27/25 - 06/03/26

< PreviousNext >

Close panel

Draft

Initial Review (IR)DraftCreated Updated

Workflow History

03/21/25 - 10:45 AM - Shinn, HeatherDraft

Instructions

Submission Checklist

All validations in this area have been completed

Notes

Submitter Actions

Please complete the submission checklist

DELETE IRCancelSAVE

Module Connection - Sponsor Funding Form

# Module Connection – Related Records Humans and Agreements

Testing Related Records

Download

IR Submitted (v0.2)

Title: Testing Related Records  
PI, Institution: Lyon, Ksenia, Emory University

Protocol #: 2025P000089  
Type: Emory – Reviewed Research Protocol

Overall Status: Submitted  
Immediate Sponsor: MERCK AND COMPANY

more ▾

Related Records

Funding/Support Agreement Records (1)

Record #	Grant #	Project Period	PI Name	Sponsor	Record Type	Process	Link Date	Link Status
<a href="#">2025A030774</a> ↗		03/27/25 - 06/03/26	Shinn, Heather	MERCK AND COMPANY	Proposals and Funded Agreements	IR		Draft

Other Agreement Records (0)

Record #	Grant #	Project Period	PI Name	Sponsor	Record Type	Process	Link Date	Link Status
No data found.								



# Staff

**Study Staff** – Anyone doing research on the protocol. Requires CITI training.

- Indicates of staff needs CITI training
- Shows CITI training expiration date

**Non-Study Staff** – Admin staff who need access to the protocol, don't need CITI training.

- Reviewing letters, creating amendments to be submitted but not part of the research.

**Financial Delegate** - Ties in with Epic integration.

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# 2025P000089

Forms

Staff

Staff

☐ Search Study Staff History

Study Staff (1)

Name	Degree	Organization	Role	Permission	Process	eCOI	Training	Staff Cert.	Contact
Lyon, Ksenia		Emory > Emory University > SVP - Research > Research Administration > Institutional Review Board	Principal Investigator	Manage	IR	<a href="#">Review Not Needed</a>	03/11/28		

Non-study Staff (1)

Name	Organization	Permission	Comments	Contact
Shinn, Heather	Emory > Emory University > SVP - Research > Research Administration > Conflict of Interest	Manage		

Financial Delegate

Grant #	Financial delegate
No data found.	

# Module Connection

## – Investigator Disclosure

- Have to disclose any financial interest involved with a study/protocol.
- If Yes for the PI, going to trigger an event in the Disclosures module.
- If Yes for a study staff member, Conflict of Interest Disclosure office will be notified and will create an event for the study staff member to complete in Disclosures.

### Investigator Disclosure, part II

#### Definition of financial interest

**Who holds the interest?** The individual involved in the research, or the immediate family of the researcher. "Immediate" family means the spouse, domestic partner, children, or dependents.

**Interest in what?** The study sponsor, a competitor of the sponsor, or a product or service being tested.

**What is an interest? Any of the following:**

- Ownership interest of any value including (but not limited to) stocks and options, exclusive of interests in publicly-traded, diversified mutual funds.
- Compensation of any amount including (but not limited to) honoraria, consultant fees, royalties, or other income.
- Proprietary interest of any value including (but not limited to) patents, trademarks, copyrights, and licensing agreements.
- Board or executive relationship, regardless of compensation.
- Reimbursed or sponsored travel by an entity other than a federal, state, or local government agency, higher-education institution or affiliated research institute, academic teaching hospital, or medical center.

1. Do you or any immediate family members of yours have a financial interest in the company sponsoring the study or IP being used in the study?

☐ Yes ☐ No

2. Do any of your study staff members have a financial interest in the company sponsoring the study or in the IP being used in the study? Or, do any immediate family members of any study staff members have such a financial interest?

☐ Yes ☐ No

Is any licensed Emory intellectual property (IP) used in this project?

☐ Yes ☐ No

# Approved IRB Protocol & Additional Actions

Heather S

Meetings Administration

Administration

# 2025P000089

Forms

Staff

Attachments

Related Records 1

Summary Notes

Actions

Create Research Protocol

Create Ceded Research Protocol

Create Single Pt Tx Use

Create Amendment

Create Administrative Action

Create Staff Updates

Create Other Event

Create Continuing Review or Continuing Review/Amendment

Testing Related Records

Currently approved (v1.0)

Protocol #: 2025P000089

PI, Institution: Lyon, Ksenia, Emory University

Overall Status: Active, C

Type: Emory - Reviewer

Protocol Published Documents

View	Name
------	------

Protocol Status History

Description
Protocol Status Change
Protocol Status Change
Protocol Status Change

Actions

Create Research Protocol

Create Ceded Research Protocol

Create Single Pt Tx Use

Create Amendment

Create Administrative Action

Create Staff Updates

Create Other Event

Create Continuing Review or Continuing Review/Amendment

Close panel

Review

Initial Review (IR)

Approved

Created on: 03/20/25

Updated on: 03/20/25

Workflow History

03/20/25 - 05:32 PM

Completed

03/20/25 - 05:32 PM - Rotterman, Briana

Approved and Completed by Expedited Reviewer

03/20/25 - 05:26 PM - Rotterman, Briana

Routed to Expedited Review by Triage

03/20/25 - 05:02 PM - Parker, Jackson

Acceptable for IRB review by PI Department Chair

03/20/25 - 05:00 PM - Kraft, Colleen

Accepted by PI

03/20/25 - 03:59 PM - Shinn, Heather

Submitted

03/20/25 - 03:58 PM - Shinn, Heather

Draft

# IRB Migrations

- Can continue to submit new studies, amendments, and continuing reviews as soon as possible in eIRB.
- TBD - Cutoff date for new study submissions in eIRB.
- Couple Migration waves
  - 1<sup>st</sup> Wave: Fully approved, has no active follow-on submissions
  - 2<sup>nd</sup> Wave: Finish work of what is in progress in eIRB and then migrate studies.
- At some point, the cutoff in eIRB will occur and you may have to resubmit in Insight if not fully approved by a certain date.



# User Acceptance Testing April 22 – May 19, 2025

**Volunteers for Humans and/or Disclosures**

**Email Heather Shinn**  
**heather.shinn@emory.edu**

**Volunteers for Agreements**  
**Email Cindy Cha**  
**Cindy.cha@emory.edu**

Milestone	User Acceptance Testing (UAT) Completed	Final Application Sign-off	Go-live
Anticipated Timing	<b><u>Sprints 167 to 168</u></b> (April 22, 2025 to May 19, 2025)	<b>May 20, 2025</b>	<b><u>Details to be finalized</u></b> Weekend of June 20, 2025
Tasks + Outstanding Work	<ul style="list-style-type: none"><li>• Includes application, migration, integration and reporting testing</li><li>• Training Schedule</li><li>• Training Materials</li><li>• Communication Plan</li></ul>	<ul style="list-style-type: none"><li>• Final Sign-off on phase 1 modules</li></ul>	<ul style="list-style-type: none"><li>• Align on final go-live timeframe and post go-live support</li></ul>

# User Acceptance Testing April 22 – May 19, 2025

## **Volunteers for Humans and Disclosures**

**Email Heather Shinn**  
**heather.shinn@emory.edu**

## **Volunteers for Agreements**

**Email Cindy Cha**  
**cindy.cha@emory.edu**

## **UAT Testing**

- Testing will occur every Tuesday, Wednesday, and Thursday.
- Location: Tentatively RSPH - Rita Anne Rollins Room, GCR 8<sup>th</sup>
- Submitter sessions are 3 hours in the morning. Join when it works with your schedule.
- Submitter and Reviewer roles.
- Invite series have been sent out.
- **Bring your laptop if onsite.**

UAT will have  
both onsite/in-  
person &  
virtual options!

# Burning Questions



## IS TRAINING REQUIRED?

- Yes. The self-paced learning will be required in Brainier.
- Completion of training will drive access to Insight.



## WHEN WILL WE BEGIN TRAINING?

- You can start learning now in exploration sessions, work groups, and User Acceptance Testing.
- Formal training starts in May.



## I FORGOT WHAT I JUST LEARNED!!!

- First, don't panic!
- There is in-app guidance.
- You'll have Superusers.
- There's a number to call for virtual how-to support!



# LEARNING JOURNEYS

There will be different learning journeys based on what you'll do in the system.



**Insight Core** is for all users to learn the basics of insight (est. 1 hour)

---



**Submitter** is for users who submit protocols and agreements (est. 1 hour)

---



**Reviewer** is for users responsible for reviewing but not approving submissions (est. 10 min)

---



**Approver** is for users who are responsible for sign off and final approval of submissions (est. 15 min)



# PHASE 1 – GO-LIVE JUNE 20th, 2025

[Comprehensive Phase 1 Sprint document](#)



## Agreements

- Proposals and Funding Agreements
- Material Transfer (MTA)
- Data Use (DUA)
- Confidential Disclosure (CDA)
- External Activities



## Disclosures

- Conflict of Interest (COI)



## Humans (IRB)

- All current studies will be transferred into INSIGHT



## Core Items

- Administration
- Manage Profiles & Security
- Infrastructure
- Training Plan
- Communication Plan
- Post Live Support

# PHASE II – GO-LIVE AUGUST 2026



## Animals



## Personnel



## Export Controls



## Financials



## Biosafety



## Space Management



## Effort Reporting



## Innovation/Tech Transfer

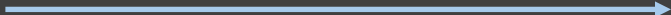
# Insight Workflow: Changes from eIRB

- Teams will need to provide tracked-changes and clean versions each time documents are revised - either during the Initial Review or within Amendments.
- There is currently not an option for a “PI Proxy” in Insight.
- The PI will need to sign off on each submission/re-submission for new studies, amendments, Other Events, and Continuing Reviews.
  - The **good news** is that we were able to remove the requirement for each study team member to sign off for initial submission!
  - We’ve asked the vendor to scope out a product update requiring fewer PI touchpoints

# Insight Workflows, continued

- Research that falls into “**Exempt**” regulatory categories: Streamlined forms and no required protocol attachment
- Emergency- and non-Emergency single patient treatment uses (drugs/devices): Also very streamlined, and no CITI required
- “Not human subjects research” determination form: Still available via the IRB’s website (outside of Insight)

# Nomenclature updates from eIRB to INSIGHT

eIRB 	INSIGHT
New Study	Initial Review (IR)
Modification (MOD)	Amendment (AME)
Reportable New Information (RNI)	Other Event (OE)
External IRB Submission	CEDE Protocol
IRB concurrence for non-Emergency single patient treatment use via RNI	Single Pt Tx Use

# Clean Up...

Data migration from SaaS to INSIGHT will **only** include studies without in-progress submissions.

As a result, please do the following:

- **Discard** any pending New Studies, Modifications or CRs that are not moving forward (can restart in Insight)
- **Close out** studies that are no longer active  
If no one is left to submit, alert the IRB
- **Clean up** submissions via Modification  
Specifically: funding sources, inactive documents, study team members, and incomplete questions in the smartform (e.g; Clinical Research/Expanded Access Only)





# CITI Training

- Must have current CITI to be listed as “study staff,” and Insight checks automatically – no option to upload certificates
  - Insight also knows what courses are required for your study and role
- **Use Emory SSO to sign in to CITI now if you have not done so before** (choose “Log in through my Organization”)
- If you have multiple CITI accounts: contact CITI support to merge them to the one related to your SSO login
- Children’s and VA CITI records: Project team is working on solution to populate CITI data for those who need to be listed as local study team (not external).
  - Hoping a direct feed can be in place soon after implementation

Share your  
thoughts!

## Feedback on Insight - Humans Module



# INSIGHT TEST ENVIRONMENT

[Marietta Testing Environment](https://marietta-emory.researchinsight.org/)

<https://marietta-emory.researchinsight.org/>



Website

Keep up with progress

Watch demos

Visit our FAQs page





**Questions**