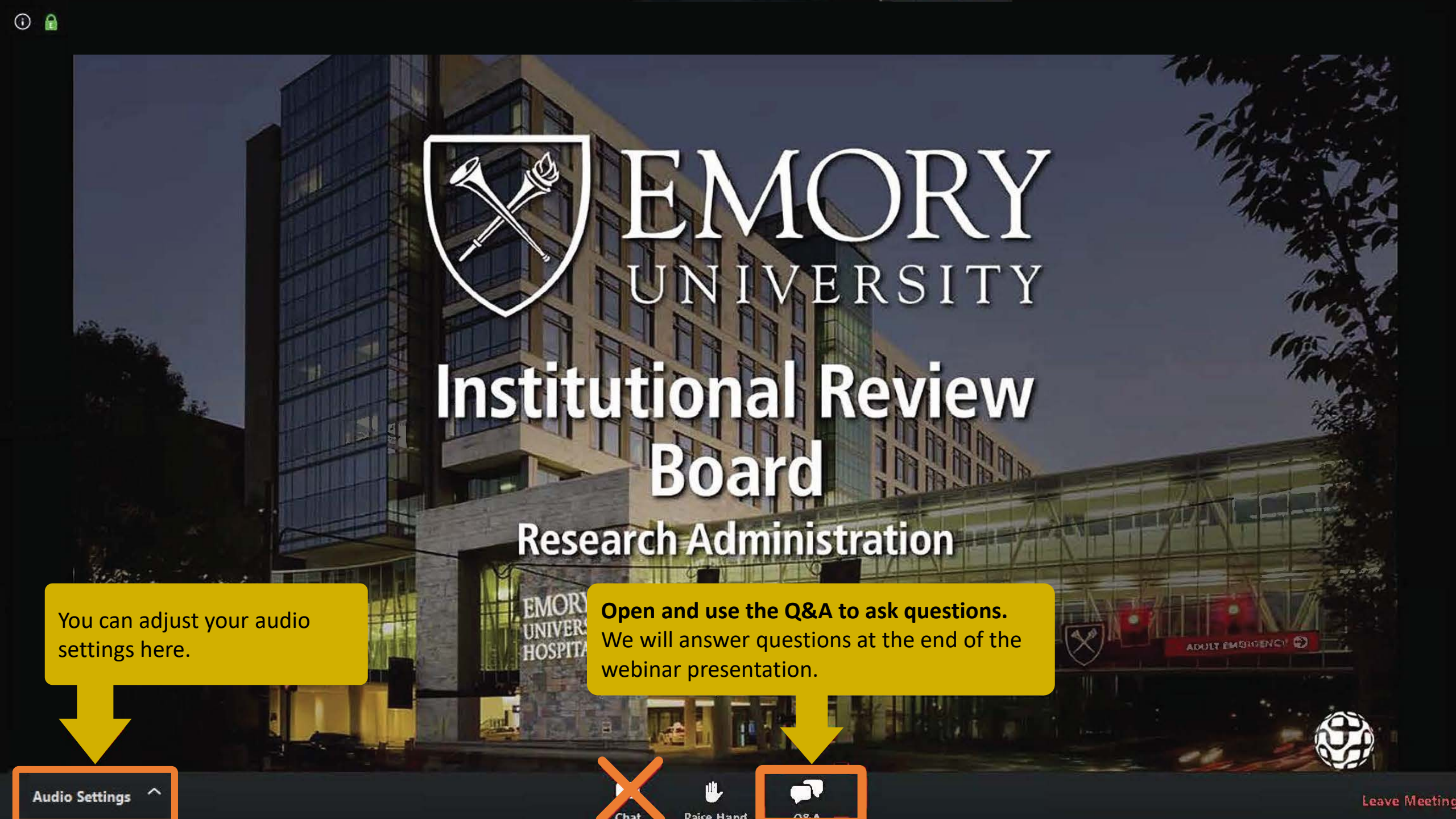

EMORY
UNIVERSITY
Institutional Review Board
Research Administration
You can adjust your audio settings here.
Open and use the Q&A to ask questions.
We will answer questions at the end of the webinar presentation.
Audio Settings
Chat
Raise Hand
Q&A
Leave Meeting

Insight

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

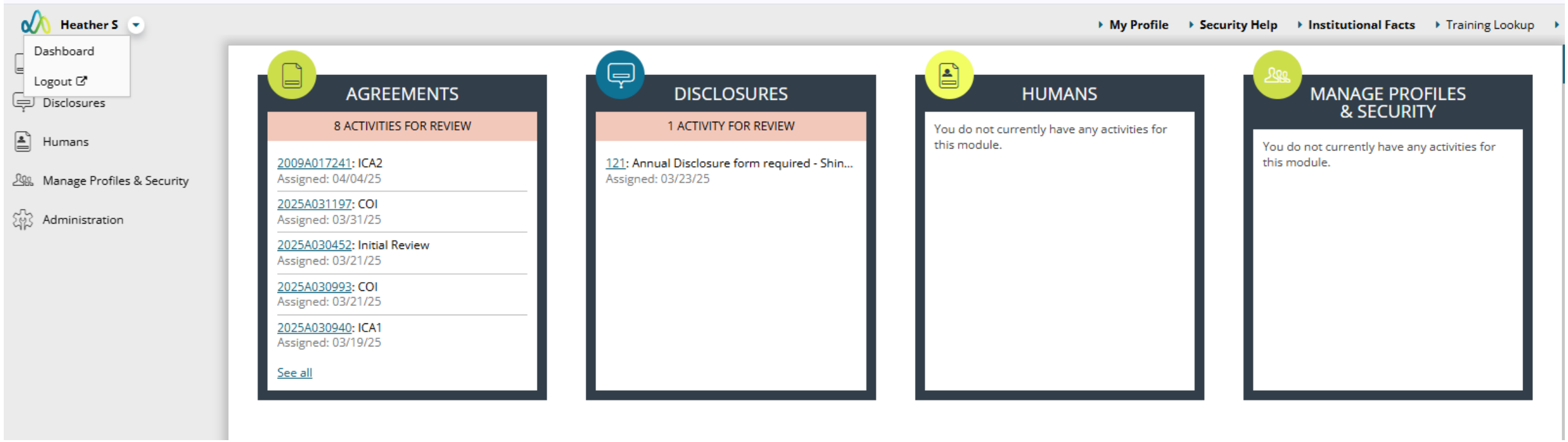
Phase I: Where to go now?

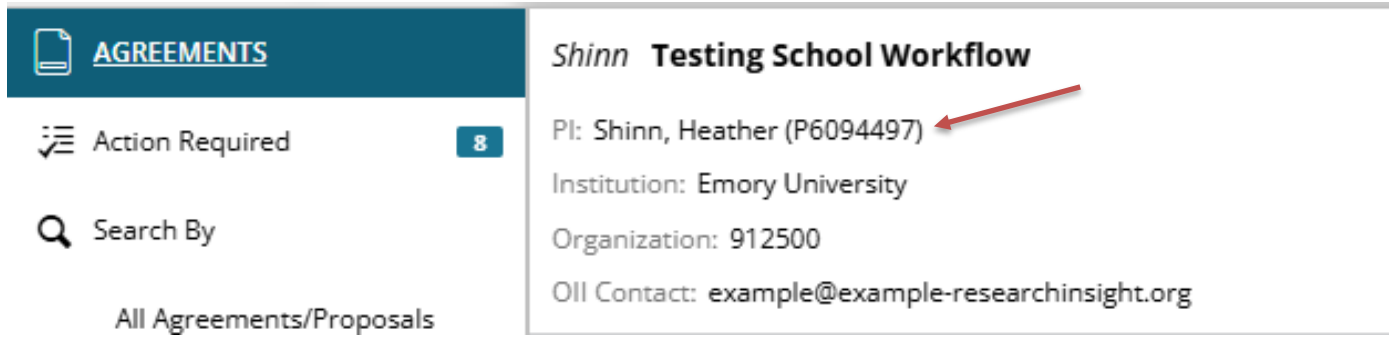
Submit	Current	June 20th 2025!
IRB	EMORY eIRB	INSIGHT Humans
Grant, Contract, CDA, MTA Agreements	Intent to Submit; EPEX; Minuet; (EGTS); (eCTS)	INSIGHT Agreements
Disclosures	EMORY eDisclose; eCOI electronic Conflict of Interest	INSIGHT Disclosures

Future State

PeopleSoft

Insight Home Dashboard

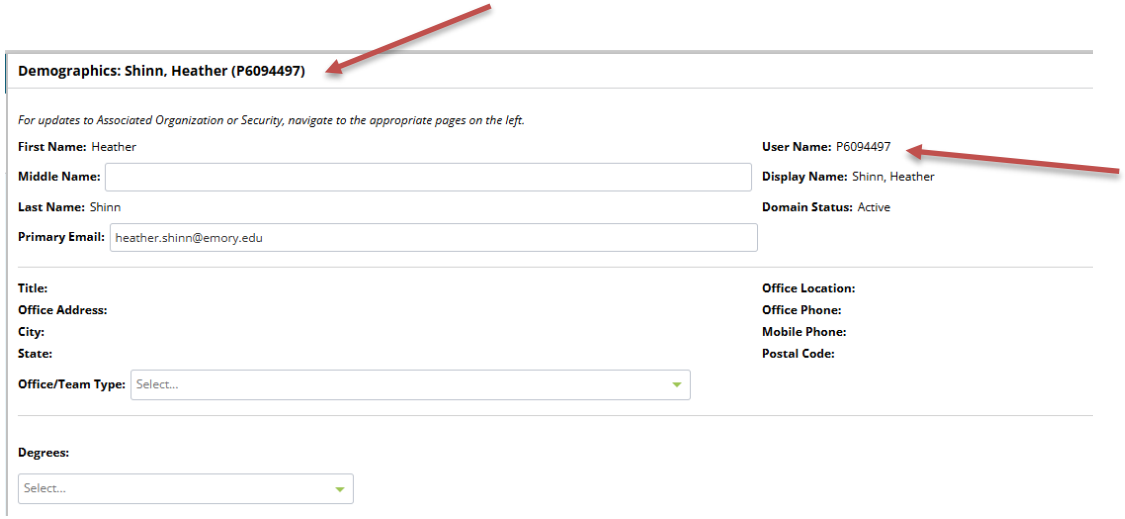


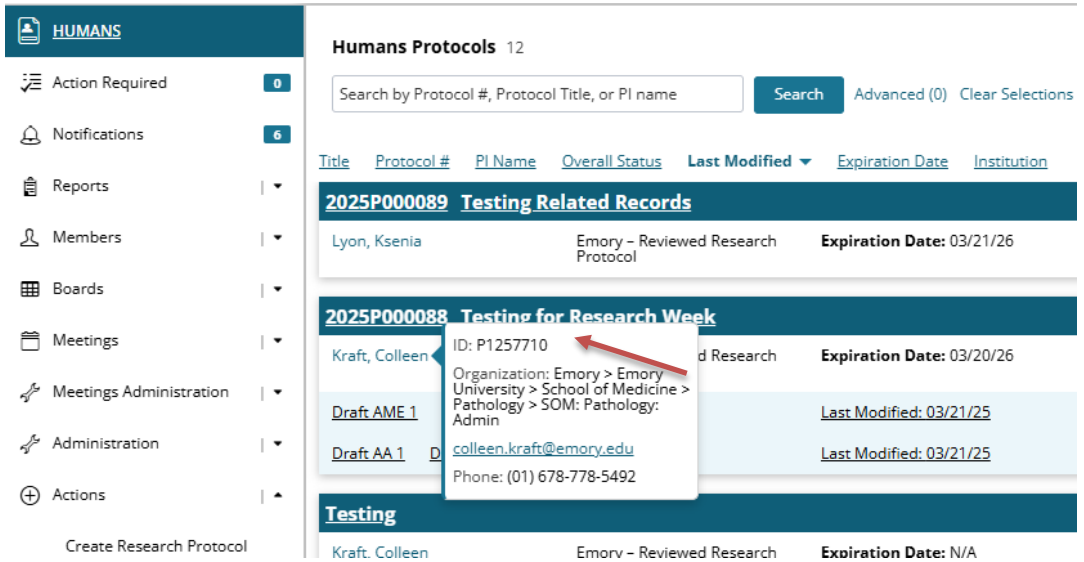


SSO access to Insight w/ Network login

Get to Know your PPID

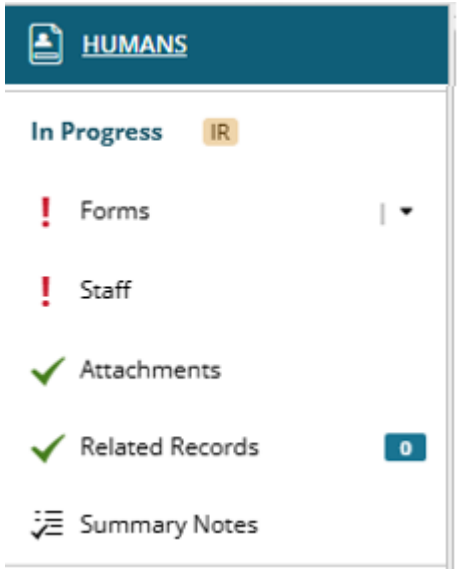
- Unique identifier to everyone at Emory.
- Issues with Insight, you will be asked for your PPID.

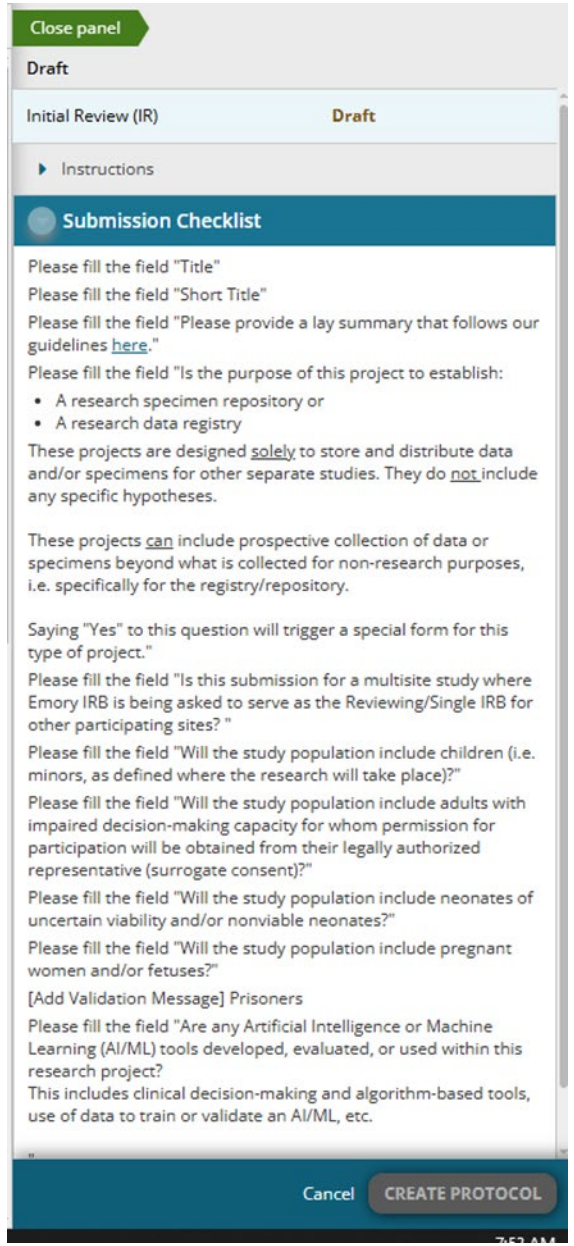




Left Panel flags for submitter what is still required with Red Explanation Point

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





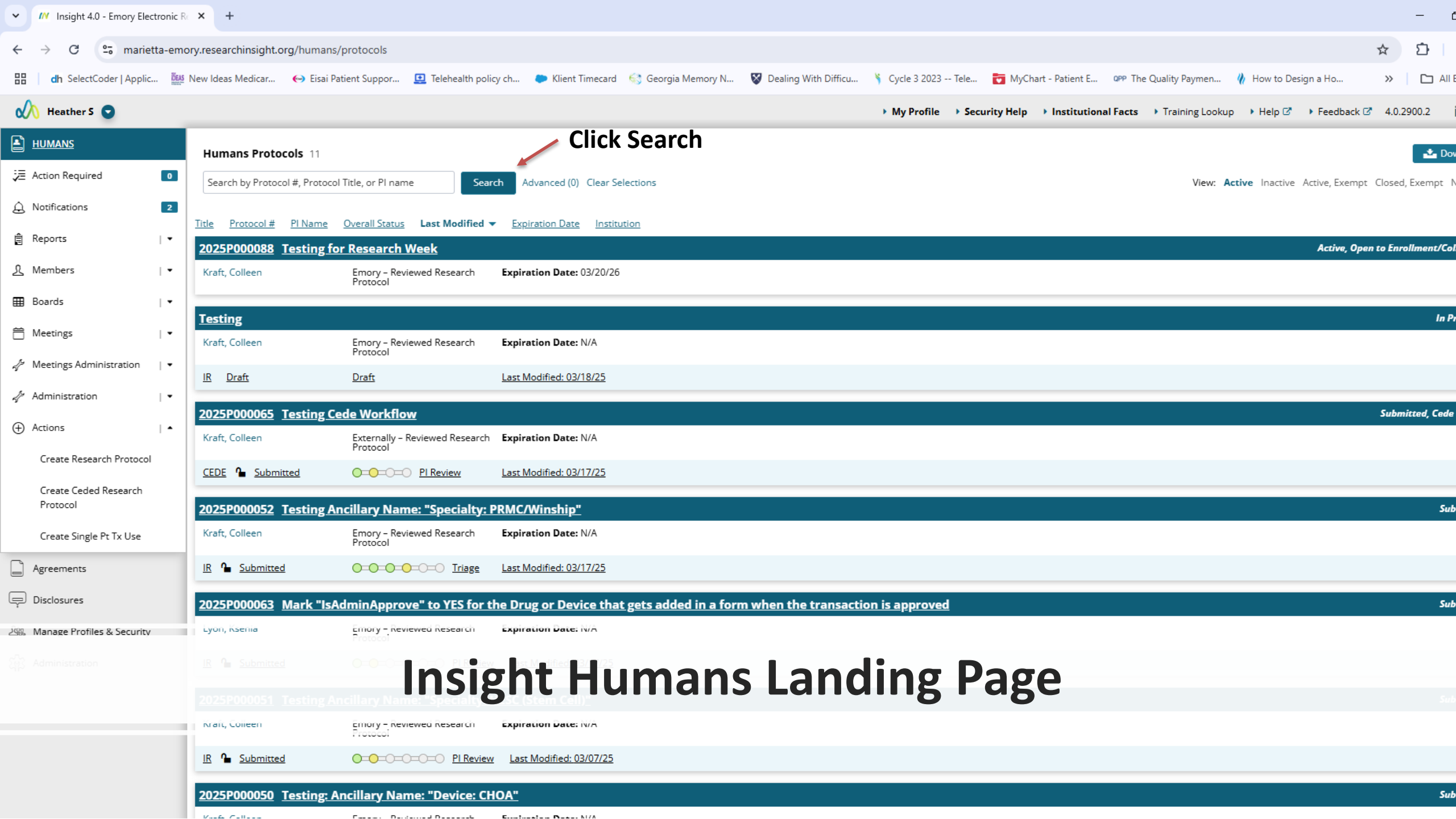
Insight Humans Module (IRB)

Humans Module Quick Wins

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

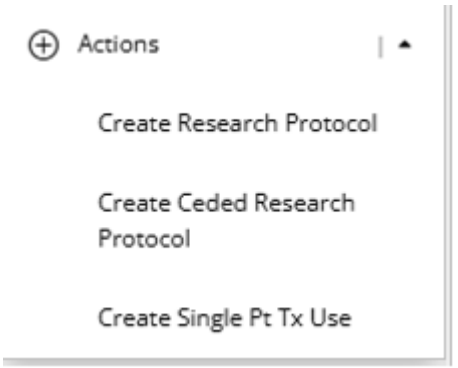
Streamlined exemption process.

Some submissions will no longer require Protocol attachments.


Insight 4.0 - Emory Electronic R
marietta-emory.researchinsight.org/humans/protocols
Heather S
My Profile
Security Help
Institutional Facts
Training Lookup
Help
Feedback
4.0.2900.2
HUMANS
Action Required
Notifications
Reports
Members
Boards
Meetings
Meetings Administration
Administration
Actions
Create Research Protocol
Create Ceded Research Protocol
Create Single Pt Tx Use
Agreements
Disclosures
Manage Profiles & Security
Humans Protocols 11
Click Search
Search by Protocol #, Protocol Title, or PI name
Search
Advanced (0)
Clear Selections
View: Active Inactive Active, Exempt Closed, Exempt
Title
Protocol #
PI Name
Overall Status
Last Modified
Expiration Date
Institution
2025P000088 Testing for Research Week
Active, Open to Enrollment/Col
Kraft, Colleen
Emory – Reviewed Research Protocol
Expiration Date: 03/20/26
Testing
In Pr
Kraft, Colleen
Emory – Reviewed Research Protocol
Expiration Date: N/A
IR Draft
Draft
Last Modified: 03/18/25
2025P000065 Testing Cede Workflow
Submitted, 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 approved
Sub
2025P000051
IR Submitted
PI Review
Last Modified: 03/07/25
2025P000050 Testing: Ancillary Name: "Device: CHOA"
Sub
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.

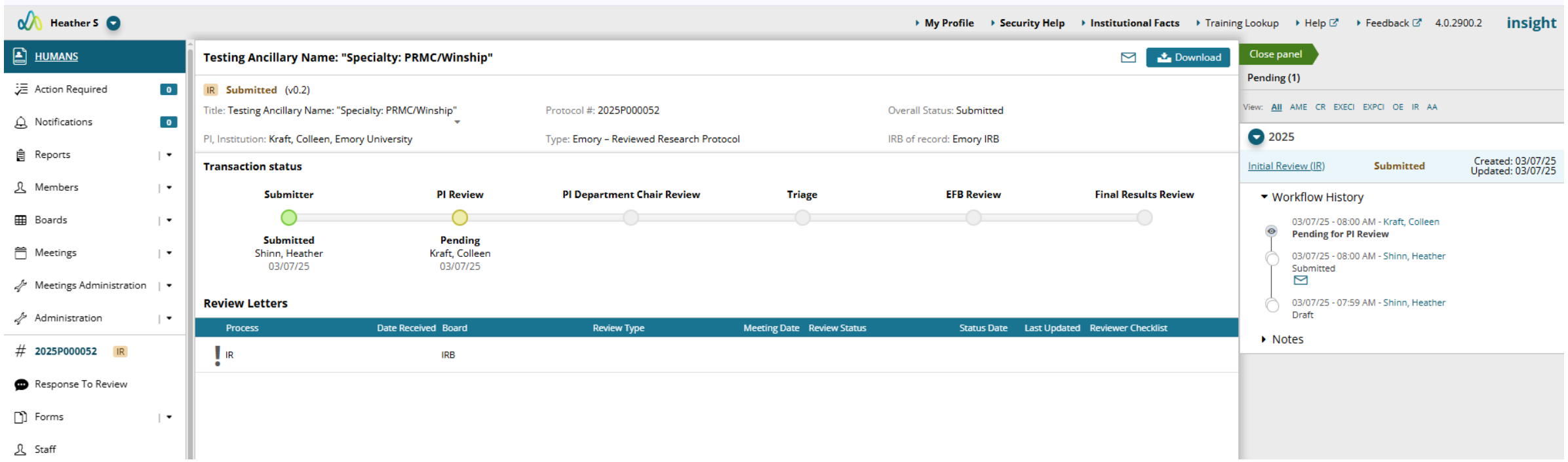
IRB Forms

- 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 + Add New Form

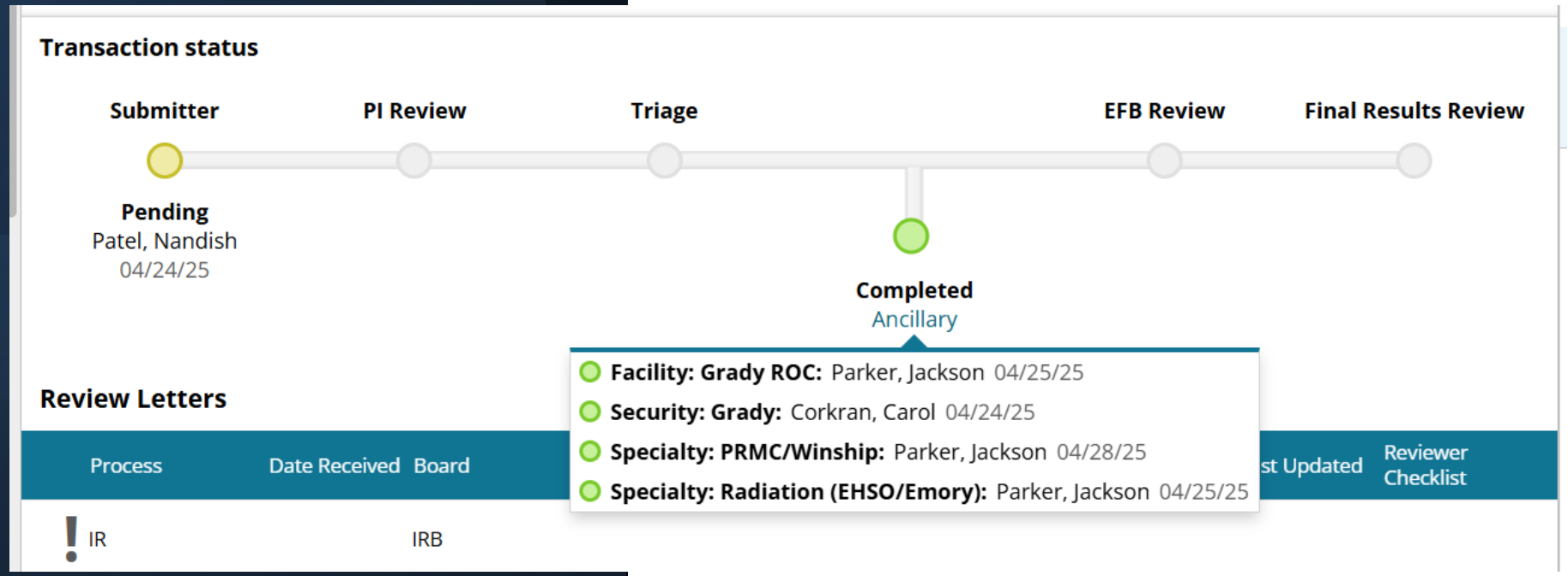
	Last Modified	Modified By	Process	
Initial Questionnaire				
Study Overview	03/21/25	Shinn, Heather	IR	
Study Funding Sources				
MERCK AND COMPANY [Corporate]	03/21/25	Shinn, Heather	IR	
Intervention				
~~Health Data and Security~~	~~03/21/25~~	~~Shinn, Heather~~	~~IR~~	↺
Study Subject Areas	03/21/25		IR	✕
Conflicts of Interest	03/21/25		IR	✕
Study Details	03/21/25		IR	✕
Clinical Trials Registration	03/21/25		IR	✕
Study Population	03/21/25		IR	✕
Research Locations	03/21/25		IR	✕
Recruitment	03/21/25		IR	✕
Compensation	03/21/25		IR	✕
Informed Consent	03/21/25		IR	✕
Data Privacy, Confidentiality, and Sharing	03/21/25		IR	✕
Data Collection Tools	03/21/25		IR	✕
Secondary Use of Data and/or Specimens				
Secondary Use of Data and/or Specimens	03/21/25		IR	✕

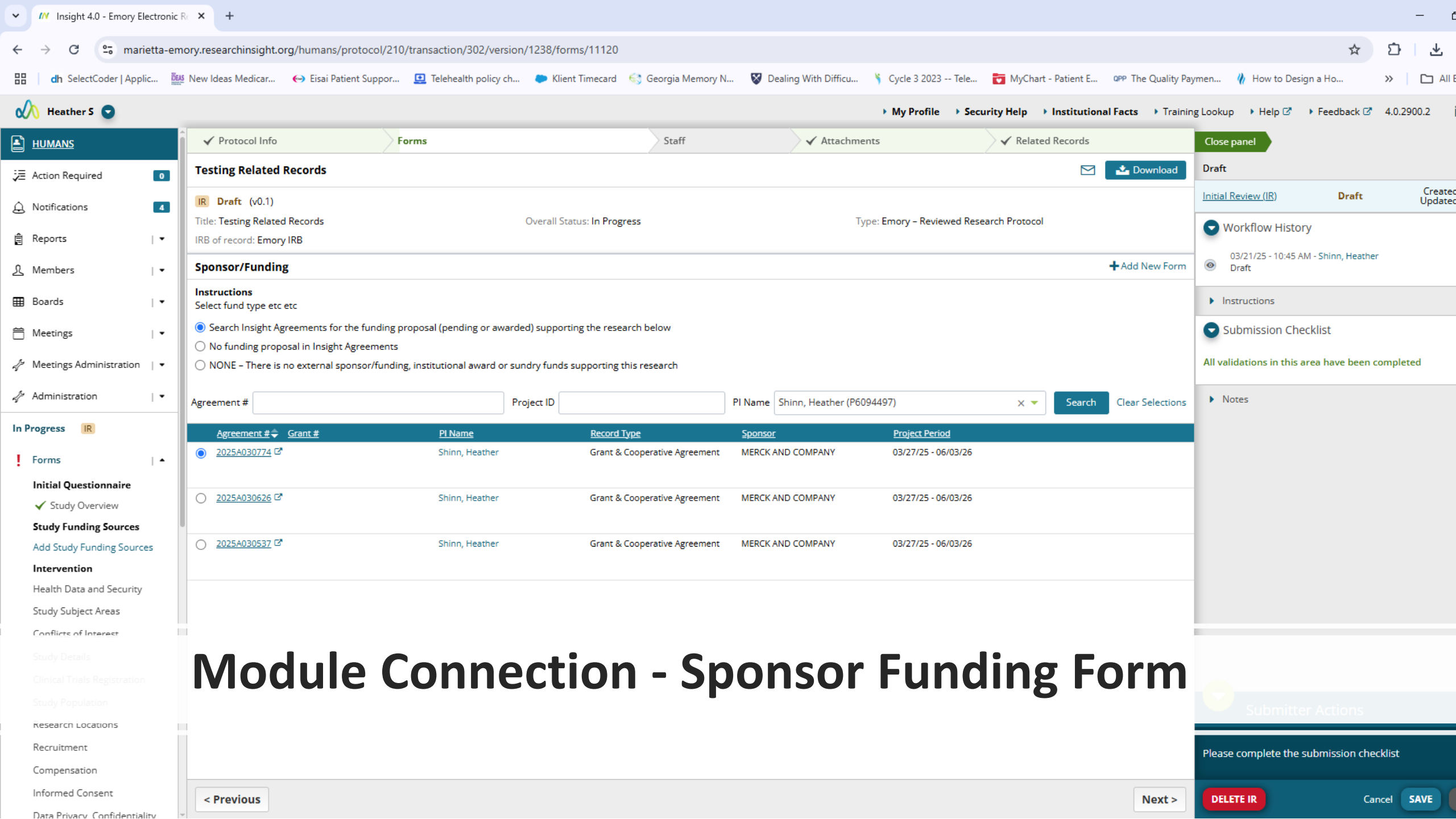
Subway Map for Workflow Tracking



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.

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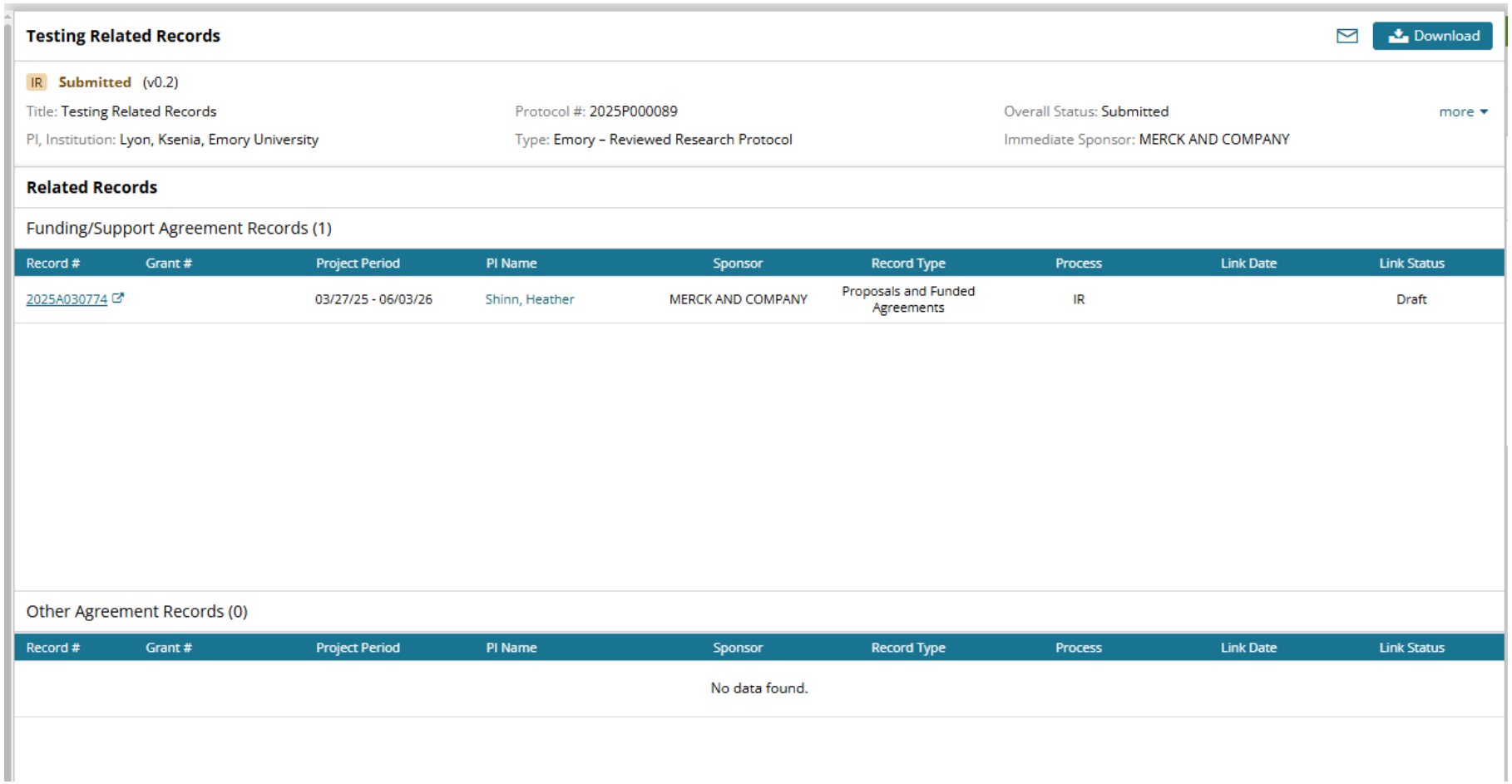
Heather S
My Profile
Security Help
Institutional Facts
Training Lookup
Help
Feedback
4.0.2900.2
HUMANS
Action Required 0
Notifications 4
Reports
Members
Boards
Meetings
Meetings Administration
Administration
In Progress IR
Forms
Initial Questionnaire
Study Overview
Study Funding Sources
Add Study Funding 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 Info
Forms
Staff
Attachments
Related Records
Close panel
Testing Related Records
Download
IR Draft (v0.1)
Title: Testing Related Records
Overall Status: In Progress
Type: Emory – Reviewed Research Protocol
IRB of record: Emory IRB
Sponsor/Funding
Add New Form
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 ID
PI Name
Shinn, Heather (P6094497)
Search
Clear Selections
Agreement # Grant # PI Name Record Type Sponsor Project Period
2025A030774 Shinn, Heather Grant & Cooperative Agreement MERCK AND COMPANY 03/27/25 - 06/03/26
2025A030626 Shinn, Heather Grant & Cooperative Agreement MERCK AND COMPANY 03/27/25 - 06/03/26
2025A030537 Shinn, Heather Grant & Cooperative Agreement MERCK AND COMPANY 03/27/25 - 06/03/26
Draft
Initial Review (IR) Draft Created Updated
Workflow History
03/21/25 - 10:45 AM - Shinn, Heather
Draft
Instructions
Submission Checklist
All validations in this area have been completed
Notes
Module Connection - Sponsor Funding Form
Submitter Actions
Please complete the submission checklist
< Previous
Next >
DELETE IR
Cancel
SAVE

Module Connection – Related Records Humans and Agreements



Testing Related Records

Download

IR **Submitted** (v0.2)

Title: Testing Related Records
Protocol #: 2025P000089
Overall Status: Submitted
more

PI, Institution: Lyon, Ksenia, Emory University
Type: Emory – Reviewed Research Protocol
Immediate Sponsor: MERCK AND COMPANY

Related Records

Funding/Support Agreement Records (1)

Record #	Grant #	Project Period	PI Name	Sponsor	Record Type	Process	Link Date	Link Status
2025A030774		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

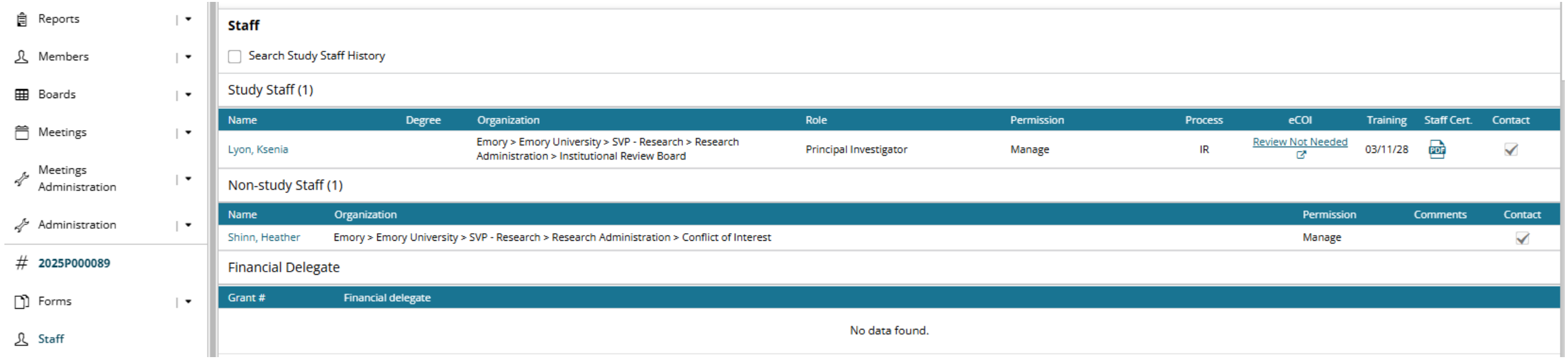
Study Staff – Anyone doing research on the protocol. Requires CITI training.

- 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.

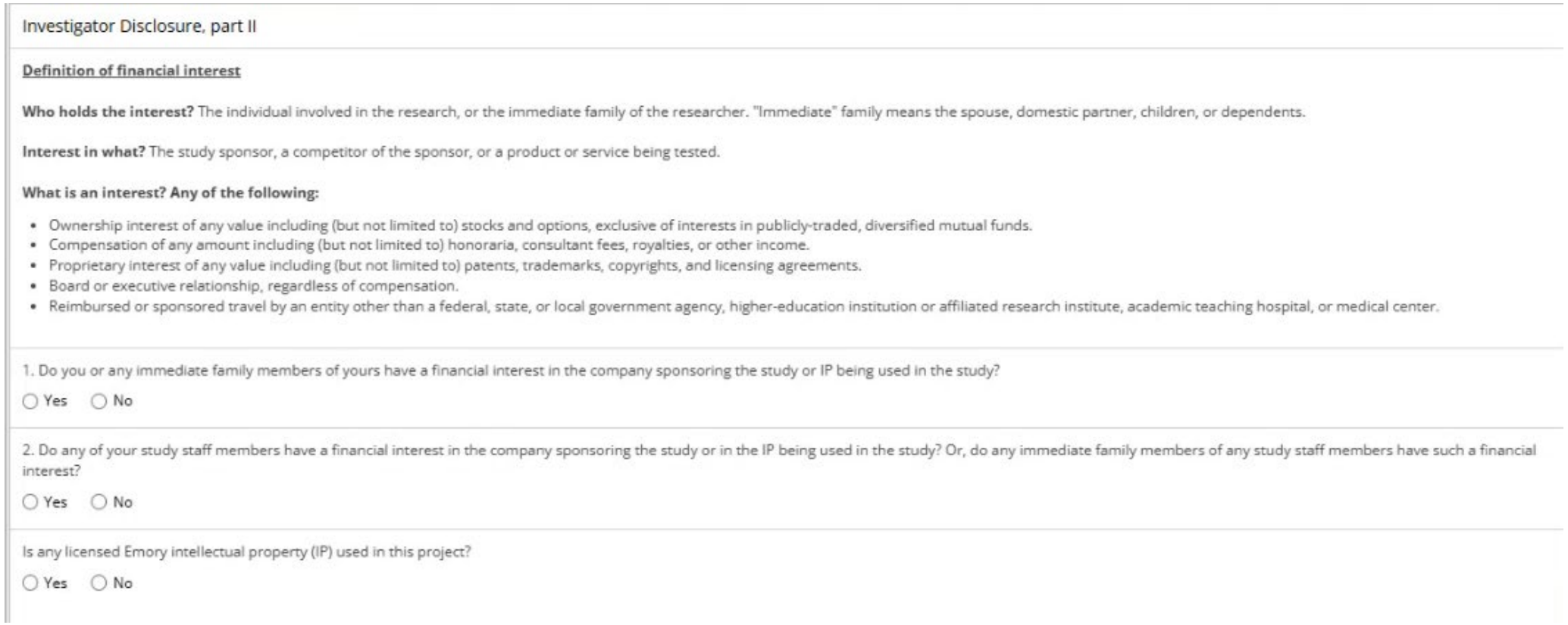
- Reviewing letters, creating amendments to be submitted but not part of the research.

Financial Delegate - Ties in with Epic integration.



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

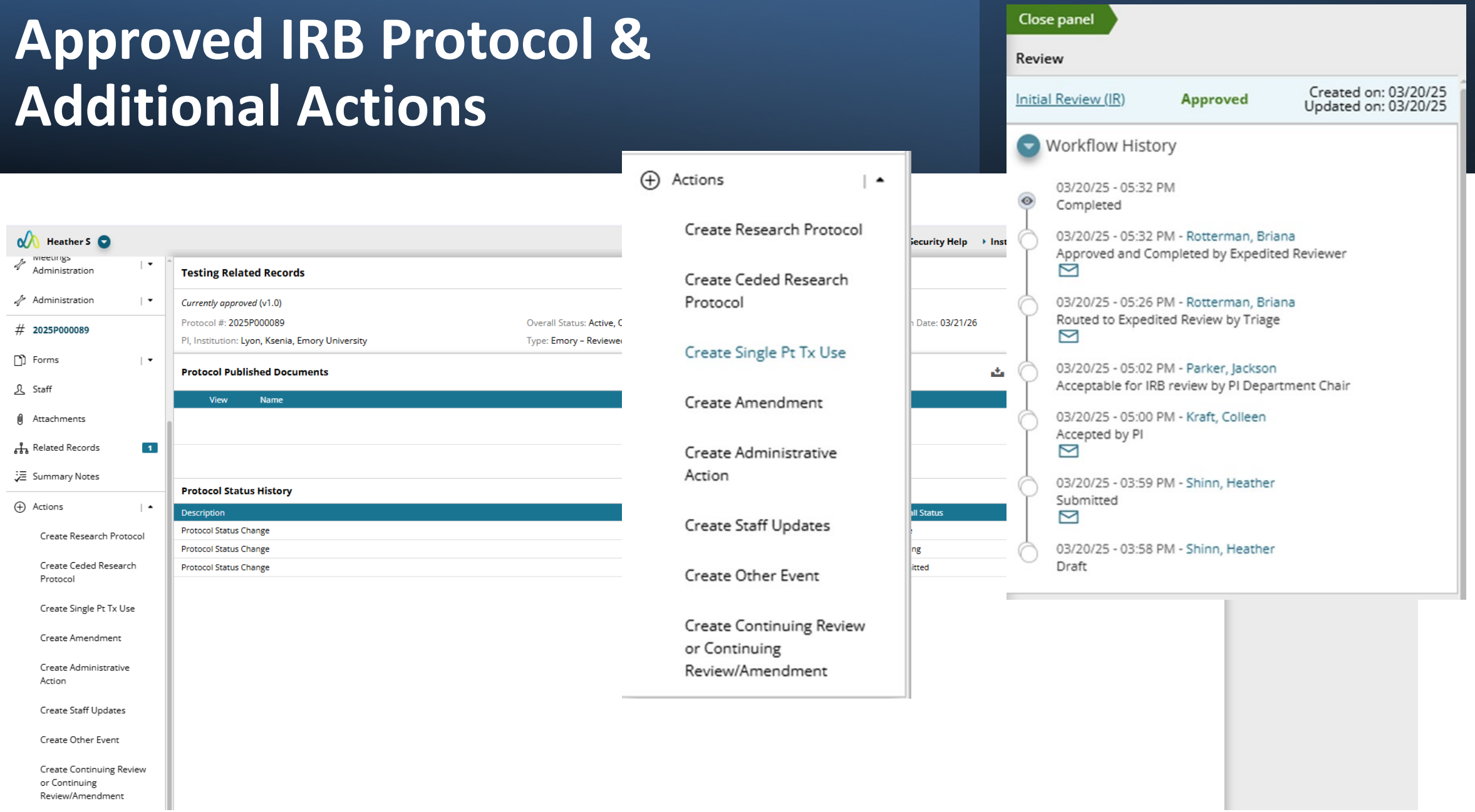
2. Do any of your study staff members have a financial interest in the company sponsoring the study or in the IP being used in the study? Or, do any immediate family members of any study staff members have such a financial interest?

◯ Yes ◯ No

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

◯ Yes ◯ No

Approved IRB Protocol & Additional Actions



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
  - 1st Wave: Fully approved, has no active follow-on submissions
  - 2nd 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

Milestone	User Acceptance Testing (UAT) Completed	Final Application Sign-off	Go-live
Anticipated Timing	**Sprints 167 to 168** (April 22, 2025 to May 19, 2025)	**May 20, 2025**	**Details to be finalized** Weekend of June 20, 2025
Tasks + Outstanding Work	• Includes application, migration, integration and reporting testing • Training Schedule • Training Materials • Communication Plan	• Final Sign-off on phase 1 modules	• Align on final go-live timeframe and post go-live support

Volunteers for Humans and/or Disclosures
Email Heather Shinn
heather.shinn@emory.edu

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

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 8th
- 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 <u>now</u> 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!

INSIGHT TEST ENVIRONMENT

Marietta Testing Environment https://marietta-emory.researchinsight.org/

Website

Keep up with progress

Watch demos

Visit our FAQs page

Questions