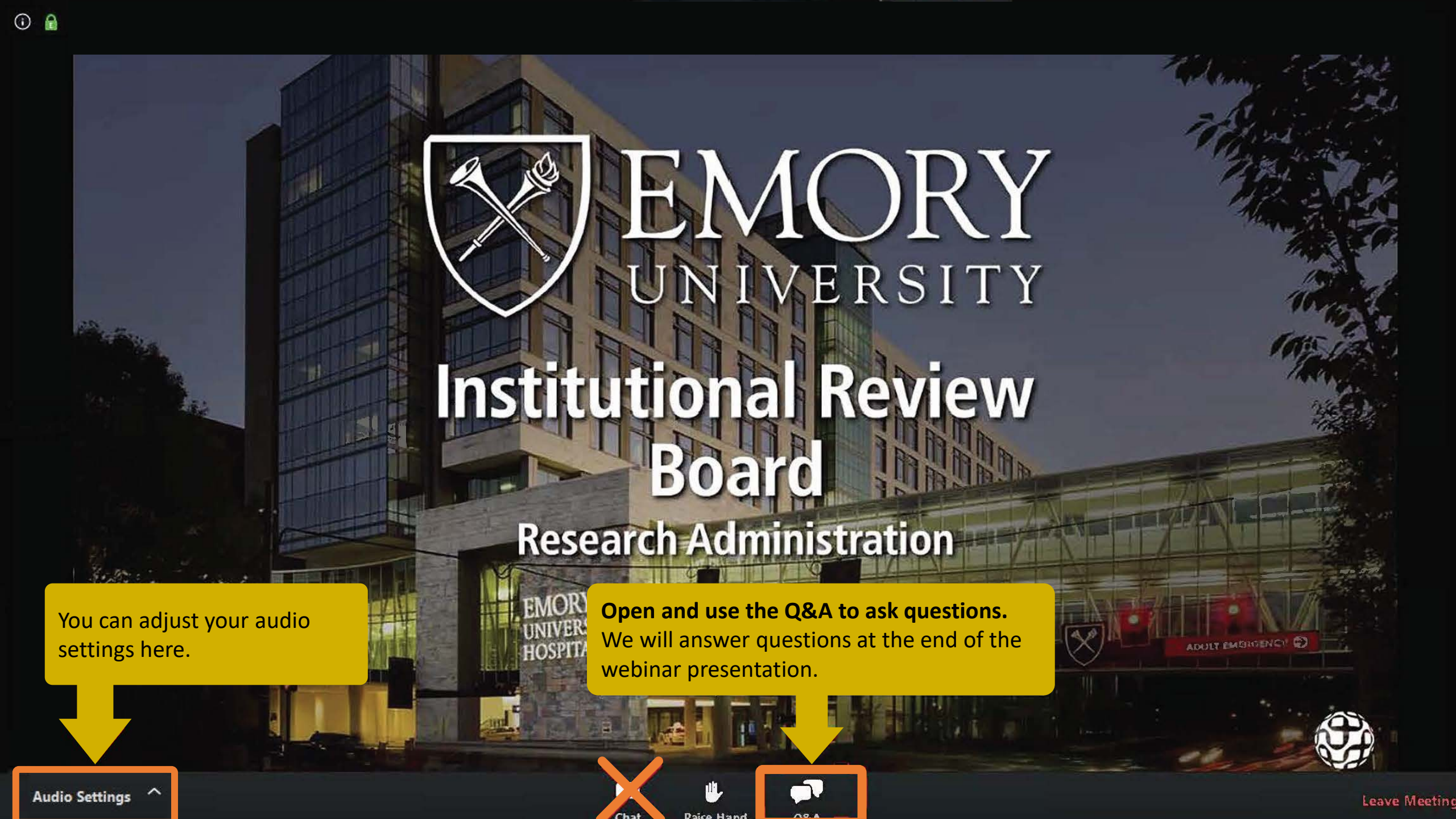

EMORY
UNIVERSITY
Institutional Review Board
Research Administration
You can adjust your audio settings here.
Open and use the Q&A to ask questions.
We will answer questions at the end of the webinar presentation.
Audio Settings
Chat
Raise Hand
Q&A
Leave Meeting

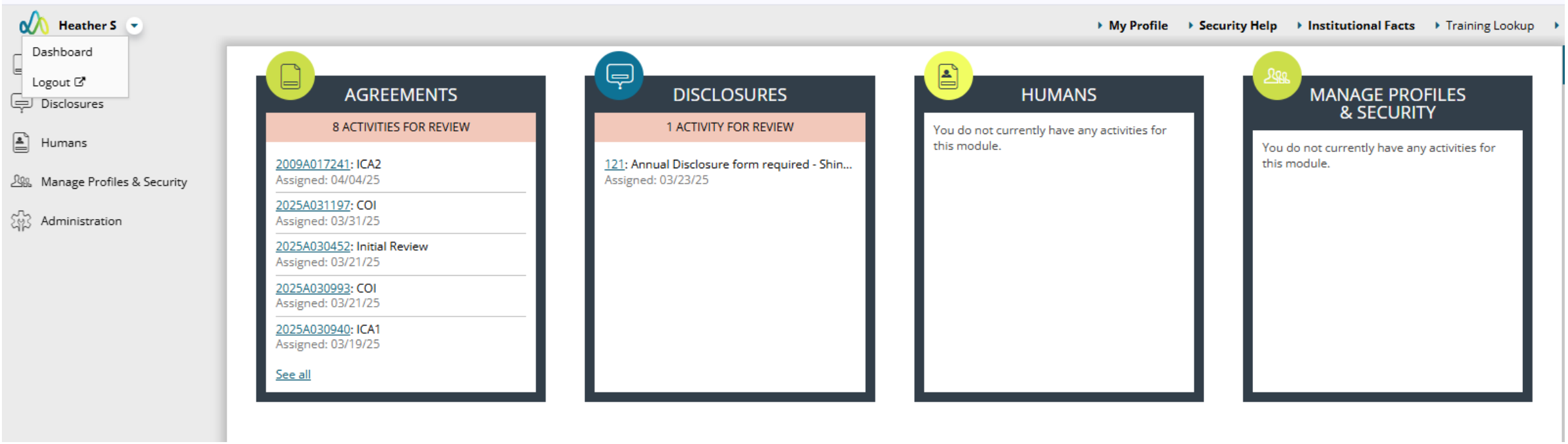
Insight

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:

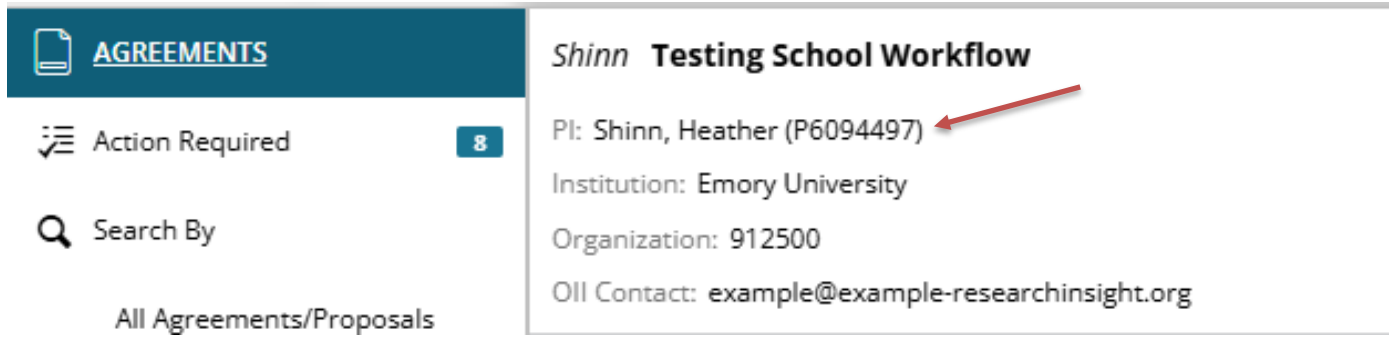
- Reduce redundancy across the enterprise
- Enhance patient safety and billing compliance
- Transparent, real-time data and reporting
- Integration with other enterprise-wide systems

Insight Home Dashboard



Required Training

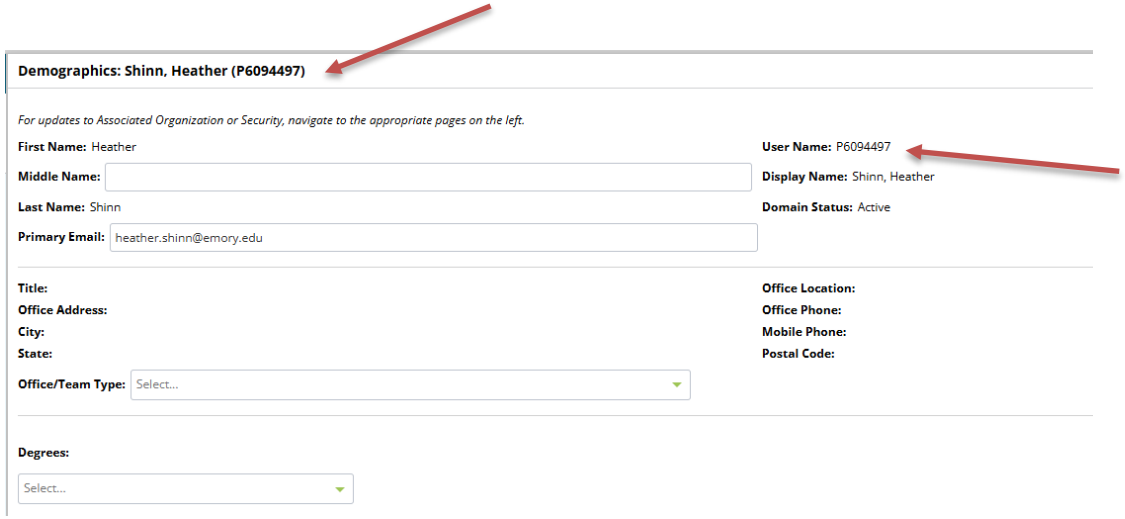
- Please take the required **training** in **Brainier** before using Insight.
  - Your assigned trainings will show up automatically in the "Assigned" tab under My Learning
  - Your access may be **revoked** after a certain grace period, until you complete the training.

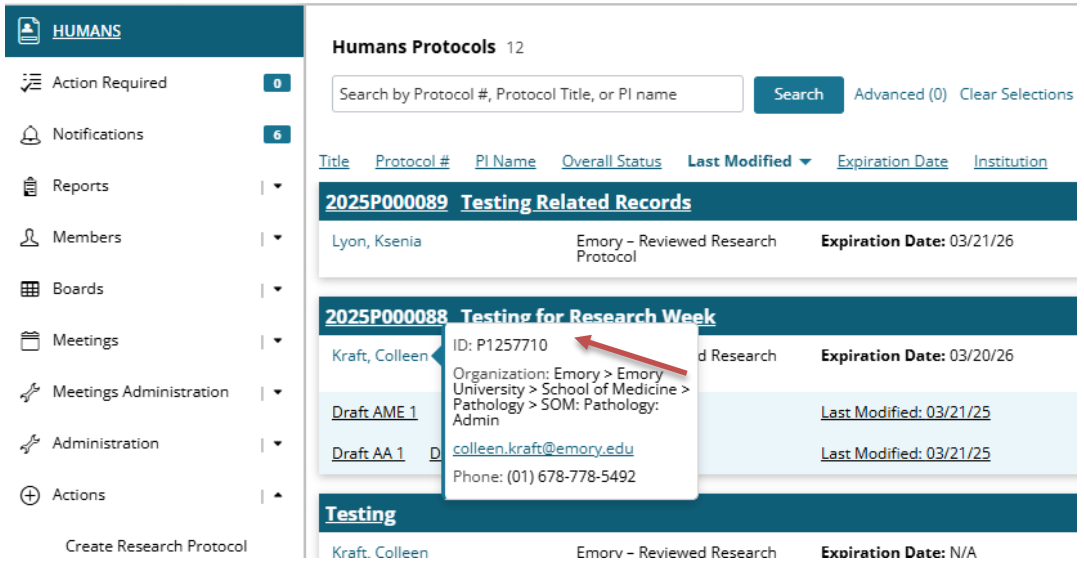


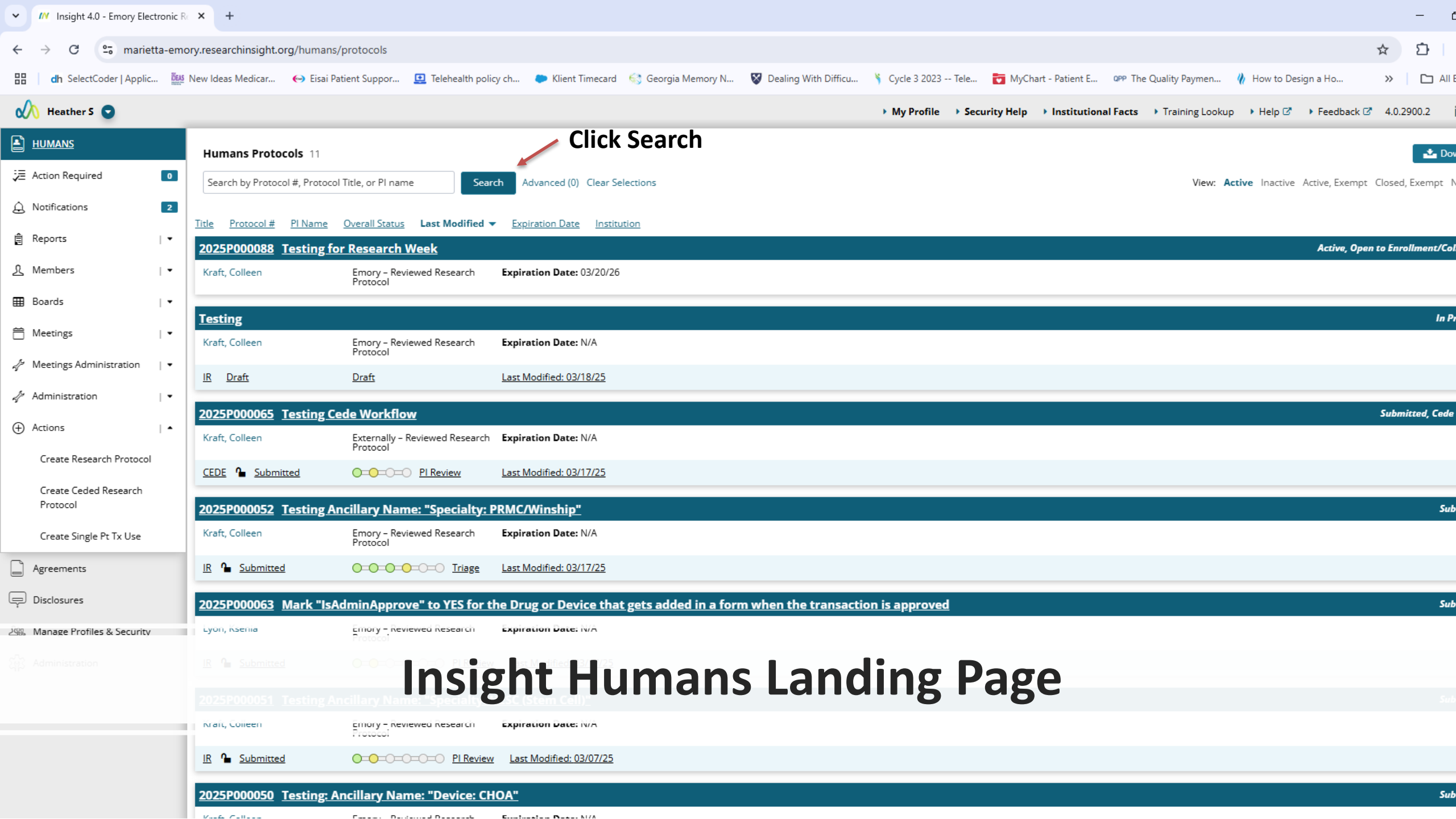
SSO access to Insight w/ Network login

Get to Know your PPID

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

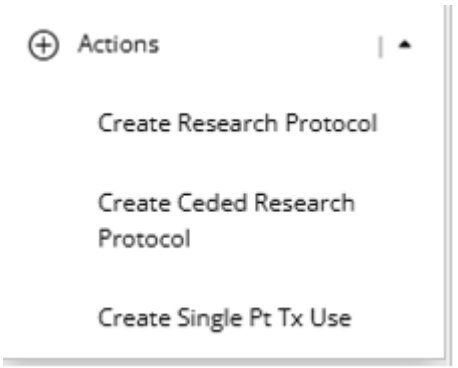





Insight 4.0 - Emory Electronic R
marietta-emory.researchinsight.org/humans/protocols
Heather S
My Profile
Security Help
Institutional Facts
Training Lookup
Help
Feedback
4.0.2900.2
HUMANS
Action Required
Notifications
Reports
Members
Boards
Meetings
Meetings Administration
Administration
Actions
Create 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

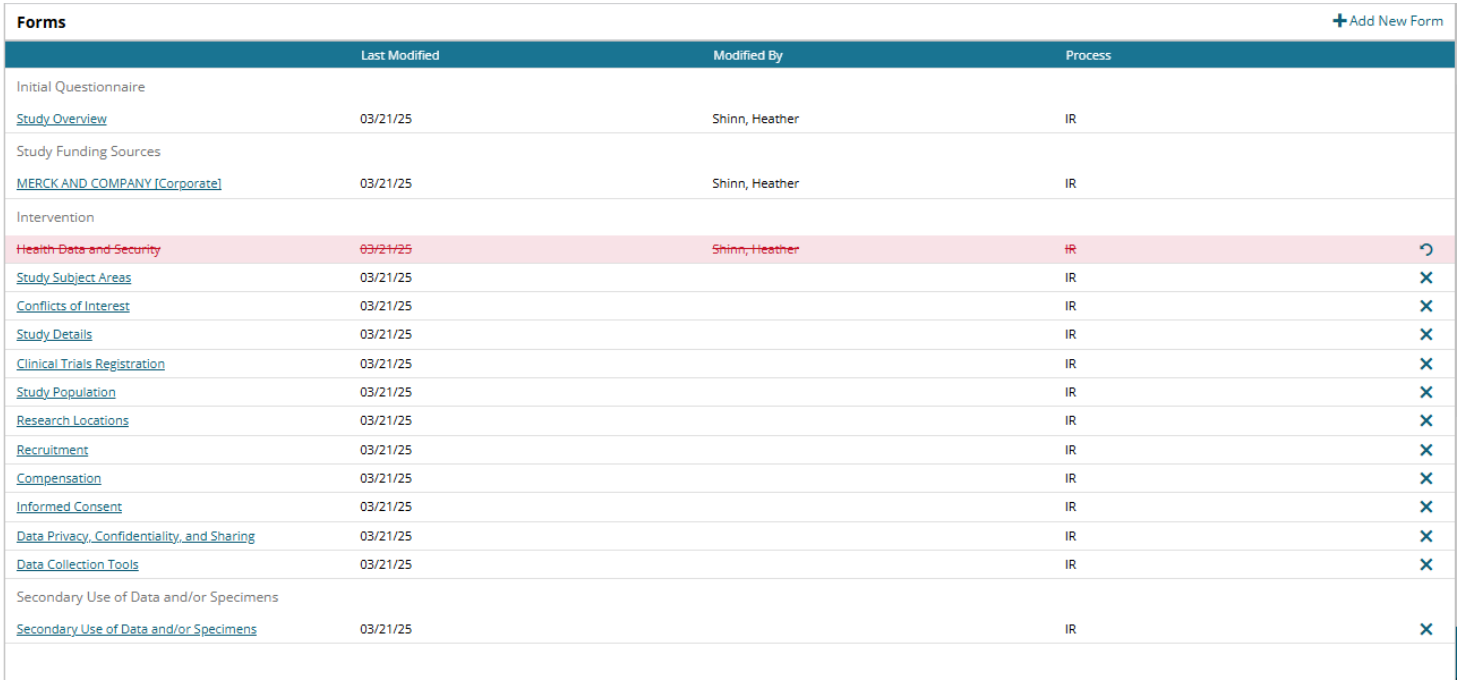
- **Research Protocol (IR)** – Standard, new IRB protocol
- **Ceded Research Protocol -** External IRB
- **Single Pt Tx Use** – For certain single-patient uses of unapproved drugs/devices.
- **Protocol Nomenclature**
  - 2025PXXXXXX



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 once you “Create Protocol”.
- There are additional forms that may trigger based on how questions are answered in the initial forms.

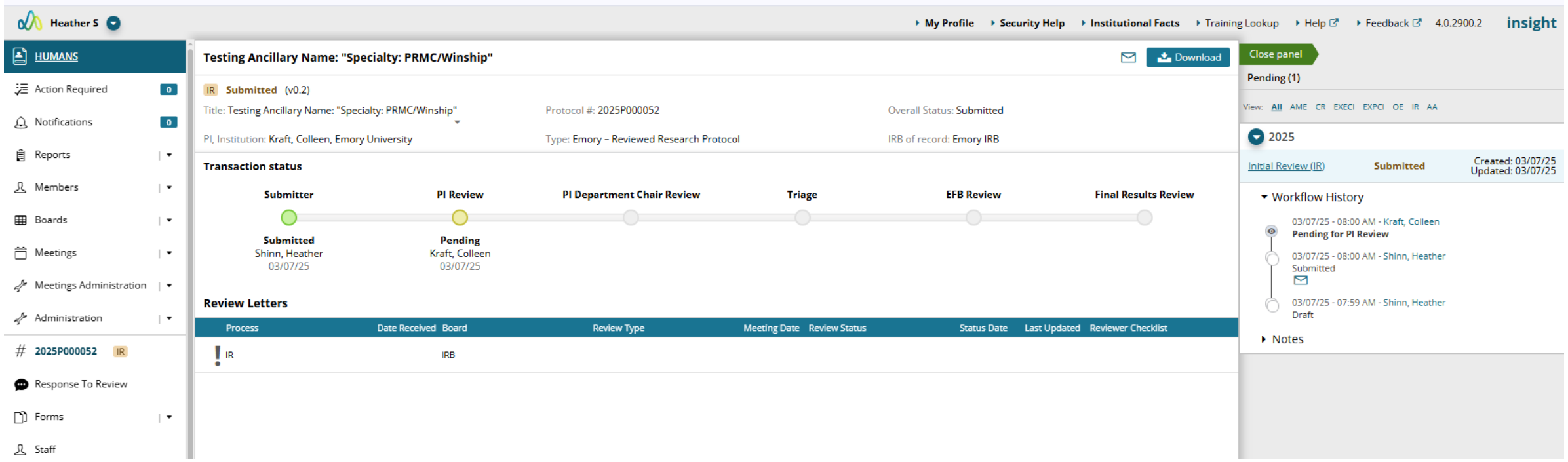


Forms + Add New Form

	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	✕

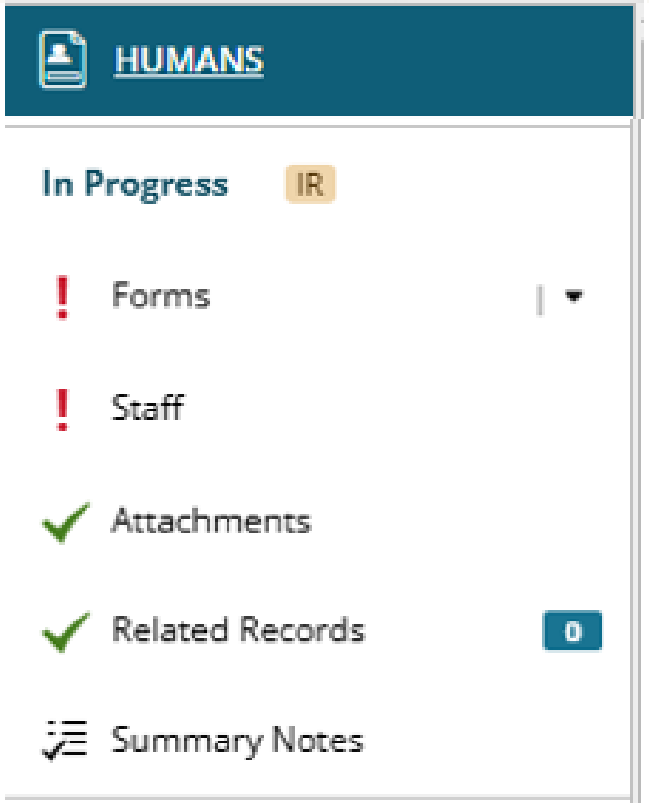
Note: Once you complete the “Study Overview” and click “Create Protocol” a record will be created.

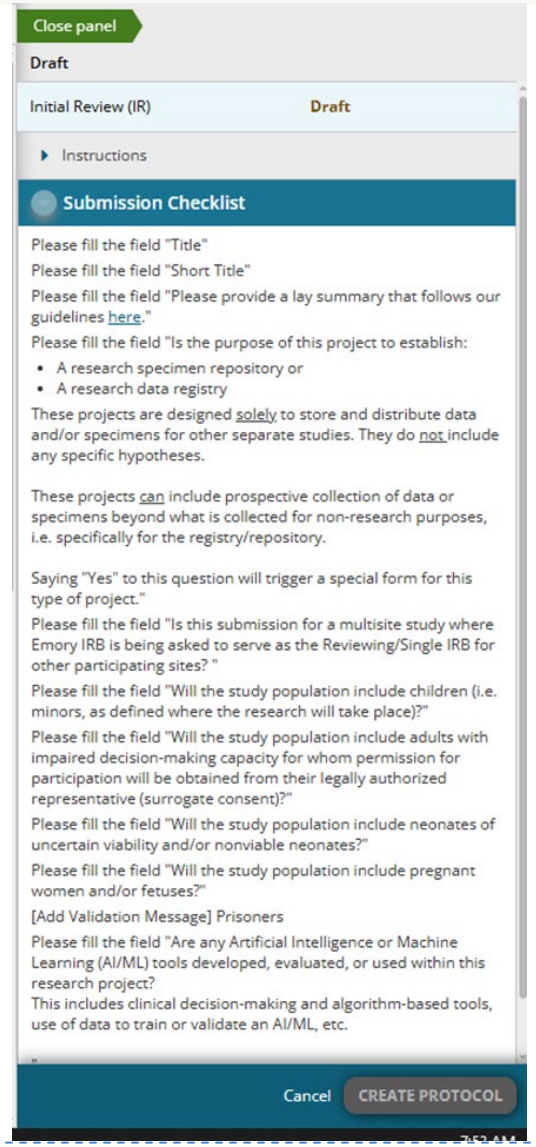
Subway Map for Workflow Tracking

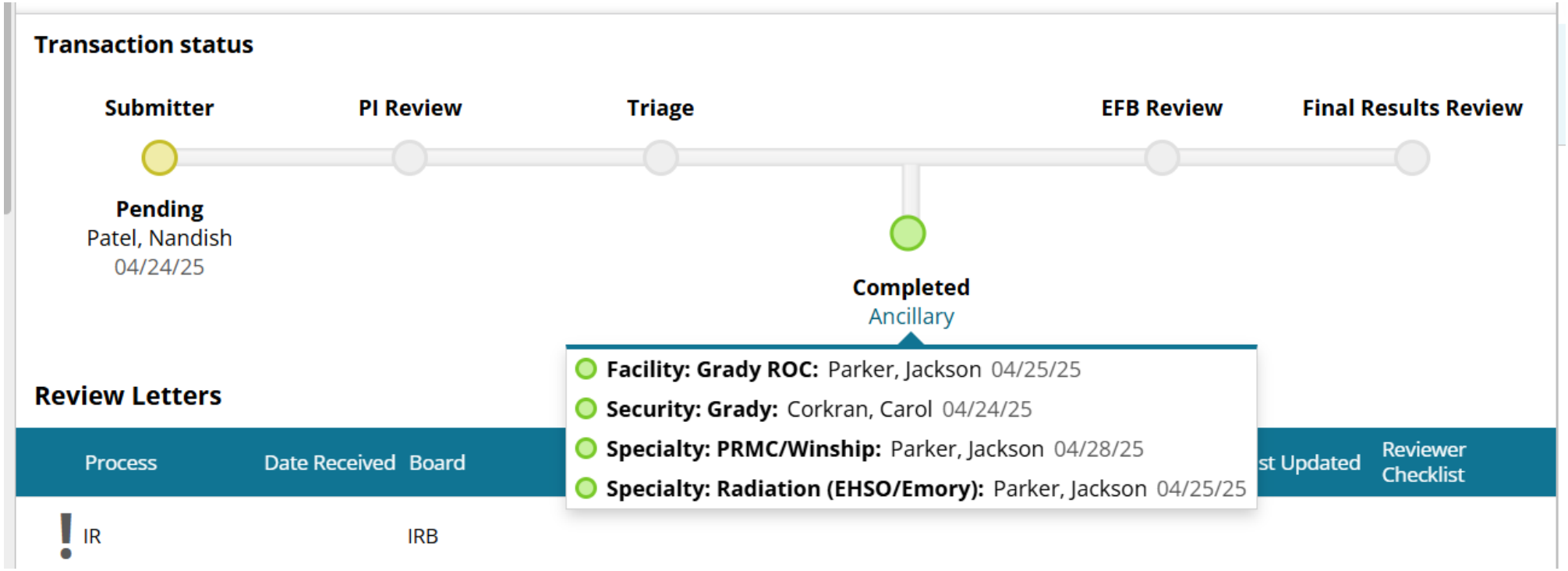


Left Panel flags for submitter what is still required with Red Explanation Point

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



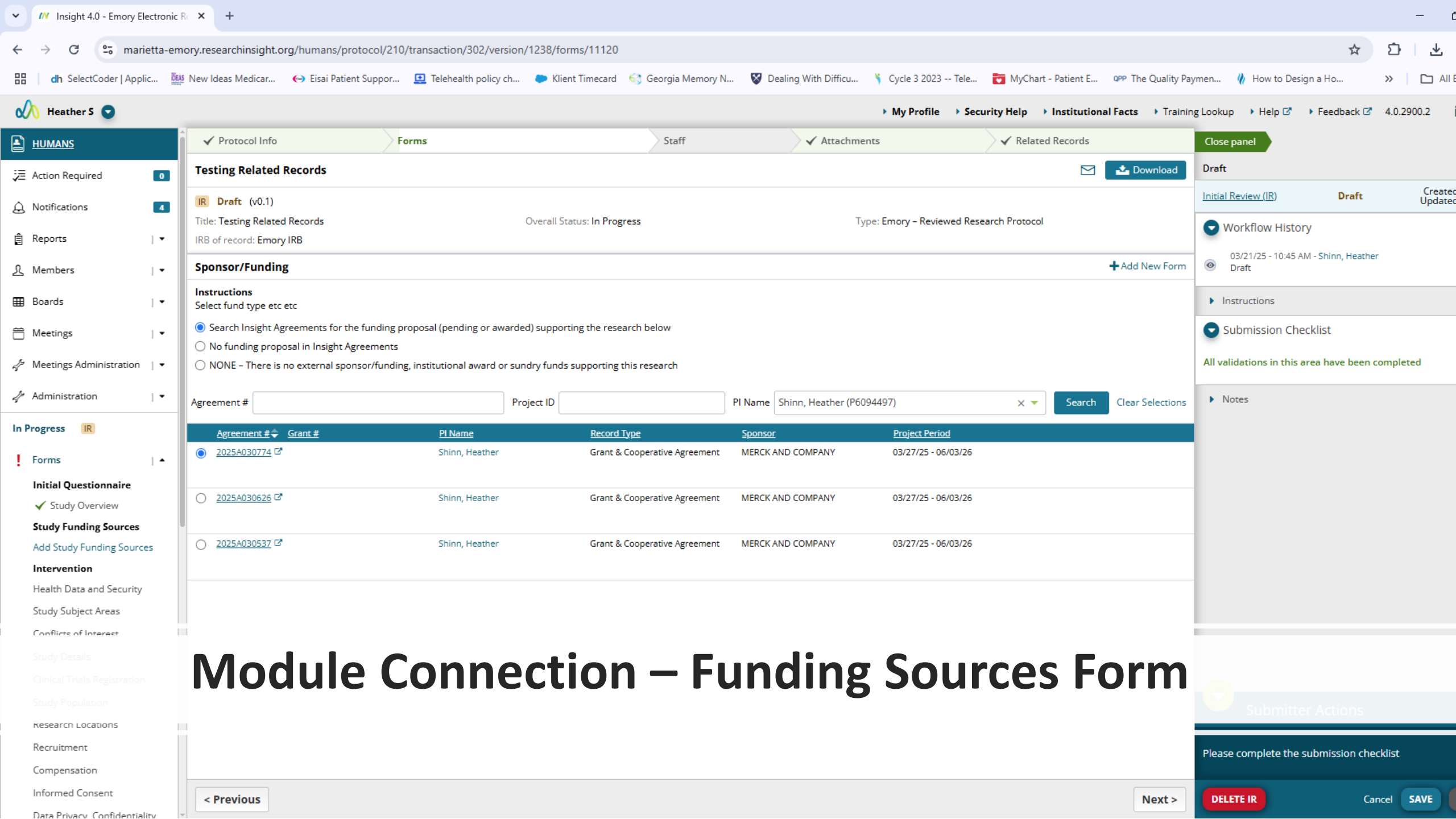




Ancillary Reviews

Radiation Safety, Biosafety, COI, PRMC, Dept, etc

- Ancillaries are built in Insight, same as current state
- Insight triggers an activity to the assigned ancillary reviewer(s) who can Approve, or require changes
- Study will not be ***approved*** by the IRB until all are complete
- Study will not ***arrive*** at the IRB until Department Review is complete
    - Based on PI's primary department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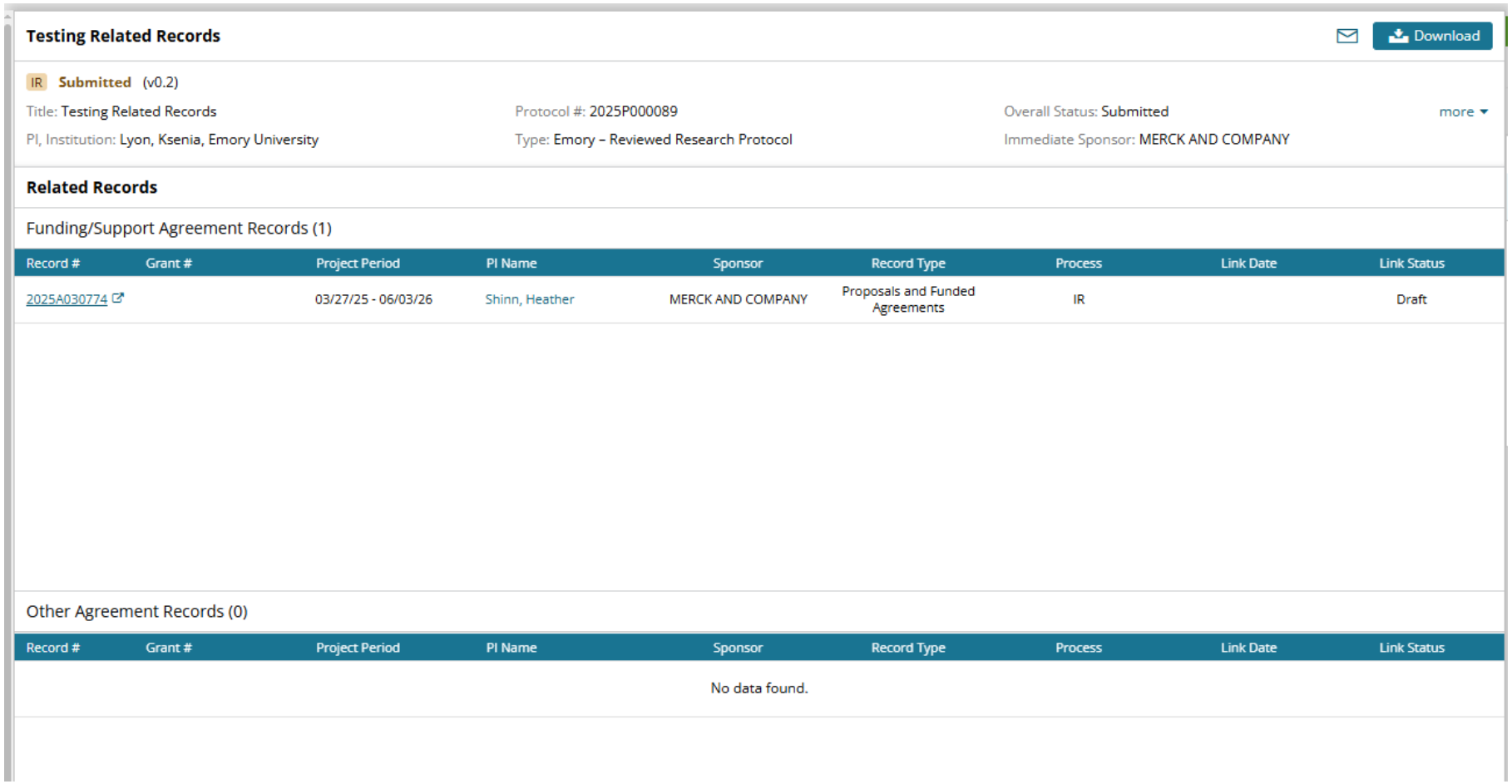
My Profile
Security Help
Institutional Facts
Training Lookup
Help
Feedback
4.0.2900.2
HUMANS
Action Required 0
Notifications 4
Reports
Members
Boards
Meetings
Meetings Administration
Administration
In Progress IR
Forms
Initial Questionnaire
Study Overview
Study Funding Sources
Add Study Funding Sources
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 – Funding Sources 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)

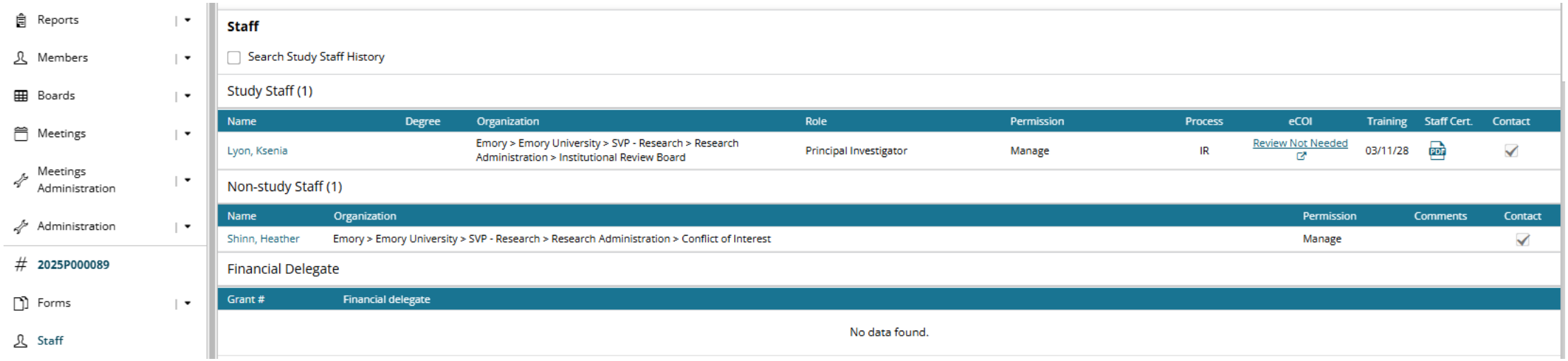
Record #	Grant #	Project Period	PI Name	Sponsor	Record Type	Process	Link Date	Link Status
2025A030774		03/27/25 - 06/03/26	Shinn, Heather	MERCK AND COMPANY	Proposals and Funded Agreements	IR		Draft

Other Agreement Records (0)

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

Tips on Agreements

- For migrated studies, Funding will be refreshed from Compass – may differ from what was in eIRB
- You should be able to find any Agreement you are listed on in Compass
- Agreements integration eliminates the old “new sponsor request” process
- Agreements in “Development” status won’t appear for selection. Will need to add to Humans study once in later status.



Staff

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

- The system indicates if staff needs CITI training
- Reflects CITI training expiration date

Non-Study Staff – Admin staff (not doing human research) who need access to the protocol, don't need CITI training. Everyone has this role at first, then must be moved.

Financial Delegate - Ties in with Epic integration

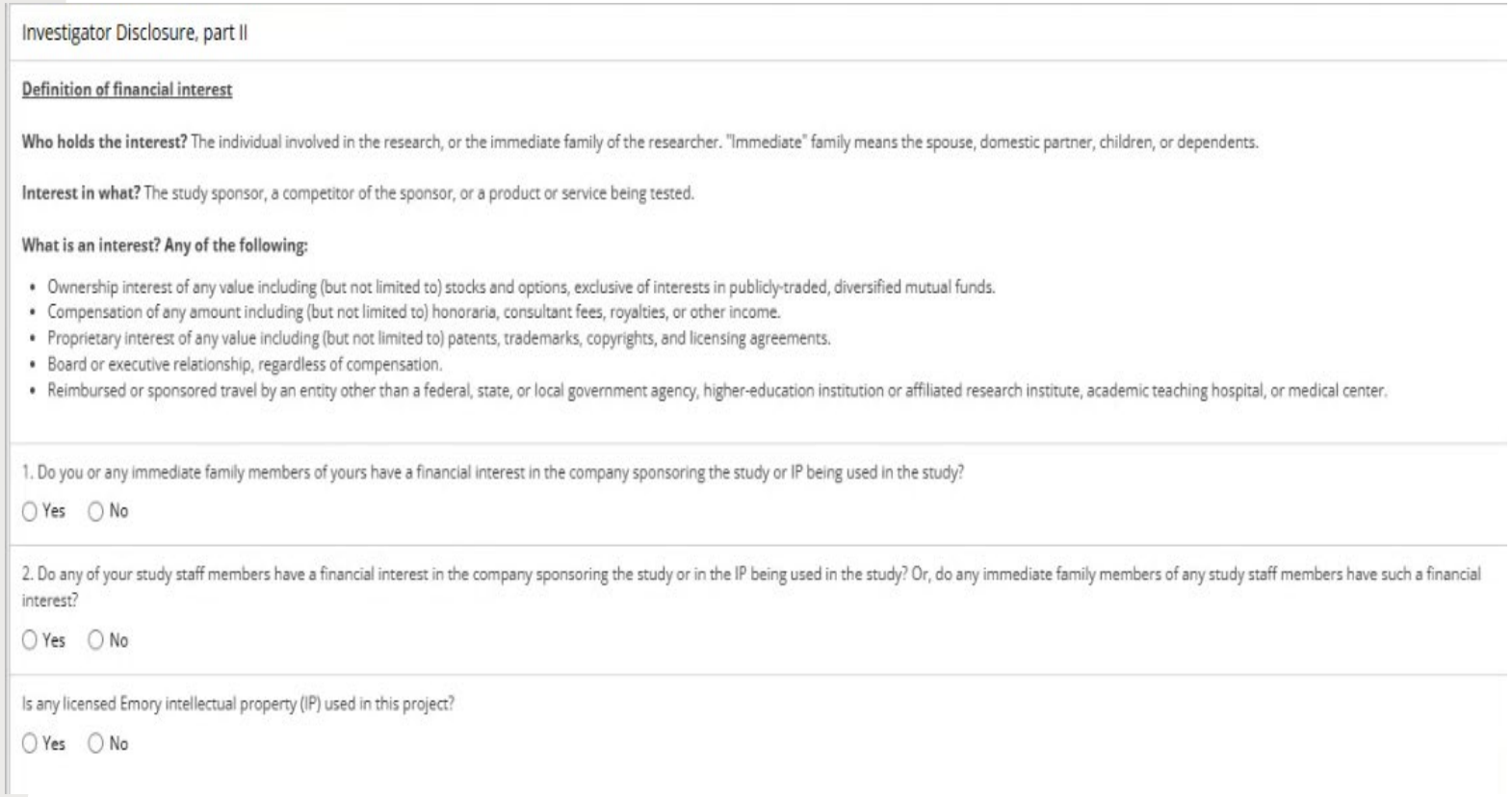
External Study Staff – Do not add here; upload spreadsheet in "Attachments" instead

Module Connection – Investigator Disclosure

- PI needs to disclose financial interest of anyone involved with a study/protocol.
- Done at PI Sign Off step.

- If “Yes” for the PI, will 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

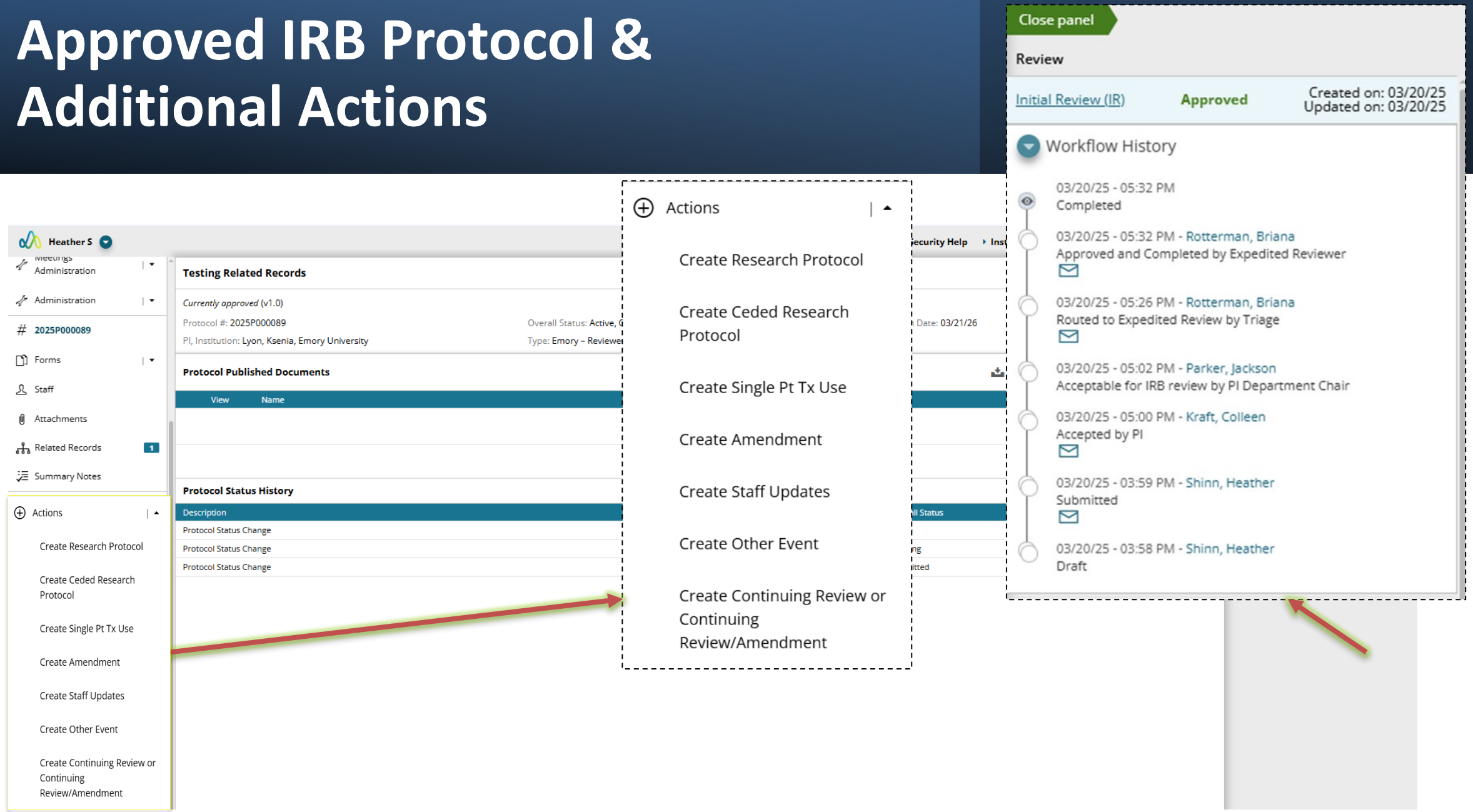
2. Do any of your study staff members have a financial interest in the company sponsoring the study or in the IP being used in the study? Or, do any immediate family members of any study staff members have such a financial interest?

○ Yes ○ No

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

○ Yes ○ No

Approved IRB Protocol & Additional Actions



Terminology 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

Humans Module Quick Wins

CITI Training will be integrated with Study Staff, so it's a quick approval

Streamlined exemption process

Some submissions will no longer require Protocol attachments

eIRB Migrations

- There will be a few Migration “waves”
  - 1st Wave: At Go-Live…
    - Studies closed within past 3 years
    - Fully approved studies with no in-process Mods or CR’s
  - 2nd/3rd Wave: All other active studies

- To be determined: Final cut-off date for migration

Clean Up…

Data migration from eIRB to INSIGHT will **only** include studies <u>without</u> 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

Close-Outs

Submit a continuing review to close your study in eIRB as soon as all of the following apply:

- Study is permanently closed to enrollment
- All research activities are complete including data analysis.
  - Do not leave studies open to allow for secondary data analysis in the future unless it's a repository, as those require new IRB submissions.

See the closeout instructions at the bottom of our Insight and eIRB System Help page.

MIGRATED STUDIES

- You may see different **Funding** information in migrated studies, since we will get data directly from Compass.
- **You will not see** past Amendments, Continuing Reviews, or RNI's in Insight, at least initially.
- eIRB will still be available for a few months, after which there will be an archive for any records that are not placed into the Insight study record.
- We are transferring as much data as we can, **but you‘ll need to complete many new form questions when you submit your first Continuing Review or Amendment.**
- Please make it clear in the amendment summary whether there are **actual changes** versus **adding missing information.**

New Studies and Mods

As noted in our recent IRB Blast, the deadline to submit new studies and modification was July 30th.

- **Only projects meeting the below criteria will be processed in SaaS:**
  - New trial with competitive enrollment
  - New trial with strict sponsor requirement for start up (e.g. NCI)
  - Investigator-Initiated Clinical Trial
  - Modification with impact on subject safety or welfare
  - Study team update Modifications

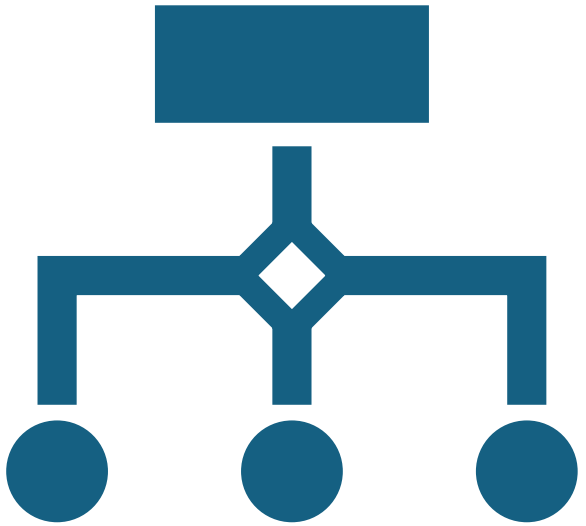
- **Note**: Any submissions awaiting study team response for **more than 60 days will be withdrawn** before go-live and need to be resubmitted in Insight.

Continuing Reviews (CR's)

- For studies **expiring before September 30,** the the CR cutoff was July 30 to avoid a lapse.
- **If you missed the deadline**, you can still submit but we can't guarantee the study won't lapse.

Insight Workflow: Important Changes from eIRB

- Back to needing “tracked-changes” and clean versions each time documents are revised - either during the Initial Review or within Amendments.
- There is currently **not** 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

- Emergency- and non-Emergency single patient treatment uses (drugs/devices): Very streamlined, and no CITI required
- “Not human subjects research” determination form: Still available via the IRB’s website (outside of Insight)
- IRB Submission Numbers will not be created until studies are submitted to the IRB, not right when the submission is created.
    - Other Emory stakeholders are aware of this, and all are preparing workarounds

Protocol Requirements

- The following studies will ***not*** require a “Detailed Protocol” – just need detailed Lay Summary instead

  - Secondary Data Analysis
  - Chart reviews
  - Exempt projects that fall into the Exemption categories on the *Study Overview* form

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 continuing to work on a 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

Cede Review - What Stays the Same?

- You will want to go to our website to review current guidance and documents. https://irb.emory.edu/guidance/research-types/collaborative.html

- Once the overall study is approved by the external IRB, you will submit the same documents to us

Cede Review- What Will Be Different?

- The workflow will be different – we will review and issue signoff by sending submission back to you. We may have to email you reliance documents to upload in attachments. You will submit back once you have obtained external IRB approval.

- To provide us CR approval or amendments that meet our criteria (see website) you will need to email those to irb.reliance@emory.edu. We are working with the vendor to get the CR and amendment forms updated for cede studies. Stay tuned for updates after go-live.

- Lay summary is in the cede review form and you will need to complete it.

Single IRB (sIRB)

- Staying the same –
  - Reach out and reach out early when planning to submit federal grant, multi-site
  - You need quote for sIRB fees to add to budget

- Changing –
  - No “p-sites” in Insight; sites are listed in a form
  - No separate “form” for each site – each site has own place on “Attachments” form

Non-Insight Updates

CITI updated their Group 5 content as of July 23 based on the new ICH E6(R3) Guideline for Good Clinical Practice. If you use this Module:

- Emory will not require you to complete the updated version before your normal refresher date, unless your sponsor or other governing body requires it.
- You would need to send a request to the Emory IRB, then we will ask CITI to expire your current GCP so you can refresh with the updated course.

Questions