



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

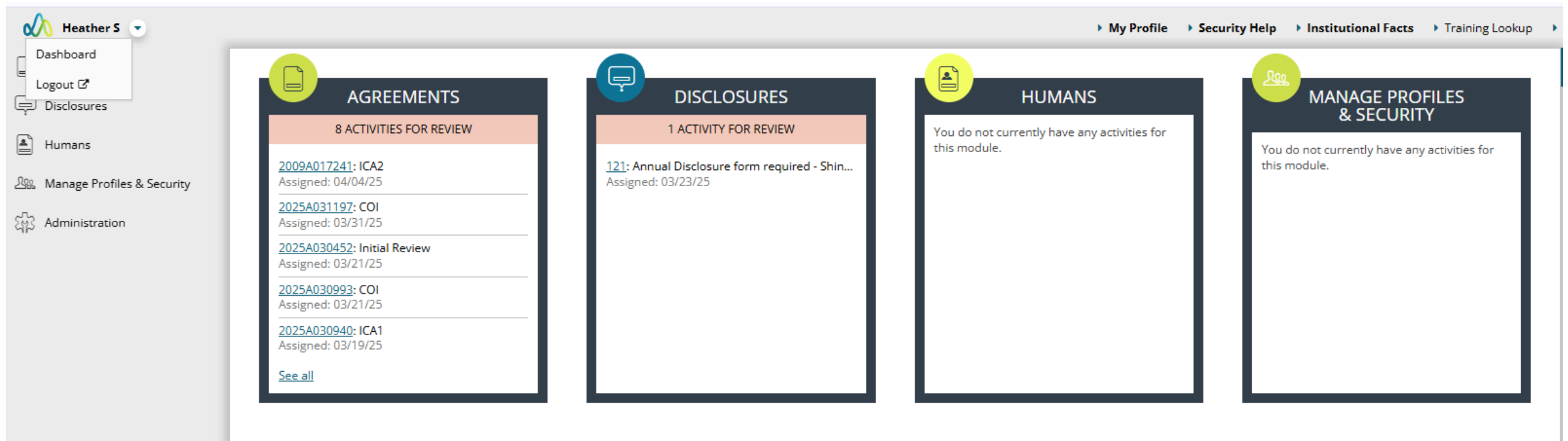
Enhance patient
safety and billing
compliance

Transparent, real-
time data and
reporting

Integration with
other enterprise-
wide systems



Insight Home Dashboard



The screenshot displays the Insight Home Dashboard. At the top, a navigation bar includes the user name 'Heather S' and a dropdown menu with options: Dashboard, Logout, Disclosures, Humans, Manage Profiles & Security, and Administration. The main content area is divided into four panels: AGREEMENTS (8 activities for review), DISCLOSURES (1 activity for review), HUMANS (no activities), and MANAGE PROFILES & SECURITY (no activities). Each panel lists specific activities with their assigned dates and a 'See all' link.

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.

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.



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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Actions

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 Organization: Emory > Emory University > School of Medicine > Pathology > SOM: Pathology: Admin Last Modified: 03/21/25

Draft AA 1 colleen.kraft@emory.edu Last Modified: 03/21/25

Phone: (01) 678-778-5492

Testing

Kraft, Colleen Emory - Reviewed Research Expiration Date: N/A

Insight 4.0 - Emory Electronic R

marietta-emory.researchinsight.org/humans/protocols

Heather S

HUMANS

Action Required0

Notifications2

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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

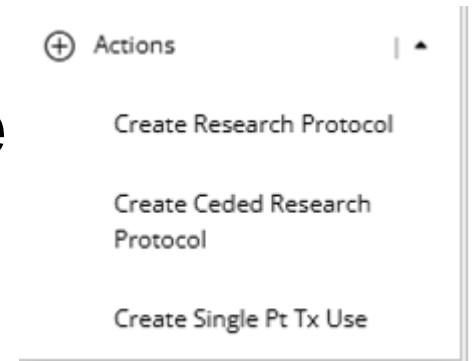
Title	Protocol #	PI Name	Overall Status	Last Modified	Expiration Date	Institution
2025P000088 Testing for Research WeekActive, Open to Enrollment/Col						
Kraft, Colleen		Emory - Reviewed Research Protocol	Expiration Date: 03/20/26			
TestingIn Pr						
Kraft, Colleen		Emory - Reviewed Research Protocol	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.

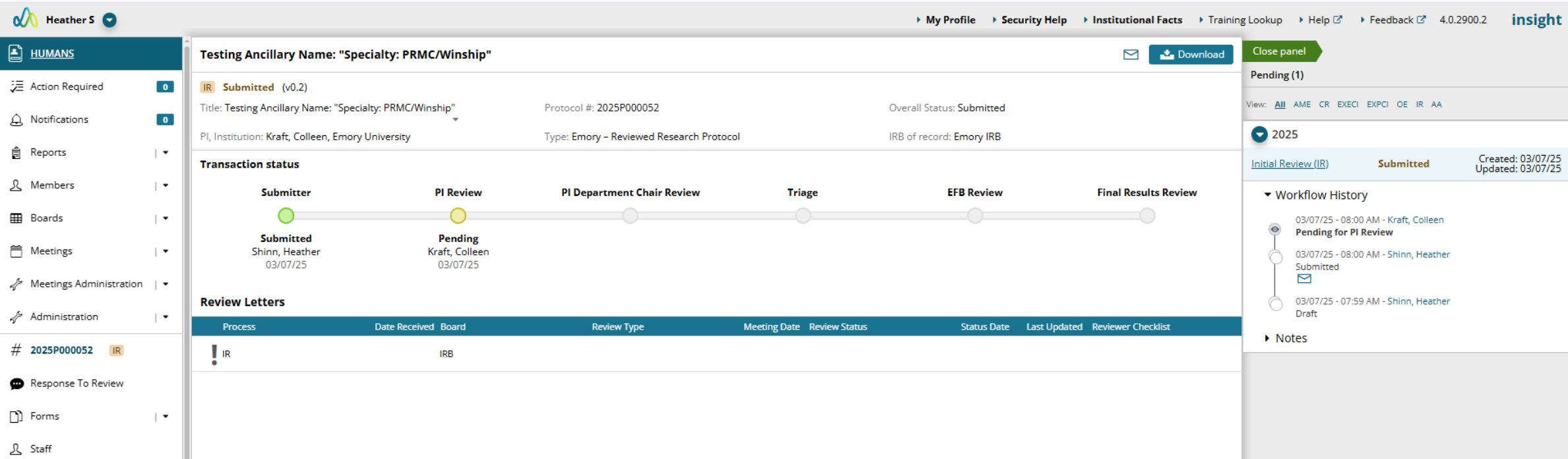
IRB Forms

- IRB Forms have been built into Insight.
- There are a base set of forms that will trigger 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.

 **HUMANS**

In Progress IR

!

 Forms

!

 Staff

✓

 Attachments

✓

 Related Records 0

☑

 Summary Notes

Close panel

Draft

Initial Review (IR) **Draft**

▶ Instructions

Submission Checklist

Please fill the field "Title"

Please fill the field "Short Title"

Please fill the field "Please provide a lay summary that follows our guidelines [here](#)."

Please fill the field "Is the purpose of this project to establish:

- A research specimen repository or
- A research data registry

These projects are designed solely to store and distribute data and/or specimens for other separate studies. They do not include any specific hypotheses.

These projects can include prospective collection of data or specimens beyond what is collected for non-research purposes, i.e. specifically for the registry/repository.

Saying "Yes" to this question will trigger a special form for this type of project."

Please fill the field "Is this submission for a multisite study where Emory IRB is being asked to serve as the Reviewing/Single IRB for other participating sites?"

Please fill the field "Will the study population include children (i.e. minors, as defined where the research will take place)?"

Please fill the field "Will the study population include adults with impaired decision-making capacity for whom permission for participation will be obtained from their legally authorized representative (surrogate consent)?"

Please fill the field "Will the study population include neonates of uncertain viability and/or nonviable neonates?"

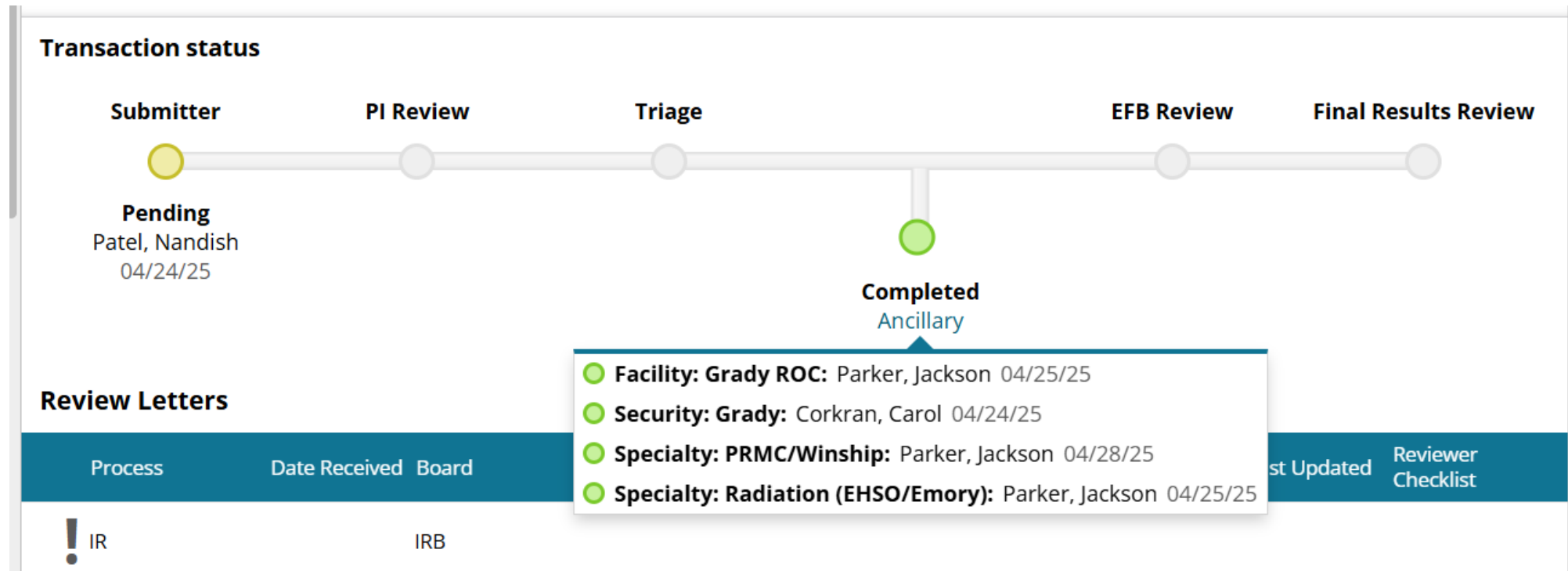
Please fill the field "Will the study population include pregnant women and/or fetuses?"

[Add Validation Message] Prisoners

Please fill the field "Are any Artificial Intelligence or Machine Learning (AI/ML) tools developed, evaluated, or used within this research project?"

This includes clinical decision-making and algorithm-based tools, use of data to train or validate an AI/ML, etc.

Cancel **CREATE PROTOCOL**



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

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 – Funding Sources Form

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.

Reports

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Administration

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	Review Not Needed	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.	

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

Heather S

Meetings Administration

Administration

2025P000089

Forms

Staff

Attachments

Related Records 1

Summary Notes

Testing Related Records

Currently approved (v1.0)

Protocol #: 2025P000089

PI, Institution: Lyon, Ksenia, Emory University

Overall Status: Active, G

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 Staff Updates

Create Other Event

Create Continuing Review or Continuing Review/Amendment

Security Help

Inst

Date: 03/21/26

Full Status

ing

itted

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

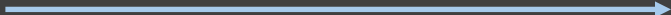
03/20/25 - 03:59 PM - Shinn, Heather

Submitted

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

Draft

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 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



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.



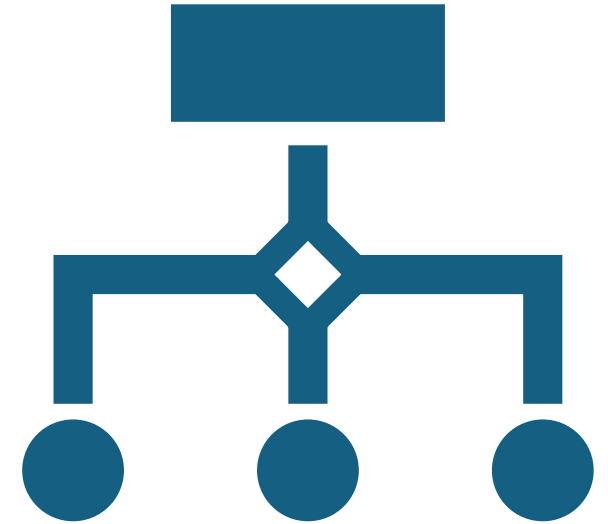
Continuing Reviews (CR's)

- For studies **expiring before September 30**, the 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 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 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