



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 !\[\]\(67f2870f14660d0c1a2612f703dff40d_img.jpg\)](#)
[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

Members

Boards

Meetings

Meetings Administration

Administration

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

Draft AA 1

Organization: Emory > Emory University > School of Medicine > Pathology > SOM: Pathology: Admin
Admin
colleen.kraft@emory.edu
Phone: (01) 678-778-5492

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.

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

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

Notifications2

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

Administration

My Profile

Security Help

Institutional Facts

Training Lookup

Help

Feedback

4.0.2900.2

Humans Protocols11

Search by Protocol #, Protocol Title, or PI name

Search

Advanced (0)

Clear Selections

View: ActiveInactiveActive, ExemptClosed, Exempt

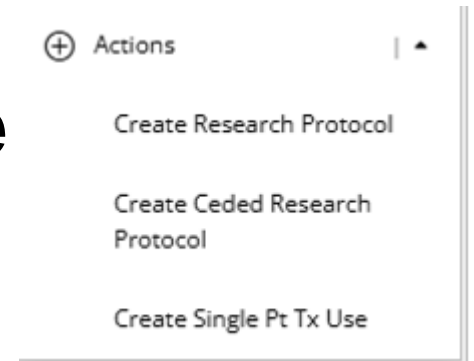
Title	Protocol #	PI Name	Overall Status	Last Modified	Expiration Date	Institution
2025P000088 Testing for Research WeekActive, Open to Enrollment/Col						
Kraft, ColleenEmory - Reviewed Research ProtocolExpiration Date: 03/20/26						
TestingIn Pr						
Kraft, ColleenEmory - Reviewed Research ProtocolExpiration Date: N/A						
IR DraftDraftLast Modified: 03/18/25						
2025P000065 Testing Cede WorkflowSubmitted, Cede						
Kraft, ColleenExternally - Reviewed Research ProtocolExpiration Date: N/A						
CEDESubmittedPI ReviewLast Modified: 03/17/25						
2025P000052 Testing Ancillary Name: "Specialty: PRMC/Winship"Sub						
Kraft, ColleenEmory - Reviewed Research ProtocolExpiration Date: N/A						
IRSubmittedTriageLast 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, KseniaEmory - Reviewed Research ProtocolExpiration Date: N/A						
IRSubmittedPI ReviewLast Modified: 03/17/25						
2025P000051 Testing Ancillary Name: "Specialty: PRMC/Winship"Sub						
Kraft, ColleenEmory - Reviewed Research ProtocolExpiration Date: N/A						
IRSubmittedPI ReviewLast Modified: 03/07/25						
2025P000050 Testing: Ancillary Name: "Device: CHOA"Sub						
Kraft, ColleenEmory - Reviewed Research ProtocolExpiration 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 + 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

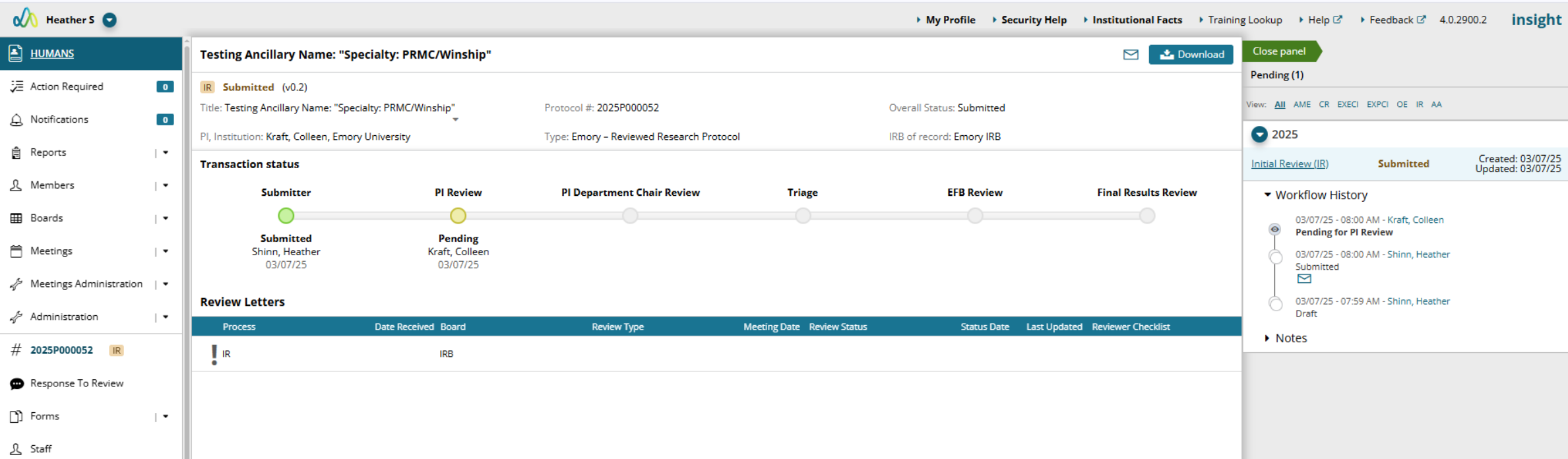
Ancillary Reviews

- 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
- Study will not be approved until ancillary reviews are completed.
- PI and Department Chair will need to review/signoff before going to IRB team.

IRB Migrations

- Can continue to submit new studies, amendments, and continuing reviews due at the end of June 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.

Subway Map for Workflow Tracking



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

Notifications4

Reports

Members

Boards

Meetings

Meetings Administration

Administration

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
<input checked="" type="radio"/> 2025A030774		Shinn, Heather	Grant & Cooperative Agreement	MERCK AND COMPANY	03/27/25 - 06/03/26
<input type="radio"/> 2025A030626		Shinn, Heather	Grant & Cooperative Agreement	MERCK AND COMPANY	03/27/25 - 06/03/26
<input type="radio"/> 2025A030537		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

Email icon

Download

IR Submitted (v0.2)

Title: Testing Related RecordsProtocol #: 2025P000089Overall Status: Submittedmore

PI, Institution: Lyon, Ksenia, Emory UniversityType: Emory – Reviewed Research ProtocolImmediate 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 if 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.

Reports

Members

Boards

Meetings

Meetings Administration

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.	

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

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

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



User Acceptance Testing April 22 – May 19, 2025

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

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

Milestone	Stabilization Period	User Acceptance Testing (UAT) Completed	Final Application Sign-off	Go-live
Anticipated Timing	<u>April 8, 2025</u>	<u>Sprints 167 to 168</u> (April 22, 2025 to May 19, 2025)	May 20, 2025	<u>Details to be finalized</u> Weekend of June 20, 2025
Tasks + Outstanding Work	<ul style="list-style-type: none"> • No development past this point to ensure successful testing and subsequent go-live 	<ul style="list-style-type: none"> • Includes application, migration, integration and reporting testing • Training Schedule • Training Materials • Communication Plan 	<ul style="list-style-type: none"> • Final Sign-off on phase 1 modules 	<ul style="list-style-type: none"> • Align on final go-live timeframe and post go-live support

User Acceptance Testing April 22 – May 19, 2025

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

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

UAT Testing

- Testing will occur every Tuesday, Wednesday, Thursday (in person).
- Location: Tentatively RSPH - Rita Anne Rollins Room, GCR 8th
- There will be morning and afternoon sessions. About 2-4 hours each session.
- Submitter and Reviewer roles.
- Communications to be 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!



Audiences

Audiences will be grouped by primary functions in the system within each module.



Submitters are the individuals that start a workflow or process.



Reviewers are the individuals that take and work the submissions.



Administrative Management has a higher understanding of business processes and the system.



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



Questions