

Streamlining Compliance: *The New eIRB+ Compliance Workspace*

November 13, 2024

Presented by:
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Topics

- Overview of Post-Approval Monitoring (PAM)
- PAM Process within the eIRB+ Compliance Workspace
- What about the Post-Approval Monitoring (PAM) process is changing?
- Navigating the eIRB+ Compliance Workspace
- Tips on Preparing for a PAM
- Training & Support
- Q & A with the Compliance Team

Biomedical Research



Compliance and Education



IRB Office Administration



Reliance



Social and Behavioral Research



Post-Approval Monitoring (PAM)

What?

- All active non-exempt human research studies are subject to routine post-approval monitoring (including those where Northwestern University or its affiliates ceded IRB review to an external IRB)
- Collaborative, education-focused activity between IRB Compliance and Investigator

Why?

- Ensures compliance with applicable federal regulations, state laws, institutional policies, and research best practices
- Improves the conduct of human research
- Protects research participants' rights and welfare
- Source of guidance, resources, and educational support

Post-Approval Monitoring (PAM) Process



IRB Compliance Team randomly selects studies for routine monthly self-assessment monitoring



IRB Panel(s), Institutional Official, or IRB Office staff may request a study undergo monitoring



May take place completely virtually, in-person, or a combination of both



Investigator self-assessment or compliance conducted review of study conduct and documentation



Current PAM Workflow

- Manually driven
 - Email communication
 - Word documents and PDFs
- Prone to human error and inconsistencies
- Inefficient workflows
- Limited data analysis capabilities

Northwestern

CHECKLIST: Post Approval Monitoring – Human Research

APPROVED BY	EFFECTIVE DATE	PAGE
Executive Director, IRB Office, Northwestern University	09/01/2023	Page 1 of 8

CHECKLIST: Post Approval Monitoring – Participant File

NUMBER	APPROVED BY	EFFECTIVE DATE	PAGE
HRP-428	Executive Director, IRB Office, Northwestern University	02/28/2022	Page 1 of 2

Instructions: Please complete this page for a randomly selected ten percent of enrolled participants; not to exceed 10 participants. **Reminder:** In Human Research, identifiable data about living individuals and identifiable biospecimens are equivalent to the person. If the answer is "no" or "not applicable," please justify by typing or writing in additional information as needed. If you determine that your responses in the checklist would be the same for all participant files, you do not need to complete separate checklists. Instead, complete one copy of the Participant File checklist and include the Participant IDs for records you reviewed in the Participant ID space below, noting any differences by Participant ID within the General Comments section below. You do not have to include documentation with the completed checklist unless requested. **For research conducted with a waiver of consent, please still complete sections 1 and 4.**

Principal Investigator	Participant File
Research Study Title	
Participant ID	
Type of Consent(s) Obtained	
Version Number or STU Number Reflected in the Document's Header	
Name of Person Completing Checklist	
Date Checklist Completed	

1 Participant Information

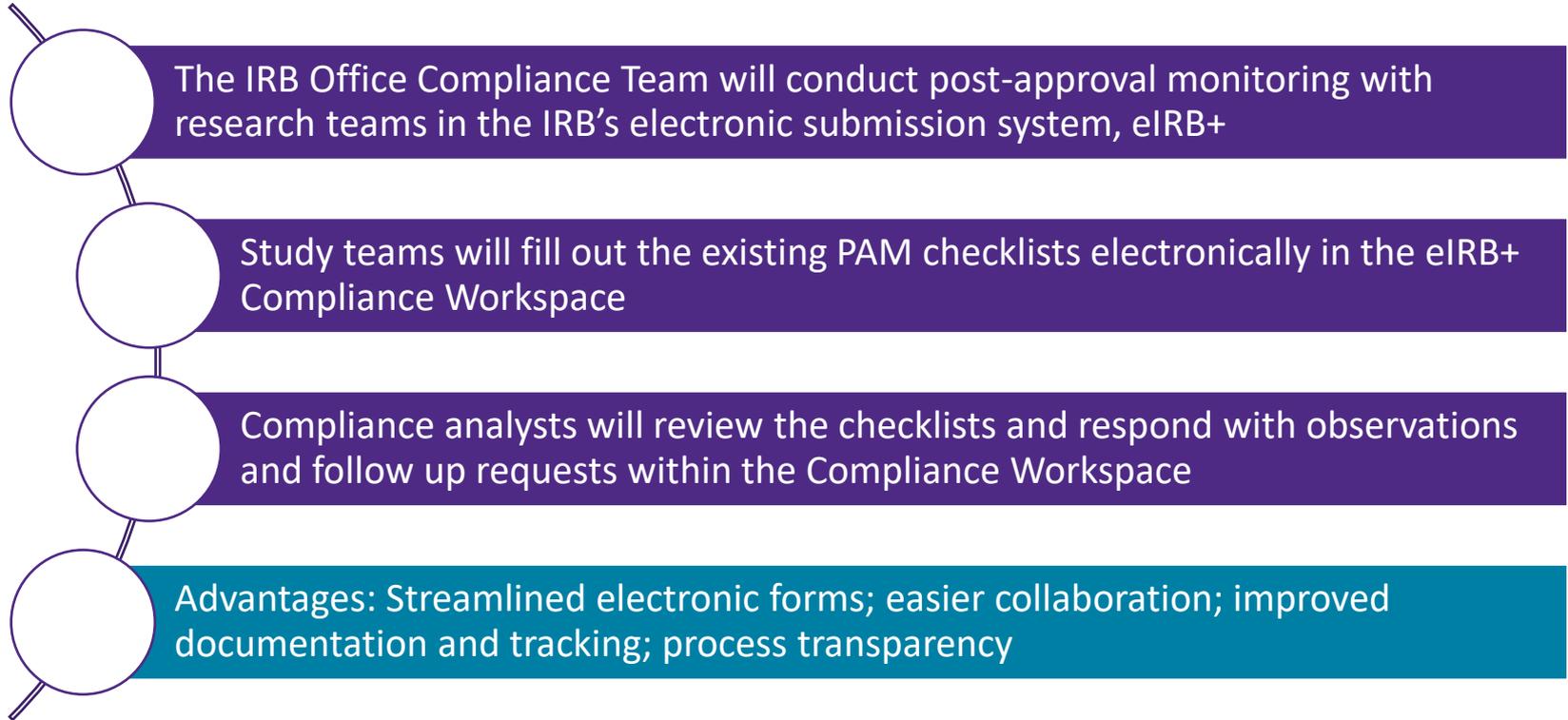
1	2	3	4	5	6
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A
Participant met inclusion/exclusion criteria	There is a completed, dated, and signed eligibility checklist. If not, please explain how eligibility is both verified and documented in the comments section.	Participant consented before participation in any research activity with the then current version of the consent document	The consent process is implemented per the study protocol and IRB SOPs	Participant completed all study related activities as outlined in the consent document	Compensation was dispensed to this participant per the protocol and is documented

2 Written Consent - if N/A check here and move to the next section

Type of Study: Clinical Trial Checklist HRP-1 Checklist

If selected, also complete HRP-1 Checklist

Future PAM Workflow



(NEW!) eIRB+ Compliance Workspace

- The eIRB+ Compliance Workspace is within eIRB+ but separate from the IRB review activities performed in eIRB+.

NU Institutional Review Board Office *dev site* Hello, Principal Investigator 1

My Inbox Home IRB **Compliance** Help

Compliance

Inbox My Reviews Archived All Reviews

Filter ID Enter text to search for Go Add Filter Clear All

ID	Compliance Activity	Compliance Activity Type	Studies	PI First Name	PI Last Name	Status	Date Modified
COM00000414	Post-Approval Monitoring Assessment	Routine Full Study Assessment	STU00215105	Principal	Investigator 1	Pre-Submission	1/30/2024 2:44 PM
COM00000379	Post-Approval Monitoring Assessment	Corrective and Preventative Action (CAPA) Assessment	RN000004705	Principal	Investigator 1	Pre-Submission	10/31/2023 11:07 AM
COM00000377	Post-Approval Monitoring Assessment	New Investigator Assessment	STU00215105	Principal	Investigator 1	Pre-Submission	10/31/2023 11:04 AM
COM00000376	Post-Approval Monitoring Assessment	Routine Full Study Assessment	STU00215105	Principal	Investigator 1	Pre-Submission	10/31/2023 10:33 AM
COM00000370	Post-Approval Monitoring Assessment	Corrective and Preventative Action (CAPA) Assessment	RN000004705	Principal	Investigator 1	Pre-Submission	10/27/2023 10:10 AM

0 Items < page 1 of 1 > 10 / page

Institutional Review Board Office
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Phone: 312.563.8338 Fax: 312.563.0555 E-mail: irb@northwestern.edu
[View IRB Web Site](#) [University Policy Statements](#) [Northwestern University](#)
This eIRB+ application is unavailable during daily system maintenance from 7-3:30 AM CST.



My Inbox

Home

IRB

Compliance

What about the PAM process is changing?

NEW!

- Researchers work with Compliance Team members in the **eIRB+ Compliance Workspace** rather than over **email**

Not Changing

- The PAM process is **still initiated** by the Compliance team
- The PAM Checklists are the **same questions** and **still available** on the IRBO Website

Navigating the eIRB+ Compliance Workspace

- Completing the PAM Checklists
 - Communication
 - Close-out
 - Documentation



Congratulations! You've been selected to undergo a PAM in the new Compliance Workspace!

- An eIRB+ auto generated email will be sent to the PI and primary contact associated with the study in the eIRB+ system.
 - An attached notification letter from the assigned IRB Compliance Analyst will contain resources, due date, and other relevant information
 - The IRB Compliance Analyst will prompt the PI to review their study records and initiate the PAM by logging into eIRB+ and accessing the Compliance Workspace.
 - The IRB Compliance Analyst conducting the review will take special care to provide the PI with education and resources to help them become more familiar with required and recommended human research practices.

Recorded Demonstration #1: Logging in & Filling out Checklists



NU Institutional
Review Board Office *dev site*



Login



Home

As of Wednesday, November 17th, if a modification to local site record for an External IRB project **only** involves minor changes to the study team, it will be automatically approved. However, these modifications may not be submitted unless all Study Team Members have current CITI training.

NetID:

Password:

Remember me

After signing in to this site, you are bound by the terms and conditions set forth when you received your account.

Communication during the PAM Activity

- For initial access, only the PI can enter and receive notifications from the Compliance Workspace.
- If additional team members need access to support the PI in completing the PAM, the PI must grant them PI Proxy status.
- Similar to IRB Communications:
 - Communication regarding observations and follow-up actions will take place mainly in eIRB+
 - When action is needed, eIRB+ will send system notifications via email to the PI and all PI Proxies assigned to the PAM assigned PI Proxy status
 - You can contact the assigned Compliance Analyst in eIRB+ using the [Add Comments](#) icon but may still also email the assigned Compliance analyst at anytime

Recorded Demonstration #2: Responding to Observations

Response Required (Pre-Review)
 Created On: 10/31/2024 2:02 PM
 Updated On: 10/31/2024 10:45 PM

Print Review

COM00000503
Principal Investigator: Principal Investigator 1
Compliance Analyst: Compliance Analyst 1
Created By: Compliance Analyst 1
PI Proxies: There are no items to display

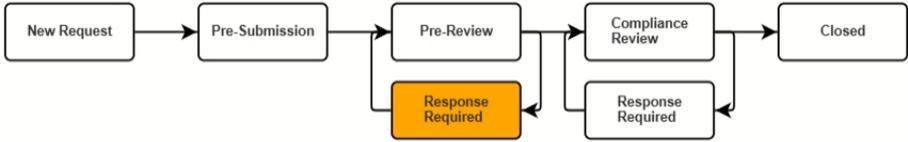
Compliance Activity: Post-Approval Monitoring Assessment
Activity Type: Routine Full Study Assessment
Status: Response Required (Pre-Review)
Response Due Date: 11/14/2024

Next Steps

- Respond to Observations
- Submit Response (Pre-Review)

Add Comments

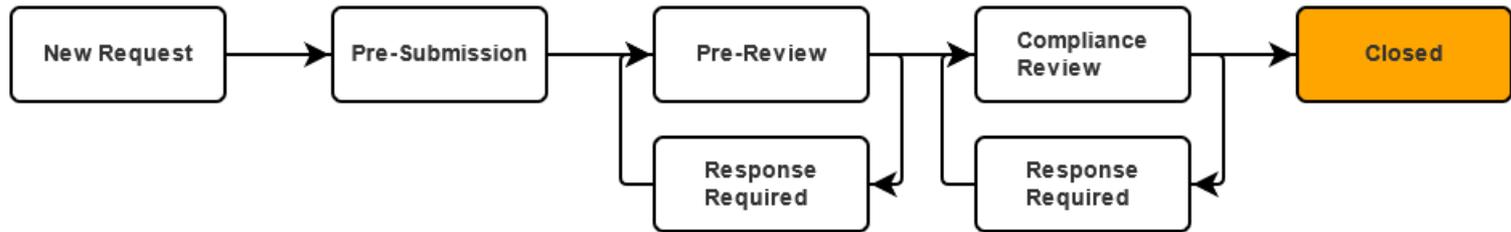
Assign PI Proxy



Item Number	Description	Researcher Response	Item Addressed?	Required Action	Notes Trail	Documents
OB-001	The checklist in Section 2 (IRB Documentation on File) indicates "n/a" that the PI has modification letters on file. However, the study's eIRB+ record demonstrates two modification submissions in the past year. Please confirm.					

Closeout & Documentation of the PAM activity

- The PAM is not complete until the PAM is in a closed state. When the activity is officially closed, the PI and all PI Proxies will receive an eIRB+ system email notification with a closeout letter attached.



- Print or save the electronic copies of the compliance activity (Notification letter, Close-out letter, and print review page of the activity) to your study's research records.

Recorded Demonstration #3: Close-out & Print Review

Closed

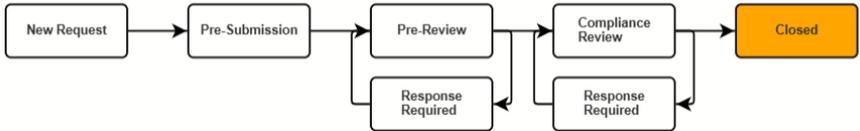
Created On: 10/19/2023 10:27 AM
Updated On: 10/27/2023 11:32 AM

Print Review

COM00000361

Principal Investigator: Principal Investigator 1
Compliance Analyst: Compliance Analyst 1
Created By: Compliance Analyst 1
PI Proxies: There are no items to display

Compliance Activity: Post-Approval Monitoring Assessment
Activity Type: Routine Full Study Assessment
Status: Closed
Response Due Date:



Add Comments

Follow Up Actions	Observations	Studies	History	Documents
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Follow Up Actions:

Item Number	Type	Description	Researcher Response	Item Addressed?	Required Action	Notes Trail	Documents	Related IRB Submission
FA-001	ID00000001	<p>Lorem ipsum dolor sit amet, consectetur adipiscing elit, sed do eiusmod tempor incididunt ut labore et dolore magna aliqua. Ut enim ad minim veniam, quis nostrud exercitation ullamco laboris nisi ut aliquip ex ea commodo consequat. Duis aute irure dolor in reprehenderit in voluptate velit esse cillum dolore eu fugiat nulla pariatur. Excepteur sint occaecat cupidatat non proident, sunt in culpa qui officia deserunt mollit anim id est laborum.</p>	<p>Lorem ipsum dolor sit amet, consectetur adipiscing elit, sed do eiusmod tempor incididunt ut labore et dolore magna aliqua. Ut enim ad minim veniam, quis nostrud exercitation ullamco laboris nisi ut aliquip ex ea commodo consequat. Duis aute irure dolor in reprehenderit in voluptate velit esse cillum dolore eu fugiat nulla pariatur. Excepteur sint occaecat cupidatat non proident, sunt in culpa qui officia deserunt mollit anim id est laborum.</p>	yes		<p>10/27/2023 - Principal Investigator 1 Lorem ipsum dolor sit amet, consectetur adipiscing elit, sed do eiusmod tempor incididunt ut labore et dolore magna aliqua. Ut enim ad minim veniam, quis nostrud exercitation ullamco laboris nisi ut aliquip ex ea commodo consequat. Duis aute irure dolor in reprehenderit in voluptate velit esse cillum dolore eu fugiat nulla pariatur. Excepteur sint occaecat cupidatat non proident, sunt in culpa qui officia deserunt mollit anim id est laborum.</p>	PI response to follow-up action	

Tips on Preparing for a PAM

- Review your eIRB+ application, protocol, and informed consent forms for accuracy and consistency
- Familiarize yourself with IRB Office [Resources & Guidance](#)
- Use the IRB Office [Study Support Resources and Templates](#)
 - Use the [Regulatory Binder or Research Record tool](#) to ensure your research record is up to date and in compliance
 - [Delegation of Authority \(DOA\) log](#) to track study team member roles and responsibilities.
- Review the [Post-Approval Monitoring Page](#) & [PAM Checklists](#)
- Review your open studies for [closure criteria](#)

Training & Support



1:1 with a Compliance Analyst



Office Hours



System Demonstrations



Dedicated Webpage



Training Manual

Call for Research Community Volunteers!

Do you know a PI, research team, or department that might like to participate in our pilot phase?



Expectations: Complete a post-approval monitoring self-assessment on 1 study in the eIRB+ Compliance Workspace and provide feedback during a meeting with a compliance analyst



Benefits: Specialized collaboration with a compliance team member and ensures the PI will not undergo routine monitoring again for at least 1 year

Email IRBCompliance@northwestern.edu

Q/A with the Compliance Team!



PIPER HAWKINS GREEN
Associate Director, IRB
Compliance, Reliance, and
Education



ALEC HENDERSON
IRB Compliance, Education,
and Communication
Manager



ANGELA BAUMGARTNER
Lead Compliance Analyst



KIM ROWAN
Senior Compliance Analyst



YASMEEN KHAN
Compliance Analyst



JENNIE THAI
Senior Compliance Analyst



BRITTANÉ GARYET
Senior Compliance Analyst