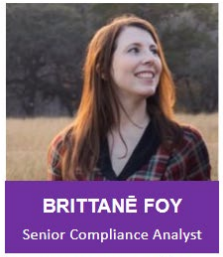
Keeping Up with Compliance:
A Peek into Post-Approval Monitoring Assessments

Brittanē Foy, BA, Senior IRB Compliance Analyst
Kim Rowan, MBA, CIP, Senior IRB Compliance Analyst
Jennie Thai, BA, Senior IRB Compliance Analyst
Yasmeen Khan, MSL, IRB Compliance Analyst
Institutional Review Board Office | Northwestern University

Agenda

- Compliance and Education Team
- Compliance Roots
- Post-approval monitoring
- Metrics
- Take Aways & Study Support Resources
- Check your knowledge
- Questions

Who are we?



irbcompliance@northwestern.edu & irbtraining@northwestern.edu

Mission Statement:

Enhance the caliber of research performed

Increase the effectiveness of the Human Research Protection Program

Ensure research at Northwestern and its affiliates complies w/ federal regulations and institutional policies that govern human research

Design our unit to ensure YOU have the educational resources and guidance necessary to conduct research SUCCESSFULLY and COMPLIANTLY

Compliance & Education **Activities**

Why is **Research Compliance** Important?

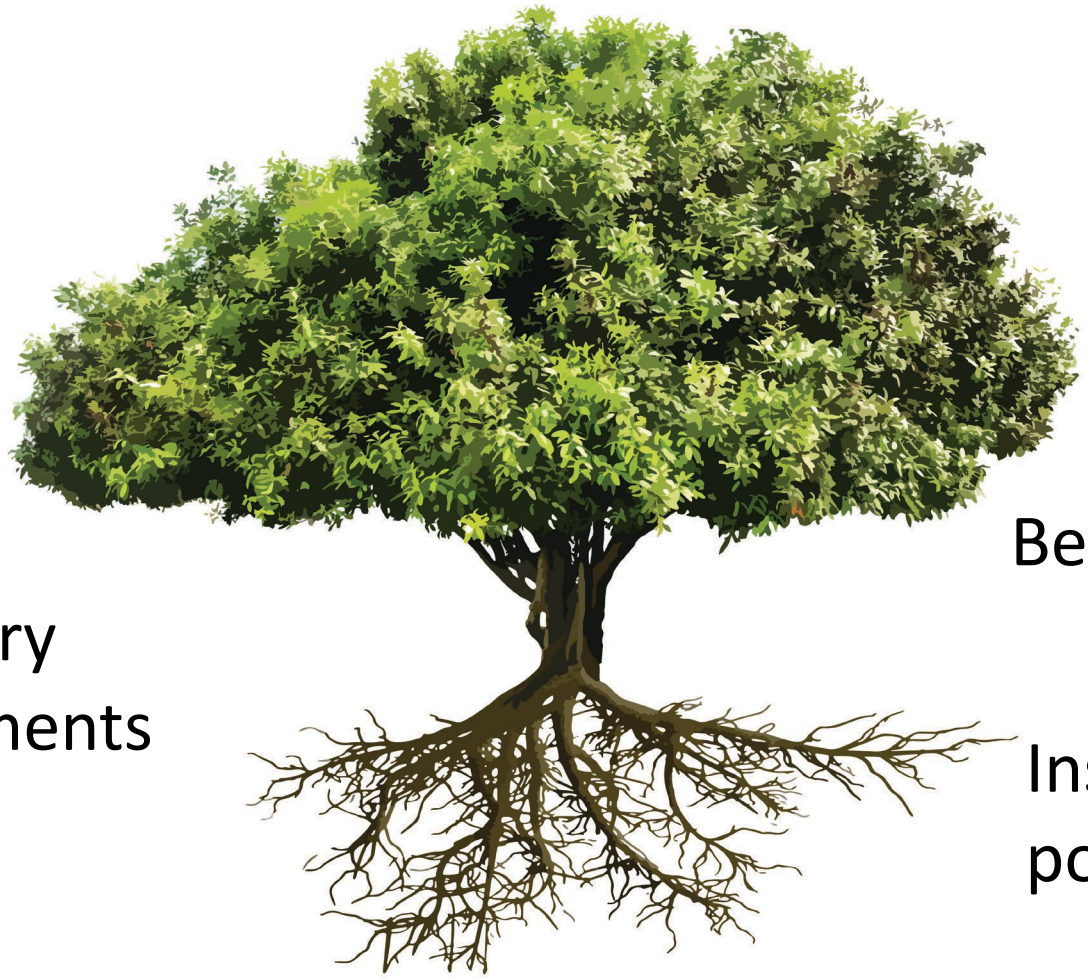
Research should be conducted in an ethical and responsible manner

Ensure researchers are following all applicable laws and regulations related to their research

Protects participants and institutions by reducing risk and enhancing safety

Maintain the integrity and credibility of research findings

Compliance Roots



Best Practices

Regulatory Requirements

Institutional policies

Ethical principles

Compliance Roots

Regulatory Requirements

- The Common Rule
- FDA Regulations
- Additional Federal Agency Criteria (NIH, DoD, VA, etc.)

Ethical Principles and Guidance

- The Belmont Report
- International Council on Harmonization (ICH) & Good Clinical Practice (GCP)

Institutional Policies

- Northwestern University Policies
- IRB Office Policies & Guidance
- Office for Research Policies and Guidance
- Feinberg School of Medicine (FSM) and Department/School Policies

Applicability: Compliance Roots

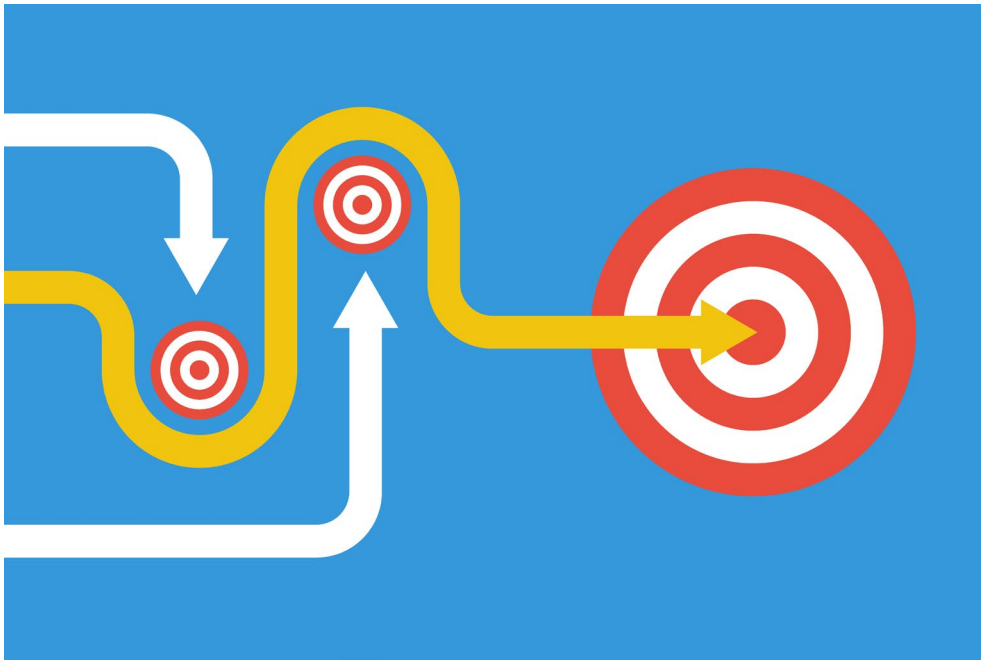
All Human Research at Northwestern University must adhere to:

- Ethical Principles
- Northwestern University Human Research Protection Program (HRPP)
- Northwestern IRB Office Policies, SOPs
- Other institutional (school or department-related) Policies and Procedures relevant to human research
- Human Research Protections Training
- Principal Investigator Responsibilities
- Informed Consent & HIPAA, PHI, & PII (when applicable)
- Data and Participant Safety
- Documenting Deviations and (when applicable) Reporting Events that Occur
- Research Document Retention Requirements for Principal Investigators
- Post-Approval Monitoring

Applicability: Compliance Roots

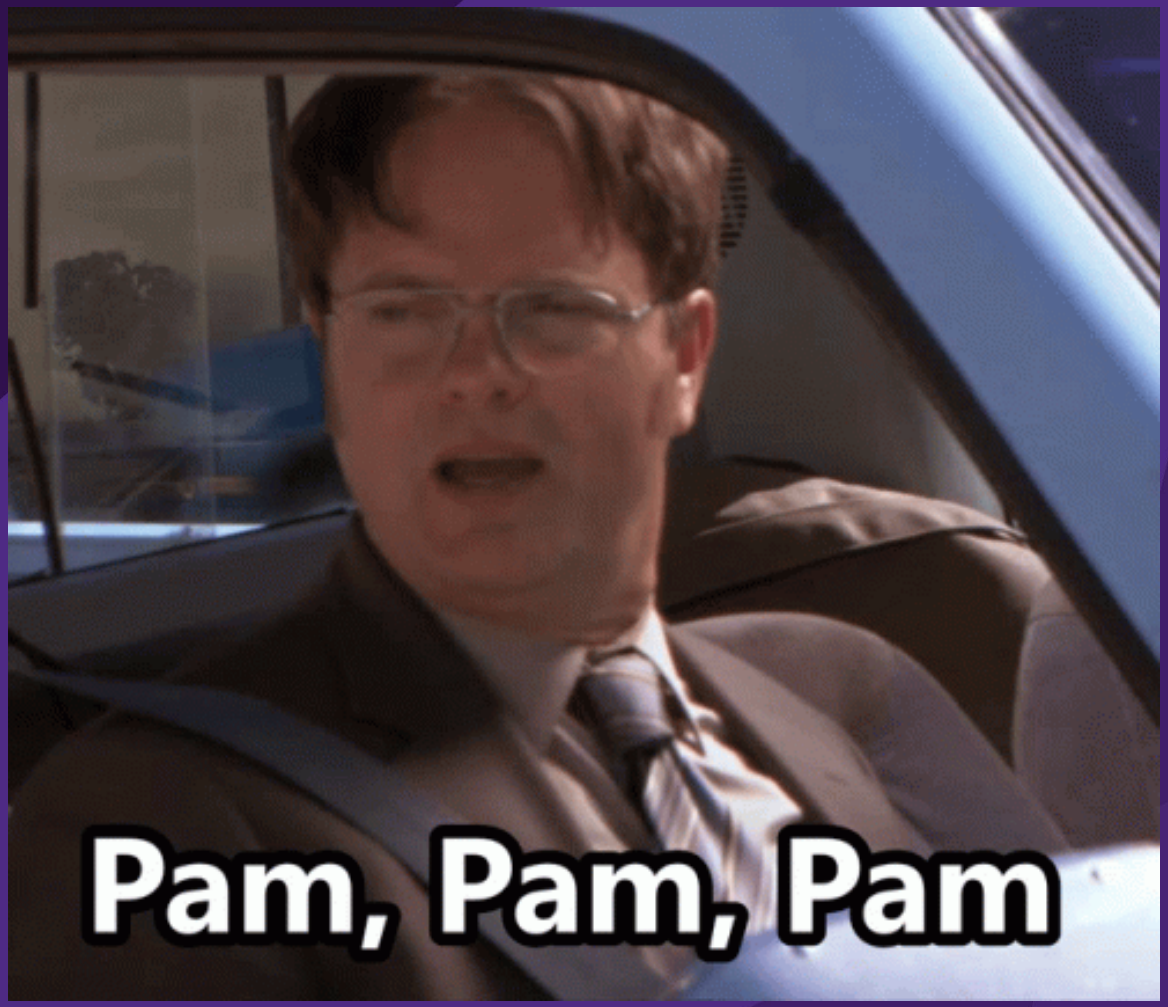
- **All Northwestern University researchers** are responsible for upholding the highest standards of ethical conduct as defined in University policies, procedures, and guidelines, and sponsoring agency policies and regulations
- **AAHRPP**: The **A**ssociation for the **A**ccreditation of **H**uman **R**esearch **P**rotection **P**rograms
  - Voluntary, peer-driven, educational model to ensure HRPP meets rigorous standards for quality and protection
  - AAHRPP accreditation = **"gold standard" of quality for IRBs**
- **Diversity, Equity, and Inclusion** considerations
  - Fostering Accessibility and Inclusivity in Research (FAIR)

Keeping Up With Compliance…can be challenging!



- Evolving regulations
- Compliance at multiple points during a research study
- Compliance is a moving target

Post-Approval Monitoring!



Post-Approval Monitoring (PAM) Self-Assessments

Description:

- Education-focused, routine compliance review
- Monitor active studies to confirm the research is being conducted as approved by the IRB
- Ensure compliance with institutional, state, and federal regulations, policies, and guidelines
- Promote best research practices

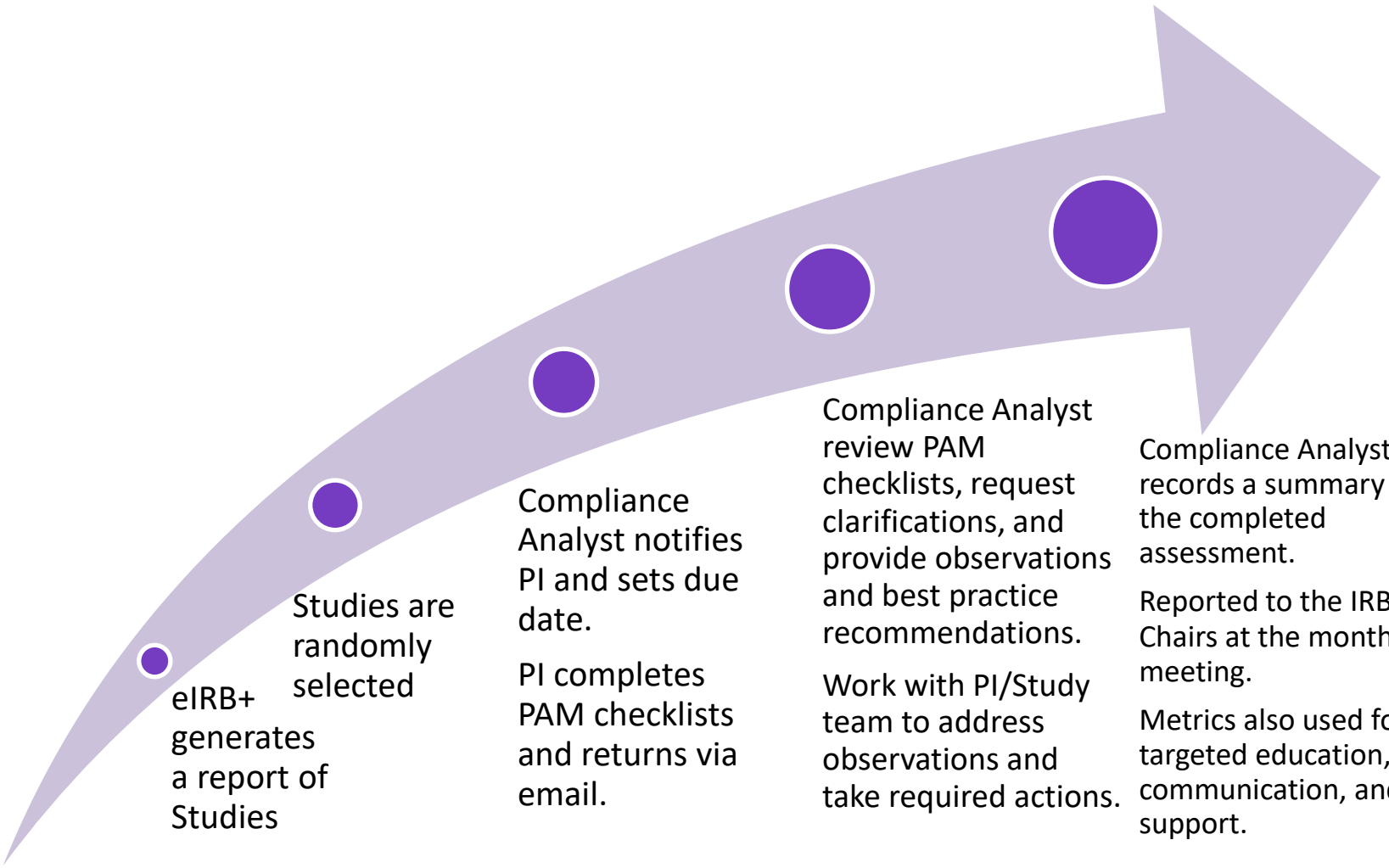
Types:

- Self-Assessment
- Corrective And Preventive Action (CAPA) Plan Assessment
- New Investigator Assessment
- New! Study Status Assessment

PAM Self-Assessment Monthly Selection

- **All currently open** non-exempt human research studies are eligible for review
- Studies are **randomly selected** each month from a variety of departments and study types:
  - Studies approaching expiration & Studies without an expiration date
  - Studies under the Northwestern University IRB & Studies reviewed by External IRB
- Goal = **monitor 3-5% of the open research portfolio**, so the number varies year to year
- FY23 Monthly Selections are based off our active portfolio:
  - Biomedical Research (66%)
  - Social and Behavioral Research (34%)
  - Studies reviewed by an external IRB (13%)

PAM Self-Assessment Process



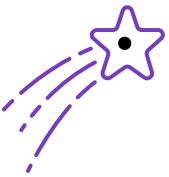
What Analysts Look For In Self-Assessment Checklists

- Consistency and accuracy of information between checklists and eIRB+ application, and documents (protocol, consent documents, etc.)
- Adherence to the IRB-approved protocol and documents
- Adherence to federal, state, local, and institutional regulations, policies, and best practices
- Educational opportunities including sharing resources and best practices

Responding to PAM Observations

IRB Compliance:

- The Compliance Analyst may provide the following with an observation:
  - Required Actions
  - Best Practice recommendations
  - Education or Resource(s) provided
- Include the regulation / policy / law or best practice the observation is rooted in
- May find PAM is as expected with no observations.



You:

- Respond to each observation via email in line, **bold** or change color of your text
- Take any required actions
- Respond to requested actions, providing supporting documentation if asked to
- Do not need to send revised checklists unless asked to

Closing a PAM Self-Assessment

- We guide you in making corrections or reconciliations with your research record
  - Required vs. Recommended actions
- Once all observations are addressed, we send a closure notification email
- The results of the PAM self-assessment are reported in aggregate at monthly IRB Chairs' meetings
- PAM metrics are recorded and used for reports, targeted education, support, and communications
  - Education needed
  - Ready for closure
  - Submissions required
  - Checklist/Section(s) with observations

Common PAM Observations

- Study ready for closure
- Outdated funding or study personnel
- Consent forms
  - Blank lines or no witness signature obtained when required
  - Non-IRB-watermarked consent version used
  - Optional procedures not appropriately marked

Principal Investigator Oversight:

- Inadequate documentation
  - Storage and retention of research records
  - Missing IRB correspondence or approvals
- Enrolling over the IRB-approved target enrollment number
  - Including retrospective chart reviews!
- Failure to meet IRB reporting timeframes
  - Use of Short Form consent process

Common Observations

Required Actions

- Continuing Review
- Modification
  - Update funding sources
  - Remove personnel no longer working on study
  - Update eIRB+ and study documents
- Reportable New Information (RNI)
- Filling missing CVs or Human Participant Research Training (CITI)
- Note to File

Common Observations

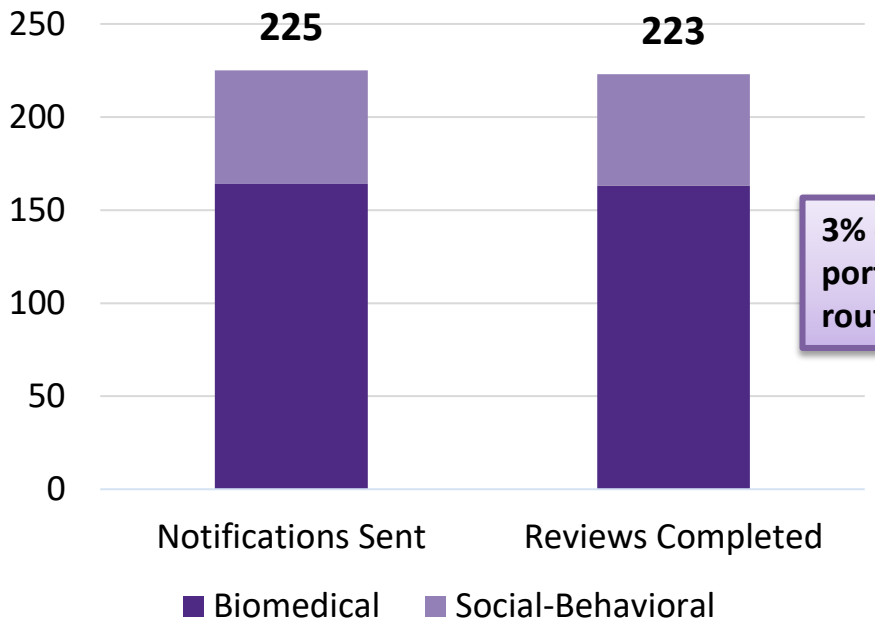
Required Actions

- DSMB reports indicating no changes to the study must be submitted at time of CRs
- Closing a study in a timely manner when study is ready for closure
- Maintain CITI training for all study personnel within the research record
- Record retention and regulatory documentation

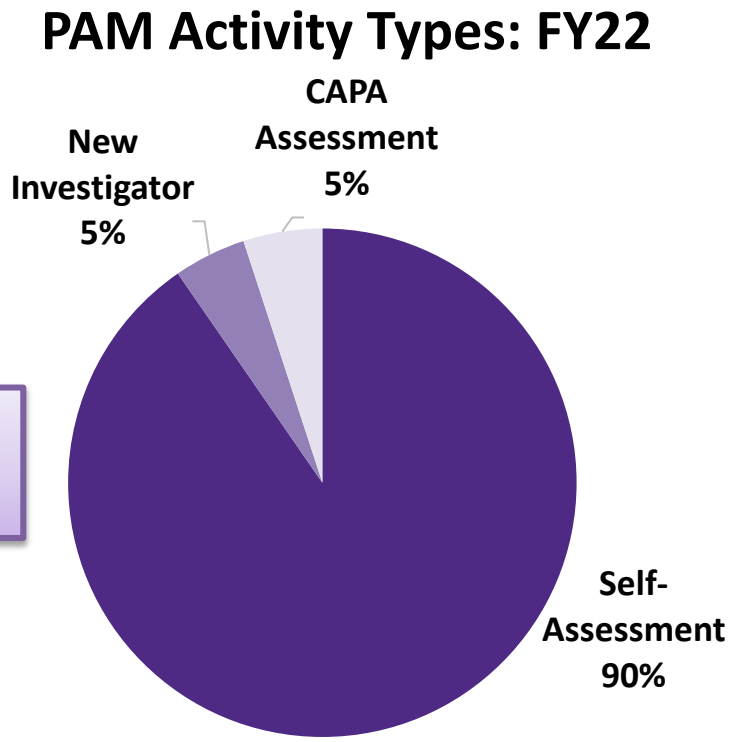
Best Practices and Recommended Actions

- Creating a **Delegation of Authority (DOA) Log**
  - Document study team qualifications & delegation
- Using an **Eligibility Checklist**
  - Track screening, enrollment, withdrawals
- **Including** Non-English-Speaking participants
  - Enhance diversity, equity, inclusion, & justice in research
- Maintaining **documentation** when implementing **Corrective and Preventive Action (CAPA) Plans**
- Documenting a **Note To File**
  - Add context/additional information to your research record

FY22 PAM Metrics

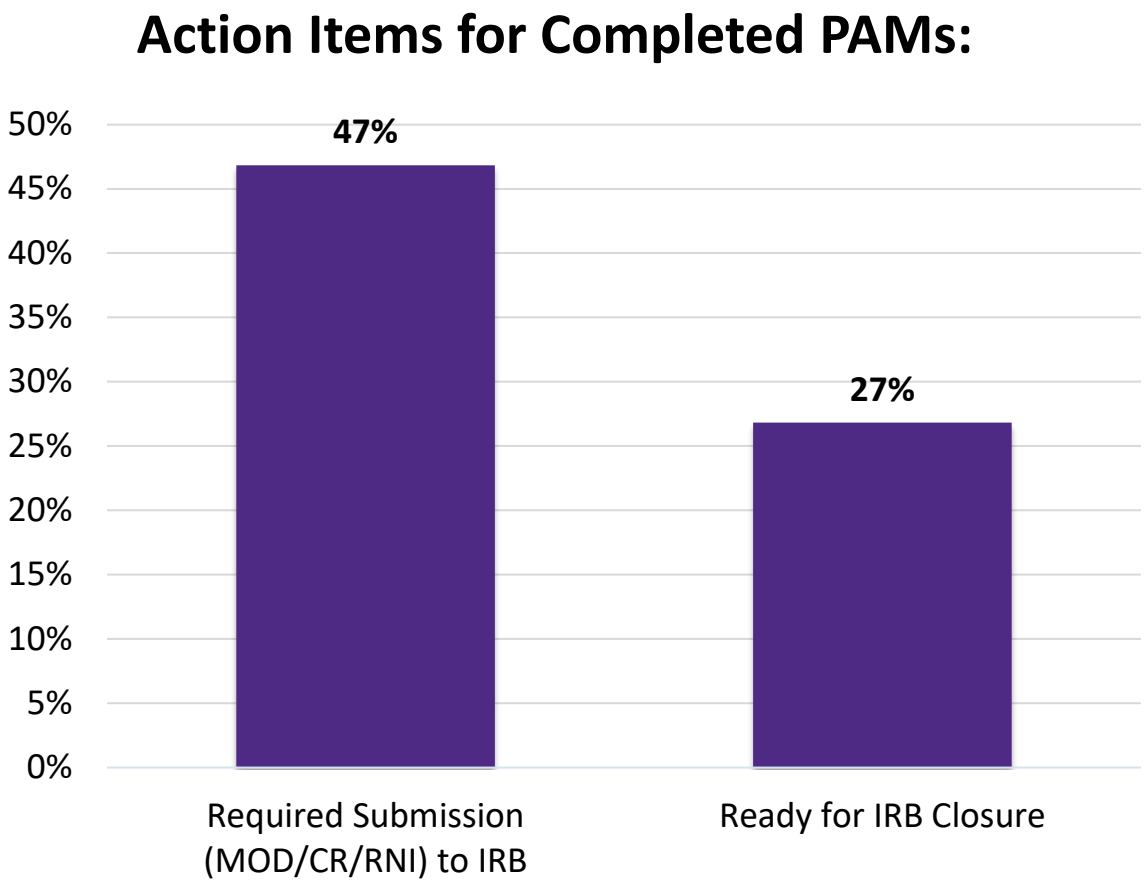


3% of IRB project portfolio underwent routine PAM

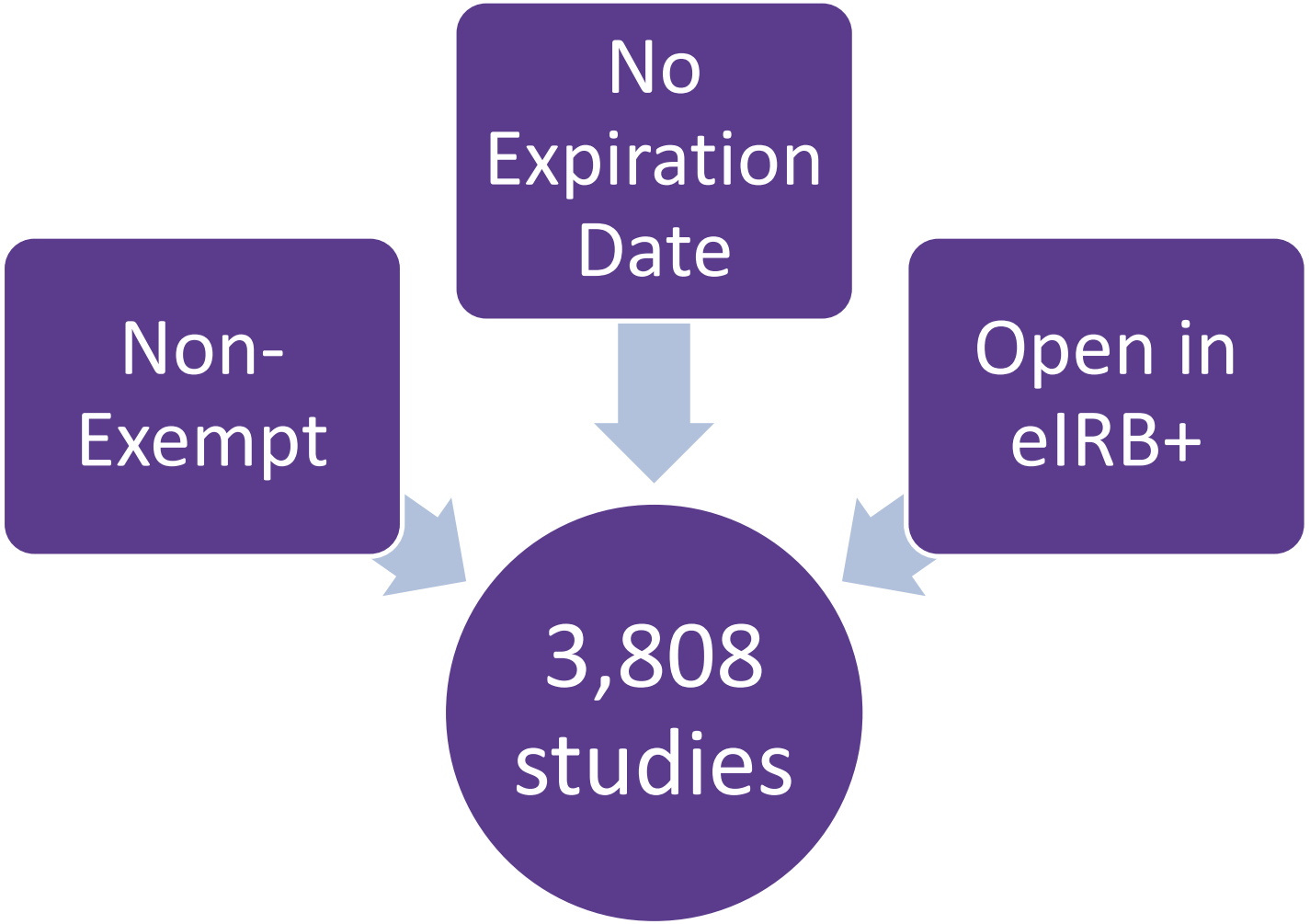


Note: All routine post-approval monitoring occurred remotely during FY22

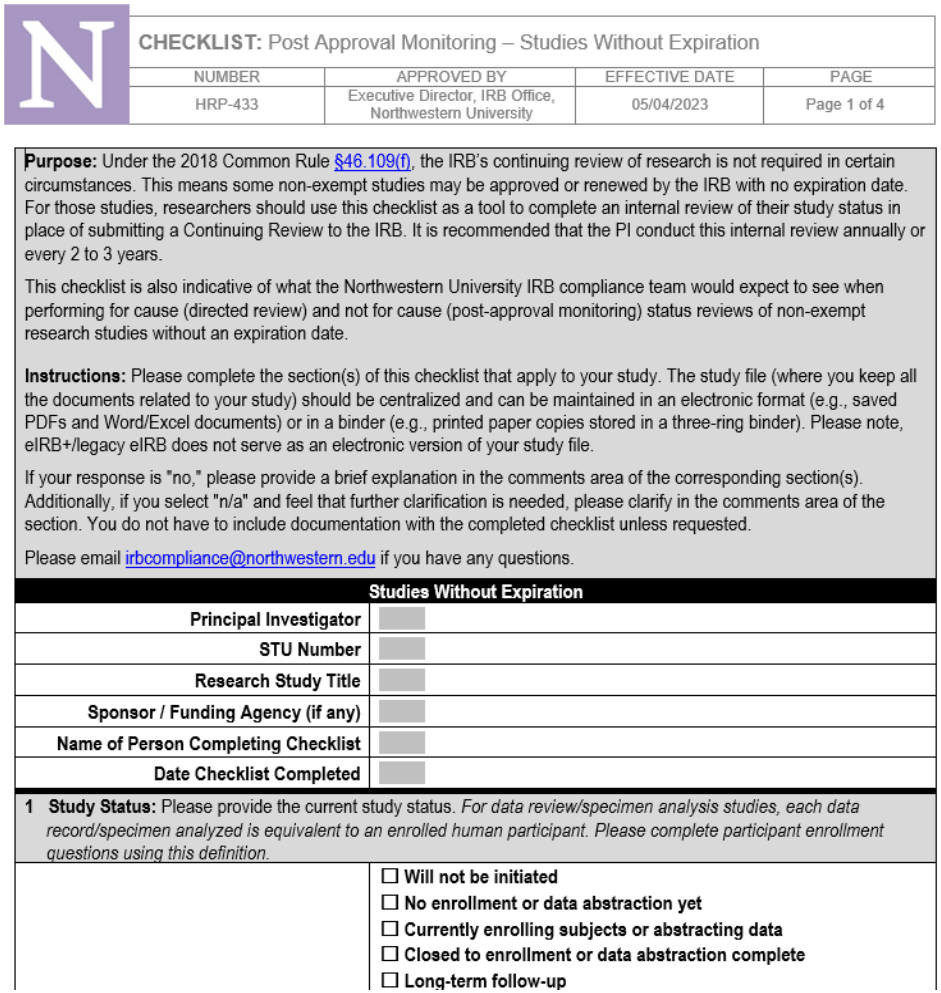
FY22 PAM Metrics



More Metrics!



Introducing a new Post-approval Monitoring Checklist: **Study Status Assessment**



CHECKLIST: Post Approval Monitoring – Studies Without Expiration

NUMBER	APPROVED BY	EFFECTIVE DATE	PAGE
HRP-433	Executive Director, IRB Office, Northwestern University	05/04/2023	Page 1 of 4

Purpose: Under the 2018 Common Rule §46.109(f), the IRB's continuing review of research is not required in certain circumstances. This means some non-exempt studies may be approved or renewed by the IRB with no expiration date. For those studies, researchers should use this checklist as a tool to complete an internal review of their study status in place of submitting a Continuing Review to the IRB. It is recommended that the PI conduct this internal review annually or every 2 to 3 years.

This checklist is also indicative of what the Northwestern University IRB compliance team would expect to see when performing for cause (directed review) and not for cause (post-approval monitoring) status reviews of non-exempt research studies without an expiration date.

Instructions: Please complete the section(s) of this checklist that apply to your study. The study file (where you keep all the documents related to your study) should be centralized and can be maintained in an electronic format (e.g., saved PDFs and Word/Excel documents) or in a binder (e.g., printed paper copies stored in a three-ring binder). Please note, eIRB+/legacy eIRB does not serve as an electronic version of your study file.

If your response is "no," please provide a brief explanation in the comments area of the corresponding section(s). Additionally, if you select "n/a" and feel that further clarification is needed, please clarify in the comments area of the section. You do not have to include documentation with the completed checklist unless requested.

Please email irbcompliance@northwestern.edu if you have any questions.

Studies Without Expiration	
Principal Investigator	
STU Number	
Research Study Title	
Sponsor / Funding Agency (if any)	
Name of Person Completing Checklist	
Date Checklist Completed	

1 Study Status: Please provide the current study status. *For data review/specimen analysis studies, each data record/specimen analyzed is equivalent to an enrolled human participant. Please complete participant enrollment questions using this definition.*

- ☐ Will not be initiated
- ☐ No enrollment or data abstraction yet
- ☐ Currently enrolling subjects or abstracting data
- ☐ Closed to enrollment or data abstraction complete
- ☐ Long-term follow-up

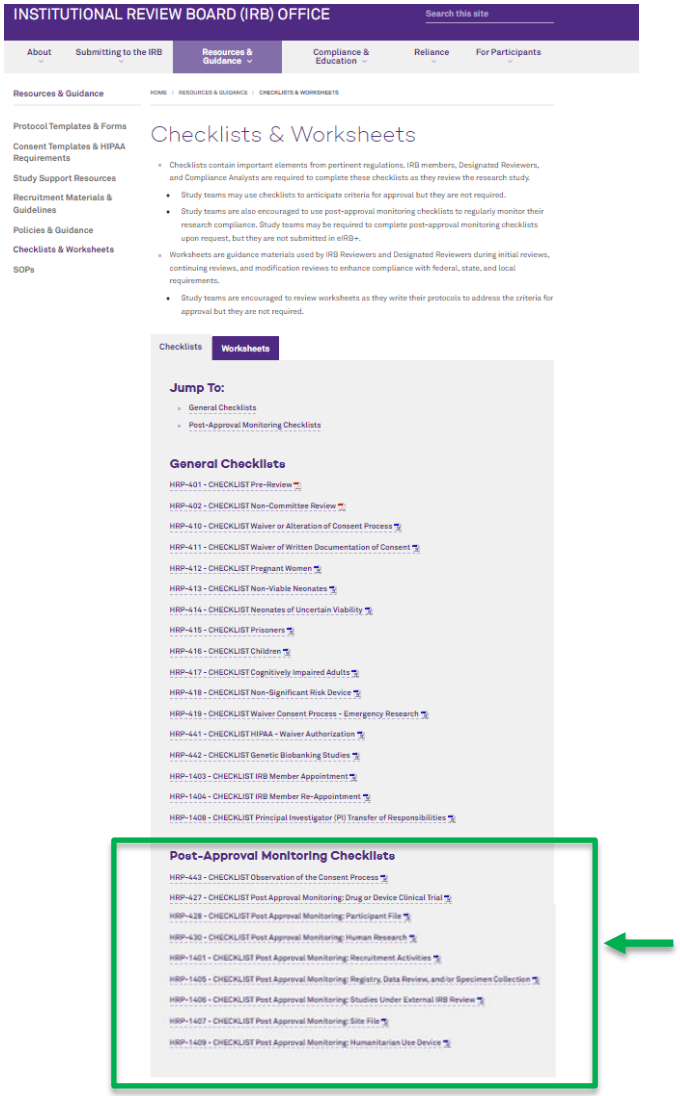
HRP-433 Studies Without Expiration Date PAM Checklist

- Adding to our toolkit – a *new* post-approval monitoring checklist and assessment type that is tailored specifically to monitor non-exempt studies that **do not have an expiration date.**
  - AKA Continuing Review is not required annually

Post-approval Monitoring Assessment: Study Status Assessment

- Target minimal risk studies without an IRB approval expiration date. These studies may be prospective or retrospective chart reviews, specimen collection and retention, registries, interview-only, etc.
- Possible Outcomes: Records reconciliation, Study closure, updating the study team list or modifications
- Monthly PAM assessments may utilize this checklist
- Empower PIs to KEEP UP WITH COMPLIANCE by conducting an internal review annually or every 2-3 years

Resources and Guidance



Checklists & Worksheets

The Post Approval Monitoring Checklists are available for you to use at any point. You can complete the checklists after the first participant has been enrolled to ensure your research records are in compliance.

Resources & Guidance

Protocol Templates & Forms

Consent Templates & HIPAA Requirements

Study Support Resources

Recruitment Materials & Guidelines

Policies & Guidance

SOPs

Checklists & Worksheets

Resources & Guidance

Throughout the lifecycle of a research study, many regulations, policies, and standard operating procedures apply – from the initial submission, through continuing reviews and modifications, and finally to study closure. Our resources can provide navigation for the research community, as well as for IRB analysts and reviewers.

- It is important to always download these resources directly from the IRB website, instead of saving a personal copy or re-using from a previous study, to ensure you have current information since our resources may be updated at any time.

Definitions

- Protocol Templates & Forms
- Consent Templates & HIPAA Requirements
- Study Support Resources
- Recruitment Materials & Guidelines
- Policies & Guidance

Resources & Guidance

Protocol Templates & Forms

Consent Templates & HIPAA Requirements

Study Support Resources

Recruitment Materials & Guidelines

Policies & Guidance

SOPs

Checklists & Worksheets

HOME > RESOURCES & GUIDANCE > STUDY SUPPORT RESOURCES

Study Support Resources and Templates

The Northwestern University Institutional Review Board (IRB) provides a variety of resources to help investigators conduct compliant human participant research. The tools below were created to support investigators in properly organizing paper based or electronically retained regulatory documentation and research data.

Investigators are encouraged to maintain a real-time accounting of all study related documents and data. Investigators should have all regulatory and participant-related information properly documented, as it plays a crucial role in validating research results throughout the life of the study.

Not all documents in the table below will be applicable to all studies. All study support resources and templates are editable. The user is encouraged to make changes to the tools to suit the study specific needs.

Activity/Process:	Resources:	Instructions:
Enrollment	Assent and Parental Permission Enrollment Log Screening, Enrollment, & Withdrawal Log	Tracks participant enrollment in real-time (including screening and withdrawals).
Delegation of Authority (DOA)	Biomedical Research DOA Clinical Trial DOA Social Behavioral Research DOA	Tracks the roles and responsibilities of study team members over time. With minor edits, you can also track training and CV/resume expiration dates.
Consent Process	Documentation of Consent Process Form (Word) Consent Form Collection Alternative (Excel)	Documents the consent process for individual participants in real-time.

5 Key Takeaways

*Set yourself up for success before the study starts, regularly check-in, and use the IRB Office resources to **KEEP UP WITH COMPLIANCE***

1. **We are in this together!** Familiarize yourself with the **Compliance Roots**:
   - Investigator Manual HRP-101
   - Human Research Resources, Policies, SOPs, & Guidance

2. **Principal Investigator Responsibilities & Oversight**
   - PI must provide the necessary oversight for all aspects of the study
   - Principal Investigator Responsibilities, Eligibility, and Permissions

3. **Documentation!**
   - Research Document Retention Requirements
   - Regulatory Binder / Research Record

4. **Expect the Unexpected**
   - Incident Assessment Tool and reporting timelines: Reportable New Information
   - Corrective and Preventive Action (CAPA) Plans
   - Protocol Deviation Log, Note To File

5. **Use the IRB Office Resources: we are here to help!**
   - Study Support Resources and Templates
   - SOPs
   - Recruitment Materials & Guidelines
   - Checklists & Worksheets: Find PAM Checklists here

Check Your Knowledge!

I am doing a department-funded survey/interview study.

What are the requirements that apply?

a. FDA
b. Common Rule
c. Institutional and ethical principles and guidance
d. All of the above

Why is Research Compliance Important?

a. Research is conducted in an ethical and responsible manner
b. Ensure researchers are following all applicable laws and regulations related to their research
c. Protects participants and institutions from risk and enhance safety
d. Maintain the integrity and credibility of research findings
e. All of the above

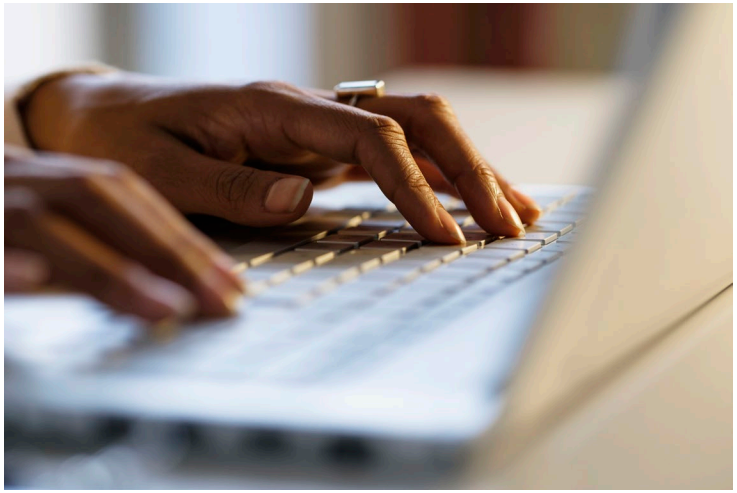
How do I close a study without an expiration date?

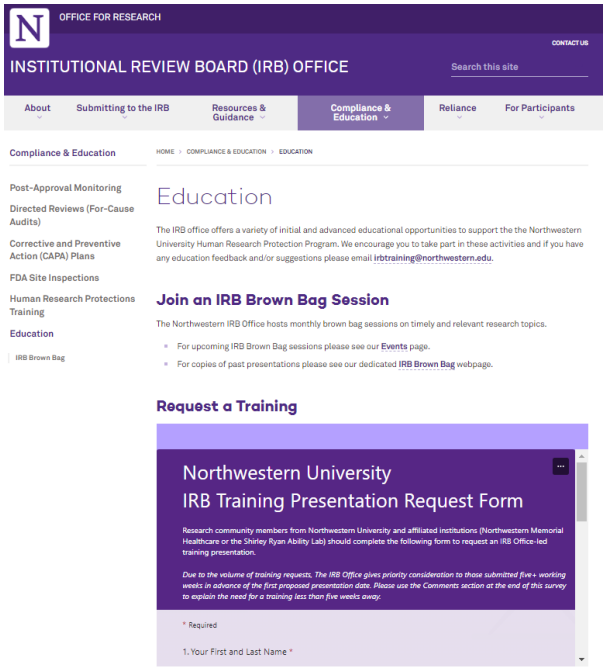
a. Wait for the IRB to close it administratively
b. Email the IRB office asking to close the study
c. Submit a continuing review application in eIRB+ for closure.
d. Take no action - if there is no expiration date the study does not need to be closed

Contact Us!

Contact Us

- Reach out! The IRB Office may be able to support your department and school through targeted education or resources. See the Education Page for the Training Request Form.
- IRBCompliance@northwestern.edu
- IRBTraining@northwestern.edu





Questions

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Thank you