

Keeping Up with Compliance:

Post-Approval Resources & Quality Assurance

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Introducing a new webpage:

Post-Approval Compliance & Quality Assurance

The screenshot displays the Northwestern Institutional Review Board (IRB) Office website. The header includes the Northwestern University logo (a purple square with a white 'N') and the text 'OFFICE FOR RESEARCH' and 'INSTITUTIONAL REVIEW BOARD (IRB) OFFICE'. A search bar is located in the top right corner with the text 'Search this site' and a magnifying glass icon. A navigation menu is positioned below the header, featuring links for 'About', 'Submitting to the IRB', 'Resources & Guidance', 'Education', 'Compliance', and 'Reliance'. The 'Compliance' link is highlighted in purple. Below the navigation menu, the breadcrumb trail reads 'HOME > COMPLIANCE > POST-APPROVAL MONITORING'. The main content area is titled 'Post-Approval Monitoring' in a large purple font. A purple box highlights the 'Post-Approval Compliance & Quality Assurance' link in the left-hand navigation menu, with a purple arrow pointing from this link to the main heading. The main content area contains several paragraphs of text. The first paragraph describes Post-approval monitoring (PAM) assessments as collaborative, education-focused reviews of the conduct of IRB-approved studies. The second paragraph explains that the Compliance Team provides post-approval monitoring checklists as a tool to ensure ongoing compliance with research regulations. The third paragraph states that the PI and their research personnel must fully and promptly cooperate with all monitoring conducted by the IRB. The fourth paragraph notes that the Compliance Team provides a summary of PAM activities to the IRB Chairperson's Committee for their review.

Compliance

HOME > COMPLIANCE > POST-APPROVAL MONITORING

Post-Approval Monitoring

Post-Approval Compliance & Quality Assurance

Directed Reviews (For-Cause Audits)

Corrective and Preventive Action (CAPA) Plans

FDA Site Inspections

eIRB+ Compliance Workspace

Post-Approval Monitoring

Post-approval monitoring (PAM) assessments are collaborative, education-focused reviews of the conduct of IRB-approved studies. The purpose is to improve research practices and protect research participants' rights and welfare by providing guidance, resources, and educational support for conducting compliant human research. All active non-exempt human research studies are subject to routine monitoring, including those where Northwestern University or its affiliates ceded IRB review to an external IRB. Researchers engage with the Compliance Team on PAM assessments to ensure compliance with applicable federal regulations, state laws, institutional policies, and research best practices.

The Compliance Team provides post-approval monitoring checklists as a tool to ensure ongoing compliance with research regulations after a study has been approved by the IRB. It helps Principal Investigators (PIs) and staff confirm that key aspects of the study, such as informed consent procedures, documentation practices, and adherence to protocol, are properly maintained throughout the study's duration. The [post-approval monitoring \(PAM\) checklists](#) serve to identify any areas needing correction and support continuous oversight, enhancing the protection of research participants and the integrity of the research process. All post-approval monitoring checklists are available to the research community and can be found on the IRB Office's [Checklists and Worksheets](#) page.

The PI and their research personnel must fully and promptly cooperate with all monitoring conducted by the IRB, regulatory agencies, funding agencies, and study sponsors. In addition, the PI must implement the appropriate corrective and preventative actions to resolve any observations and ensure that their research aligns with applicable federal regulations, state laws, and institutional policies.

The Compliance Team provides a summary of PAM activities to the IRB Chairperson's Committee for their review. The IRB Office utilizes post-approval monitoring findings to assess and enhance human participants' involvement in research at Northwestern and its affiliates through targeted training, education, and the ongoing development of [study support resources](#).



Post-Approval Monitoring

[Post-Approval Compliance & Quality Assurance](#)
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Post-Approval Compliance & Quality Assurance

Ensuring the ethical conduct of research goes beyond initial IRB review and continuing oversight—it requires ongoing attention to how studies are conducted in practice.

The Compliance Team conducts [post-approval monitoring](#) as part of its routine oversight of IRB-approved studies. These reviews aim to improve research practices and protect research participants' rights and welfare through IRB Office guidance, resources, and educational support. However, the entire Northwestern HRPP, research teams included, is responsible for the conduct of compliant human research, which can be facilitated by internal Quality Assurance (QA) reviews.

This page provides researchers with essential guidance to support them in conducting QA reviews, particularly through the use of the IRB Office's post-approval monitoring (PAM) checklists as a structured compliance tool.

'Initial IRB review and continuing review are crucial gatekeepers, but the true test of our commitment to human subjects lies in our ongoing oversight of research as it is conducted. We must move beyond a reactive stance and only investigator reporting and embrace a culture of continuous monitoring to ensure that approved protocols are executed ethically and in accordance with the approved protocol and regulatory standards. Post approval compliance monitoring should not be used to punish but to educate. We must invest in ongoing education.'

Dr. Molly Klote

Using the Post-Approval Monitoring Checklists during an internal Quality Assurance Review

Objectives

- ❖ Explain the purpose of post-approval monitoring and internal Quality Assurance (QA) reviews in maintaining compliance with IRB and regulatory requirements.
- ❖ Outline when and how to conduct internal QA reviews throughout the lifecycle of a research study.
- ❖ Identify and apply appropriate Post-Approval Monitoring (PAM) checklists during QA reviews.
- ❖ Recognize common observations and recommendations when conducting a QA reviews.

Let's be Inspired!

*'Initial IRB review and continuing review are crucial gatekeepers, but the true test of our commitment to human subjects lies in our ongoing oversight of research as it is conducted. We must move beyond a reactive stance and only investigator reporting and embrace a culture of continuous monitoring to ensure that approved protocols are executed ethically and in accordance with the approved protocol and regulatory standards. **Post approval compliance monitoring should not be used to punish but to educate. We must invest in ongoing education.'***

-Dr. Molly Klote

Why conduct a Quality Assurance Review?



The IRB Compliance Team conducts post-approval monitoring (PAM) to fulfill a mandatory regulatory obligation driven by federal regulations (45 CFR 46 and 21 CFR 56) that ensures approved research continues to protect participant safety, welfare, and data integrity.



However, the entire [Northwestern HRPP](#), research teams included, is responsible for the conduct of compliant human research, which can be facilitated by **internal Quality Assurance (QA) reviews**.

Why should **research teams** conduct a Quality Assurance Review?

- Proactively ensure compliance with IRB-approved protocols, regulations, and institutional policies
- Strengthen research practices and documentation
- Increase team confidence in meeting regulatory and ethical requirements
- Identify and address issues early



Using the Post-Approval Monitoring Checklists during an internal QA review

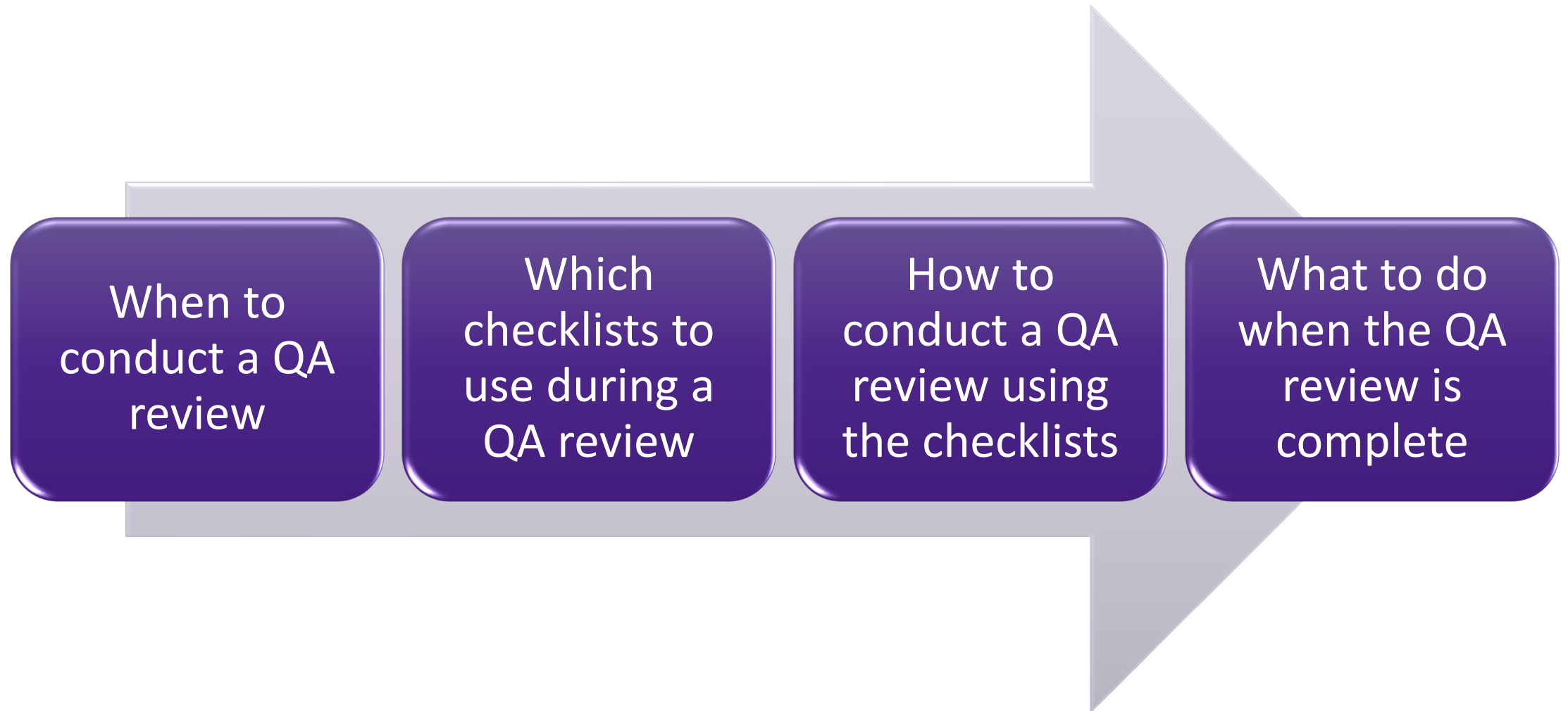
The Compliance Team recommends that researchers use the post-approval monitoring checklists *independently* to help ensure their study complies with applicable federal regulations, state laws, institutional policies, and best practices.

The checklists highlight the key documents and processes research teams should have in place to demonstrate ongoing compliance with the IRB and regulatory requirements.

The checklists may serve as documentation of ongoing oversight of study conduct.

The checklists can help prepare study teams for quality assurance visits by external monitors or auditors.

Internal QA Review Process



When to conduct a QA review:

At Study Startup:

Conduct a QA review after:

- a) The Principal Investigator has obtained IRB approval,
- b) The study team has completed the required training,
- c) Study files are organized, and
- d) The first participant has been enrolled

This review helps confirm that regulatory and study procedures are in place and compliant at the beginning of the study, preventing larger issues down the road.

When to conduct a QA review:

Mid-points of the Study:

Conduct QA reviews quarterly or bi-annually, or as appropriate based on the pace of enrollment, risk level, and complexity of the study.

These periodic reviews help maintain ongoing compliance and may identify areas requiring corrective action.

When to conduct a QA review:

End of Study:

Conduct a QA review to ensure that outstanding issues (e.g., unresolved deviations, missing reports, or incomplete study documentation) are addressed, and the study is ready for IRB closure and record retention in accordance with institutional and regulatory requirements.

When to conduct a QA review:

For-Cause:

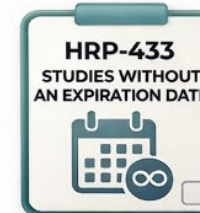
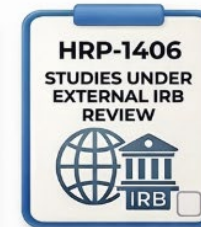
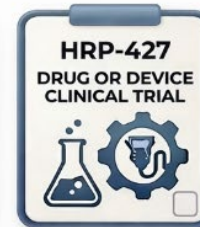
Conduct a QA review in response to unanticipated events or concerns such as repeated protocol deviations, serious non-compliance, participant safety concerns, or data integrity challenges. (e.g., serious, suspected, or repeated non-compliance, safety risks to participants, or data integrity issues).

Types of Post-Approval Monitoring Checklists

Foundational

Supplemental

Stand-Alone



Types of Post-Approval Monitoring Checklists

Foundational Checklists: Address core regulatory requirements, study oversight responsibilities, and participant protection expectations that apply across most study types and phases.

Human Research (HRP-430)

- For use in non-exempt studies

Participant File (HRP-428)

- For use when the Principal Investigator has initiated a medical record review, specimen collection, and/or has consented and enrolled participants.

Types of Post-Approval Monitoring Checklists

Supplemental Checklists: address additional considerations for specific types of research activities

- **Data Review, Registries, or Specimen Collection (HRP-1405)**
 - For use if the research involves medical record (data) reviews, registries, and/or specimen collection.
- **Drug or Device Clinical Trial (HRP-427)**
 - For use if the study is a clinical trial and involves an investigational drug or device.
- **Studies Under External IRB Review (HRP-1406)**
 - For use if the study relies on an External IRB for review.
- **Site File (HRP-1407)**
 - For use if external study sites, excluding Northwestern affiliates, rely on the Northwestern IRB for review.
 - Complete one Site File checklist for each site that relies on Northwestern IRB.
- **Humanitarian Use Device (HRP-1409)**
 - For use if the study involves treatment plans with a humanitarian use device (HUD).

Types of Post-Approval Monitoring Checklists

Stand-Alone Checklists: designed to evaluate a specific research activity

- **Studies Without an Expiration Date (HRP-433)**
 - For focused Study Status Assessments of non-exempt, minimal-risk studies with no IRB expiration date.
 - May be used as an internal study status review in place of an annual Continuing Review submission.
 - Recommended for the Principal Investigator (PI) or a designee to complete annually or every 2-3 years while the study remains open.
- **Observation of the Consent Process (HRP-443)**
 - For real-time QA review of the informed consent process to ensure clear communication and respects participants' rights to informed decision-making.
 - Participant must verbally agree in advance to allow the observation; if not, the consent proceeds without an observer.
- **Recruitment Activities (HRP-1401)**
 - For use if the study utilizes recruitment advertisements to assess whether they follow regulatory and institutional requirements.

How to use the checklists during a QA review:

An example..

- Biomedical study
- Collects data retrospectively from EPIC
- We serve as the IRB of Record for an external site

Post-Approval Monitoring Checklists

[HRP-443 - CHECKLIST Observation of the Consent Process](#)

[HRP-427 - CHECKLIST Post Approval Monitoring: Drug or Device Clinical Trial](#)

[HRP-428 - CHECKLIST Post Approval Monitoring: Participant File](#)

[HRP-430 - CHECKLIST Post Approval Monitoring: Human Research](#)

[HRP-433 - CHECKLIST Post Approval Monitoring: Studies Without an Expiration Date](#)

[HRP-1401 - CHECKLIST Post Approval Monitoring: Recruitment Activities](#)

[HRP-1405 - CHECKLIST Post Approval Monitoring: Registry, Data Review, and/or Specimen Collection](#)

[HRP-1406 - CHECKLIST Post Approval Monitoring: Studies Under External IRB Review](#)

[HRP-1407 - CHECKLIST Post Approval Monitoring: Site File](#)

[HRP-1409 - CHECKLIST Post Approval Monitoring: Humanitarian Use Device](#)

How to use the checklists during a QA review

- Electronically or Print Out
- Use the **comment** section as needed
- Select **N/A** when appropriate

Data Review, Registries, or Specimen Collection	
Principal Investigator	█
STU Number	█
Name of Person Completing Checklist	█
Date Checklist Completed	█
1 Data Review: Please indicate whether the procedures below are followed (elaborate if the response is "no"). If the research does not involve data review, please mark N/A here and move to the next section <input type="checkbox"/>	
<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	1. Data are collected in a manner consistent with the current IRB approved protocol.
<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A	2. Data from NMHC were obtained with appropriate approval from the Northwestern University Enterprise Data Warehouse (EDW).
<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	3. An exception from EDW was obtained to access NMHC data directly from EPIC.
<input type="checkbox"/> N/A	4. If EDW was not utilized, an exception was not granted, or NMHC data were not used, indicate the data source(s) and by what authority the data were extracted: █
<input type="checkbox"/> N/A	5. Indicate the type of data review as well as date range: <input checked="" type="checkbox"/> Retrospective review: data already existed at the time study was submitted for initial IRB approval Date range of date to be reviewed: █ to █ <input type="checkbox"/> Prospective review: data did not exist at the time study was submitted for initial IRB approval <input type="checkbox"/> Both retrospective and prospective review Date range of date to be reviewed: █ to █
<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	6. The protocol details that identifiable data will be destroyed at the earliest opportunity. If identifiable data are not destroyed, please explain: █
<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	7. If data are collected from other sources such as media, interviews, literature, educational records, etc., the protocol details the data collection methods and sources.
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	8. The protocol details a data retention plan and provisions to protect privacy and data confidentiality.
Section 1 Additional Comments	Medical record data were not obtained through EDW, per #3 we have documentation of an exception from the EDW to obtain medical record data directly from Epic

Recommendations to Address Common Observations

- Observation: Insufficient documentation of the consent process
 - Recommendation: Implement a [consent process checklist](#) to ensure the consent process for each participant is documented in real time and maintained in the study records.
- Observation: Identification of protocol deviations, missing study documentation, or other study issues
 - Recommendation: Recover and file missing documentation where possible, document past deviations and unrecoverable documentation in [Notes-to-File](#), and record deviations in real time on a protocol deviation log moving forward. Use our [Study Support Resources and Templates](#) as needed.

After Completing a QA review:

- **Report:** If during the review you identify a finding, assess whether the information meets the IRB's reporting criteria and, if so, submit the information, as appropriate, to the IRB.
 - Use the [Incident Assessment Tool \(IAT\)](#)
 - Review the [Reportable New Information \(RNI\)](#) webpage
 - Review the [Corrective and Preventive Action \(CAPA\) Plans](#) webpage
- **Document:** Create and retain documentation of the QA review, including all findings, assessments, and any corrective or preventive actions implemented as part of post-approval monitoring. Non-compliance or deviations that do not rise to the level of reporting to the IRB should still be documented and maintained.

Key Takeaways:

Post-Approval Resources & QA Review



Promote Ethical, Compliant Research

Education & Prevention



Shared Responsibility

Research Teams Engaged



Use PAM Checklists

Structured & Audit-Ready



Startup



Periodic



End of Study



For-Cause

Follow Through & Report



Document Findings



Apply CAPA



Report to IRB

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THANK YOU