Keeping Up with Compliance:

Post-Approval Resources & Quality Assurance

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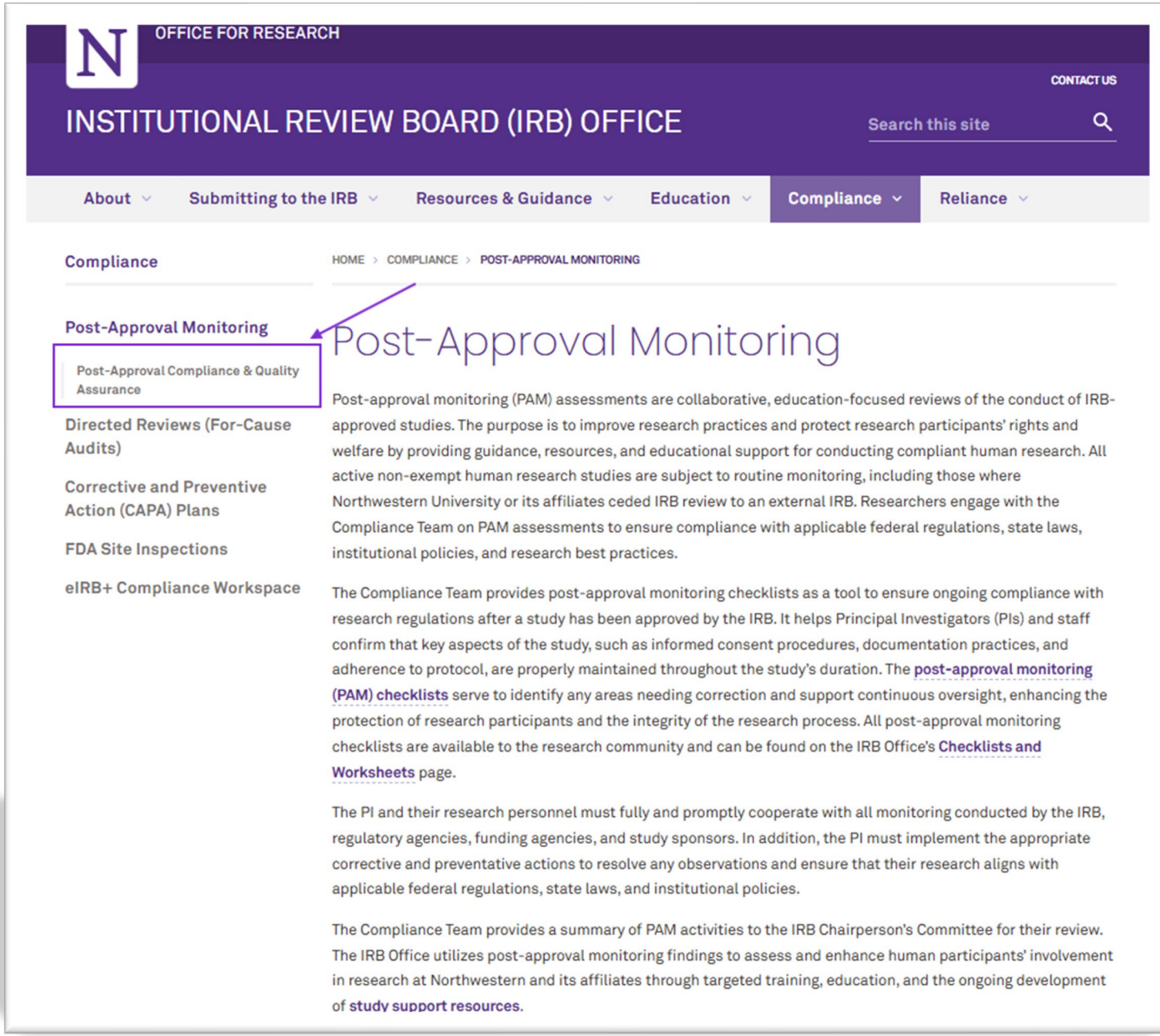
Introducing a new webpage:

Post-Approval Compliance & Quality Assurance



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

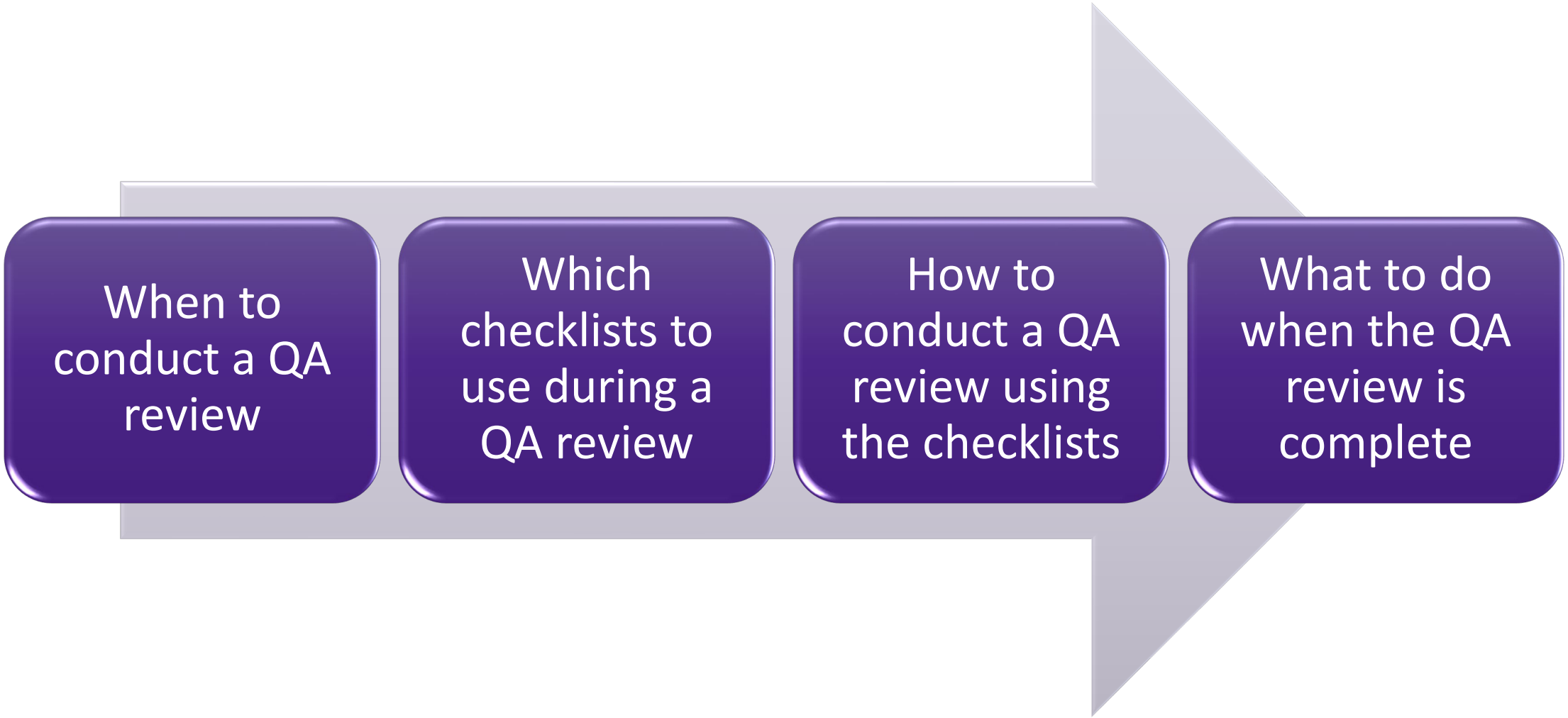
The Compliance Team recommends that researchers use the post-approval monitoring checklists *independently* to help ensure their study complies with applicable federal regulations, state laws, institutional policies, and best practices.

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:

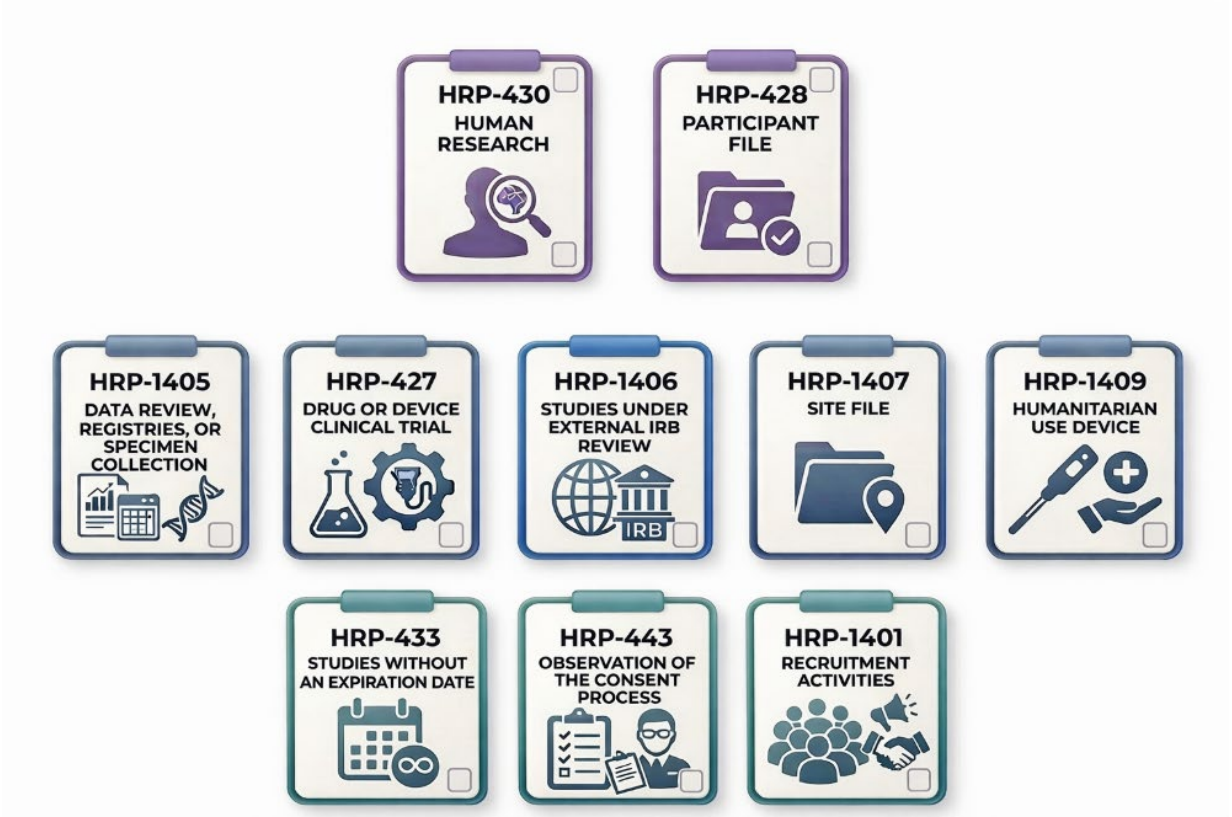
Conduct a QA review in response to unanticipated events or concerns such as repeated protocol deviations, serious non-compliance, participant safety concerns, or data integrity challenges. (e.g., serious, suspected, or repeated non-compliance, safety risks to participants, or data integrity issues).

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.

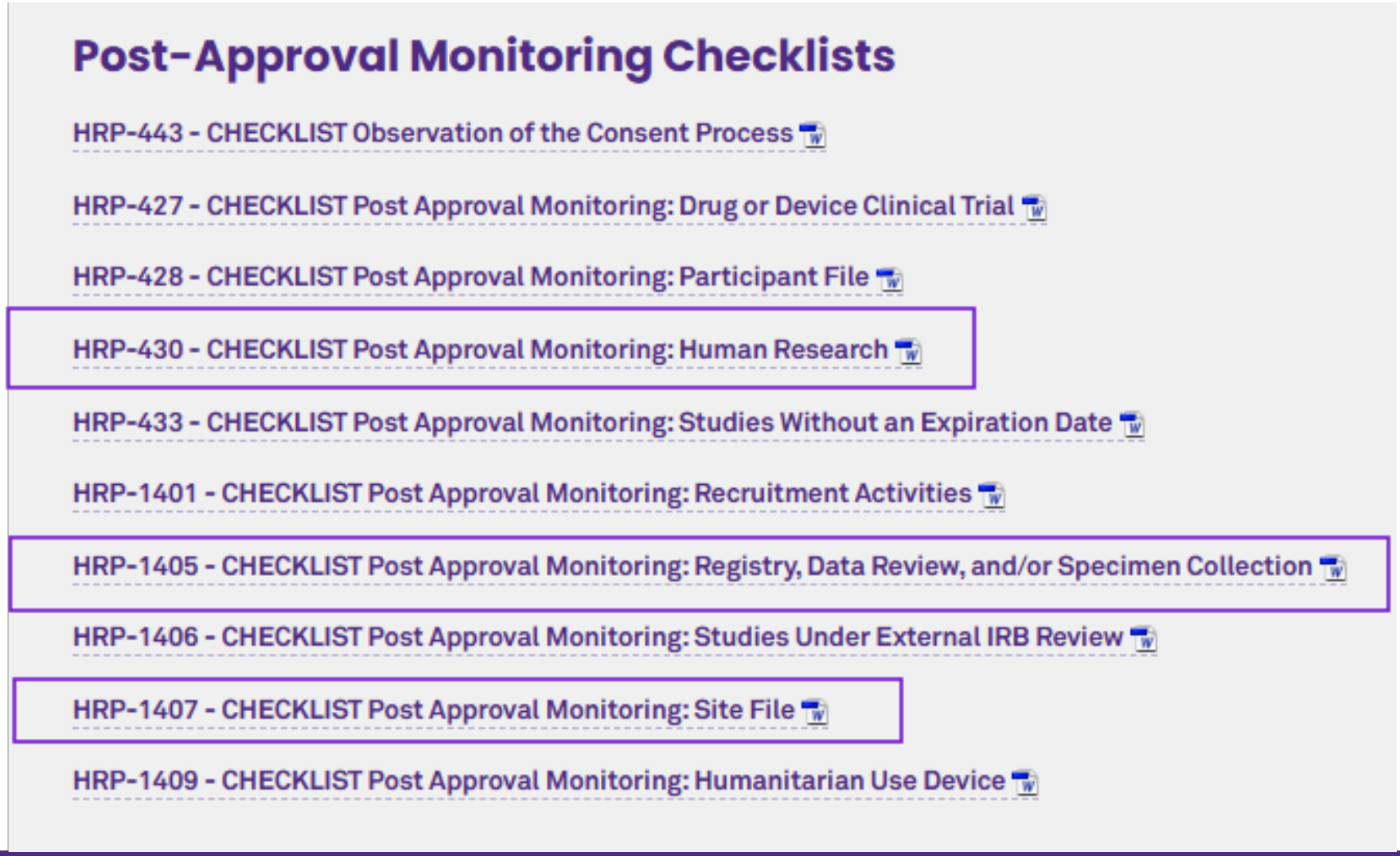
- Observation of the Consent Process (HRP-443)
  - For real-time QA review of the informed consent process to ensure clear communication and respects participants' rights to informed decision-making.
  - Participant must verbally agree in advance to allow the observation; if not, the consent proceeds 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



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 ☐	
☒ Yes ☐ No ☐ N/A	1. Data are collected in a manner consistent with the current IRB approved protocol.
☐ Yes ☒ No ☐ N/A	2. Data from NMHC were obtained with appropriate approval from the Northwestern University Enterprise Data Warehouse (EDW).
☒ Yes ☐ No ☐ N/A	3. An exception from EDW was obtained to access NMHC data directly from EPIC.
☐ 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:
☐ N/A	5. Indicate the type of data review as well as date range: ☒ **Retrospective review:** data already existed at the time study was submitted for initial IRB approval Date range of date to be reviewed: **to** ☐ **Prospective review:** data did not exist at the time study was submitted for initial IRB approval ☐ **Both retrospective and prospective review** Date range of date to be reviewed: **to**
☒ Yes ☐ No ☐ N/A	6. The protocol details that identifiable data will be destroyed at the earliest opportunity. If identifiable data are not destroyed, please explain:
☒ Yes ☐ No ☐ 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.
☐ Yes ☐ No ☐ 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

Follow Through & Report

Document Findings

Apply CAPA

Report to IRB

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.

THANK YOU