



SOP: Post-Approval Monitoring Assessment

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1 PURPOSE

- 1.1 This procedure establishes the process to conduct IRB post-approval monitoring (PAM).
- 1.2 The process begins when the (IRB Office) Compliance Team generates the following reports:
 - 1.2.1 Non-exempt studies due for Continuing Review,
 - 1.2.2 Non-exempt studies without an IRB approval expiration date,
 - 1.2.3 Reportable New Information (RNI) items containing a Corrective and Preventive Action (CAPA) plan, and
 - 1.2.4 Investigators who have recently submitted their first non-exempt human research project to Northwestern IRB.
- 1.3 The process ends when the PAM has been completed and reported to the Northwestern University Institutional Review Board at the IRB Chairs' Meeting.

2 PREVIOUS VERSION

- 2.1 Revised from previous version dated 04/14/2021.

3 POLICY

- 3.1 In accordance with the regulations that govern human research and institutional policy, the IRB has the authority to observe or have a third party observe the consent process and the [conduct of] research (45 CFR [§46.109](#) (g) and 21 CFR [§56.109](#) (f)).
- 3.2 The IRB Office has the responsibility to (1) Implement a Directed (For cause) Review program to monitor compliance and improve compliance in identified problem areas, and (2) Investigate and remediate identified systemic problem areas and, where necessary, request that the Vice President for Research remove individuals from involvement in the Human Research Protection Program (Human Research Protection Program Plan (HRP-101)).
- 3.3 The IRB Office and IRB investigate allegations of non-compliance in Human Research and impose corrective actions as needed. In addition to Directed Reviews conducted by the IRB Office in response to reports of alleged non-compliance, the IRB Office also conducts routine post-approval monitoring of Human Research studies to ensure the compliant conduct of Human Research at the University and its affiliates.

4 RESPONSIBILITIES

- 4.1 The Compliance Team carries out the activities related to post-approval monitoring.
- 4.2 The Compliance Team reports the post-approval monitoring activities at the IRB Chairs' Meeting.

5 PROCEDURE

- 5.1 The Compliance Team will conduct post-approval monitoring on a 3%-5% sampling of active non-exempt Human Research studies, regardless of the IRB of record. This sampling will include a ratio of studies that no longer require a continuing review and, therefore, do not have an IRB approval expiration date.
- 5.2 The (IRB Office) Compliance Analyst will generate a list of research studies that will be due for continuing review in three months, a list of studies that no longer require a continuing review whose initial approval date anniversary is in three months, a list of Reportable New Information items where there is a CAPA plan and where the IRB made the final determination six months prior, and a list of studies whose Principal Investigator (PI) has recently received IRB approval for their first non-exempt human research project at Northwestern University ("New Investigator").
- 5.3 The Compliance Analyst will select the appropriate number of studies (according to the sampling level) from the lists.



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- 5.3.1 Studies may be selected randomly using a random number generator.
- 5.3.2 Studies may be selected with input from IRB Managers.
- 5.3.3 The Compliance Analyst will make an effort not to select multiple studies from the same Principal Investigator within the past 12 months for PAM review, excluding CAPA assessments.
- 5.3.4 The Compliance Analyst may select studies for routine in-person or virtual PAM assessments.
- 5.3.5 The Compliance Analyst may select all or a portion of the studies without an expiration date to undergo a Study Status Assessment.
- 5.3.6 The Compliance Analyst will select the remaining studies, which will undergo a Principal Investigator (PI) self-assessment PAM.
- 5.3.7 The Compliance Analyst will also select a portion of RNIs with CAPA plans to undergo a CAPA Assessment. The routine CAPA assessment process is outlined in SOP: Corrective and Preventive Action (CAPA) Plan Assessments (HRP-098).
- 5.4 The Compliance Analyst will send the proposed study selections to the Compliance Team and Manager for feedback. Selections may be replaced if necessary.
- 5.5 Once the selections are confirmed, for each selection, the assigned Compliance Analyst will notify the PI and Primary Contact using the appropriate notification template letter listed in the **Materials** section below.
 - 5.5.1 The formal notification letter will include the following:
 - 5.5.1.1 Instructions for completing the PAM.
 - 5.5.1.2 Identify the appropriate checklist(s) the PI will need to complete:
 - 5.5.1.2.1 HRP-427: Drug or Device Clinical Trial
 - 5.5.1.2.2 HRP-428: Participant File
 - 5.5.1.2.3 HRP-430: Human Research
 - 5.5.1.2.4 HRP-433: Studies Without an Expiration Date
 - 5.5.1.2.5 HRP-1405: Data Review, Registries, or Specimen Collection
 - 5.5.1.2.6 HRP-1406: Studies Under External IRB Review
 - 5.5.1.2.7 HRP-1407: Site File
 - 5.5.1.2.8 HRP-1409: Humanitarian Use Device
 - 5.5.2 The deadline for completing the PAM checklist(s) (30 calendar days from the email date, which can be extended by a few days to ensure the deadline does not fall on a weekend or holiday).
 - 5.5.3 For the in-person visits and virtual assessments, proposed dates for the assessment and the deadline for completing the PAM checklist (7 calendar days prior to the scheduled assessment date).
- 5.6 For the Principal Investigator Self-Assessments, the assigned Compliance Analyst will do the following:
 - 5.6.1 After the PI completes the applicable checklist(s) outlined above, review the responses and send queries to the PI and designee as necessary.
 - 5.6.2 When the checklist is complete, all queries are resolved, and the PI has taken the directed actions, where applicable, send the PI a Close-Out email.
 - 5.6.3 Save the notification letter, completed checklist(s), PI-provided documents (if applicable), email correspondence, and Close-Out email in the corresponding electronic Compliance Team folder.
 - 5.6.4 Record the PAM activity in the Compliance Tracker and report the PAM at an IRB Chairs' Meeting.
 - 5.6.4.1 Any significant observations identified during the review will be reported at the Chairs' Meeting.



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- 5.6.5 The PI is responsible for maintaining records documenting the post-approval monitoring review and all correspondence with IRB compliance analysts in their study files.
- 5.7 For the IRB Compliance Conducted Reviews (in-person visit or virtual review), the assigned Compliance Analyst will do the following:
 - 5.7.1 Schedule the visit or access to the records.
 - 5.7.2 After the PI returns the completed checklist previously sent in section 5.4, review the responses and note potential items for review during the visit or virtual assessment.
 - 5.7.3 Conduct the visit or virtual assessment:
 - 5.7.3.1 Review consent forms as appropriate.
 - 5.7.3.2 Review participant files as appropriate.
 - 5.7.3.3 Review regulatory documentation as appropriate.
 - 5.7.3.4 Reference the appropriately completed checklist(s) at the visit.
 - 5.7.4 Send the PI a letter with any observations and suggestions for improvement with instructions that the PI should respond to the letter within 2 weeks via email using the Post-Approval Monitoring Visit – Observations template (HRP-1714).
 - 5.7.5 Review the PI's response to the PAM visit letter and send queries to the PI as necessary.
 - 5.7.6 When the visit or virtual assessment is complete, all queries are resolved, and the PI has taken the directed actions, where applicable, send the PI a Close-Out email.
 - 5.7.7 Save the notification letter, completed checklist(s), email correspondence, copies of relevant study files, and Close-Out email in the corresponding electronic Compliance Team folder.
 - 5.7.8 Record the PAM activity in the Compliance Tracker and report the IRB Compliance Conducted Review at an IRB Chairs' Meeting.
 - 5.7.8.1 Any significant observations identified during the review will be reported at the Chairs' Meeting.
 - 5.7.9 The PI is responsible for maintaining records documenting the post-approval monitoring review and all correspondence with IRB compliance analysts in their study files.
- 5.8 PI failure to engage in PAM activities or complete the PAM process for the selected studies will result in escalating notifications from the IRB Office Compliance team up to the appropriate level of school/department/institutional leadership.
 - 5.8.1 A first reminder and subsequent follow-up notices will be sent to the PI and Primary Contact.
 - 5.8.2 If the PI or primary contact fails to respond, the follow-up query is sent to the PI's direct supervisor, the Executive Director, the Associate Director of IRB Compliance and Reliance, and the IRB Compliance Manager, followed by subsequent notices to their school's research dean, and culminating with a notice to the Institutional Official.
 - 5.8.3 The Compliance Analyst will record escalations in the Compliance Tracker.
 - 5.8.4 Investigators who fail to engage or complete a routine post-approval monitoring activity will be documented and reported at an IRB Chairs' Meeting.
 - 5.8.5 Continued failure to participate in post-approval monitoring may impact future submissions to the IRB and result in additional corrective actions imposed, including but not limited to administrative study suspension or termination.
- 5.9 Studies that are on hold for litigation purposes will be excluded from the post-approval monitoring process. Once the hold is lifted, the study will be eligible for post-approval monitoring.



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6 MATERIALS

- 6.1 SOP: Corrective and Preventive Action (CAPA) Plan Assessments (HRP-098)
- 6.2 CHECKLIST: Post Approval Monitoring - Clinical Trial (HRP-427)
- 6.3 CHECKLIST: Post Approval Monitoring - Participant File (HRP-428)
- 6.4 CHECKLIST: Post Approval Monitoring - Human Research (HRP-430)
- 6.5 CHECKLIST: Post Approval Monitoring - Studies Without an Expiration Date (HRP-433)
- 6.6 CHECKLIST: Post Approval Monitoring - Data Review, Registries, or Specimen Collection (HRP-1405)
- 6.7 CHECKLIST: Post Approval Monitoring - Studies Under External IRB Review (HRP-1406)
- 6.8 CHECKLIST: Post Approval Monitoring - Site File (HRP-1407)
- 6.9 CHECKLIST: Post Approval Monitoring - Humanitarian Use Device (HRP-1409)
- 6.10 TEMPLATE: Post Approval Monitoring Self Assessment - Notification (HRP-1715)
- 6.11 TEMPLATE: Post Approval Monitoring Visit - Notification (HRP-1702)
- 6.12 TEMPLATE: Post Approval Monitoring Visit - Observations (HRP-1714)

7 REFERENCES

- 7.1 SOP: Ongoing HRPP Evaluations (HRP-061)
- 7.2 POLICY: Human Research Protection Program Compliance (HRPP)
- 7.3 GENERAL DOCUMENT: Human Research Protection Program Plan (HRP-101)
- 7.4 GENERAL DOCUMENT: Investigator Manual (HRP-103)
- 7.5 45 CFR 46.109 (g)
- 7.6 21 CFR 56.109 (f)