1 PURPOSE

1.1 This procedure establishes the process to conduct IRB post-approval monitoring (PAM).

1.2 The process begins when a list of studies due for Continuing Review, a list of studies that no longer require Continuing Review, and a list of Investigators who have recently submitted their first project to Northwestern IRB are generated.

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 09/11/2019.

3 POLICY

3.1 In accordance to the regulations that govern human research, the IRB Office 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 Subject Protection Program (Human Research Protection Program Plan (HRP-101).

3.3 The IRB Office and IRB investigates allegations of non-compliance in Human Subject Research and imposing corrective actions as needed. In addition to Directed Reviews conducted by the IRB Office in response to reports of alleged noncompliance, the IRB Office also conducts routine post-approval monitoring of Human Subject Research studies in order to review and ensure compliance in the conduct of Human Subject Research at the University. (Human Research Protection Program Compliance policy).

4 RESPONSIBILITIES

4.1 The IRB Office Compliance Team carries out the activities related to post-approval monitoring.

4.2 The IRB Office Compliance Team reports the post-approval monitoring activities at the IRB Chairs Meeting.

5 PROCEDURE

5.1 The Compliance Analyst will conduct a post-approval monitoring review on a 3%-5% sampling of active non-exempt human subjects' 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 expiration date.

5.2 The Compliance Analyst will generate a list of research studies that will be due for continuing review in three months and a list of studies that no longer require a continuing review whose initial approval date anniversary is in three months.

5.3 The Compliance Analyst will select the appropriate number of studies (according to the sampling level) from the list.

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 to not select multiple studies from the same Principal Investigator within the same calendar year for PAM review.

5.3.4 The Compliance Analyst will send the proposed study selections to the IRB Managers to get feedback.

5.3.5 The Compliance Analyst will select one of the studies for a routine, in-person, PAM Visit, and the remaining studies will undergo a Principal Investigator (PI) self-assessment PAM.

5.4 For each selected study, the Compliance Analyst will email the PI and Primary Contact using either the Post Approval Monitoring Self-Assessment - Notification template (HRP-1715), the Post Approval Monitoring Visit - Notification template (HRP-1702), or the Post Approval Monitoring Self-Assessment New Investigator Assessment Notification (HRP-1823).

5.5 The email and formal notification letter will include:

5.5.1 Instructions for completing the PAM.

5.5.2 Identify the appropriate checklists the PI will need to complete:

5.5.2.1 HRP-427: Drug or Device Clinical Trial Checklist

5.5.2.2 HRP-428: Participant File Checklist

5.5.2.3 HRP-430: Human Research Checklist

5.5.2.4 HRP-1405: Registry, Data Review, and/or Specimen Collection Checklist

5.5.2.5 HRP-1406: Studies Under External IRB Review Checklist

5.5.2.6 HRP-1407: Site File Checklist

5.5.2.7 HRP-1409: Humanitarian Use Device Checklist

5.5.3 The deadline for completing the PAM checklist (30 days from the date of the email, which can be extended by a few days to ensure the deadline not fall on a weekend.)

5.5.4 For the in-person PAM Visit, proposed dates for the visit and the deadline for completing the PAM checklist (7 days prior to the scheduled visit date).

5.6 For the self-assessment PAMs, the Compliance Analyst will do the following:

5.6.1 After the PI returns the completed checklist previously sent in section 5.4, the Compliance Analyst will review the responses and send queries to the PI as necessary.

5.6.2 When the checklist is completed and all queries are resolved, the Compliance Analyst will send the PI a closeout email.

5.6.3 Save the completed checklist, email correspondence, and Close-Out email in the corresponding electronic folder.

5.6.4 Record the PAM activity in the Compliance Tracker and report the PAM at the IRB Chairs' Meeting.

5.6.5 The PI is responsible for maintaining the post-approval monitoring review and all correspondence with IRB compliance analysts in their study files.

5.7 For the in-person PAM Visit, the Compliance Analyst will do the following:

5.7.1 Schedule the visit.

5.7.2 After the PI returns the completed checklist previously sent in section 5.4, the Compliance Analyst will review the responses and make note of potential items for review during the visit.

5.7.3 Conduct the visit:

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 appropriate 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 is complete, PI response is satisfactory, and all queries are resolved, the Compliance Analyst will send the PI a Close-Out email.

5.7.7 Save the completed checklist(s), email correspondence, copies of relevant study files, and Close-Out email in the corresponding electronic folder.

5.7.8 Record the PAM activity in the Compliance Tracker and report the in-person PAM Visit at the IRB Chairs' Meeting.

5.7.9 The PI is also responsible for maintaining 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 process for the selected studies, will result in escalating notifications from the IRB Office Compliance unit, up to the appropriate level of school/department/institutional leadership.

5.8.1 An initial reminder and subsequent follow-up notices will be sent to the PI regarding the status of the investigator's completed checklist or clarification response.

5.8.2 If the PI and/or primary contact fail to respond, the follow-up query is sent to the PI's direct supervisor, the Executive Director, and Compliance Manager, followed by subsequent notices to their school's research dean, and culminating with a notice to the Institutional Official.

5.8.3 Investigators who fail to engage or complete a routine post-approval monitoring activity will be documented and reported at the IRB Chairs' Meeting.

5.8.4 Continued failure to participate in post-approval monitoring may impact future submissions to the IRB and/or result in additional corrective actions imposed.

6 MATERIALS

6.1 CHECKLIST: Post-Approval Monitoring - Clinical Trial (HRP-427)

6.2 CHECKLIST: Post-Approval Monitoring - Participant File (HRP-428)

6.3 CHECKLIST: Post-Approval Monitoring - Human Research (HRP-430)

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

6.5 CHECKLIST: Post Approval Monitoring: Studies Under External IRB Review (HRP-1406)

6.6 CHECKLIST: Post Approval Monitoring: Site File (HRP-1407)

6.7 CHECKLIST: Post Approval Monitoring: Humanitarian Use Device (HRP-1409)

6.8 TEMPLATE: Post Approval Monitoring Self Assessment_New Investigator Assessment_Notification (HRP-1823)

6.9 TEMPLATE: Post-Approval Monitoring Self-Assessment - Notification (HRP-1715)

6.10 TEMPLATE: Post-Approval Monitoring Visit - Notification (HRP-1702)

6.11 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

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)