SOP: Post Approval Monitoring - Recruitment Materials and Process

1 PURPOSE
1.1 This procedure establishes the process to conduct IRB post-approval monitoring (PAM) review of IRB approved study recruitment material(s).
1.2 The process begins when a recruitment tool is identified and selected.
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 None.

3 POLICY
3.1 The IRB Office conducts routine post-approval monitoring on recruitment materials and processes used in Human Participant Research studies in order to ensure compliance with the recruitment process.

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 IRB Compliance analyst will conduct a post-approval monitoring assessment on a random sampling of recruitment tool(s) used in active human participants’ research studies.
5.2 The IRB Compliance analyst will retain a copy of the advertisement or take a picture of the recruitment material(s) taking note of the posting’s location.
5.3 The IRB Compliance analyst will assess the content of the recruitment item(s) and process using checklist HRP-1401 “Post Approval Monitoring of Recruitment Materials” and compare the contents of the recruitment item to the materials approved by the IRB.
5.4 The IRB Compliance analyst will inform the PI and study team of the activity and identify any items that require clarification or correction, when applicable.
5.5 When the checklist is completed and all queries are resolved, the IRB Compliance Analyst will send the PI a Close-Out email.
5.6 The IRB Compliance Analyst will save the completed checklist, modification application and updated recruitment tool(s) (if applicable), and email correspondence in the corresponding electronic folder.
5.7 The IRB Compliance analyst will record the PAM activity in the Compliance Tracker and provide a summary of the recruitment review activities at the IRB Chairs’ Meeting.

6 MATERIALS
6.1 CHECKLIST: Post-Approval Monitoring – Post Approval Monitoring of Recruitment Materials (HRP-1401)
6.2 POLICY: Human Research Protection Program Compliance (HRP-1001)
6.3 GENERAL DOCUMENT: Human Research Protection Program Plan (HRP-101)
6.4 TEMPLATE: Recruitment Materials Assessment Email Text (HRP-1818)

7 REFERENCES
7.1 None