



## SOP: Post Approval Monitoring - Recruitment Materials and Process

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### 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