



## 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 Revised from previous version dated 12/06/2019.

### 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 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 Activities 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 using the Recruitment Activities Assessment template email text (HRP-1818) 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 closeout 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 appropriate compliance tracking mechanism and provide a summary of the recruitment review activities at the IRB Chairs' Meeting.
- 5.8 The PI is responsible for maintaining documentation related to the post-approval monitoring of the subject recruitment activities and all correspondence with IRB compliance analysts within their study files.
- 5.9 PI failure to engage in PAM activities or complete the process for the selected study, will result in escalating notifications from the IRB Office Compliance unit, up to the appropriate level of school/department/institutional leadership.



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- 5.9.1 An initial reminder and subsequent follow-up notices will be sent to the PI regarding the status of the PAM request or clarification response.
- 5.9.2 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.
- 5.9.3 Investigators who fail to engage or complete a routine post-approval monitoring activity will be documented and reported at the IRB Chairs' Meeting.
- 5.9.4 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 – 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)
- 6.5 CHECKLIST: Post Approval Monitoring of Recruitment Activities (HRP-1401)

### 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)