SOP: Post Approval Monitoring - Recruitment Materials and Process			
NUMBER	APPROVED BY	EFFECTIVE DATE	PAGE
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1 PURPOSE

1.1 This procedure establishes the process to conduct an IRB post-approval monitoring (PAM) review of 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 the previous version dated 05/26/2021.

3 POLICY

3.1 In accordance with 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 of 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 unit carries out the activities related to post-approval monitoring.

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

5 PROCEDURE

5.1 The IRB Office Compliance unit will randomly select recruitment tools for monitoring. The IRB Compliance Analyst may identify a recruitment tool to undergo post-approval monitoring.

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 the CHECKLIST: Post Approval Monitoring of Recruitment Activities (HRP-1401) 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 Primary Contact of the activity using the TEMPLATE: Recruitment Activities Assessment Email Text (HRP-1818) and identify any items that require clarification or correction, when applicable.

5.5 When the IRB Compliance Analyst has completed the checklist and resolved all queries, the IRB Compliance Analyst will send the PI and Primary Contact a closeout email.

5.6 The IRB Compliance Analyst will save the completed checklist, documentation of the reviewed recruitment material, 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 the IRB Compliance Analyst within their study files.

5.9 If the PI fails to engage in PAM activities or complete the process for the selected study, the IRB Compliance Analyst will support the PI by sending escalating notifications from the IRB Office Compliance unit up to the appropriate level of school/department/institutional leadership.

5.9.1 The IRB Compliance Analyst will send an initial reminder and subsequent follow-up notices to the PI and Primary Contact regarding the status of the PAM request or clarification response.

5.9.2 If the PI or Primary Contact fails to respond, the IRB Compliance Analyst will send follow-up queries to the PI's direct supervisor, the Executive Director, the Associate Director of IRB Compliance, Reliance and Education, and the IRB Compliance, Education, and Communication Manager, followed by subsequent notices to their school's research dean, and culminating with a notice to the Institutional Official.

5.9.3 The IRB Compliance unit will document and report investigators who fail to engage or complete a routine post-approval monitoring activity at IRB Chairs' Meetings.

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, including but not limited to administrative study suspension or termination.

6 MATERIALS

6.1 CHECKLIST: Post Approval Monitoring of Recruitment Activities (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 Activities Assessment Email Text (HRP-1818)

7 REFERENCES

7.1 SOP: Ongoing HRPP Evaluations (HRP-061)
7.2 POLICY: Human Research Protection Program Compliance (HRP-1001)
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)