



SOP: Ongoing HRPP Evaluations

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1 PURPOSE

- 1.1 This procedure establishes the process to conduct quality improvement of the human subject protection program.
- 1.2 The process begins the first business day of each quarter.
- 1.3 The process ends when all evaluations have been completed and, if needed, acted upon.

2 PREVIOUS VERSION

- 2.1 Revised from previous version 11/22/2018.

3 POLICY

- 3.1 The goal of the quality improvement plan is to achieve and maintain compliance and to achieve targeted levels of quality, efficiency, and effectiveness of the HRPP.
- 3.2 Objectives of the quality improvement program are to:
 - 3.2.1 Improve compliance of investigators with their responsibilities.
 - 3.2.2 Improve compliance of minutes with regulatory compliance.
 - 3.2.3 Improve compliance of Designated Reviews with regulatory compliance
 - 3.2.4 Increase efficiency of recording and finalizing minutes.

4 RESPONSIBILITIES

- 4.1 IRB Office staff ensure completion of these procedures.

5 PROCEDURE

- 5.1 Conduct HRPP Quality Improvement Assessment:
 - 5.1.1 Review the results of all Investigator QI Assessments sent out the previous quarter and examine for significant trends.
- 5.2 Complete "AUDIT CHECKLIST: Minutes Quality Assurance Assessment (HRP-431)" on the minutes of the previous quarter. Track compliance and examine for significant trends.
 - 5.2.1 Send the results to the Executive Director, IRB Office and Institutional Official / Organizational Official (IO/OO) or designee.
 - 5.2.2 If the results of any evaluations demonstrate inconsistency, recurring noncompliance or misinterpretation of HRPP requirements, high variability or are outside performance targets, work with the Executive Director, IRB Office and Institutional Official / Organizational Organization (IO/OO) to implement corrective action and training.
 - 5.2.3 Interventions may include policy and procedure modifications, education and training efforts, system modifications, or other corrective actions.
- 5.3 Complete "AUDIT CHECKLIST: Expedited Review Quality Assurance Assessment (HRP-432)" on the Expedited, Non-Committee Reviews of the previous quarter. Track compliance and examine for significant trends.
 - 5.3.1 Send the results to the Executive Director, IRB Office and Institutional Official or designee.
 - 5.3.2 If the results of any evaluations demonstrate high variability or are outside performance targets, work with the Executive Director, IRB Office and Institutional Official to implement corrective action and training.
- 5.4 Conduct a quality improvement assessment of Investigator responsibilities in accordance with "SOP: Post Approval Monitoring (HRP-028)":
 - 5.4.1 At least monthly, complete "TEMPLATE LETTER: Investigator Quality Improvement Assessment (HRP-534)" and send either "AUDIT CHECKLIST: Post Approval Monitoring: Biomedical Research (HRP-429)" or "AUDIT CHECKLIST: Post Approval



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Monitoring: Social Behavioral Research (HRP-430)” to a randomly selected sample of investigators. Track compliance and examine for significant trends.

- 5.4.2 Send the results to the Executive Director, IRB Office and Institutional Official or designee.
- 5.4.3 If significant trends exist work with the Executive Director, IRB Office, IRB and Institutional Official to implement corrective action and training, as appropriate

6 MATERIALS

- 6.1 SOP: Post Approval Monitoring (HRP-028)
- 6.2 AUDIT CHECKLIST: Post Approval Monitoring: Biomedical Research (HRP-429)
- 6.3 AUDIT CHECKLIST: Post Approval Monitoring: Social Behavioral Research (HRP-430)
- 6.4 AUDIT CHECKLIST: Minutes Quality Assurance Assessment_ Qualtrics Survey (HRP-431)
- 6.5 AUDIT CHECKLIST: Expedited Review Quality Assurance Assessment _ Qualtrics Survey (HRP-432)

7 REFERENCES

- 7.1 None