



SOP: Ongoing HRPP Evaluations

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1 PURPOSE

- 1.1 This procedure establishes the process to conduct routine quality improvement evaluation of the human research 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 the appropriate follow-up actions have been taken.

2 PREVIOUS VERSION

- 2.1 Revised from previous version 11/03/2022.

3 POLICY

- 3.1 The goal of the HRPP quality improvement plan is to achieve and maintain compliance, and 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 requirements.
 - 3.2.3 Improve compliance of Designated (Expedited) Reviews with regulatory requirements.
 - 3.2.4 Increase efficiency of recording and finalizing minutes.
- 3.3 The measures of the quality improvement program are defined in the list of materials referenced below in Section 6 of this SOP.

4 RESPONSIBILITIES

- 4.1 IRB Office staff ensure completion of these procedures.

5 PROCEDURE

- 5.1 Complete "AUDIT CHECKLIST: Minutes Quality Assurance Assessment (HRP-431)" on a sample of minutes from the previous quarter. Track compliance and examine for significant trends.
 - 5.1.1 Send the results of the Minutes Quality Assurance Assessment and any related corrective action plans to the Executive Director, IRB Office, and Institutional Official / Organizational Official (IO/OO) or designee. If there are no findings, or the findings are not significant, the Institutional Official can be notified of the quarterly results of the Minutes Quality Assurance Assessment in the Annual HRPP Report.
 - 5.1.2 If the results of any evaluations demonstrate inconsistency, recurring non-compliance, 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 identify the systemic factors that may have led to the outcome, and implement corrective and preventative actions and training.
 - 5.1.3 Interventions may include policy and procedure modifications, updates of existing tools/resources, creation and implementation of new tools/guidance/resources, education and training efforts, system modifications, or other corrective/preventive actions.
- 5.2 Complete "AUDIT CHECKLIST: Expedited Review Quality Assurance Assessment (HRP-432)" on a sample of Expedited, Non-Committee Reviews from the previous quarter. Track compliance and examine for significant trends.
 - 5.2.1 Send the results of the Expedited Review Quality Assurance Assessment and any related corrective action plans to the Executive Director, IRB Office, and Institutional Official or designee. If there are no findings, or the findings are not significant, the Institutional Official can be notified of the quarterly results of the Expedited Review



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Quality Assurance Assessment in the Annual HRPP Report. If the results of any evaluations demonstrate inconsistency, recurring non-compliance, or misinterpretation of HRPP requirements, high variability, or are outside performance targets, work with the Executive Director, IRB Office, and Institutional Official to implement corrective action and training.

- 5.2.2 Interventions may include policy and procedure modifications, updates of existing tools/guidance/resources, implementation of new tools/resources, education and training efforts, system modifications, or other corrective/preventive actions.
- 5.3 Conduct a quality improvement assessment of Investigator responsibilities in accordance with "SOP: Post Approval Monitoring (HRP-028)".
 - 5.3.1 Review the results of all Investigator QI Assessments sent out the previous quarter and examine for significant trends.
 - 5.3.2 At least monthly, complete routine post-approval monitoring for a randomly selected sample of investigators. Track compliance and examine for significant trends.
 - 5.3.3 Send the results to the Executive Director, IRB Office, and Institutional Official or designee on a quarterly basis.
 - 5.3.4 If significant trends exist, work with the Executive Director, IRB Office, IRB, and Institutional Official to implement corrective/preventive action and training, as appropriate.

6 MATERIALS

- 6.1 SOP: Post Approval Monitoring (HRP-028)
- 6.2 AUDIT CHECKLIST: Minutes Quality Assurance Assessment _ Qualtrics Survey (HRP-431)
- 6.3 AUDIT CHECKLIST: Expedited Review Quality Assurance Assessment _ Qualtrics Survey (HRP-432)

7 REFERENCES

- 7.1 None