



HRP-061 | 9/26/24

SOP: Quarterly Evaluations of the HRPP

1 PURPOSE

- 1.1 This procedure establishes the process to conduct quality improvement 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 if needed, acted upon.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None

3 POLICY

- 3.1 The goal of the quality improvement plan is to achieve and maintain compliance and to achieving 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 Increase efficiency of recording and finalizing minutes.
- 3.3 The measures of the quality improvement program are defined in:
 - 3.3.1 UMass Boston Post-Approval Monitoring (PAM) Review Checklist
 - 3.3.2 HRP-431 - CHECKLIST - Minutes Quality Improvement Assessment

4 RESPONSIBILITIES

- 4.1 IRB staff and the Associate Director of Research Compliance and Integrity and/or designee of the Associate Director of Research Compliance and Integrity ensure completion of these procedures.

5 PROCEDURE

- 5.1 Conduct Investigator QI Assessment:
 - Based on the document "University of Massachusetts Boston Post-Approval Monitoring (PAM)," selected investigator(s) are contacted.
- 5.2 Review the results of "UMass Boston Post-Approval Monitoring (PAM) Review Checklist" completed the previous quarter, track the results, and examine for significant trends.
- 5.3 Conduct HRPP Quality Improvement Assessment:
 - 5.3.1 Review the results of all Investigator QI Assessments sent out the previous quarter and examine for significant trends.
- 5.4 Complete HRP-431 - CHECKLIST - Minutes Quality Improvement Assessment on the minutes of the previous quarter. Track compliance and the days required to complete minutes and examine for significant trends.
- 5.5 Send the results to the IRB manager and Institutional Official/ Organizational Official (IO/OO) or designee.

- 5.5.1 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 IRB manager and IO/OO to implement an intervention.
- 5.5.2 Interventions may include policy and procedure modifications, education and training efforts, system modifications, or other corrective actions.

6 MATERIALS

6.1 University of Massachusetts Boston Post-Approval Monitoring (PAM)

6.2 UMass Boston Post-Approval Monitoring (PAM) Review Checklist

6.3 HRP-431 - CHECKLIST - Minutes Quality Improvement Assessment

7 REFERENCES

7.1 AAHRPP elements I.5.A, I.5.B, I.5.D, I-9