

<b>SOP: Monthly Evaluations of the HRPP</b>				
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## **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 month.
- 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 HRP-430 - CHECKLIST - Investigator Quality Improvement Assessment
  - 3.3.2 HRP-431 - CHECKLIST - Minutes Quality Improvement Assessment

## **4 RESPONSIBILITIES**

- 4.1 IRB staff ensure completion of these procedures.

## **5 PROCEDURE**

- 5.1 Conduct Investigator QI Assessment:
  - 5.1.1 At least monthly, complete HRP-534 - LETTER - Investigator QI Assessment and send HRP-430 - CHECKLIST - Investigator Quality Improvement Assessment to 2 investigators.
- 5.2 Review the results of HRP-430 - CHECKLIST - Investigator Quality Improvement Assessment sent out the previous month, 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 month. Track compliance and the days required to complete minutes and examine for significant trends.
- 5.5 Complete review of HRP-416 checklists for three randomly selected studies (One convened board and two expedited review) reviewed within the previous 30 days. Ensure appropriate responses to questions. Report findings to HRPP Director who will re-educate the involved reviewers.
- 5.6 Send the results to the HRPP Director. The HRPP Director will forward a summary of findings to the Institutional Official/ Organizational Official (IO/OO) or designee twice per year.
  - 5.6.1 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 HRPP Director and IO/OO to implement an intervention.
  - 5.6.2 Interventions may include policy and procedure modifications, education and training efforts, system modifications, or other corrective actions.

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## **6 MATERIALS**

- 6.1 HRP-430 - CHECKLIST - Investigator Quality Improvement Assessment
- 6.2 HRP-431 - CHECKLIST - Minutes Quality Improvement Assessment
- 6.3 HRP-534 - LETTER - Investigator QI Assessment

## **7 REFERENCES**

- 7.1 None