1 PURPOSE

1.1 This procedure establishes the process to conduct quality improvement of the human research protection program.
1.2 The process occurs at a minimum on a quarterly basis.
1.3 The process ends when all evaluations have been completed and if needed, acted upon.

2 REVISIONS FROM PREVIOUS VERSION

2.1 8.21.23.

3 POLICY

3.1 The goal of the quality improvement plan is to achieve and maintain compliance and to achieve standard 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.
  - 3.2.2.1 Increase efficiency of recording and finalizing minutes.
- 3.2.3 Improve compliance of Designated Reviews with regulatory compliance.

3.3 The measures of the quality improvement program are defined in Section 6. Materials below.

4 RESPONSIBILITIES

4.1 HRPP Quality Assurance & Evaluation (QA&E) Team 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 or assign to designees to complete 12.107 (HRP-431) - CHECKLIST - Minutes Quality Improvement Assessment on the minutes of previous months. Track compliance and the days required to complete minutes and examine for significant trends.
5.3 Provide the results for the HRPP Directors Meeting.
- 5.3.1 If the results of any evaluations demonstrate inconsistency, recurring noncompliance or misinterpretation of HRPP requirements, high variability, or are outside performance targets, notify the Director, Research Regulatory Affairs.
- 5.3.2 Further actions may include policy and procedure modifications, education and training efforts, system modifications, or other corrective actions.
- 5.3.3 Conduct a quality improvement assessment of Investigator responsibilities in accordance with 12.002 (HRP-025) – SOP: Post Approval Monitoring.
- 5.3.4 At least quarterly, send 12.301 (HRP-534) - LETTER: Investigator Quality Improvement Assessment and complete appropriate Assessment Checklist at 12.102 -12.106 (HRP-430 a-e), itemized in Section 6 Materials, to a selected sample of investigators as described in 12.001 (HRP-028) -SOP: Post Approval Monitoring. Track compliance and examine for significant trends.
- 5.4.2 Provide the results for the HRPP Directors Meeting.
- 5.4.3 If significant trends exist, notify the Director, Research Regulatory Affairs.

6 MATERIALS

6.1 12.002 (HRP-025) – SOP - Post Approval Monitoring (PAM) Initial Interview for Routine and Directed (For-Cause) Review.

6.2 12.102 (HRP-430a) - CHECKLIST - Investigator Quality Improvement Assessment - Drug, Devices, Clinical Trial.

6.3 12.103 (HRP-430b) – CHECKLIST – Investigator Quality Improvement Assessment – Participant File.

6.4 12.104 (HRP-430c) – CHECKLIST – Investigator Quality Improvement Assessment – Biomedical Research.

6.5 12.105 (HRP-430d) – CHECKLIST – Investigator Quality Improvement Assessment – Social Behavioral Research.

6.6 12.106 (HRP-430e) – CHECKLIST – Investigator Quality Improvement Assessment – Humanitarian Use Device.

6.7 12.107 (HRP-431) - CHECKLIST - Minutes Quality Improvement Assessment .

6.8 12.301 (HRP-534) - LETTER - Investigator QI Assessment.

7 REFERENCES

7.1 None.