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 CHECKLIST: Investigator Quality Improvement Assessment (HRP-430)

   3.3.2 CHECKLIST: Minutes Quality Improvement Assessment (HRP-431)

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 “TEMPLATE LETTER: Investigator Quality Improvement Assessment (HRP-534)” and Send “CHECKLIST: Investigator Quality Improvement Assessment (HRP-430)” to 10 investigators.

5.2 Review the results of “CHECKLIST: Investigator Quality Improvement Assessment (HRP-430)” 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 “CHECKLIST: Minutes Quality Improvement Assessment (HRP-431)” on the minutes of the previous month. Track compliance and the days required to complete minutes and examine for significant trends.

5.5 Send the results to the IRB manager and Organizational Official / Institutional 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 CHECKLIST: Investigator Quality Improvement Assessment (HRP-430)
6.2 CHECKLIST: Minutes Quality Improvement Assessment (HRP-431)
6.3 TEMPLATE LETTER: Investigator Quality Improvement Assessment (HRP-534)

7 REFERENCES

7.1 None