1 PURPOSE

1.1 This procedure establishes the process to conduct quality improvement of the human research protection program (HRPP).

1.2 The compliance improvement process begins upon receipt of the results of an HRPP Quality Improvement Assessment. The HRPP quality improvement 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 Significant revisions for AAHRPP accreditation; replaces version dated 12/17/2013.

3 POLICY

3.1 The goal of the quality improvement plan is to achieve and maintain compliance and to 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 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: HRPP Quality Improvement Assessment (HRP-430)

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

4 RESPONSIBILITIES

4.1 Research Compliance Officer ensures completion of CHECKLIST: HRPP Quality Improvement Assessment (HRP-430).

4.2 Research Compliance Officer and IRB staff review completed CHECKLIST: HRPP Quality Improvement Assessment (HRP-430) in accordance with the HRP-024 – SOP – New Information.

4.3 Research Compliance Officer ensures completion of the CHECKLIST: Minutes Quality Improvement Assessment (HRP-431).

5 PROCEDURE

5.1 Complete “TEMPLATE LETTER: Investigator Quality Improvement Assessment (HRP-534)” and send “CHECKLIST: HRPP Quality Improvement Assessment (HRP-430)” to 3 investigators.

5.2 Review the results of “CHECKLIST: HRPP Quality Improvement Assessment” sent out the previous month in accordance with HRP-024 – SOP – New Information and examine for significant trends.

5.3 Complete “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.

5.4 Send results to the IRB Chair and Organizational Official or designee.

5.5 If the results of any evaluations demonstrate significant trends such as inconsistency, recurring noncompliance or misinterpretation of AEHN IRB requirements, high variability or are outside performance targets, work with the IRB staff and Organizational Official to implement an intervention.

5.6 Interventions may include policy and procedure modifications, education and training efforts, system modifications, or other corrective actions.

6 MATERIALS

6.1 CHECKLIST: HRPP 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