1 PURPOSE
1.1 This procedure establishes the process to conduct quality improvement of the human research protection program that periodically assesses the quality, efficiency, or effectiveness of the HRPP.
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) or equivalent.
  3.3.2 CHECKLIST: Minutes Quality Improvement Assessment (HRP-431) or equivalent.

4 RESPONSIBILITIES
4.1 IRB staff ensure completion of these procedures.

5 PROCEDURE
5.1 Review the results of “CHECKLIST: Investigator Quality Improvement Assessment (HRP-430)” or equivalent sent out the previous month, track the results, and examine for significant trends.
5.2 Complete “CHECKLIST: Minutes Quality Improvement Assessment (HRP-431)” or equivalent on the minutes of the previous month. Track compliance and the days required to complete minutes and examine for significant trends.
5.3 Send the results to the IRB director and Institutional Official or designee.
5.4 If the results of any evaluations demonstrate high variability or are outside performance targets, work with the IRB director and Institutional Official to implement an intervention.

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