1. PURPOSE
1.1. This procedure establishes the process to conduct quality improvement of the human research protection program.
1.2. This procedure begins the first business date of each quarter.
1.3. This procedure ends when evaluations have been completed and if needed, acted upon.

2. POLICY
2.1. 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.
2.2. Objectives of the quality improvement program are to:
   2.2.1. Improve compliance of investigators with their responsibilities.
   2.2.2. Improve compliance of minutes with regulatory compliance.
   2.2.3. Increase efficiency of recording and finalizing minutes.
2.3. The measures of the quality improvement program are:
   2.3.1. Quarterly Results of investigator post-audit surveys
       2.3.1.1. Reference “SURVEY: Investigator Post –Audit Survey”
   2.3.2. Bi-Annual Results of IRB minutes quality improvement assessment
       2.3.2.1. Reference “QI Evaluation of Minutes”

3. RESPONSIBILITY
3.1. IRB Quality Improvement staff members carry out these procedures.

4. PROCEDURE
4.1. Send the Investigator Post-audit Survey of each Random Audit Visit conducted during the current quarter.
4.2. Review the results of investigators post-audit surveys sent out the previous quarter and examine and document significant trends.
4.3. Review a sample of IRB minutes for each IRB twice a year for compliance. Reference “POLICY: Minutes (HRP-108).” Track compliance and examine and document significant trends.
4.4. Send the results to the IRB Chairs, Assistant Director of IRBs and the [HRPP Administrator] or designee.
4.5. If the results of any evaluation demonstrates significant trends such as inconsistency, recurring noncompliance, or misinterpretation of the IRB requirements, work with Assistant Director of IRBs, IRB Chair and [HRPP Administrator] or designee to implement an intervention.
4.6. Intervention may include policy and procedure modifications, education and training efforts, system modification or other corrective actions.

5. REFERENCES
5.1. None