SOP: Quality Improvement Plan of the HRPP

1. PURPOSE
   1. This procedure establishes the process to conduct continuous quality improvement (QI) of the human research protection program.
2. REVISIONS FROM PREVIOUS VERSION
   1. Revisions to quality improvement activities and tools used to document QI activities
3. POLICY
   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. The objectives of the quality improvement program are to provide continuous monitoring and improvement in three main areas:
      1. Efficiency, quality and consistency across the HRPP
      2. Documentation compliance (e.g. minutes) with regulatory standards
      3. HRPP compliance by investigators within their areas of responsibility
   3. The measures of the quality improvement program are defined in:
      1. HRP-430 - CHECKLIST - Investigator Quality Improvement Assessment
      2. HRP-431 - CHECKLIST - Minutes Quality Improvement Assessment
      3. HRP-432 – CHECKLIST - Extended Expirations for Expedited Studies (EEE) Quality Improvement Assessment
4. RESPONSIBILITIES
   1. Chairs ensure completion of these procedures.
5. PROCEDURE
   1. Complete HRP-432 – CHECKLIST - Extended Expirations for Expedited Studies (EEE) Quality Improvement Assessment on all EEE determinations made in the previous quarter to assess accuracy of determination and sufficiency of information obtained to support the determination.
      1. If the results are outside performance target, implement an intervention to achieve performance target.
   2. Complete HRP-431 – CHECKLIST - Minutes Quality Improvement Assessment on the minutes of the previous quarter. Track compliance and the days required to complete minutes.
      1. If the results are outside performance target, implement an intervention to achieve performance target.
   3. Review internal audit findings with the IRB Chair for significant trends.
      1. If the results demonstrate a need for additional education/training, implement an intervention to achieve increased investigator compliance and to increase effectiveness of the HRPP.
   4. Review PPHS monthly statistics report to access efficiency and workload.
      1. If reports indicate any negative trends, consider implementation of intervention to reverse trend or re-balance workload.
6. MATERIALS
   1. HRP-431 - CHECKLIST - Minutes Quality Improvement Assessment
   2. HRP-432 - CHECKLIST – Extended Expirations for Expedited Studies Quality Improvement Assessment
7. REFERENCES
   1. AAHRPP elements I.5.A, I.5.B, I.5.D, I-9