



SOP: Monthly Evaluations of the HRPP

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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 GUIDING PRINCIPLES

- 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.

4 RESPONSIBILITIES

- 4.1 HSRO and RCQA staff ensure completion of these procedures.

5 PROCEDURE

- 5.1 The RCQA staff conduct routine and directed quality reviews of investigators, the HSRO and the IRBs.
- 5.2 A qualified HSRO team member reviews at least 50% of the IRB Minutes using the Minutes Template.
 - 5.2.1 The team member will notify the HSRO Director, appropriate HSRO managers and the HSRO staff member who created the minutes if any deficiencies are noted.
 - 5.2.2 RCQA reviews IRB minutes during its evaluation of the HSRO and IRB.
- 5.3 The HSRO reviews the results of RCQA activities and follows HRP-024-SOP – New Information.

6 MATERIALS

- 6.1 HRP-430 - CHECKLIST - Investigator Quality Improvement Assessment
- 6.2 HRP-431 - CHECKLIST - Minutes Quality Improvement Assessment
- 6.3 HRP-534 - LETTER - Investigator QI Assessment

7 REFERENCES

- 7.1 AAHRPP elements I.5.A, I.5.B, I.5.D, I-9