

<b>SOP Number:</b> SOP CW AHC 229	<b>SOP Name:</b> Monthly Tasks
<b>Location:</b> *Company-Wide Policies	<b>Responsible Department:</b> Research Services
<b>Executive Owner:</b> Executive Director of Research Services	<b>Original Creation Date:</b> 01/18/2022
<b>Effective Date:</b> 04/04/2022	<b>Review Date:</b> 04/04/2022

- I. SCOPE:** This standard operating procedure (SOP) applies to the HRPP Personnel
- II. PURPOSE:** This procedure establishes the process to conduct monthly tasks related to the Human Research Protection Program (HRPP). This procedure begins the first business date of each month. This procedure ends when evaluations and corrective actions are completed.
- III. QUALIFIED PERSONNEL:** HRPP Personnel carry out these procedures.
- IV. TRAINING:** Not applicable
- V. SUPPLIES & EQUIPMENT:** Not applicable
- VI. PROCESS/PROCEDURE:**
  - A. 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.
  - B. Objectives of the quality improvement program are to:
    - 1. Improve compliance of Investigators with their responsibilities.
    - 2. Improve compliance of minutes with regulatory compliance.
    - 3. Increase efficiency of recording and finalizing minutes.
  - C. The measures of the quality improvement program are:
    - 1. Results of Investigator self-assessments
    - 2. Errors on minutes
  - D. Review the results of Investigators self-assessments sent out the previous month.
    - 1. Track the results.
    - 2. Examine for significant trends.
    - 3. Design interventions for adverse trends.
  - E. Review the results of Investigators surveys sent out the previous month.
    - 1. Track the results.
    - 2. Examine for significant trends.
    - 3. Design interventions for adverse trend.
  - F. Review a sample of minutes of the previous month for compliance with SOP CW AHC 208 Minutes.
    - 1. Track the results.

*The electronic version of this SOP is considered to be the controlled version. Printed copies are considered uncontrolled documents. Before using a printed copy, verify that it is the current version*

2. Examine for significant trends.
  3. Design interventions for adverse trend.
- G. Review the turnaround times for committee review and non-committee review.
1. Track the results.
  2. Examine for significant trends.
  3. Design interventions for adverse trends.
- H. Send the results to the HRPP Administrator and Organization Official.
- I. Send HRP-901 – Investigator Self-Assessment and HRP-902– Investigator Self-Assessment Instructions to 5 Investigators.
- J. Send HRP-903 – Investigator Satisfaction Survey to 5 Investigators. Provide IRB members with a list of approvals using the expedited procedure from the previous month.

**VII. DEFINITION(S):** For capitalized terms not defined in this policy, refer to CW AHC 107 Definitions in Human Research.

For capitalized designations not defined in this policy, refer to CW AHC 103 Designations in Research.

**VIII. EXCEPTION(S):** CW AHC 101 Research Oversight

**IX. REFERENCE(S):** Not applicable

**X. RELATED DOCUMENT(S) / ATTACHMENT(S):**

- CW AHC 107 Definitions in Human Research
- CW AHC 103 Designations in Research
- CW AHC 101 Research Oversight
- CW AHC 108 Human Research Protection Program
- SOP CW AHC 208 Minutes
- Self-Assessments are located in IRBNet
  - HRP-901 – Investigator Self-Assessment
  - HRP-902 – Investigator Self-Assessment Instructions
    - HRP-903 – Investigator Satisfaction Survey (link in HRP-902)