Standard Operating Procedure (SOP)

SOP Number: SOP CW AHC 230	**SOP Name:** Daily Tasks
Location: *Company-Wide Policies	**Responsible Department:** Research Services
Executive Owner Executive Director of Research Services	**Original Creation Date:** 01/18/2022
Effective Date: 04/04/2022	**Review Date:** 02/12/2024

I. SCOPE: This standard operating procedure (SOP) applies to Institutional Review Board (IRB) staff.

II. PURPOSE: This procedure establishes the process to conduct daily tasks related to supporting the IRB. This procedure begins each business day. This procedure ends when reminders, notifications, and corrective actions are completed.

III. QUALIFIED PERSONNEL: IRB staff members

IV. TRAINING: Not applicable

V. SUPPLIES & EQUIPMENT: Not applicable

VI. PROCESS/PROCEDURE:

A. Reminders and notifications required by this SOP are to be provided in writing and may also be provided orally.

B. Remind Investigators, whose study has continuing review, progress report is due in 30 days.

C. Notify Investigators whose IRB approval has expired due to non-completion of continuing review.

1. When possible, contact the Investigator to determine whether already enrolled subjects should continue in the research because it is in their best interest.
2. Inform the Investigator:
   a) Which subjects may continue
   b) What procedures may continue
   c) All other research activities must stop, including advertisement, recruitment, screening, enrollment, consent, interventions, interactions, and collection or analysis of private identifiable information
   d) New subjects may not be enrolled
   e) The continuing review progress report must be submitted as soon as possible
3. Make the Investigator Restricted.
4. Process as a Noncompliance using SOP CW AHC 212 New Information.

D. Remind Investigators who have failed to submit modifications to secure approval following convened review within 90 days of communication from the IRB.

E. Notify Investigators who have failed to submit modifications to secure approval of exempt or expedited eligible submissions within 30 days of communication from the IRB. Withdraw the submission 15 days following notification if modifications are not received.

F. Notify Investigators who conducted an emergency use, previously reported to the IRB, where the Investigator has not submitted a protocol to the IRB within 30 days for subsequent use.

1. Make the Investigator Restricted.
2. Process as a Noncompliance using SOP CW AHC 212 New Information.

G. Notify Investigators who conducted an emergency use where the Investigator has not submitted a report to the IRB within 5 days or has not submitted a standing protocol for subsequent use within 30 days.

1. Make the Investigator Restricted.
2. Process as a Noncompliance using SOP CW AHC 212 New Information.

VII. DEFINITION(S):

For capitalized terms not defined in this policy, refer to CW AHC 107 Definitions in Human Research.

VIII. EXCEPTION(S):

See CW AHC 101 Research Oversight

IX. REFERENCE(S):

21 CFR §56.104(c)

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

- CW AHC 107 Definitions in Human Research
- CW AHC 101 Research Oversight
- CW AHC 108 Human Research Protection Program
- SOP CW AHC 212 New Information