

SOP: DAILY TASKS

Document No.:	Edition No.:	Effective Date:	Page:
CM-123	001	1 May 2015	Page 1 of 1

1. PURPOSE

- 1.1. This procedure establishes the process to conduct daily tasks of the HRPP.
- 1.2. This procedure begins each business day.
- 1.3. This procedure ends when reminders, notifications, and corrective actions are complete.

2. POLICY

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

3. RESPONSIBILITY

- 3.1. HRPP staff members carry out these procedures.

4. PROCEDURE

- 4.1. Remind investigators whose study has continuing review progress report is due in 30 days.
- 4.2. Notify investigators whose study is no longer approved due to lack of continuing review.
 - 4.2.1. When possible contact the investigator to determine whether already enrolled subjects should continue in the research because it is in their best interest.
 - 4.2.2. Inform the investigator:
 - 4.2.2.1 Which subjects may continue
 - 4.2.2.2 What procedures may continue
 - 4.2.2.3 All other research activities must stop, including advertisement, recruitment, screening, enrollment, consent, interventions, interactions, and collection or analysis of private identifiable information
 - 4.2.2.4 New subjects may not be enrolled
 - 4.2.2.5 The continuing review progress report must be submitted as soon as possible
 - 4.2.3. Make the investigator <Restricted>.
 - 4.2.4. Process as a <Finding of Noncompliance>
- 4.3. Notify investigators who conducted an emergency use where the investigator has not submitted a protocol to the IRB within 30 days for subsequent use.
 - 4.3.1. Make the investigator <Restricted>.
 - 4.3.2. Process as a <Finding of Noncompliance>
- 4.4. Notify investigators who conducted an emergency use where the investigator has not submitted a report to the IRB within 5 day or has not submitted a standing protocol for subsequent use within 30 days.
 - 4.4.1. Make the investigator <Restricted>.
 - 4.4.2. Process as a <Finding of Noncompliance>

5. REFERENCES

- 5.1. 21 CFR §56.104(c)