# Standard Operating Procedure (SOP)

| SOP #: 401.143 | HRP-143 Daily Tasks | |
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| Executive Owner: Vice President Research Operations | | Effective Date: 6/11/2018<br>Review Date: 10/03/2019 |

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| **Scope** | This SOP applies to the HRPP staff. |
| **Purpose** | This procedure establishes the process to conduct daily tasks related to the HRPP. This procedure begins each business day. This procedure ends when reminders, notifications, and corrective actions are completed. |
| **Qualified Personnel** | HRPP staff members carry out these procedures. |
| **Training** | Not applicable. |
| **Supplies & Equipment** | Not applicable. |
| **Procedure** | 1. Reminders and notifications required by this SOP are to be provided in writing and may also be provided orally.<br>2. Remind investigators whose study has continuing review progress report is due in 30 days.<br>3. Notify investigators whose study is no longer approved due to lack of continuing review.<br>3.1. When possible contact the investigator to determine whether already enrolled subjects should continue in the research because it is in their best interest.<br>3.2. Inform the investigator:<br>3.2.1. Which subjects may continue<br>3.2.2. What procedures may continue<br>3.2.3. All other research activities must stop, including advertisement, recruitment, screening, enrollment, consent, interventions, interactions, and collection or analysis of private identifiable information<br>3.2.4. New subjects may not be enrolled<br>3.2.5. The continuing review progress report must be submitted as soon as possible<br>3.3. Make the investigator <Restricted>.<br>3.4. Process as a <Noncompliance> using "SOP: New Information (HRP-112)."<br>4. Remind investigators who have failed to submit modifications to secure approval following convened review within 90 days of communication from the IRB.<br>5. 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.<br>5.1. Withdraw the submission 15 days following notification if modifications are not received. |

6. Notify investigators who conducted an emergency use where the investigator has not submitted a protocol to the IRB within 30 days for subsequent use.
   - 6.1. Make the investigator <Restricted>.
   - 6.2. Process as a <Noncompliance> using "SOP: New Information (HRP-112)."
7. 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.
   - 7.1. Make the investigator <Restricted>.
   - 7.2. Process as a <Noncompliance> using "SOP: New Information (HRP-112)."

**Definition(s)**

IRB: Institutional Review Board

**Reference(s)**

21 CFR §56.104(c)

**Related Documents**

Not applicable.

**Keywords**

IRB, institutional review board, tasks