1 PURPOSE
1.1 This procedure establishes the process to complete daily tasks required to monitor the research review process.
1.2 The process begins each day.
1.3 The process ends when the tasks have been completed.

2 REVISIONS FROM PREVIOUS VERSION
2.1 None

3 GUIDING PRINCIPLES
3.1 The HSRO Electronic System checks the database for protocols that have expired due to lack of continuing review and sends the “TEMPLATE LETTER: Expiration of IRB Approval (HRP-533).”
3.2 When reviewing initial studies and modifications, HSRO staff checks the CITI database for study personnel whose training has lapsed and sends “TEMPLATE LETTER: Training Reminder (HRP-531).”
3.3 The HSRO Electronic System checks the database for protocols whose continuing review progress report is due in 45 business days and sends “TEMPLATE LETTER: Continuing Review Reminder (HRP-530)”
3.4 The HSRO Electronic System checks the database for continuing review progress reports that have not been submitted 45 days prior to protocol expiration and sends “TEMPLATE LETTER: Failure to Submit Continuing Review Progress Report (HRP-550).”

4 RESPONSIBILITIES
4.1 HSRO staff members are responsible for carrying out this procedure.

5 PROCEDURE
5.1 Check for emergency uses where the IRB has not received a standing protocol within 30 days if so requested:
5.1.1 Complete and send “TEMPLATE LETTER: Failure to Submit Emergency Use Protocol.”
5.1.2 Place the principal investigator on the Restricted list.
5.1.3 Process the failure to submit as a Finding of Non-Compliance under “SOP: New Information (HRP-024).”
5.2 Check for emergency uses where the IRB has not received a report, within 5 days:
5.2.1 Complete and send “TEMPLATE LETTER: Failure to Submit Emergency Use Report (HRP-551).”
5.2.2 Place the principal investigator on the Restricted list.
5.2.3 Process the failure to submit as a Finding of Non-Compliance under “SOP: New Information (HRP-024).”
5.3 If the HSRO Electronic System finds continuing review progress reports that have not been submitted 45 days prior to protocol expiration:
5.3.1 Complete and send “TEMPLATE LETTER: Failure to Submit Continuing Review (HRP-550).”
5.3.2 Place the principal investigator on the Restricted list.
5.3.3 Process the failure to submit as a Finding of Non-Compliance under “SOP: New Information (HRP-024).”
5.4 Check for protocols that have expired due to lack of continuing review:
5.4.1 Complete and send the “TEMPLATE LETTER: Expiration of IRB Approval (HRP-533) or equivalent.”

5.4.2 Follow “SOP: Expiration of IRB Approval (HRP-063)"

6 MATERIALS

6.1 SOP: New Information (HRP-024)
6.2 SOP: Expiration of IRB Approval (HRP-063)
6.3 SOP: IRB Membership Removal (HRP-083)
6.4 TEMPLATE LETTER: Continuing Review Reminder (HRP-530)
6.5 TEMPLATE LETTER: Expiration of IRB Approval (HRP-533)
6.6 TEMPLATE LETTER: Training Reminder (HRP-531)
6.7 TEMPLATE LETTER: Failure to Submit Emergency Use Protocol (HRP-553)
6.8 TEMPLATE LETTER: Failure to Submit Emergency Use Report (HRP-551)
6.9 TEMPLATE LETTER: Failure to Undergo Training (HRP-554)
6.10 TEMPLATE LETTER: Failure to Submit Continuing Review (HRP-550)

7 REFERENCES

7.1 None