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 POLICY
   3.1 Receipt deadlines are maintained in the InfoEd System.
   3.2 Protocol history is maintained in the InfoEd System.

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

5 PROCEDURE
   5.1 Check the database for individuals whose training will lapse in the next 30 days who have not yet been sent a reminder.
      5.1.1 Complete and send “TEMPLATE LETTER: Training Reminder.”
   5.2 Check the database for protocols whose continuing review progress report is due in 30 days who have not yet been sent a reminder.
      5.2.1 Complete and send “TEMPLATE LETTER: Continuing Review Reminder”
   5.3 Check the database for protocols where the IRB requested modifications to secure approval, more than 90 days have lapsed without receipt of the modifications, and the following steps have not taken place:
      5.3.1 Send to each affected individual “TEMPLATE LETTER: Failure to Submit Modifications Required to Secure Approval.”
      5.3.2 Update the protocol history
      5.3.3 Update the database to indicate that protocol was “Withdrawn by IRB.”
   5.4 Check the database for emergency use notifications where the IRB the IRB has not received a report, where more than 5 days have lapsed since the emergency use, and the following steps have not taken place:
      5.4.1 Complete and send “TEMPLATE LETTER: Failure to Submit Protocol for Emergency Use.”
      5.4.2 Update the protocol history
      5.4.3 Place the individual on the Restricted list.
      5.4.4 Process the failure to submit as a Finding of Non-Compliance under “SOP: New Information.”
   5.5 Check the database for emergency use notifications where the IRB the IRB has not received a report, where more than 5 days have lapsed since the emergency use, and the following steps have not taken place:
      5.5.1 Complete and send “TEMPLATE LETTER: Failure to Submit Five-Day Report of Emergency Use.”
      5.5.2 Update the protocol history
      5.5.3 Place the individual on the Restricted list.
      5.5.4 Process the failure to submit as a Finding of Non-Compliance under “SOP: New Information.”
   5.6 Check the database for continuing review progress reports that have not been submitted 30 days prior to protocol expiration and the following steps have not taken place:
5.6.1 Complete and send “TEMPLATE LETTER: Failure to Submit Continuing Review Progress Report.”
5.6.2 Update the protocol history
5.6.3 Place the individual on the Restricted list.
5.6.4 Process the failure to submit as a Finding of Non-Compliance under “SOP: New Information.”

5.7 Check the database for individuals whose Human research training has lapsed and the where following steps have not taken place:
5.7.1 Send to each affected individual “TEMPLATE LETTER: Failure to Undergo Training.”
5.7.2 Place the individual on the Restricted list.
5.7.3 Process the failure to submit as a Finding of Non-Compliance under “SOP: New Information.”
5.7.4 If the individual is an IRB member, Follow “SOP: IRB Membership Removal.”

5.8 Check the database for protocols that have expired due to lack of continuing review and where the following steps have not taken place:
5.8.1 Send the “TEMPLATE LETTER: Expiration of IRB Approval.”
5.8.2 Update the protocol history

5.9 Follow “SOP: IRB Records” to update IRB records.

6 MATERIALS
6.1 InfoEd System
6.2 InfoEd System
6.3 SOP: New Information
6.4 SOP: IRB Records
6.5 SOP: IRB Membership Removal
6.6 TEMPLATE LETTER: Continuing Review Reminder
6.7 TEMPLATE LETTER: Expiration of IRB Approval
6.8 TEMPLATE LETTER: Training Reminder
6.9 TEMPLATE LETTER: Failure to Submit Modifications Required to Secure Approval
6.10 TEMPLATE LETTER: Failure to Submit Protocol For Emergency Use
6.11 TEMPLATE LETTER: Failure to Submit Five-Day Report of Emergency Use
6.12 TEMPLATE LETTER: Failure to Undergo Training
6.13 TEMPLATE LETTER: Failure to Submit Continuing Review Progress Report

7 REFERENCES
7.1 None