



SOP: Daily Tasks

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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 Reconciliation to Huron HRPP Toolkit 4.5, dated 12/10/2021

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 HRP-533 - LETTER - Expiration of IRB Approval.
- 3.2 When reviewing initial studies and modifications of new personnel, HSRO staff checks the CITI database for study personnel whose training has lapsed and sends a comment in the electronic system notifying the study team of the training requirement. The HSRO Electronic System checks the database for protocols whose continuing review progress report is due in 45 business days and sends HRP-530-LETTER- Continuing Review Reminder.
- 3.3 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 HRP-550 - LETTER - Failure to Submit Continuing Review.

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 an IRB-required standing protocol within 30 days if so requested:
 - 5.1.1 Complete and send HRP-553 - LETTER - Failure to Submit EU Protocol, or equivalent.
 - 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 HRP-024 - SOP - New Information
- 5.2 Check for emergency uses where the IRB has not received a report, within 5 days:
 - 5.2.1 Complete and send HRP-551 - LETTER - Failure to Submit EU Report
 - 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 HRP-024 - SOP - New Information
- 5.3 For continuing review progress reports that have not been submitted 45 days prior to protocol expiration:
 - 5.3.1 Complete and send HRP-550 - LETTER - Failure to Submit Continuing Review
 - 5.3.2 Process the failure to submit as a Finding of Non-Compliance under HRP-024 - SOP - New Information
- 5.4 Check for protocols that have expired due to lack of continuing review:
 - 5.4.1 Complete and send the HRP-533 - LETTER - Expiration of IRB Approval or equivalent.
 - 5.4.2 Follow HRP-063 - SOP - Expiration of IRB Approval
 - 5.4.3 When reviewing initial studies and continuing review, HSRO staff checks the CITI database for study personnel whose training has lapsed and sends HRP-531 - LETTER - Training Reminder.

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6 MATERIALS

- 6.1 HRP-024 - SOP - New Information
- 6.2 HRP-063 - SOP - Expiration of IRB Approval
- 6.3 HRP-083 - SOP - IRB Membership Removal
- 6.4 HRP-530 - LETTER- Continuing Review Reminder
- 6.5 HRP-531 - LETTER - Training Reminder
- 6.6 HRP-533 - LETTER - Expiration of IRB Approval
- 6.7 HRP-535 - LETTER - Annual Reminder
- 6.8 HRP-550 - LETTER - Failure to Submit Continuing Review
- 6.9 HRP-551 - LETTER - Failure to Submit EU Report
- 6.10 HRP-553 - LETTER - Failure to Submit EU Protocol
- 6.11 HRP-554 - LETTER - Failure to Undergo Training

7 REFERENCES

- 7.1 AAHRPP elements I.1.A, I.7.C, II.2.E-II.2.E.2, II.2.F-II.2.F.3