



TITLE: Routine Tasks

PURPOSE: Complete daily tasks required to monitor research

RESPONSIBILITIES: HSPP Staff

PROCEDURES:

Daily

Throughout the day, check the departmental email account and complete tasks as assigned.

After processing each item, the designated HSPP staff member updates HSPP files to reflect the current status of the submission. Follow the procedures for data entry in the UAR manual. As necessary:

- Make requested changes to UAR from HSPP staff. Changes may be correction of typos, change in IRB oversight, or changes in the research (such as PI or title).
- If more than 30 days have lapsed without receipt of HSPP or IRB requested changes
 - Send to each affected individual an HSPP Correspondence Form indicating that the file has been withdrawn due to lack of response by the PI.
 - Update UAR that the project has been returned for lack of response by the PI.

Weekly

The Director checks for emergency use notifications where the IRB has not received a standing protocol, if required, or where the IRB has not received a report where more than five (5) days have lapsed since the emergency use.

- Complete and send to PI a “Failure to Submit Protocol/Five-Day Report of Emergency Use.”
- Place the individual on the Restricted list.
- Process the failure to submit as a Finding of Non-Compliance under “Reportable Information that is Potentially Problematic.”

Each Friday

The assigned IRB Associate queries the list of projects due for continuing review that have expired within that week (from Monday to Sunday of the same week). For each of these projects:

- Confirm that the project was not reviewed. If the project was reviewed, update HSPP files accordingly.
- Follow the procedures outlined in the UAR Manual for processing the administrative closure.

Monthly

On the first day of the month, the HSPP Coordinator or designated Associate reviews HSPP files for protocols whose continuing review progress report is due in sixty (60) days and the investigator has not yet been sent a reminder.

- Print out a list of projects queried from UAR that are due for review by IRB committee and give to the IRB Coordinator.
- Send “Continuing Review Reminder” to the PI, Co-PI/advisor, and alternate contact.



Quarterly

Review and update the website as necessary.
Archive news items that are greater than six (6) months old.
Follow “SOP 070: IRB Records” to update IRB records.

MATERIALS:

- D600 - Awaiting Receipt
- SOP 010: Incoming Items Directed to the IRB
- SOP 011: Pre-Review
- SOP 013: Reportable Items
- SOP 070: IRB Records

REFERENCES:

None.

REVIEW/REVISIONS: From 10/01/2010 version: Removed the requirement to process every administrative closure as a finding of non-compliance; Removed reference to specific communication forms; Indicated that withdrawals of projects will be sent to the investigator, alternate contact, advisor (if applicable), unit reviewer, and R&D office (if applicable); From Indicated that administrative closures will be sent to the investigator, alternate contact, advisor (if applicable), department head, and R&D office (if applicable).

From 08/01/2011 version: Updated according to UAR Manual

From 01/2014 version: Renumbered from P&P-060; The following Materials updated to reflect the new numbering system: P&P-020 to SOP 010; P&P-021 to SOP 011; P&P-024 to SOP 013; P&P 070 to SOP 070.