SOP: Incoming Items

NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-020	12/6/18	T. Bechert	G. Ostrander	1 of 2

1 PURPOSE

1.1 This procedure establishes the process to triage information submitted to the IRB.

1.2 The process begins when any communication is received by the IRB.

1.3 The process ends when an IRB staff member determines the appropriate action for the received information.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None.

3 POLICY

3.1 None

4 RESPONSIBILITIES

4.1 IRB staff members carry out these procedures.

5 PROCEDURE

5.1 If the item is a request either for this IRB to review for another participating site (pSite) or for this institution to rely on an external IRB, follow "SOP: Site Validation (HRP-803)."

   5.1.1 Once the ability to review for the pSite is confirmed, then follow "SOP: Pre-Review (HRP-021)."

   5.1.2 Once the ability to rely on an external IRB is confirmed, then follow "SOP: Site Pre-Review (HRP-804)."

5.2 If the item is a request for an approval or determination[1] by this institution's IRB that does not include other pSites, follow "SOP: Pre-Review (HRP-021)."

5.3 If the item is an update to a study for which an external IRB is the IRB or record, follow "SOP: Site Updates (HRP-805)."

5.4 If the item is a request to withdraw a submission from consideration, withdraw the submission.

5.5 If the item is a request to remove a pSite from a Single IRB (sIRB) Study, remove the site by executing the "Update Site Status" activity.

5.6 If the item includes new or modified contact information, update the contact information.

5.7 If the item includes new or modified training information, update the training information.

5.8 If the item is an investigator's request to continue subjects in expired research have a Designated Reviewer follow "SOP: Expiration of IRB Approval (HRP-063)."

5.9 If the item does not fit into the above categories:

   5.9.1 If the item is a question, concern, or complaint:

      5.9.1.1 Document the nature of the question, concern, or complaint and the contact information of the person contacting the IRB.

      5.9.1.2 Respond to any questions or concerns. When appropriate, tell the person that you will call/email him/her once you have been able to find additional information. If necessary, consult with your supervisor.

   5.9.2 Follow "SOP: New Information (HRP-024)."

6 MATERIALS

6.1 SOP: Expiration of IRB Approval (HRP-063)

6.2 SOP: Financial Conflicts of Interests (HRP-055)

6.3 SOP: New Information (HRP-024)

6.4 SOP: Pre-Review (HRP-021)

6.5 SOP: Site Validation (HRP-803)

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[1] A "request for an approval or determination" includes approval of new research, response to modifications required to secure approval, continuing review of research, modification to previously approved research, request for study closure, or a determination whether an activity is exempt Human Research or is not Human Research. Submission of an updated list study personnel is not considered a modification of research and is therefore not a "request for an approval or determination."

6.6   SOP: Site Pre-Review (HRP-804)

6.7   SOP: Site Updates (HRP-805)

7   REFERENCES

7.1   None