



SOP: Incoming Items				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-020	06/28/2019	L. Smith	C.Gates	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.
- 2.2 Added provisions for submissions from external site and for Central IRB.

3 GUIDING PRINCIPLES

- 3.1 None

4 RESPONSIBILITIES

- 4.1 HSRO staff members carry out these procedures.

5 PROCEDURE

- 5.1 If the item includes new or modified contact information, update the contact information.
- 5.2 If the item includes new or modified training information, update the training information.
- 5.3 If the item includes an updated list of study personnel:
 - 5.3.1 Send “TEMPLATE LETTER: Acknowledgement of Personnel Update (HRP-524).”
 - 5.3.2 If there are financial disclosures, follow “SOP: Financial Conflicts of Interests (HRP-055)”.
- 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 for an approval or determination¹, and the submission does not include an external site or external IRB, follow “SOP: Pre-Review (HRP-021).”
- 5.6 If the item is a request for the UM IRB to review for an external participating site (pSite), follow “SOP: Site Validation (HRP 803).” After a determination is made that the UM will review for the pSite:
 - 5.6.1 Obtain a site submission form from the pSite.
 - 5.6.2 Follow “SOP: Prev—Review HRP-021” after a determination is made that the UM will review for the pSite.
- 5.7 If the item is a request for a UM site to rely on an external IRB, follow “SOP-84 External IRB Review.
- 5.8 If the item is a notification of an emergency use of a test article in a life-threatening situation have a Designated Reviewer follow “SOP: Emergency Use (HRP-023).”
- 5.9 If the item is an investigator’s request to continue subjects in research for which IRB approval has lapsed, have a Designated Reviewer follow “SOP: Expiration of IRB Approval (HRP-063).”

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 of study personnel is not considered a modification of research and is therefore not a “request for an approval or determination.”



SOP: Incoming Items				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-020	06/28/2019	L. Smith	C.Gates	2 of 2

5.10 If the item is a Report of New Information and does not fit in a category above, follow "SOP-New Information HRP-024."

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

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

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

5.11.1.2 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.

6 MATERIALS

6.1 SOP: Emergency Use (HRP-023)

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

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

6.4 SOP: New Information (HRP-024)

6.5 SOP: Pre-Review (HRP-021)

6.6 TEMPLATE LETTER: Acknowledgement of Personnel Update (HRP-524)

7 REFERENCES

7.1 None