

SOP: Incoming Items

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 Assign items to IRB staff for pre-review within 1 business day.

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 HRP-021 - SOP - Pre-Review.
- 5.2 If the item is a request for an approval or determinationⁱ by this institution's IRB that does not include other pSites, follow HRP-021 - SOP - Pre-Review.
 - 5.2.1 If there are financial disclosures, follow HRP-055 - SOP - Financial Conflicts of Interests.
- 5.3 If the item is a notification of an emergency use of a test article in a life-threatening situation assign to IRB staff and then have a Designated Reviewer follow HRP-023 - SOP - Emergency Use, Compassionate Use, Indiv Patient Expanded Access.
- 5.4 If the item is an investigator's request to continue subjects in expired research assign to IRB staff and then have a Designated Reviewer follow HRP-063 - SOP - Expiration of IRB Approval.
- 5.5 If the item does not fit into the above categories:
 - 5.5.1 If the item is a question, concern, or complaint involving research or human subjects:
 - 5.5.1.1 Document the nature of the question, concern, or complaint and the contact information of the person contacting the IRB.
 - 5.5.1.2 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.
 - 5.5.2 Follow HRP-024 - SOP - New Information.

6 MATERIALS

- 6.1 HRP-021 - SOP - Pre-Review
- 6.2 HRP-023 - SOP - Emergency Use, Compassionate Use, Indiv Patient Expanded Access
- 6.3 HRP-024 - SOP - New Information
- 6.4 HRP-055 - SOP - Financial Conflicts of Interests
- 6.5 HRP-063 - SOP - Expiration of IRB Approval
- 6.6 HRP-805 - SOP - External IRB Updates

7 REFERENCES

7.1 AAHRPP elements I.1.A, I.4.A, I.5.D, I.7.C, I-9, II.2.A, II.2.B, II.2.E-II.2.E.2, II.2.F-II.2.F.3

ⁱ 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.