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 HRP-803 - SOP - Reliance Pre-Review.

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 HRP-021 - SOP - Pre-Review.

5.3 If the item is an update to a study for which an external IRB is the IRB of record, follow HRP-805 - SOP - External IRB Updates.

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

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

5.6 If the item includes an updated list of study personnel:

5.6.1 Send HRP-524 - LETTER - Ack Personnel Update for studies which are not relying on an external IRB.

5.6.2 If there are financial disclosures, follow HRP-055 - SOP - Financial Conflicts of Interests.

5.7 If the item is a notification of an emergency use of a test article in a life-threatening situation have a Designated Reviewer follow HRP-023 - SOP - Emergency Use, Compassionate Use, Indiv Patient Expanded Access.

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

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 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

[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."

6.5 HRP-063 - SOP - Expiration of IRB Approval
6.6 HRP-524 - LETTER - Ack Personnel Update
6.7 HRP-803 - SOP - Reliance Pre-Review
6.8 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