1 PURPOSE

1.1 This SOP 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 Revised from previous version dated 5/30/2017

3 SOP Statement

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 a TAMU 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.

5.1 If the item is a request for an approval or determination[1] by a TAMU IRB that does not include other pSites, follow HRP-021 - SOP - Pre-Review.

5.2 If the item is an update to a study for which and external IRB is the IRB of Record for a Single IRB study, process the update.

5.3 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.

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

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

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

5.4.1.2 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.

5.4.2 Follow SOP: New Information (HRP-024).

5.5 If the item includes safety risk or non-compliance information:

5.5.1 Follow HRP-024 - SOP - New Information.

6 MATERIALS

6.1 HRP-063 – SOP - Expiration of IRB Approval

6.2 HRP-024 – SOP - New Information.

6.3 HRP-021 – SOP - Pre-Review

6.4 HRP-803 - SOP - Reliance Pre-Review

7 REFERENCES

7.1 AAHRPP I.1.A, I.4.A, I.5.D, I.7.C, 1-9, II.2.A; II.2.B, II.2.E, II.2.F, II.2.3

[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 study personnel list is not considered a modification of research and is therefore not a "request for an IRB approval or determination."