## 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 Office staff member determines the appropriate action for the received information.

## 2 PREVIOUS VERSION

2.1 Revised from previous version dated 08/01/2024.

## 3 POLICY

3.1 None.

## 4 RESPONSIBILITIES

4.1 IRB Office 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 or for this institution to rely on an external IRB, the following should be considered:

5.1.1 Once the ability to review for the Participating Site is confirmed, then follow WORKSHEET: Pre-Review (HRP-308).

5.1.2 Once the ability to rely on an external IRB is confirmed, then follow SOP: External IRBs (HRP-092).

5.2 If the item is a request for an approval or determination[1] by this institution's IRB that does not include other Participating Sites, follow WORKSHEET: Pre-Review (HRP-308).

5.3 If the item is an update to a study for which an external IRB is the IRB of record, follow SOP - External IRBs (HRP-092).

5.4 If the item is a request to discard a submission from consideration, ask the study team to discard the submission.

5.5 If the item is a request to remove a Participating Site from a Single IRB (sIRB) Study, process the modification.

5.6 If the item is a request for an approval or determination[1], follow SOP: Pre-Review (HRP-021).

5.7 If the item is a notification of an emergency use of a test article in a life-threatening situation or compassionate use of an investigational device, have a Designated Reviewer follow SOP: All Emergency Use and Compassionate Use [Device Only] Review and Notification (HRP-023).

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

5.9 If the items do not fit into the above categories:

5.9.1 If the item is a question, concern, or complaint involving research or human participants:

5.9.1.1 Document the nature of the questions, concern, or compliant 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 them once you are able to find additional information. If necessary, consult with your supervisor.

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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."

5.9.1.3 If the item is a concern, complaint, or allegation of non-compliance, follow SOP: Handling Complaints and Allegations of Non-Compliance (HRP-095).

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

## 6 MATERIALS

6.1 SOP: Pre-Review (HRP-021)
6.2 SOP: Emergency Use (HRP-023)
6.3 SOP: Reportable New Information (HRP-024)
6.4 SOP: Compassionate Use (Device Only), and IRB Waiver for Individual Patient Expanded Access (Drug Only) (HRP-027)
6.5 SOP: Lapse [Expiration] of IRB Approval (Continuation of Current Participants) (HRP-063)
6.6 SOP: Handling Complaints and Allegations of Non-Compliance (HRP-095)

## 7 REFERENCES

7.1 None.