HRP-020 | 02/01/2024 | Author: T. Bechert | Approver: S. Brooks

**SOP: Incoming Items**

1. **PURPOSE**
   1. This procedure establishes the process to triage information submitted to the IRB.
   2. The process begins when any communication is received by the IRB.
   3. The process ends when an IRB staff member determines the appropriate action for the received information.
2. **REVISIONS FROM PREVIOUS VERSION**
   1. Revised pre-review reference; 2/1/24.
3. **POLICY**
   1. Incoming submissions to the IRB office are assigned to a member of the HRPP staff for pre-review within two business days of receipt.
4. **RESPONSIBILITIES**
   1. IRB generalists (staff members serving as both administrators and analysts) carry out these procedures.
5. **PROCEDURE**
   1. For a submission appearing in the unclaimed tab in RAMS-IRB that is a request for an approval or determination[[1]](#footnote-1) by this institution’s IRB that does not include other pSites, refer to the Tracking Log to assign for review by an available, appropriately trained staff member. Note the number of submissions currently in process for each staff member to ensure an equitable distribution of workload. Staff will follow HRP-021 - SOP - Pre-Review.
      1. If the submission is a response to modifications required to secure approval received within 30 days of the IRB review date, it will route directly to the previously assigned IRB coordinator.
      2. If the submission is a continuing review, modification or report of new information, the submission will automatically route to the initial IRB Coordinator. Re-assign to active staff where applicable.
      3. Submissions are assigned by review level (reliance, exempt/expedited, full board) and submission type (initial, amendment, CR, RNI) - consult the HRPP org chart and Tracking Log to determine submission assignment. Engagement and Not Human Subjects Research submissions are reviewed by IRB Analysts on the Exempt/Expedited Team whereas submissions requiring full board review, and non-personnel minor modifications to greater than minimal risk research, are assigned to IRB Administrators on the Full Board Team.
   2. If the item is a request for an approval or determination by this institution’s IRB, or 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.
   3. If the item is an update to a study for which an external IRB is the IRB of record, the submission will automatically route to the initial IRB Administrator or Reliance Coordinator (or the first IRB staff assigned as coordinator) who will follow HRP-805 - SOP - External IRB Updates Re-assign to active staff where applicable.
   4. If the item includes new or modified contact information for independent investigators, update the contact information in the Reliance Tracker on Google Drive.
   5. If the item is a notification of an emergency use of a test article in a life-threatening situation, assign to an IRB Administrator who will follow HRP-023 - SOP - Emergency Use, Compassionate Use, Indiv Patient Expanded Access. Notify the staff member, HRPP Director and IRB Chair of the assignment.
   6. If the item is an investigator’s request to continue subjects in expired research, assign to an IRB Administrator (full board submissions) or IRB Analyst (exempt/expedited submissions) who will have a Designated Reviewer follow HRP-063 - SOP - Expiration of IRB Approval.
   7. If the item does not fit into the above categories:
      1. If the item is a question, concern, or complaint involving research or human subjects:
         1. Document the nature of the question, concern, or complaint and the contact information of the person contacting the IRB.
         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.
      2. Follow HRP-024 - SOP - New Information.
6. **MATERIALS**
   1. HRP-021 - SOP - Pre-Review
   2. HRP-023 - SOP - Emergency Use, Compassionate Use, Indiv Patient Expanded Access
   3. HRP-024 - SOP - New Information
   4. HRP-063 - SOP - Expiration of IRB Approval
   5. HRP-805 - SOP - External IRB Updates
7. **REFERENCES**
   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

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.” [↑](#footnote-ref-1)