1. PURPOSE
   1. This procedure establishes the process to pre-review a request for approval (approval of new research, humanitarian use device (HUD), compassionate use, emergency use of a test article, continuing review of research, or modification to previously approved research, request for study closure) or a determination whether an activity is exempt Human Research or is not Human Research.
   2. The process begins when the IRB receives a request for approval.
   3. The process ends when the information has been placed on the agenda for an IRB meeting or will be handled by Non-Committee Review.
2. REVISIONS FROM PREVIOUS VERSION
   1. None.
3. POLICY
   1. Protocol history is maintained in CICERO.
   2. The addition of a participating site to a previously approved protocol for which the IRB will serve as the IRB of record for that participating site is considered a modification to previously approved research.
   3. A new HUD protocol submission must be reviewed at a convened IRB meeting. Continuing review of a HUD can be handled by Non-Committee Review.
4. RESPONSIBILITIES
   1. IRB staff members carry out these procedures.
5. PROCEDURE
   1. Assess for appropriate review path, choose the activity “Adjust Review Path”, and then choose the correct review path.
   2. In CICERO, assign the appropriate Internal Reviewer and Full Board Coordinator and/or Analyst by using the corresponding activities (if not already assigned).
   3. Choose the activity “Create Reviewer Checklist.”
      1. Assign the reviewer.
      2. Choose the action to be performed.
      3. Select “Administrative Reviewer” as the review.
      4. Choose “Pre-Review/Administrative Reviewer Checklist” unless submission is NHSR.
      5. Choose “Human Research Determination Checklist”, if needed.
   4. Complete the “Pre-Review/Administrative Review” and “Human Research Determination” checklist (as appropriate)[[1]](#footnote-1) in CICERO.
      1. If the information is not complete or there are contingencies required prior to IRB review, enter the questions/comments in CICERO and request administrative modifications from the investigator. If the investigator will not make the modifications, continue processing.
   5. If the request is for an initial approval and investigator or research staff member is Restricted, contact the investigator. Explain that the investigator or research staff member is Restricted, give the reasons, and indicate that if a new protocol goes to the IRB, the IRB policy is to disapprove the research.
      1. If the investigator wishes to withdraw the protocol, either choose Admin Withdraw or send the submission back to investigator for withdrawal.
      2. If the investigator takes the appropriate steps to remove the Restricted status or still wants the protocol to be reviewed by the IRB, continue processing.
   6. Evaluate the most likely level of review:
      1. Re-assess the review path. If the review path needs to be changed, choose the activity “Adjust Review Path”, and then select the appropriate review path. If the review path is appropriate, continue to 5.6.2.
      2. If the request can be handled as a Non-Committee Review and the investigators and research staff are not Restricted, follow “SOP: Non-Committee Review Preparation.”
      3. If the request cannot be handled as a Non-Committee Review, (such as the PI will not make requested changes) place the protocol on the agenda for a convened IRB meeting in an IRB with appropriate scope. (Do not assign a Veterans Administration (VA) protocol to a commercial IRB.)
         1. Choose the activity “Assign to Meeting” and choose which meeting the submission should be assigned to.
            1. If the submission was previously deferred by the convened IRB, assign to the same panel that did the first review if possible.
      4. Follow “SOP: IRB Meeting Preparation.”
6. MATERIALS
   1. CHECKLIST: Pre-Review (HRP-401)
   2. WORKSHEET: Pre-Review (HRP-308)
   3. HUMAN RESEARCH PROTECTION PROGRAM PLAN (HRP-101)
   4. SOP: All Emergency Use, and Compassionate Use (Device Only) and IRB Waiver for Individual Patient Expanded Access (Drug Only) Review
   5. SOP: New Information (HRP-024)
   6. SOP: Non-Committee Review Preparation
   7. SOP: IRB Meeting Preparation
   8. SOP: Post-Review
   9. WORKSHEET: Human Research Determination (HRP-411)
   10. WORKSHEET: Engagement Determination
   11. WORKSHEET: Exemption Determination
   12. WORKSHEET: Expedited Review
   13. WORKSHEET: Criteria for Approval for HUD
   14. TEMPLATE LETTER: Closure
7. REFERENCES
   1. AAHRPP elements I.1.A, I-2, I.6.B, I.7.A, I-9, II.2.A-D, II.2.E-II.2.E.2, II.2.F-II.2.F.3

1. These checklists are “CICERO CHECKLIST: Pre-Review/Administrative Review and CICERO CHECKLIST: Human Research Determination”. [↑](#footnote-ref-1)