1. PURPOSE
   1. This procedure establishes the process to pre-review a request for approval (approval of new research, humanitarian use device (HUD), continuing review of research, or modification to previously approved research) 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 local IRB approval, including requests from other institutions when this institution is the IRB of record, e.g., for a Collaborative Study or Multi-Site Study.
   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. Submissions (i.e., requests for IRB approval or determinations of whether an activity is exempt Human Research or is not Human Research) received by the Parkview IRB Office are pre-reviewed by IRB Office staff members, before the information is placed on the agenda for an IRB meeting or handled by Non-Committee Review.
   2. 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. If the submission is a response to modifications required to secure approval:
      1. Evaluate whether the investigator made the required modifications.
      2. If the investigator made the required modifications, follow “SOP: Post-Review (HRP-052)” to issue an approval.
      3. If the investigator did not make the required modifications, offer the investigator the opportunity to correct the submission.
         1. If the investigator will correct the submission, have the investigator resubmit and stop processing the current submission.
         2. If the investigator will not correct the submission, continue processing.
   2. For all other submissions, complete the IRB Office Checklist in IRB Manager and note all remaining contingencies.
   3. If the request is for an initial approval and principal investigator is Restricted, contact the investigator. Explain that the investigator is Restricted, give the reasons, and indicate that if a new protocol goes to the IRB, the IRB policy is to disapprove the research. Offer the investigator the opportunity to withdraw the submission pending removal of the Restricted status.
      1. If the investigator withdraws the submission, stop processing the current submission.
      2. If the investigator will not withdraw the submission, discuss whether you may continue to process the submission with the IRB Manager.
   4. Evaluate the most likely level of review. Consider using “WORKSHEET: Human Research Determination (HRP-310)”, “WORKSHEET: Engagement Determination (HRP-311)”, “WORKSHEET: Exemption Determination (HRP-312)”, “WORKSHEET: Expedited Review (HRP-313)”, and/or “WORKSHEET: Criteria of Approval for HUD (HRP-323) as references.
      1. If the request can be handled as a Non-Committee Review and the principal investigator is not Restricted, Follow “SOP: Non-Committee Review Preparation (HRP-031).”
      2. If the request cannot be handled as a Non-Committee Review, place the protocol on the agenda for a convened IRB meeting.
   5. If the study can be closed, complete and send a closure letter in IRB Manager.
6. MATERIALS
   1. HUMAN RESEARCH PROTECTION PROGRAM PLAN (HRP-101)
   2. SOP: New Information (HRP-024)
   3. SOP: Non-Committee Review Preparation (HRP-031)
   4. SOP: IRB Meeting Preparation (HRP-040)
   5. SOP: Post-Review (HRP-052)
7. REFERENCES
   1. None