1 PURPOSE
  1.1 This procedure establishes the process to pre-review a request for approval (approval of new research, 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.
  1.2 The process begins when the IRB receives a request for approval.
  1.3 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
  2.1 Replaces version dated 7/18/2012.

3 POLICY
  3.1 The addition of a previously approved protocol at a new site or sites that will be overseen by a principal investigator who will take separate and full responsibility for that site or those sites is considered a modification to previously approved research.

4 RESPONSIBILITIES
  4.1 IRB staff members carry out these procedures.

5 PROCEDURE
  5.1 If the submission is a response to modifications required to secure approval received within 90 days of the IRB review date:
     5.1.1 Evaluate whether the investigator made the required modifications.
     5.1.2 If the investigator made the required modifications, follow “SOP: Post-Review (HRP-052)” to issue an approval.
     5.1.3 If the investigator did not make the required modifications or made unrequested modifications, contact the investigator. Offer the investigator the opportunity to correct the submission.
       5.1.3.1 If the investigator will correct the submission, have the investigator resubmit and stop processing the current submission.
       5.1.3.2 If the investigator will not correct the submission, continue processing.
  5.2 For all other submissions, complete “CHECKLIST: Pre-Review (HRP-401)” or review the previously completed “CHECKLIST: Pre-Review (HRP-401)” and revise as needed, considering the items on page two and note all remaining contingencies in the “Final Contingencies” section.
  5.3 If the information is not complete, contact the investigator. Offer the investigator the opportunity to provide additional information.
     5.3.1 If the investigator will provide additional information, have the investigator resubmit and stop processing the current submission.
     5.3.2 If the investigator will not provide additional information, continue processing.
  5.4 If the research represents a type of research the organizational does not conduct or oversee or where the organizational relies on an external IRB, contact the investigator.
     5.4.1 If the investigator withdraws the submission, stop processing the current submission.
     5.4.2 If the investigator will not withdraw the submission, continue processing.
  5.5 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.
     5.5.1 If the investigator withdraws the submission, stop processing the current submission.
     5.5.2 If the investigator will not withdraw the submission, continue processing.
  5.6 Evaluate the most likely level of review:
5.6.1 If the request is for a study closure complete and send “TEMPLATE LETTER: Closure (HRP-511)”.

5.6.2 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).”

5.6.3 If the request cannot be handled as a Non-Committee Review, place the protocol on the agenda for a convened IRB meeting in an IRB with appropriate scope.

6 MATERIALS

6.1 CHECKLIST: Pre-Review (HRP-401)
6.2 HUMAN RESEARCH PROTECTION PROGRAM PLAN (HRP-101)
6.3 SOP: New Information (HRP-024)
6.4 SOP: Non-Committee Review Preparation (HRP-031)
6.5 SOP: Post-Review (HRP-052)
6.6 CHECKLIST: Pre-Review (HRP-401)
6.7 TEMPLATE LETTER: Closure (HRP-511)

7 REFERENCES

7.1 None