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 not Human Research or is Human Research that does not engage the Institution.
   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 None.

3 POLICY
   3.1 The addition of a new site to a previously approved protocol is considered a modification to previously approved research, including when the site is overseen by a principal investigator who takes full responsibility for that site.
   3.2 Updates to the list of study personnel that meet the personnel qualifications described in the IRB approved protocol are not considered a modification to previously approved research.

4 RESPONSIBILITIES
   4.1 IRB staff members carry out these procedures.

5 PROCEDURE
   5.1 If the item includes an updated list of study personnel submitted between approvals:
      5.1.1 Send “TEMPLATE LETTER: Acknowledgement of Personnel Update (HRP-524)” or equivalent.
      5.1.2 If there are financial disclosures, follow “SOP: Financial Conflicts of Interests (HRP-055)”.
   5.2 If the submission is a response to modifications required to secure approval received within 25 business days of the IRB review date:
      5.2.1 Evaluate whether the investigator made the required modifications.
      5.2.2 If the investigator made the required modifications and did not make unrequested modifications, follow “SOP: Post-Review (HRP-052)” to issue an approval.
   5.3 If the request is a continuing review that meets closure criteria, follow “SOP: Post-Review (HRP-052)” to close the study.
   5.4 If the request is for study closure that does not meet closure criteria, contact the investigator.
      5.4.1 Explain the issue and offer the investigator and opportunity to withdraw or correct the submission.
      5.4.2 If the investigator withdraws the submission, stop processing.
      5.4.3 If the investigator will not withdraw the submission, the submission requires review by a convened IRB.
   5.5 Use “WORKSHEET: Pre-Review (HRP-308),” or equivalent and complete “CHECKLIST: Pre-Review (HRP-401)” or equivalent, or revise, as needed, the previously completed “CHECKLIST: Pre-Review (HRP-401),” or equivalent.
   5.6 Consider whether the investigator needs to be contacted.
      5.6.1 Communicate with the investigator if any of the following are true:
         5.6.1.1 The investigator has requested that the study be closed and the study does not meet closure criteria.
         5.6.1.2 In response to modifications required to secure approval, the investigator did not make the required modifications or made unrequested modifications.
         5.6.1.3 The request is for an initial approval and principal investigator is Restricted.
         5.6.1.4 The type of research is not conducted or overseen by the Institution.
         5.6.1.5 The type of research is reviewed by an external IRB.
         5.6.1.6 Submitted information is incomplete.
5.6.2 Explain the issue and offer the opportunity to withdraw or correct the submission.
5.6.3 If the investigator withdraws the submission, stop processing.
5.6.4 If the investigator will not withdraw the submission, handle, place the submission on the agenda for a convened IRB meeting in an IRB with appropriate scope.

5.7 Evaluate the most likely level of review:

5.7.1 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).”

5.7.2 If the request involved an investigator who would not correct or withdraw a submission or otherwise cannot be handled as a Non-Committee Review, place the submission 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 SOP: Financial Conflicts of Interests (HRP-055)
6.3 SOP: Non-Committee Review Preparation (HRP-031)
6.4 SOP: Post-Review (HRP-052)
6.5 TEMPLATE LETTER: Acknowledgement of Personnel Update (HRP-524)
6.6 WORKSHEET: Pre-Review (HRP-308)

7 REFERENCES

7.1 None