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. The process begins when the HRPO receives a request for HRRC approval.
1.2 The process ends when the information has been placed on the agenda for an HRRC meeting or will be handled by Non-Committee Review.

2 REVISIONS FROM PREVIOUS VERSION
2.1 None.

3 POLICY
3.1 The HRPO staff members conduct a pre-review of incoming submissions to ensure that the submission is complete and that the HRRC has the information and materials necessary to conduct their review.
3.2 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.
3.3 New study submissions are not accepted from investigators in Restricted status.

4 RESPONSIBILITIES
4.1 HRPO Pre-Team members carry out these procedures.

5 PROCEDURE
5.1 Complete the Pre-Review Activity or review the previously completed Pre-Review Activity and revise as needed.
5.1.1 Complete and attach the Pre-Review “CHECKLIST: Pre-Review for New Study (HRP-401)” or “CHECKLIST: Pre-Review for Follow-on Submissions (HRP-451),” as appropriate.
5.1.2 If the submission is a response to modifications required to secure approval, reference the pending submission in the Pre-Review notes to the Reviewer.
5.2 If the information is not complete, contact the investigator by selecting the “Request Pre-Review Clarifications” Activity. Offer the investigator the opportunity to provide additional information.
5.2.1 Continue processing once the investigator responds to the request for additional information.
5.3 If the request is for an initial approval and the principal investigator is Restricted, contact the investigator. Explain that the investigator is Restricted, give the reason(s), explain that the HRRC will not accept a new study until the Restricted status is removed and give the investigator the opportunity to withdraw the submission.
   5.3.1 If the investigator withdraws the submission, stop processing.
   5.3.2 If the investigator will not withdraw the submission, discard the submission.

5.4 Evaluate the most likely level of review:
   5.4.1 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)."
   5.4.2 If the request involved an investigator who would not correct or withdraw a submission or otherwise cannot be handled as a Non-Committee Review, follow "SOP: Meeting Preparation (HRP-040).

6 MATERIALS
   6.1 CHECKLIST: Pre-Review for New Study (HRP-401)
   6.2 CHECKLIST: Pre-Review for Follow-on Submissions (HRP-451)
   6.3 SOP: Non-Committee Review Preparation (HRP-031)
   6.4 SOP: Meeting Preparation (HRP-040)

7 REFERENCES
   7.1 None