



SOP: Pre-Review				
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1 PURPOSE

- 1.1 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.
- 1.2 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.
- 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 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.
- 3.2 Single subject protocol exceptions are reviewed as modifications to previously approved research.¹
- 3.3 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

- 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 30 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 HRP-052 - SOP - Post-Review to issue an approval.
 - 5.1.3 If the investigator did not make the required modifications or made unrequested modifications, execute the "Request Pre-Review Clarification" activity from 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 make changes then execute the "Submit Changes" activity and stop processing the current submission until changes are received.
 - 5.1.3.2 If the investigator will not correct the submission, have the investigator execute the "Submit Changes" activity to resubmit and continue processing.
- 5.2 For all other submissions, complete HRP-401 - CHECKLIST - Pre-Review or review the previously completed HRP-401 - CHECKLIST - Pre-Review and revise as needed, considering the

¹ Per OHRP correspondence dated 07/22/2011, protocol exceptions are considered changes to previously approved research and eligible for review via expedited procedure.



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items on HRP-308 - WORKSHEET - Pre-Review and note all remaining contingencies in the “Final Contingencies” section.

- 5.3 For all other submissions, complete Pre-Review Activity or review the previously completed Pre-Review Activity and revise as needed, considering the items on HRP-308 - WORKSHEET - Pre-Review and note all remaining contingencies in the “Final Contingencies” section.
- 5.4 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.
 - 5.4.1 Continue processing once the investigator responds to the request for additional information.
- 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, discuss whether you may continue to process the submission with the HRPP Director.
- 5.6 Evaluate the most likely level of review using HRP-310 - WORKSHEET - Human Research Determination, HRP-311 - WORKSHEET - Engagement Determination, HRP-312 - WORKSHEET - Exemption Determination, HRP-313 - WORKSHEET - Expedited Review, and/or HRP-323 - WORKSHEET - Criteria for Approval HUD as references:
 - 5.6.1 If the study can be closed, complete and send HRP-511 - LETTER – Closure.
 - 5.6.2 If the request can be handled as a Non-Committee Review and the principal investigator is not Restricted, Follow HRP-031 - SOP - Non-Committee Review Preparation.
 - 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.
 - 5.6.4 If the request is a non-emergency individual patient expanded access use of an investigational drug for which an IRB waiver is requested, follow HRP-031 - SOP - Non-Committee Review Preparation and HRP-023 - SOP - Emergency Use, Compassionate Use, Indiv Patient Expanded Access.

6 MATERIALS

- 6.1 HRP-023 - SOP - Emergency Use, Compassionate Use, Indiv Patient Expanded Access
- 6.2 HRP-024 - SOP - New Information
- 6.3 HRP-031 - SOP - Non-Committee Review Preparation
- 6.4 HRP-040 - SOP - IRB Meeting Preparation
- 6.5 HRP-052 - SOP - Post-Review
- 6.6 HRP-308 - WORKSHEET - Pre-Review
- 6.7 HRP-310 - WORKSHEET - Human Research Determination
- 6.8 HRP-311 - WORKSHEET - Engagement Determination
- 6.9 HRP-312 - WORKSHEET - Exemption Determination
- 6.10 HRP-313 - WORKSHEET - Expedited Review
- 6.11 HRP-323 - WORKSHEET - Criteria for Approval HUD
- 6.12 HRP-401 - CHECKLIST - Pre-Review

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6.13 HRP-511 - LETTER - Closure

7 REFERENCES

7.1 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