SOP: Pre-Review

1 PURPOSE

This procedure establishes the process to pre-review a request for approval (approval of new research, approval to rely on an external IRB, humanitarian use device (HUD), continuing review of research, or modification to previously approved research) or a determination whether an activity is exempt Human Research, self-exempt Human Research or is not Human Research.

1.1 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, or a request to rely on an external IRB.

1.2 The process ends when the information has been placed on the agenda for an IRB meeting or will be handled by Non-Committee Review, or the information is sent to the Reliance Coordinator or IRB staff to review the request to rely on an external IRB.

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. [i]

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 corrects the submission, have the investigator make changes then execute the “Submit Response” 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 Response” activity to resubmit and continue processing.

5.2 If the request is for this institution to rely on an external IRB:

5.2.1 Refer to HRP-806 - SOP - Review Request to Rely on External IRB

5.3 If the request includes review of a pSite submission:

5.3.1 Determine if the pSite is engaged in the non-exempt human subjects research using HRP-311- WORKSHEET - Engagement Determination.

5.3.1.1 If the pSite is not engaged in the non-exempt human subjects research, execute the "Submit Invitation Decision" activity to notify the lead investigator using HRP-850 - LETTER - Decline to Serve that this IRB will not serve as the IRB of Record for the pSite.

5.3.2 If the pSite is engaged, click on the Institutional Profile area in the IRB system and:

5.3.2.1 Confirm that the pSite has an active profile. If not, see 5.3.2.2.1.

5.3.2.2 Determine whether an existing Authorization Agreement covers the study activities for the pSite.

5.3.2.2.1 If not, follow HRP-801 - SOP - Establishing Authorization Agreements to collect the information needed to confirm reliance and create a new or updated Institutional Profile in the IRB system.

5.3.3 Execute the "Submit Invitation Decision" activity to notify the pSite using HRP-851 - LETTER - Invitation Decision or HRP-850 - LETTER - Decline to Serve that this IRB will or will not serve as the IRB of Record for their participation in the study.

5.3.4 If the IRB will serve as the sIRB for the pSite, after all site materials are submitted, proceed to Section 5.7.

5.4 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 "Notes" section.

5.5 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.

5.5.1 Continue processing once the investigator responds to the request for additional information.

5.6 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.

5.6.1 If the investigator withdraws the submission, stop processing the current submission.

5.6.2 If the investigator will not withdraw the submission, discuss whether you may continue to process the submission with the IRB Manager.

5.7 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 - PI WORKSHEET - Criteria for Approval HUD as references:

5.7.1 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.

5.7.2 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 using the "Assign Meeting" activity. Follow HRP-040 - SOP - IRB Meeting Preparation. (Do not assign a Veterans Administration (VA) protocol to a commercial IRB unless it has been specifically designated by the VA Office of Research and Development to serve as an IRB for cooperative research.[ii])If the request is a non-emergency individual patient expanded access use of an investigational drug for which an IRB waiver is requested or device compassionate use, follow HRP-031 - SOP - Non-Committee Review Preparation and HRP-023 - SOP - Emergency Use, Compassionate Use, Indiv Patient Expanded Access.

5.8 Pre-Review is conducted by IRB staff within 5 business days.

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 - PI WORKSHEET - Criteria for Approval HUD
6.12 HRP-806 - SOP - Review Request to Rely on External IRB
6.13 HRP-850 - LETTER - Decline to Serve
6.14 HRP-851 - LETTER - Invitation Decision

7 REFERENCES

None.

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[i] Per OHRP correspondence dated 07/22/2011, protocol exceptions are considered changes to previously approved research and eligible for review via expedited procedure.
[ii] Refer to the VA application process for the use of a commercial IRB approved by ORD: https://www.research.va.gov/programs/epros/irb_relationships.cfm