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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 5/17/21.

3 POLICY

- 3.1 The federal regulations for the protection of human subjects in research (45 CFR 46, Subparts A, B, C, & D; 21 CFR 50, 56, 312, and 812) will be considered and applied as applicable to the review of human research submitted to the IRB. If the research is supported by other Federal Departments, then additional requirements may be required.
- 3.2 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.
- 3.3 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 Review of New Applications (Convened or Non-Committee Reviews)
For all other submissions, complete **3.102 (HRP-401) – CHECKLIST - Pre-Review** in eIRB+ or review the previously completed **3.102 (HRP401) – CHECKLIST - Pre-Review** and revise as needed, considering the items on the **3.201 (HRP-308a) – WORKSHEET - Management Assistant Pre-Review** and the **3.202 (HRP-308b) – WORKSHEET - Preliminary Administrative Pre-Review** and note all remaining contingencies in the “Final Contingencies” section.
 - 5.1.1 For all other submissions, complete Pre-Review Activity or review the previously completed Pre-Review Activity and revise as needed, considering the items on **3.205 (HRP-305) – WORKSHEET - Pre-Review** and note all remaining contingencies in the “Final Contingencies” section.
 - 5.1.2 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.
 - 5.1.2.1 Continue processing once the investigator responds to the request for additional information.
 - 5.1.3 If the request is for an initial approval and the Principal Investigator is On-Probation contact the investigator. Explain that the investigator is On-Probation, give the reasons, and indicate that if a new protocol goes to the IRB, the IRB policy is to not accept the research. Offer the investigator the opportunity to withdraw the submission pending removal of the Probationary status.



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- 5.1.3.1 If the investigator withdraws the submission, stop processing the current submission.
- 5.1.3.2 If the investigator will not withdraw the submission, discuss whether you may continue to process the submission with the IRB Manager.
- 5.1.4 Evaluate the most likely level of review using **3.207 (HRP-310) – WORKSHEET - Human Research Determination, 3.208 (HRP-311) – WORKSHEET - Engagement Determination, 3.209 (HRP-312) – WORKSHEET - Exemption Determination, 4.201 (HRP-313) – WORKSHEET - Expedited Review, and/or 8.204 (HRP-323) – WORKSHEET - Criteria for Approval for HUD** as references:
 - 5.1.4.1 If the study can be closed, complete and send closure letter through eIRB+.
 - 5.1.4.2 If the request can be handled as a Non-Committee Review and the principal investigator is not On-Probation, Follow **3.004 (HRP-031) – SOP - Non-Committee Review Preparation**.
 - 5.1.4.3 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.
 - 5.1.4.4 If the request is a non-emergency individual patient expanded access use of an investigational drug for which an IRB waiver is requested, follow **3.004 (HRP-031) – SOP - Non-Committee Review Preparation** and “SOP: All Emergency Use, and Compassionate Use (Device Only) and IRB Waiver for Individual Patient Expanded Access (Drug Only) Review (HRP-023).”
- 5.2 Review of Resubmissions to New Applications (Convened or Non-Committee Reviews)

If the submission is a response to modifications required to secure approval received within 30 days of the IRB review date: (i.e., changes or clarifications to secure approval)

 - 5.2.1 Review the previously completed **3.102 (HRP-401) – CHECKLIST - Pre-Review** and revise as needed, considering the items on the **3.201 (HRP-308a) – WORKSHEET - Management Assistant Pre-Review** and the **3.202 (HRP-308b) – WORKSHEET - Preliminary Administrative Pre-Review** and note all remaining contingencies in the “Final Contingencies” section.
 - 5.2.2 If the resubmission is for a New Application reviewed by a Convened IRB, review the IRB deferral or conditional approval letter that provided the stipulations for approval and/or the IRB minutes.
 - 5.2.3 If the resubmission is for a New Application reviewed by a Non-Committee Review, review the IRB deferral or conditional approval letter that provided the stipulations for approval.
 - 5.2.4 Evaluate whether the investigator appears to have made the required modifications.
 - 5.2.5 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.
 - 5.2.5.1 If the investigator will not correct the submission, consult with the HRPP Director.
 - 5.2.5.2 If the investigator corrects the submission, continue processing.
 - 5.2.6 If the investigator did not make the required modifications or made unrequested modifications, execute the “Request Changes/Clarifications” activity from the IRBA to the investigator. Offer the investigator the opportunity to correct the submission.
 - 5.2.6.1 If the investigator will not correct the submission, have the investigator make changes then execute the “Submit Changes” activity and stop processing the current submission until changes are received.



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- 5.2.6.2 If the investigator corrects the submission, have the investigator execute the “Submit Changes” activity and continue processing.
- 5.2.7 If the changes for approval were requested by a Convened IRB and the motion made for approval was to have the changes reviewed by the IRB Chair or an IRB member, the resubmission will be forwarded to the designated IRB member(s) to confirm that the requested changes were addressed satisfactorily. Likewise, if the IRB Chair/member conducting a Non-committee review requested to review the changes for approval, the submission will be forwarded to them for their review.
- 5.2.8 If the investigator made the required modifications, follow **3.012 (HRP-052) - SOP - Post-Review** to issue an approval.

5.3. Review of Modifications/Amendments to Previously Approved Research (Convened or Non-Committee Reviews)

- 5.3.1 Follow the Modifications Desk Procedures.

5.4 Review of Continuing Reviews (Convened or Non-Committee Reviews)

- 5.4.1 Follow the Continuing Review and Closures Desk Procedures.

5.5 Review of Closures

- 5.5.1 Follow the Continuing Review and Closures Desk Procedures.

6 MATERIALS

- 6.1 1.001 (HRP-101) - HUMAN RESEARCH PROTECTION PROGRAM PLAN.
- 6.2 3.004 (HRP-031) – SOP - Non-Committee Review Preparation.
- 6.3 3.012 (HRP-052) - SOP - Post-Review.
- 6.4 3.102 (HRP-401) – CHECKLIST - Pre-Review.
- 6.5 3.201 (HRP-308a) – WORKSHEET - Management Assistant Pre-Review.
- 6.6 3.202 (HRP-308b) – WORKSHEET - Preliminary Administrative Pre-Review.
- 6.7 3.205 (HRP-308) – WORKSHEET – Pre-Review.
- 6.8 3.207 (HRP-310) – WORKSHEET - Human Research Determination.
- 6.9 3.208 (HRP-311) – WORKSHEET - Engagement Determination.
- 6.10 3.209 (HRP-312) – WORKSHEET - Exemption Determination.
- 6.11 4.201 (HRP-313) – WORKSHEET - Expedited Review.
- 6.12 5.001 (HRP-040) – SOP - IRB Meeting Preparation.
- 6.13 8.001 (HRP-023) – Emergency Use, Compassionate Use, Indiv Patient Expanded Access.
- 6.14 8.204 (HRP-323) – WORKSHEET - Criteria for Approval for HUD.
- 6.15 10.001 (HRP-024) – SOP – Reportable New Information.

7 REFERENCES

- 7.1 None.