1 PURPOSE

1.1 This procedure establishes the process to pre-review a request for approval (approval of new research, humanitarian use device (HUD), non-emergency expanded access use, 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 Editorial changes to reflect electronic implementation and Single IRB Review mandate.

2.2 2019 review. Added clarification to section 5.1.3. Referred to the “Pre-Review” worksheet as an electronic document.

2.3 Reconciliation to Huron HRPP Toolkit 4.5, dated 12/10/2021.

3 GUIDING PRINCIPLES

3.1 HSRO staff will move requests for approval through the IRB process in an efficient and expedient manner.

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 Single subject protocol exceptions are reviewed as modifications to previously approved research. [1]

3.4 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.

3.5 Non-emergency expanded access use must be reviewed at a convened IRB meeting HRP-023 - SOP - Emergency Use, Compassionate Use, Indiv Patient Expanded Access.

4 RESPONSIBILITIES

4.1 HRSO staff members carry out these procedures.

5 PROCEDURE

5.1 If the submission is a response to modifications required to secure approval received within 60 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 without including an explanation,

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

return from the submission to the investigator by executing "review required modification" and confirming that the modification was NOT completed as required. Offer the investigator the opportunity to correct the submission.

5.1.3.1 If the investigator will correct the submission as the IRB required, 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 as the IRB required, have the investigator execute the "Submit Changes" activity to resubmit and continue processing.

5.2 For all other submissions, complete the 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 Missing Materials section.

5.3 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.

5.3.1 Continue processing once the investigator responds to the request for additional information

5.4 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.

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

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

5.5 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:

5.5.1 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.

5.5.2 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.

5.5.3 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-024 - SOP - New Information

6.2 HRP-023 - SOP - Emergency Use, Compassionate Use, Indiv Patient Expanded Access

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

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