1 PURPOSE

1.1 This procedure establishes the process to pre-review a request for IRB approval (approval of new research, humanitarian use device (HUD), continuing review of research, and 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 the Northwestern University IRB serves as 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 PREVIOUS VERSION

2.1 Revised from previous version dated 05/30/2022.

3 POLICY

3.1 Submissions (i.e., requests for IRB approval or determinations of whether an activity is exempt Human Research or is not Human Research) received by the Northwestern University IRB Office are pre-reviewed by IRB Office staff members, before the information is placed on the agenda for an IRB meeting or handled by Non-Committee Review.

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 Short form consent documents for non-English speaking participants are reviewed as Reportable New Information (RNI).

3.5 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 Office staff members carry out these procedures.

5 PROCEDURE

5.1 If the submission is a response to modifications required to secure approval received within 21 calendar days of the investigator receiving the IRB determination letter:

- 5.1.1 Evaluate whether the investigator made the required modifications.
- 5.1.2 If the investigator made the required modifications, follow SOP: Post-Review (HRP-052) 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 and continue processing.

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

5.2 If the submission is a response to modifications required to secure approval received after 21 calendar days of the investigator receiving the IRB determination letter, discuss whether you may continue to process the submission with the Biomedical IRB Manager or Social Behavioral IRB Manager.

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 WORKSHEET: Pre-Review (HRP-308) and note all remaining contingencies in the "Final Contingencies" section.

5.3.1 As part of pre-review, the analyst will check past versions of the protocol and consent documents to ensure that the correct version date information is documented and to ensure that no versions of documents are missing.

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 reason, 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 Biomedical IRB Manager or Social Behavioral IRB Manager.

5.6 Evaluate the most likely level of review using WORKSHEET: Human Research Determination (HRP-310), WORKSHEET: Engagement Determination (HRP-311), WORKSHEET: Exemption Determination (HRP-312), WORKSHEET: Expedited Review (HRP-313), and/or WORKSHEET: Criteria for Approval for HUD (HRP-323) as referenced:

5.6.1 If the request is for a study closure, follow instructions in eIRB+ to close the study, LETTER: Study Closure (HRP-718)

5.6.2 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).

5.6.3 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 When reviewing a new HUD protocol, these must be reviewed at a convened meeting.

5.6.5 When reviewing a continuing review, modification, or off-label use of a HUD, these can be reviewed through a Non-Committee Review.

5.6.6 If the request is a non-emergency individual patient expanded access use of an investigational drug for which an IRB waiver is requested, follow SOP Non-Committee Review Preparation (HRP-031) and SOP: Compassionate Use (Device Only) and IRB Waiver for Individual Patient Expanded Access (Drug Only) Review (HRP-027).

6 MATERIALS

6.1 SOP: Reportable New Information (HRP-024)

6.2 SOP: Compassionate Use (Device Only), and IRB Waiver for Individual Patient Expanded Access (Drug Only) (HRP-027)

6.3 SOP: Non-Committee Review Preparation (HRP-031)

6.4 SOP: IRB Meeting Preparation (HRP-040)

6.5 SOP: Post-Review (HRP-052)
6.6 WORKSHEET: Pre-Review (HRP-308)
6.7 WORKSHEET: Human Research Determination (HRP-310)
6.8 WORKSHEET: Engagement Determination (HRP-311)
6.9 WORKSHEET: Exemption Determination (HRP-312)
6.10 WORKSHEET: Expedited Review (HRP-313)
6.11 WORKSHEET: Criteria for Approval for HUD (HRP-323)
6.12 CHECKLIST: Pre-Review (HRP-401)
6.13 LETTER: Study Closure (HRP-718)
6.14 GENERAL DOCUMENT: Human Subject Protection Program Plan (HRP-101)

7 REFERENCES

7.1 None.