1 PURPOSE

1.1 This SOP establishes the process for a Designated Reviewer or Administrative Reviewer to conduct a Non-Committee Review.

1.2 The process begins when the Designated Reviewer is notified to conduct a Non-Committee Review or the Administrative Reviewer receives a new submission.

1.3 The process ends when the Designated Reviewer notifies the assigned IRB staff member of the completion of the review or the Administrative Reviewer completes the review of an new submission.

2 REVISIONS FROM PREVIOUS VERSION

2.1 Revised from previous version 5/30/2017

3 SOP Statement

3.1 Designated Reviewers are to review the materials described in HRP-045 - SOP - IRB Member Review Expectations

3.2 The Designated Reviewer may not disapprove research.

3.3 Administrative Reviewers may review or verify administrative submissions as follows:

- 3.3.1 Requests where the research meets eligibility for study closure
- 3.3.2 Requests to change study personnel
- 3.3.3 Requests for exemption determinations
- 3.3.4 Responsive materials from investigators when the IRB approves research with conditions.
- 3.3.5 Requests to defer to an external IRB
- 3.3.6 Requests for a delayed onset human research
- 3.3.7 Annual administrative check-in

3.4 In consultation with the IRB, Administrative Reviewers may process:

- 3.4.1 Requests for non-human subjects determinations
- 3.4.2 Not Engaged - Human Subjects Research

3.5 Administrative Reviewers may not review modifications to approved research, continuing reviews or non-exempt research submissions that meet the definition of human subjects research.

4 RESPONSIBILITIES

4.1 The Designated Reviewer or Administrative Reviewer carries out these procedures.

5 PROCEDURE

5.1 Consider whether or not you have a Conflicting Interest. If not:

- 5.1.1 If the submission is a request to close the study:
  - 5.1.1.1 If the submission meets the study closure criteria, close the study and Save and Complete the submission.
  - 5.1.1.2 If the submission does not meet the study closure criteria communicate with the investigator and stop processing until the investigator revises the submission.
  - 5.1.1.3 If the investigator will not revise the submission, forward the submission for assignment to Committee Review.
- 5.1.2 If the submission is a request to defer to an external IRB use HRP-803 - SOP - Reliance Pre-Review. If the submission is an annual administrative update use HRP-322 Worksheet: Administrative Update.
- 5.1.3 If the submission is a request for a delayed onset of funded human research:

5.1.3.1 If the submission lacks definitive plans for human subjects involvement in a funded project as described by regulations at 45 CFR 46.118 process the submission and document the period of duration which cannot exceed one year.

5.2 Consider whether you have sufficient expertise to review the submission. The designated reviewer fulfills the roles described for the primary reviewer and scientific/scholarly reviewer. as described in HRP-045 - SOP - IRB Member Review Expectations.

5.2.1 If you need additional expertise, follow HRP- 051 - SOP - Consultation.

5.3 Review all materials.

5.4 If there is missing information

5.4.1 'Request Clarification; or

5.4.2 Contact IRB staff member for assistance with obtaining missing information from investigator.

5.5 Designated Reviewers or Administrative Reviewers may take one of the following actions to determine status of submission:

5.5.1 Not Human Research. Follow HRP-310 - WORKSHEET – Human Research Determination

5.5.2 Delayed Onset Human Research in accordance with 45 CFR 46.118

5.5.3 Human Research not Engaged. Follow HRP-311 - WORKSHEET – Engagement Determination

5.5.4 Exempt Human Research. Follow HRP-312 - WORKSHEET – Exemption Determination

5.5.4.1. If the Exemption requires Limited IRB Review, follow HRP-319 - WORKSHEET – Limited IRB Review

5.5.5 If unable to determine status of submission:

5.5.5.1 Consult with HRPP Director; or

5.5.5.2 Forward submission to IRB Chair or Designee

5.5.5.3 Forward to Committee Review

5.5.6 If submission does not meet criteria for Administrative Review above (Not Human Research, Delayed Onset, Human Research not Engaged, Exempt Research) forward to Designated Reviewer for Expedited Review or Committee Review

5.6 Designated Reviewers may take one of the following actions to determine the submission's required level of Review:

5.6.1 Human Research approvable using the expedited procedure. Follow HRP-313 – WORKSHEET – Expedited Review; or

5.6.2 Human Research that requires review by a convened IRB.

5.6.2.1 If the research requires review by a convened IRB place the submission on the agenda for a convened IRB meeting with the appropriate scope and follow HRP-040 - SOP - IRB Meeting Preparation.

5.6.3 Approve the initial, continuing or modification submission if meets either:

5.6.3.1 The criteria in HRP-313 – WORKSHEET – Expedited Review and HRP-314 - WORKSHEET - Criteria for Approval and other applicable worksheets and checklists as determined by the Pre-Review.

5.6.3.2 "Modifications Required to Secure Approval": The submission with changes can be given the action of "Approve."

5.6.3.3 Use HRP-302 - WORKSHEET - Approval Intervals to calculate approval period.

5.7 Document determination in the electronic system or HRP-402 - Checklist – Non-Committee Review.

5.7.1.1 If the determination is "Approve" or "Modifications Required to Secure Approval," document the level of review and any conditions for approval.

5.7.1.2 For "Exempt," document the category or categories allowing the exemption in the electronic system or in HRP-312 - WORKSHEET – Exemption. and document the end date which cannot exceed a period of three years.

5.7.1.3 For "Expedited," document the category or categories allowing review using the expedited procedure in the electronic system or in HRP-313 – WORKSHEET – Expedited Review and document the period of approval which cannot exceed one year for:

5.7.1.3.1 FDA regulated Research

5.7.1.3.2 Research Subject to the Pre-2018 Common Rule.

5.7.1.3.3 Research where Continuing review is not required in accordance with the 2018 Common Rule but the reviewer has determined otherwise

5.7.1.4 For all other research that does not require continuing review assign an Annual Administrative Check-in.

5.7.1.5 If the research falls into one or more of the categories on the HHS expedited review list but the reviewer has determined that the research involves more than minimal risk, document the rationale for that determination and have the research placed on an agenda for Committee Review.

5.7.1.6 Save and Complete the Designated Review activity.

5.8 Notify the IRB staff member handling the submission when done.

5.9 Follow HRP-052 - SOP – Post-Review to communicate outcome to investigators.

6 MATERIALS

6.1 HRP-021 - SOP - Pre-Review
6.2 HRP-040 - SOP - IRB Meeting Preparation
6.3 HRP-045 - SOP - IRB Member Review Expectations
6.4 HRP-051 - SOP - Consultation
6.5 HRP-052 - SOP - Post-Review
6.6 HRP-302 - WORKSHEET - Approval Intervals
6.7 HRP-310 - WORKSHEET - Human Research Determination
6.8 HRP-312 - WORKSHEET - Exemption
6.9 HRP-313 - WORKSHEET - Expedited Review
6.10 HRP-322 – WORKSHEET - Administrative Update
6.11 HRP-314 - WORKSHEET - Criteria for Approval
6.12 HRP-335 - WORKSHEET - Closure Criteria
6.13 HRP-402 – Checklist - Non-Committee Review

7 REFERENCES

7.1 21 CFR §56.110(b).
7.2 45 CFR §46.110(b).
7.3 AAHRPP I.1.A, I.6.B, I-9, II.2.A, II.2.B, II.2.C, II.2.F, II-5