# SOP: Non-Committee Review Conduct

## 1 PURPOSE

1.1 This procedure establishes the process for a Designated Reviewer to conduct a Non-Committee Review or a Limited IRB Review.

1.2 The process begins when the Designated Reviewer has the provided materials.

1.3 The process ends when the Designated Reviewer completes the review and returns the completed materials to an IRB staff member.

## 2 REVISIONS FROM PREVIOUS VERSION

2.1 None

## 3 POLICY

3.1 The Designated Reviewer may not disapprove research.

3.2 The Designated Reviewer utilizes all applicable worksheets in the review of research.

3.3 All applicable criteria for approval in HRP-314 - WORKSHEET - Criteria for Approval must be satisfied in order for the research to be approved using the expedited procedure.

3.4 All applicable criteria for approval in HRP-312 - WORKSHEET - Exemption Determination must be satisfied for research to be determined to be exempt (including applicable criteria for Limited IRB Review in HRP-319 - WORKSHEET - Limited IRB Review.

## 4 RESPONSIBILITIES

4.1 The HRP staff and/or a Designated Reviewer carries out these procedures.

## 5 PROCEDURE

5.1 Review all materials.

5.2 If the information is not complete, contact the investigator by selecting the “Request Designated Review Clarifications” activity. Offer the investigator the opportunity to provide additional information.

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

5.2.2 If the investigator will not correct the submission, have the investigator execute the “Submit Response” activity to resubmit and continue processing.

5.3 Make the appropriate determination:

5.3.1 Not Human Research,

5.3.2 Human Research not Engaged,

5.3.3 Exempt Research Self-Determination

5.3.4 Exempt Human Research that requires IRB review (including exempt Human Research that requires Limited IRB Review),

5.3.5 Human Research approved using the expedited procedure, or

5.3.6 Human Research that requires review by a convened IRB (Committee Review).

5.4 If consultation is needed follow HRP-051 - SOP - Consultation.

5.5 If the review is complete, execute the “Submit Designated Review” activity.

5.6 Return all materials and the required, completed worksheets (e.g., HIPAA – HRP-441) to the IRB staff within 5 business days of receipt of materials

## 6 MATERIALS

6.1 HRP-051 - SOP - Consultation

6.2 HRP-312 - WORKSHEET - Exemption Determination
6.3 HRP-314 - WORKSHEET - Criteria for Approval
6.4 HRP-319 - WORKSHEET - Limited IRB Review and Broad Consent

## 7 REFERENCES

7.1 21 CFR §56.110(b).
7.2 45 CFR §46.110(b).