

SOP: Non-Committee Review Conduct

1 PURPOSE

- 1.1 This procedure establishes the process for conducting a Non-Committee Review.
- 1.2 The process begins when the Designated Reviewer or Staff Reviewer receives the review materials.
- 1.3 The process ends when the Designated Reviewer or Staff 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 Designated Reviewer may not disapprove research.
- 3.2 Designated Reviewer and Staff Reviewer utilize all applicable worksheets in the review of research.
- 3.3 The documents, worksheets, and checklists described HRP-301 - WORKSHEET - Review Materials are provided to the reviewer to conduct their review and meet regulatory requirements.
- 3.4 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.
- 3.5 All applicable criteria 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 and Broad Consent when appropriate).
- 3.6 Reviews are completed and returned to the IRB staff within 5 business days or receipt.

4 RESPONSIBILITIES

- 4.1 The Designated Reviewer or Staff Reviewer carries out these procedures.

5 PROCEDURE

- 5.1 Review all materials.
- 5.2 Make the appropriate determination:
 - 5.2.1 Not Human Research,
 - 5.2.2 Human Research not Engaged,
 - 5.2.3 Exempt Human Research (including exempt Human Research that requires Limited IRB Review),
 - 5.2.4 Modifications required to secure approval of Human Research using the expedited procedure,
 - 5.2.5 Human Research approved using the expedited procedure, or
 - 5.2.6 Human Research that requires review by a convened IRB.
- 5.3 Notify IRB staff to re-assign the submission if:
 - 5.3.1 The submission is assigned to a Staff Reviewer and requires review using the expedited procedure.
 - 5.3.2 The submission is assigned to a Designated Reviewer and requires review by a convened IRB.
- 5.4 If consultation is needed follow HRP-051 - SOP - Consultation.

- 5.4.1 The risk level determination should reflect the entirety of the research, not components of individual follow-on submissions. For follow-on submission, update the risk level only when modifications to study procedures prompt a change in risk level of the research.
- 5.4.2 For follow-on submissions to Minimal Risk research, confirm that the review categories selected are still applicable.
 - 5.4.2.1 Update the review category(ies) only when study procedures are modified and impact the category(ies).
 - 5.4.2.2 For research initially reviewed by the convened IRB and determined to be Minimal Risk (via Category 9), leave the review category identified as Category 9.
- 5.4.3 For follow-on submission to research involving greater than Minimal Risk:
 - 5.4.3.1 For modifications, select minor modification.
 - 5.4.3.2 For continuing reviews, confirm that greater than Minimal Risk activities have not occurred during the review period and select the applicable expedited review category (8a – long-term follow-up; 8b – no subjects enrolled; 8c – data analysis).
- 5.4.4 For non-emergency individual patient expanded access use of a drug and non-emergency individual/small group compassionate use of a device, select 'IRB chair concurrence' and the corresponding sub-category.

6 MATERIALS

- 6.1 HRP-051 - SOP – Consultation
- 6.2 HRP-301 - WORKSHEET - Review Materials
- 6.3 HRP-312 - WORKSHEET - Exemption Determination
- 6.4 HRP-314 - WORKSHEET - Criteria for Approval
- 6.5 HRP-319 - WORKSHEET - Limited IRB Review and Broad Consent

7 REFERENCES

- 7.1 21 CFR §56.110(b), 21 CFR 56.111.
- 7.2 45 CFR §46.110(b), 21 CFR §46.111.
- 7.3 AAHRPP elements I.1.A, I.6.B, I.7.A, I-9, II.2.A-C, II.2.F-II.2.F.3, II.5.A