



SOP: Non-Committee Review Preparation

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1 PURPOSE

- 1.1 This procedure establishes the process to prepare for a Non-Committee Review.
- 1.2 The process begins when an HSRO staff member identifies an application as being possibly eligible for Non-Committee Review.
- 1.3 The process ends when the HSRO staff member provides the materials to the Designated Reviewer.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 11/13/2013

3 GUIDING PRINCIPLES

- 3.1 IRB rosters are maintained using “DATABASE: IRB Roster (HRP-601).”
- 3.2 For individuals who access materials through an electronic system or are provided all submitted materials, those individuals are expected to review the materials listed in the “WORKSHEET: Review Materials (HRP-301)” according to their role: “Documents Provided to All IRB Members and Alternate IRB Members,” “Additional Items Provided to Primary Reviewer,” and “Additional Items Provided to Scientific/Scholarly Reviewer.”
- 3.3 For continuing review of research, at least one IRB member is provided and reviews the complete protocol, including any protocol modifications previously approved by the IRB. The status report on the progress of the research includes the reported number of participants accrued and a summary since the last IRB review.

4 RESPONSIBILITIES

- 4.1 HSRO staff members carry out these procedures.

5 PROCEDURE

- 5.1 Use the “Assign Designated Reviewer” activity and select a Designated Reviewer.
 - 5.1.1 If a Designated Reviewer is not available, schedule the protocol to be reviewed by the convened IRB.
 - 5.1.2 Execute the “Assign Designated Reviewer” activity
- 5.2 For individuals who are provided materials to review, prepare the review materials using the “WORKSHEET: Review Materials (HRP-301)” and include all materials listed under the columns according to the individual’s role.
- 5.3 Add to the review materials:
 - 5.3.1 Any relevant minutes or correspondence.

6 MATERIALS

- 6.1 CHECKLIST: Non-Committee Review (HRP-402)
- 6.2 DATABASE: IRB Roster (HRP-601)
- 6.3 TEMPLATE LETTER: Designated Reviewer Materials (HRP-540)
- 6.4 WORKSHEET: Review Materials (HRP-301)

7 REFERENCES

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