1 PURPOSE

1.1 This procedure establishes the process to prepare for a Non-Committee Review.

1.2 The process begins when an IRB staff member identifies an application as being possibly eligible for Non-Committee Review.

1.3 The process ends when the IRB staff member provides the materials to the Designated Reviewer.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

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."

4 RESPONSIBILITIES

4.1 IRB staff members carry out these procedures.

5 PROCEDURE

5.1 Refer to "DATABASE: IRB Roster (HRP-601)" 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.

5.2 Use the "Assign Designated Reviewer" activity and select a Designated Reviewer.

5.2.1 If a Designated Reviewer is not available, schedule the protocol to be reviewed by the convened IRB.

5.2.2 Execute the "Assign Designated Reviewer" activity.

5.3 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.

5.4 Execute the "Assign Designated Reviewer" activity to send to the Designated Reviewer when Pre-review is complete.

6 MATERIALS

6.1 DATABASE: IRB Roster (HRP-601)

7 REFERENCES

7.1 21 CFR §56.110(b)

7.2 45 CFR §46.110(b)