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 the “DATABASE: IRB Roster.”

4 RESPONSIBILITIES
   4.1 IRB staff members carry out these procedures.

5 PROCEDURE
   5.1 Refer to the IRB roster 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 Prepare review materials using the “WORKSHEET: Review Materials” that includes all information listed under the columns: “Documents Provided to All IRB Members and Alternate IRB Members,” “Additional Items Provided to Primary Reviewer,” and “Additional Items Provided to Scientific/Scholarly Reviewer.”
   5.3 Add to the review materials:
      5.3.1 CHECKLIST: Non-Committee Review.
   5.4 Add to the review materials based on the likely review category:
      5.4.1 WORKSHEET: Human Research Determination.
      5.4.2 CHECKLIST: Exemption Determination.
      5.4.3 CHECKLIST: Eligibility for Review Using the Expedited Procedure.
   5.5 For modifications required to secure approval add to the review materials:
      5.5.1 Copy of all IRB meeting minutes relevant to the submission.
      5.5.2 Copy of previous “CHECKLIST: Non-Committee Review.”
   5.6 Complete “TEMPLATE LETTER: Designated Reviewer Materials” and send to the Designated Reviewer within three business days of receipt of a complete submission.
   5.7 Follow “SOP: IRB Records.”

6 MATERIALS
   6.1 CHECKLIST: Non-Committee Review
   6.2 CHECKLIST: Exemption Determination
   6.3 CHECKLIST: Eligibility for Review Using the Expedited Procedure
   6.4 SOP: IRB Records
   6.5 TEMPLATE LETTER: Designated Reviewer Materials
   6.6 WORKSHEET: Review Materials
   6.7 WORKSHEET: Human Research Determination

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