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

2 PREVIOUS VERSION
2.1 Revised from previous version dated 11/22/2018

3 POLICY
3.1 Non-Committee Reviews are completed by Designated Reviewers (Experienced IRB Members who have been designated by the IRB Chair to conduct Non-Committee Reviews).
3.2 Designated Reviewers are indicated on the IRB Rosters.
3.3 IRB rosters are maintained using “DATABASE: IRB Roster (HRP-601).”
3.4 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 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 Office staff members carry out these procedures.

5 PROCEDURE
5.1 Prepare materials for Non-Committee Review using the WORKSHEET: Review Materials (HRP-301).
5.2 Complete Pre-Review and execute the Pre-Review activity.
5.3 Refer to “DATABASE: IRB Roster (HRP-601)” and select a Designated Reviewer considering expertise, representative capacity (as needed), and availability.
5.4 Use the “Assign Designated Reviewer” activity and select a Designated Reviewer.
5.5 Execute the “Assign Designated Reviewer” activity to send to the Designated Reviewer.

6 MATERIALS
6.1 SOP: Designated Reviewers (HRP-030)
6.2 WORKSHEET: Review Materials (HRP-301)
6.3 DATABASE: IRB Roster (HRP-601)
6.4 CHECKLIST: Non-Committee Review (HRP-402)

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