1 PURPOSE
1.1 This procedure establishes the process for the HRRC Chair to designate HRRC members who can conduct Non-Committee Reviews and the process for the Institutional Official to appoint HRPO staff as HRRC members eligible, by terms of their appointment, to conduct certain Non-Committee Reviews if also designated by the HRRC Chair. .
1.2 The process begins when the Institutional Official or designee appoints an HRPO staff member to the HRRC. .
1.3 The process ends when the HRRC roster is updated and the HRRC Chair has produced a delegation letter documenting the HRRC member’s eligibility to conduct Non-Committee Reviews.

2 REVISIONS FROM PREVIOUS VERSION
2.1 Correction of spelling and grammatical errors throughout SOP.
2.2 Replaced all references to “IRB” with “HRRC.”
2.3 Section 1, Purpose – Changed authority for this process from HRRC Chair to Institutional Official or designee.
2.4 Section 3, Policy and Section 4, Procedures – Limited Designated Review to HRRC Chair(s) and senior HRPO staff members.
2.5 Section 3, Policy - Updated to describe actions for which senior HRPO staff may act as Designated Reviewer.
2.6 Updated procedures to include electronic management of approved Designated Reviewers.
2.7 Section 1, Purpose – Clarified the role of the HRRC Chair in the designation of a Non-Committee Review candidate.

3 POLICY
3.1 HRRC rosters are maintained using the “DATABASE: HRRC Roster (HRP-601).”
3.2 HRRC Chairs and selected senior HRPO staff members may act as Designated Reviewers.
3.3 Senior HRPO staff may only conduct Non-Committee Reviews if they have (1) been appointed as IRB members by the IO, and (2) designated to conduct Non-Committee Reviews by the HRRC Chair.
3.4 Senior HRPO staff may act as Designated Reviewers in a limited capacity for the following actions:
3.4.1 Reportable new information except in the following categories:
3.4.1.1 Risk: Information that indicates a new or increased risk, or a safety issue.
3.4.1.2 Harm: Any harm experienced by a subject or other individual that, in the opinion of the investigator, is unexpected and at least probably related to the research procedures.

3.4.2 Data Safety Monitoring Reports that contain no safety concerns or recommendations for changes to the study.

3.4.3 Study monitor reports that do not indicate potential serious or continuing non-compliance.

3.4.4 Exempt determinations

3.4.5 Study Closures.

3.4.6 Modifications to research team (study staff) that do not impact the feasibility of the study or the expertise.

3.4.7 Translations of previously approved study documents.

3.5 Any action for which the HRPO senior staff member does not feel adequately qualified to make the determination will be assigned to an HRRC Chair for review and determination.

4 RESPONSIBILITIES

4.1 HRPO staff members carry out these procedures.

5 PROCEDURE

5.1 If a senior HRPO staff member is identified as a Designated Reviewer, follow SOP HRP-082-HRRC Membership Appointment and Terms to appoint the staff member to the HRRC as an alternate member for all committees.

5.2 Update the “DATABASE: HRRC Roster (HRP-601)” to indicate that the HRRC Chair or senior HRPO staff member is a Designated Reviewer. HRPO staff should follow (HRP-082) when the IO appoints a senior HRPO staff member to serve as an alternate HRCC member for all committees.

5.3 Review list of HRRC Chairs and senior HRPO staff members designated to conduct Non-Committee Reviews in the “Assign Designated Reviewer” activity.

5.4 Use the “Update Eligible Designated Reviewers” activity to indicate that the HRRC member is a Designated Reviewer.

6 MATERIALS

6.1 DATABASE: HRRC Roster (HRP-601)

7 REFERENCES

7.1 21 CFR §56.110(b).

7.2 45 CFR §46.110(b).