1 PURPOSE
1.1 This procedure establishes the process for a Designated Reviewer to conduct a Non-Committee Review.
1.2 The process begins when the Designated Reviewer has the provided materials.
1.3 The process ends when the Designated Reviewer completes the review and returns the completed materials to an IRB staff member.

2 REVISIONS FROM PREVIOUS VERSION
2.1 Minor revisions since AAHRPP accreditation; replaces version dated 12/10/2012.
2.2 Minor revisions, replaces version dated 8/19/2015

3 POLICY
3.1 The Designated Reviewer may not disapprove research.

4 RESPONSIBILITIES
4.1 The Designated Reviewer carries out these procedures.

5 PROCEDURE
5.1 Review all materials.
5.2 Determine the required level of review.
5.2.1 Not Human Research. Use the “HRP-310 WORKSHEET: Human Research Determination” to determine whether the activity is Human Research.
5.2.2 Exempt Human Research. Use the “HRP-312 WORKSHEET: Exemption Determination” to determine whether the Human Research meets the exemption criteria and the organization’s ethical requirements.
5.2.3 Human Research approved using the expedited procedure. Use the “HRP-313 CHECKLIST: Expedited Review” to determine whether the Human Research meets the criteria for expedited review.
5.2.3.1 Use the “HRP-314 WORKSHEET: Criteria for Approval” to determine whether the Human Research can be approved.
5.2.4 Human Research that requires review by a convened IRB.
5.3 If consultation is needed follow “SOP: Consultation (HRP-051).”
5.4 Complete the “CHECKLIST: Non-Committee Review (HRP-402).”
5.5 Return all materials and completed checklists to the IRB staff within 5 business days of receipt of materials.

6 MATERIALS
6.1 WORKSHEET: HRP-310 Human Research Determination
6.2 WORKSHEET: HRP-312 Exemption Determination
6.3 CHECKLIST: HRP-313 Expedited Review
6.4 WORKSHEET: HRP-314 Criteria for Approval
6.5 CHECKLIST: HRP-402 Non-Committee Review
6.6 SOP: HRP-051 Consultation

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