1 PURPOSE
1.1 This procedure establishes the process for a Designated Reviewer to conduct an Administrative 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.

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 and complete the corresponding checklist(s) needed to document that review:
   5.2.1 Not Human Research. Use the “WORKSHEET: Human Research Determination” to determine whether the activity is Human Research.
   5.2.2 Exempt Human Research. Use the “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 “CHECKLIST: Eligibility for Review Using the Expedited Procedure” to determine whether the Human Research meets the criteria for expedited review.
   5.2.3.1 Use the “WORKSHEET: Criteria for Approval and Additional Considerations” 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 to the IRB.”
5.4 Complete the “CHECKLIST: Administrative Review” with your determinations.
5.5 Return all materials and completed checklists to the IRB staff within five business days of receipt of materials.

6 MATERIALS
6.1 CHECKLIST: Administrative Review.
6.2 WORKSHEET: Criteria for Approval and Additional Considerations.
6.3 WORKSHEET: Additional Federal Agency Criteria
6.4 WORKSHEET: Exemption Determination.
6.5 WORKSHEET: Human Research Determination.
6.6 WORKSHEET: Expedited Review.
6.7 SOP: Consultation to the IRB.

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