1 PURPOSE
   1.1 This procedure describes the process to handle investigator submissions of modifications required to secure approval.
   1.2 The process begins when modifications required to secure approval are received by the IRB.
   1.3 The process ends when the acceptance or rejection of the modifications is provided to the investigator.

2 REVISIONS FROM PREVIOUS VERSION
   2.1 Minor revisions for AAHRPP accreditation; replaces version dated 09/23/2009.

3 POLICY
   3.1 The IRB reports its findings and actions to the investigator.
   3.2 These reporting procedures are to be completed within ten business days of the IRB Office’s receipt of the investigator’s modifications (which are to be submitted within 90 days of the IRB’s determination that modifications are required to secure approval).

4 RESPONSIBILITIES
   4.1 IRB staff members carry out these procedures.

5 PROCEDURE
   5.1 If the investigator requests a review by the convened IRB, place on the schedule for initial review by a convened IRB and take no further action under this procedure.
   5.2 Otherwise follow “SOP: Administrative Review Preparation.”

6 MATERIALS
   6.1 SOP: Administrative Review Preparation.

7 REFERENCES
   7.1 45 CFR §46.103(b)(4)(i)
   7.2 21 CFR §56.108(a)(1)