1 PURPOSE
1.1 This procedure establishes 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 IRB uses the criteria to approve modifications to previously approved research when the modifications affect one or more criteria.
1.4 The process ends when the acceptance or rejection of the modifications is provided to the investigator.

2 REVISIONS FROM PREVIOUS VERSION
2.1 Updated logo and minor revisions to policy section; replaces version dated 12/27/2012.

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 (10) business days of the IRB Office’s receipt of the investigator’s modifications (which are to be submitted within 30 days of the date of the letter informing the investigator 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 agenda for the next convened IRB meeting with an open agenda and take no further action under this procedure.
5.2 Otherwise follow “SOP: Non-Committee Review Preparation.”

6 MATERIALS
6.1 SOP: Non-Committee Review Preparation

7 REFERENCES
7.1 None