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 an IRB staff member notifies the Designated Reviewer of the review.
1.3 The process ends when the Designated Reviewer notifies an IRB staff member of the completion of the review.

2 REVISIONS FROM PREVIOUS VERSION
2.1 None

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 If the request is a continuing review that meets closure criteria, close the study.
5.3 If the request is for study closure that does not meet closure criteria, communicate with the investigator to explain the issue and offer the opportunity to withdraw or correct the submission.
5.3.1 If the investigator withdraws the submission, stop processing.
5.3.2 If the investigator will not withdraw the submission, the submission requires review by a convened IRB.
5.4 If consultation is needed, follow “SOP: Consultation (HRP-051).”
5.5 Complete the “CHECKLIST: Non-Committee Review (HRP-402)” or equivalent.
5.6 Check the accuracy of “CHECKLIST: Pre-Review (HRP-401)” or equivalent and revise as needed.
5.7 When done, notify the IRB staff and return all hard copy materials.

6 MATERIALS
6.1 CHECKLIST: Pre-Review (HRP-401)
6.2 CHECKLIST: Non-Committee Review (HRP-402)
6.3 SOP: Consultation (HRP-051)

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