1 PURPOSE
1.1 This procedure establishes the process to communicate the review of notifications of emergency uses of test articles in a life-threatening situation.

1.2 The process begins when the Designated Reviewer has notified IRB staff of whether a proposed or actual emergency use of a test article in a life-threatening situation will or has followed FDA regulations.

1.3 The process begins when the IRB staff has communicated the results to the investigator and if necessary initiated the non-compliance process.

2 REVISIONS FROM PREVIOUS VERSION
2.1 Updated logo and date in header.

3 POLICY
3.1 Whenever possible investigators are to notify the IRB of a proposed emergency use of a test article in a life-threatening situation in advance of the use.

4 RESPONSIBILITIES
4.1 The IRB staff carries out these procedures.

5 PROCEDURE
5.1 If the Designated Reviewer has indicated that the proposed use will follow FDA regulations, complete a “TEMPLATE LETTER: Pre-Review of Emergency Use of a Test Article Situation – Criteria Met” and send to the investigator.

5.2 If the Designated Reviewer has indicated that the proposed use will NOT follow FDA regulations, complete a “TEMPLATE LETTER: Pre-Review of Emergency Use of a Test Article Situation – Criteria Not Met” and send to the investigator.

5.3 If the Designated Reviewer has indicated that the actual use followed FDA regulations, complete a “TEMPLATE LETTER: Review of Emergency Use of a Test Article Situation – Criteria Met” and send to the investigator.

5.4 If the Designated Reviewer has indicated that the proposed use did NOT follow FDA regulations:
5.4.1 Complete a “TEMPLATE LETTER: Review of Emergency Use of a Test Article Situation – Criteria Not Met” and send to the investigator.

5.4.2 Manage under “SOP: New Information” as Non-Compliance.

6 MATERIALS
6.1 SOP: New Information
6.2 TEMPLATE LETTER: Pre-Review of Emergency Use of a Test Article – Criteria Met
6.3 TEMPLATE LETTER: Pre-Review of Emergency Use of a Test Article – Criteria Not Met
6.4 TEMPLATE LETTER: Review of Emergency Use of a Test Article – Criteria Met
6.5 TEMPLATE LETTER: Review of Emergency Use of a Test Article – Criteria Not Met
6.6 WORKSHEET: Emergency Use of a Test Article

7 REFERENCES
7.1 21 CFR §50.23; 21 CFR §56.104(c).