1 PURPOSE
   1.1 This procedure establishes the process to review notifications of emergency uses of test articles in a life-threatening situation.
   1.2 The process begins when the IRB receives a notification of a proposed or actual emergency use of a test article in a life-threatening situation.
   1.3 The process ends when a Designated Reviewer has
       1.3.1 Determined whether the proposed or actual emergency use of a test article in a life-threatening situation will or has followed FDA-regulation; and
       1.3.2 Notified the investigator and IRB staff of the determination.

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.
   3.2 Patients receiving a test article in an emergency use as defined by FDA regulations are considered to be subjects in a research study as those terms are defined in “SOP: Definitions” and such are subject to FDA regulations at 21 CFR §50 (Protection of Human Subjects).
   3.3 In order to meet the criteria of for emergency uses of test article, data obtained from such uses cannot be used in a non-exempt systematic investigation designed to develop or contribute to generalizable knowledge.

4 RESPONSIBILITIES
   4.1 A Designated Reviewer carries out these procedures.

5 PROCEDURE
   5.1 For a proposed emergency use of a test article in a life-threatening situation speak with the investigator and use the “WORKSHEET: Emergency Use of a Test Article in a Life-Threatening Situation” to determine whether the circumstances will meet the regulatory criteria.
       5.1.1 If met, remind the investigator that under FDA regulations the Emergency Use of a Test Article in a Life-Threatening Situation is research and the patient is a Human Subject.
       5.1.2 If not met, inform the investigator orally that if the investigator proceeds with the use, the IRB will consider that action to be Non-Compliance.
   5.2 For notifications after the emergency use of a test article in a life-threatening situation use the “WORKSHEET: Emergency Use of a Test Article in a Life-Threatening Situation” to determine whether the circumstances met the regulatory criteria.
   5.3 Inform IRB staff of the results of the evaluation.

6 MATERIALS
   6.1 WORKSHEET: Emergency Use of a Test Article

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