1 PURPOSE

1.1 This procedure establishes the process to review notifications of:
   1.1.1 Emergency use of a drug, biologic, or device in a life-threatening situation.
   1.1.2 Compassionate use of an unapproved device without an IDE for a serious condition.

1.2 The process begins when the IRB receives a notification of a proposed or actual use.

1.3 The process ends when a Designated Reviewer has:
   1.3.1 Determined whether the proposed or actual use will follow or has followed FDA-regulation and guidance; and
   1.3.2 Notified the physician and IRB staff of the determination.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 Whenever possible physicians are to notify the IRB of a proposed emergency use of a drug, biologic, or device in a life-threatening situation in advance of the use.

3.2 Physicians are to notify the IRB of a proposed compassionate use of an unapproved device without an IDE for a serious condition.

3.3 Data obtained from uses covered by this procedure 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 Use the “WORKSHEET: Emergency Use (HRP-322)” to determine whether the circumstances will meet the regulatory and guidance criteria and indicate the results of this determination to the physician.
   5.1.1 If met, inform the physician that the physician can proceed with the use.
   5.1.2 If not met, inform the physician that if the physician proceeds with the use, the IRB will consider that action to be Non-Compliance.
   5.1.2.1 Complete a “TEMPLATE LETTER: Pre-Review of Emergency Use of a Test Article in a Life-Threatening Situation – Criteria Not Met” and send to the investigator.

5.2 For notifications after the emergency use of a test article in a life-threatening situation use the “WORKSHEET: Emergency Use (HRP-322)” to determine whether the circumstances met the regulatory and guidance criteria.

5.3 Inform IRB staff of the results of the evaluation.

6 MATERIALS

6.1 SOP: Definitions (HRP-001)
6.2 WORKSHEET: Emergency Use (HRP-322)
6.3 TEMPLATE LETTER: Pre-Review of Emergency Use - Criteria Not Met (HRP-571)
6.4 TEMPLATE LETTER: Review of Emergency Use - Criteria Met (HRP-572)
6.5 TEMPLATE LETTER: Review of Emergency Use - Criteria Not Met (HRP-573)
6.6 TEMPLATE LETTER: Pre-Review of Emergency Use - Criteria Met (HRP-570)

7 REFERENCES

7.1 21 CFR §50.23; 21 CFR §56.104(c).