

**SOP: Emergency Use Review**

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**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.
- 5.2 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)

**7 REFERENCES**

- 7.1 21 CFR §50.23; 21 CFR §56.104(c).