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1. PURPOSE

- 1.1. This **policy** establishes the process to communicate the determinations related to the review of (1) an **emergency use** of a **test article** in a **life-threatening situation**, or (2) a compassionate use of an unapproved medical device without an **Investigational Device Exemption (IDE)** for a serious condition.

2. POLICY

- 2.1. Whenever possible, **Investigators** must notify the IRB of a proposed emergency use of a drug, biologic, or device in a life-threatening situation in advance of the use.
- 2.2. Investigators must notify the IRB of a proposed compassionate use of an unapproved device without an IDE for a serious condition.
- 2.3. Data obtained from uses covered by this procedure cannot be used for any **research** purposes.
- 2.4. The Investigator must submit a protocol to the IRB as soon as possible and within 30 calendar days of the emergency use so that any future use will have prior review and approval by the IRB.

3. PROCEDURES: Institutional Review Board

- 3.1. The process begins when the **Designated Reviewer** has notified the IRB staff of an actual or proposed emergency use of a test article. The process ends when the IRB staff has communicated the determinations to the Investigator and if applicable, initiated the **non-compliance** process. See *Office of Research Compliance (ORC) Policy and Procedures: Responding to Allegations of Research Non-Compliance*.
- 3.2. For Proposed Emergency Use of a Test Article
 - 3.2.1. If the Designated Reviewer has indicated that the proposed use will follow FDA regulations:
 - 3.2.1.1. A letter using the *TEMPLATE LETTER: Pre-Review of Emergency Use - Criteria Met* is prepared and sent to the Investigator.
 - 3.2.1.2. A 5-day deadline for receipt of the 5-day report is set.
 - 3.2.2. If the Designated Reviewer has indicated that the proposed use will NOT follow FDA regulations, a letter using the *TEMPLATE LETTER: Pre-Review of Emergency Use - Criteria Not Met* is prepared and sent to the Investigator.
- 3.3. For Actual Emergency Use of a Test Article
 - 3.3.1. If the Designated Reviewer has indicated that the actual use followed FDA regulations
 - 3.3.1.1. A letter using the *TEMPLATE LETTER: Review of Emergency Use - Criteria Met* is prepared and sent to the Investigator.
 - 3.3.1.2. For uses of drugs and biologics, a 30-day deadline for receipt of an IRB protocol via the electronic submission portal is set.



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3.3.2. If the Designated Reviewer has indicated that the actual use did NOT meet FDA regulations, this is handled as **non-compliance**:

3.3.2.1. A letter using the *TEMPLATE LETTER: Review of Emergency Use - Criteria Not Met* is prepared and sent to the Investigator.

3.3.2.2. The *ORC Policy and Procedures: Responding to Allegations of Research Non-Compliance* is followed.

4. MATERIALS

- 4.1. Worksheet: Emergency Use
- 4.2. TEMPLATE LETTER: Pre-Review of Emergency Use - Criteria Not Met
- 4.3. TEMPLATE LETTER: Review of Emergency Use - Criteria Met
- 4.4. TEMPLATE LETTER: Review of Emergency Use - Criteria Not Met
- 4.5. TEMPLATE LETTER: Pre-Review of Emergency Use - Criteria Met

5. REFERENCES

- 5.1. ORC Policy and Procedures: Responding to Allegations of Research Non-Compliance
- 5.2. 21 CFR §50.23; 21 CFR §56.104(c)