1 PURPOSE
1.1 This procedure establishes the process to review notifications of emergency uses of test articles in life-threatening situations.
1.2 The process begins when the IRB receives a notification of an emergency use of a test article in a life-threatening situation.
1.3 The process ends when a Designated Reviewer a) determines whether the emergency use of a test article in a life-threatening situation will or has followed FDA-regulation and b) notifies the investigator and IRB staff of the determination.

2 REVISIONS FROM PREVIOUS VERSION
2.1 Minor revisions for AAHRPP accreditation; replaces version dated 09/23/2009.

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 After the emergency use of a test article in a life-threatening situation, investigators are to submit a protocol to the IRB within 30 days.

4 RESPONSIBILITIES
4.1 A Designated Reviewer carries out these procedures.

5 PROCEDURE
5.1 For notifications before the emergency use of a test article in a life-threatening situation, talk with the investigator and use the "WORKSHEET: Emergency Use of a Test Article in a Life-Threatening Situation" to determine whether the circumstances meet the regulatory criteria.
5.1.1 If met:
5.1.1.1 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.
5.1.1.2 Complete a “TEMPLATE LETTER: Pre-Review of Emergency Use of a Test Article in a Life-Threatening Situation – Criteria Met” and send to the investigator.
5.1.1.3 Update iRIS upon receipt of a five day report.
5.1.2 If not met:
5.1.2.1 Inform the investigator orally that if the investigator proceeds with the use, the IRB will consider that action to be Non-Compliance.
5.1.2.2 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 “CHECKLIST: Emergency Use of a Test Article in a Life-Threatening Situation” to determine whether the circumstances meet the regulatory criteria.
5.2.1 If met:
5.2.1.1 Complete a “TEMPLATE LETTER: Review of Emergency Use of a Test Article in a Life-Threatening Situation – Criteria Met” and send to the investigator.
5.2.1.2 Update iRIS to identify need for receipt of a protocol in 30 days.
5.2.2 If not met:
5.2.2.1 Complete a “TEMPLATE LETTER: Review of Emergency Use of a Test Article in a Life-Threatening Situation – Criteria Not Met” and send to the investigator.
5.2.2.2 Copy the IRB staff for management as Non-Compliance.
5.3 Follow the “SOP: IRB Records.”

6 MATERIALS

6.1 WORKSHEET: Emergency Use of a Test Article in a Life-Threatening Situation.


6.5 TEMPLATE LETTER: Review of Emergency Use of a Test Article in a Life-Threatening Situation – Criteria Not Met.

7 REFERENCES

7.1 21 CFR §50.23; 21 CFR §56.104(c)