1. PURPOSE

This procedure describes the process for the review of the emergency use of a test article which includes investigational drugs, agents, biologics, or devices.

2. PROCEDURE

A one-time emergency use of an investigational drug, device, or biologic "test article" by a PI without prior IRB review and approval is permitted under 21 CFR 56.104(c).

When a PI conducts an emergency use of a test article in a life-threatening situation without prior IRB review, the activity is research under FDA regulations and the human subject is a subject under FDA regulations. FDA may require data from an emergency use of a test article in a life-threatening situation to be reported in a marketing application.

Emergency Use: The use of a test article on a human subject in a life-threatening situation in which no standard acceptable treatment is available, and in which there is not sufficient time to obtain IRB approval (21 CFR 56.102(d)).

3. SPECIFIC PROCEDURES

3.1 PI Responsibilities

Whenever possible, PIs are to contact the Avera IRB in advance of the emergency use. In all other circumstances, the PI must submit written certification to the Avera IRB within 5 business days after the use of the test article, unless an Authorization Agreement, or other documentation explaining such an arrangement or documentation that such an arrangement is not required, is already in place with another IRB, per SOP 100.

3.2 IRB Responsibilities

3.2.1 PI contacts IRB in advance

- If the IRB Chair or designee determines that the circumstances meet regulatory criteria, the PI will be notified that they are clear to proceed without IRB review.
- If the IRB Chair or designee determines that the circumstances DO NOT meet regulatory criteria, the PI will be notified in writing and indicate that proceeding with the use of the test article without IRB approval will be non-compliance.

3.2.2 PI contacts IRB within 5 business days after use of the test article (PI was not able to obtain prior approval)

- The IRB Chair or designee will use the "HRP-322 Checklist; Emergency Use" to determine whether the circumstance of the use described in the 5 business day report met regulatory criteria.
    - If the IRB Chair or designee determines that the circumstances met regulatory criteria, the PI will be notified in writing.
    - If the IRB Chair or designee determines that the circumstances DO NOT meet regulatory criteria, the PI will be notified in writing that the use without IRB approval is non-compliance, and refers the matter to the convened IRB for review under the procedure, Protocol Deviations and Non-Compliance, 407-SOP.

4. RESPONSIBILITY

The PI should see if there is an existing Authorization Agreement with another IRB in place for the emergency use IND/IDE, etc.

The IRB Chair or designee is responsible for determining whether the circumstances of the use meet regulatory criteria.

5. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR parts 50 and 56

6. REFERENCED DOCUMENTS

HRP-322 Checklist; Emergency Use

REVISION HISTORY

Revision Number	Version Date	Approved By	Date Approved
2.0	7/03/2019	Avera Institutional Official	8/22/2019
• Added that an IRB designee may also review the submitted emergency use article, not just the IRB Chair. • There may be an Authorization Agreement in place for some specific emergency use IND/IDE, etc., so the PI would not need to submit the activity to the Avera IRB in these situations. • Additional minor administrative edits.			
1.0	August 2016	Director HSRP / August 2016	