TITLE: **Emergency Use of a Test Article**

PURPOSE: Review and communicate determinations regarding notifications of emergency uses of test articles in a life-threatening situation.

RESPONSIBILTIES: Designated Reviewer or Convened IRB

PROCEDURES:

When the HSPP office is notified that there is a proposed emergency use of a test article in a life-threatening situation, HSPP staff ask the investigator to complete the "W317 - Emergency Use of a Test Article in a Life-Threatening Situation" to determine whether the circumstances meet the regulatory criteria.

- If the regulatory criteria **are** met, inform 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.
- If the regulatory criteria **are not** met, verbally inform the investigator that if the investigator proceeds with the use, the IRB will consider that action to be Non-Compliance.

The Director or designee will notify the IRB Chair as soon as reasonably possible after receipt of request for an emergency use. If it is possible to convene a quorum of the IRB to review the emergency use, an IRB meeting will be called as soon as possible. Follow SOP-022: IRB meeting preparation.

If it is not possible to convene a quorum, notify the investigator of such.

Follow SOP-052: Emergency Use of a Test Article – Post Review.

MATERIALS:

- SOP-022: IRB Meeting Preparation
- SOP-052: Emergency Use of a Test Article – Post Review.
- Operations Manual
- W317 - Emergency Use of a Test Article

REFERENCES:

- 21 CFR §50.23; 21 CFR §56.104(c).

REVIEW/REVISIONS: From 10/01/10 version: Incorporated P&P 027 Emergency use of a test article – Post review; Updated based on current practice.

From 01/2014 version: Renumbered from P&P-023; References to P&P-040 and P&P-027 revised to SOP-022 and SOP-052, respectively, to reflect new numbering system.