# Emergency Use of a Test Article Review

| Number: | Date: | Author: | Approved By: | Page(s): |
|---|---|---|---|---|
| UGAHRP-023-2 | 04/19/2017 | HSO | IRB | Page **1** of **3** |

## 1. PURPOSE

1.1. This ***policy*** establishes the process to conduct the review of notifications 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. DEFINITIONS

2.1. ***Emergency use*****:** the use of a test article with 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. See also Section 3.4 below.

2.2. ***Test article:*** any [investigational] drug, biological product, or medical device for human use.

2.3. ***Compassionate use:*** is a provision that allows patients who do not meet the requirements for inclusion in the clinical investigation but for whom the treating physician believes the medical device may provide a benefit in treating and/or diagnosing their serious disease or condition. This provision is typically approved for individual patients but may be approved to treat a small group. Compassionate use is not the same as *off label* use of approved drugs, devices, or biologics. Note: The term *compassionate use* does not appear in the Food and Drug Administration (FDA) regulations, and its use is actively discouraged by the FDA Center for Drug Evaluation and Research (CDER). The term does appear in guidance issued by the FDA Center for Devices and Radiological Health (CDRH).

2.4. ***Off-label use:*** the clinical use of an FDA-approved drug, device or biologic for a purpose or population that has not been approved by the FDA, or in a route or dose that has not been approved by the FDA.

2.5. ***Investigational:*** this means that an item has not been approved by the FDA for marketing in the United States, or that it is being evaluated for a new and not-yet-approved indication, dosage, or formulation.

2.6. ***Investigational Device Exemption (IDE)*****:** an IDE application is the document submitted to the FDA for permission to conduct a clinical study using a significant risk device that is new or not approved for a given use. When the FDA approves an IDE application, it assigns an IDE number to the specific use of the device.

2.7. ***Life-threatening situation:*** for an emergency use of a test article, FDA regulations define this situation to include the scope of both life-threatening and severely debilitating, as defined below.

2.7.1. ***Life-threatening*****:** means diseases or conditions where the likelihood of death is high unless the course of the disease is interrupted and diseases or conditions with potentially fatal outcomes, where the end point of clinical trial analysis is survival. The criteria for life-threatening do not require the condition to be immediately life-threatening or to

immediately result in death. Rather, the subjects must be in a life-threatening situation requiring intervention before review at a convened meeting of the IRB is feasible.

2.7.2. ***Severely debilitating*****:** means diseases or conditions that cause major irreversible morbidity. Examples of severely debilitating conditions include blindness, loss of arm, leg, hand or foot, loss of hearing, paralysis or stroke.

## 3. POLICY

3.1. Whenever possible, ***Investigators*** 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. Investigators are to notify the IRB of a proposed compassionate use of an unapproved device without an IDE for a serious condition.

3.3. The FDA regulations [21 CFR 56.104(c)] allow for one emergency use of a test article without prior review and approval by the IRB. FDA regulations require that any subsequent use of the investigational product at the institution have prospective IRB review and approval. FDA acknowledges, however, that it would be inappropriate to deny emergency treatment to a second individual if the only obstacle is that the IRB has not had sufficient time to convene a meeting to review the issue.

3.4. The use of the test article must be reported to the IRB via the electronic submission portal (include *Emergency Use of Test Article* in title of submission) as soon as possible and absolutely within 5 working days after the use of the test article. An email with *Emergency Use of Test Article* on the Subject Line must be sent to irb@uga.edu to alert the IRB of this submission.

3.5. Data obtained from uses covered by this procedure cannot be used for any ***research*** purposes.

3.6. The FDA regards emergency use of a test article, other than a medical device, as a "clinical investigation" and may require data from an emergency use to be reported in a marketing application. However, DHHS regulations do not permit patient data from emergency use to be classified as human research, nor may the outcome of such care be included in any report of a research activity subject to DHHS regulations. Thus, a patient receiving an emergency use of a test article as defined by FDA regulations is not considered a research participant by DHHS regulation, and such emergency use is not "research" as covered under 45 CFR 46.

3.7. Off-label use for clinical purposes is not regulated by the IRB or the FDA; it is subject only to any policies and procedures of the clinician's institution.

## 4. PROCEDURES: Institutional Review Board

4.1. The process begins when the IRB receives a notification of a proposed or actual emergency use of a test article, and ends when a ***Designated Reviewer*** has determined whether the proposed or actual use will follow or has followed FDA-regulations and the investigator and IRB staff have been notified of the determination.

4.2. For notifications before the emergency use of a test article in a life-threatening situation, the Designated Reviewer uses the *WORKSHEET: Emergency Use* to determine whether the circumstances meet the regulatory criteria.

4.2.1. If met, the Investigator is informed that he/she can proceed with the use. The Investigator must be reminded 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.

4.2.2. If not met, the investigator is informed that he/she proceeds with the use; the IRB will consider that action to be ***Non-Compliance***. See *Office of Research Compliance (ORC) Policy and Procedures: Responding to Allegations of Research Non-Compliance*.

4.3. For notifications after the emergency use of a test article in a life-threatening situation, use the *WORKSHEET: Emergency Use* to determine whether the circumstances met the regulatory and guidance criteria.

4.4. The Designated Reviewer informs the IRB staff of the results of the review.

## 5. MATERIALS

5.1. WORKSHEET: Emergency Use

## 6. REFERENCES

6.1. 21 CFR 56.102; 21 CFR §50.23; 21 CFR §56.104(c)

6.2. ORC Policy and Procedures: Responding to Allegations of Research Non-Compliance

6.3. Guidance on Emergency and Off-Label Use of Drugs, Biologics and Medical Devices