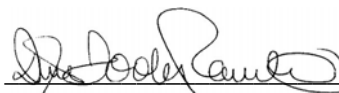


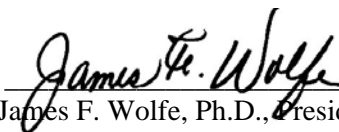
## Edward Via Virginia College of Osteopathic Medicine

Policy Order No. F019v2A2

Effective Date: April 1, 2007



Dixie Tooke-Rawlins, Dean  
And Chief Administrative Officer



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### ADDENDUM TO VCOM IRB POLICY NO. F019v2

#### VCOM Policy on Emergency Use of a Test Article

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#### 1. EMERGENCY USE CRITERIA

Emergency use is defined as the use of an investigational drug or biological product 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 Institutional Review Board (IRB) approval. The emergency use provision is an exemption from prior review and approval by the VCOM IRB. The exemption, which may not be used unless all of the conditions described in 21 CFR 56.102(d) exist, allows for one emergency use of a test article without prospective IRB review. FDA regulations require that any subsequent use of the investigational product at the institution have prospective IRB review and approval.

Each of the following conditions must exist to justify emergency use:

1. The patient is in a life-threatening condition that needs immediate treatment;
2. No generally acceptable alternative for treating the patient is available; and
3. Because of the immediate need to use the device, there is no time to use existing procedures to get FDA approval for the use.

In the event that a device is to be used in circumstances meeting the criteria listed above, the investigator must contact the VCOM Institutional Review Board (IRB) immediately. Notification will be used by the IRB to initiate tracking to ensure that the investigator files a report within the five day time-frame. The FDA regulations do not provide for expedited IRB approval in emergency situations; the VCOM IRB must either convene and give full board approval of the emergency use or, if the conditions of 21 CFR

56.102(d) are met and it is not possible to convene a quorum within the time available, the use may proceed without any IRB approval.

## 2. EXEMPTION FROM INFORMED CONSENT

The purpose of this policy is to assist VCOM's Institutional Review Board (IRB) in governing the emergent use of an investigational drug, device or biologic without informed consent. Such a condition is only allowable when the investigator and an independent physician who is not otherwise participating in the clinical investigation certify in writing the following conditions [21.CFR.50.23(a)]:

- (1) The subject is confronted by a life-threatening situation necessitating the use of the test article.
- (2) Informed consent cannot be obtained because of an inability to communicate with, or obtain legally effective consent from, the subject.
- (3) Time is not sufficient to obtain consent from the subject's legal representative.
- (4) No alternative method of approved or generally recognized therapy is available that provides an equal or greater likelihood of saving the subject's life.

If immediate use of the test article is required to preserve a subject's life, and if time is not sufficient to obtain an independent physician's determination that the four conditions above apply, the investigator should make the determination and, within five working days after the use of the article, have the determination reviewed and evaluated in writing by a physician who is not participating in the investigation. The investigator must notify the IRB within five working days after the use of the test article [21 CFR 50.23(c)]. This report is not considered an approval for the emergency use by the VCOM IRB. The use without prospective IRB approval is not research. It is considered medical treatment and therefore information derived from the emergency use cannot be included in the research data.

## 3. DEFINITIONS

Life threatening includes the scope of both life-threatening and severely debilitating, as defined below.

***Life Threatening:*** Defined as 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.

***Severely Debilitating:*** Defined as diseases or conditions that cause major irreversible morbidity, such as blindness, loss of arm, leg, hand or foot, loss of hearing, paralysis, or stroke.

***Medical Device:*** Defined, in part, as any health care product that does not achieve its primary intended purpose by chemical action or by being metabolized. Medical devices also include diagnostic aids, such as reagents and test kits for in vitro diagnosis.

***Emergency Use:*** Defined as the use of an investigational device with a human subject in a life threatening situation in which no standard acceptable device is available and in which there is not sufficient time to obtain IRB approval. The emergency use provision in the FDA regulations is an exemption from prior review and approval by the IRB and applies to the treatment of one subject. If the investigator anticipates the enrollment of additional subjects in the future, a full protocol must be submitted to the VCOM IRB for review and approval at a convened meeting.