

IRB Policy 20: IRB Emergency Use Policy

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I. Summary Policy

The policy of both the East Tennessee State University Campus Institutional Review Board (ETSU IRB) and the East Tennessee State University/Veterans Affairs Institutional Review Board (ETSU/VA) IRB is that all applicable rules and regulations will be followed in the Emergency Use of a Test Article / Single-Patient Use.

II. Definition

Emergency use is defined as the use of a test article (e.g., investigational drug, device or biologic) 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 for the use. The investigator is still required to obtain consent under these circumstances. The FDA exempts from IRB review the emergency use of a test article so long as the emergency use is reported to the IRB within five working days of its occurrence. Any subsequent use of the test article is subject to IRB review [21 CFR 50.23; 21 CFR 56.104(c)]. When emergency care involves investigational drugs, devices, or biologics, FDA requirements must be satisfied.

III. Emergency Use

When an investigator identifies a need for emergency use of a test article, the following procedures must be implemented:

- The IRB Chair or Vice Chair, or in their absence, a physician member of the IRB should be contacted. If the Chair is not an M.D., the Chair will make immediate contact with a qualified physician who is either 1) a member of the IRB, or 2) referred to the Chair by the member-physician as a qualified consulting-physician for concurrence on the emergency use approval. When the IRB Chair or Director receives a request for emergency use from a clinical investigator, the IRB Chair will examine each case, receive a collaborating statement from a physician associated with neither the patient nor the current attending physician (consult) supporting the emergency use and, upon request, assure the institution

that the emergency use was justified. A copy of the FDA 1572 and approved IND or IDE will be requested of the investigator.

The ETSU/VA IRB Chair will also determine if the research is (or was) not a systematic investigation designed to develop or contribute to generalizable knowledge. The Chair will also determine that unless the criteria for the exception to the requirement for consent are (were) met, consent will be (or was) sought from each prospective participant or the participant's legally authorized representative, in accordance with and to the extent required by FDA regulations and will be appropriately documented, in accordance with and to the extent required by FDA regulations.

- The investigator must report the emergency use of the test article to the IRB within five (5) working days. The ETSU/VA IRB Chair reviews this report using the ETSU/VA Form 100 checklist and determines whether the circumstances of the emergency use complied with regulatory requirements. If the use meets the regulatory requirements, the investigator is notified of this determination by phone and in writing. If the use does not meet the regulatory requirements, the investigator is notified verbally and in writing that if the investigator goes forward with the use, the use will likely be in non-compliance with federal regulations.

IV. Subsequent Use

Any subsequent use of the test article is subject to full IRB review. Subsequent use means any use of the test article that occurs after its initial emergency use. Should the investigator or IRB anticipate a subsequent need to use the test article, a complete formal application must be made for IRB review at a convened meeting.

V. Emergencies for which Informed Consent is not Feasible

In some emergency circumstances, it may not be feasible to obtain informed consent prior to using the test article. The regulations [21 CFR 50.23(a)(1-4) and (b-c)], [.116(d)(3) and .116(d)(4)(f)], therefore provide an exception for informed consent requirements for such situations. Except as stated below, in order for the exception to apply, both the investigator and a physician who is not otherwise participating in the clinical investigation must certify in writing all of the following: (1) the subject is confronted by a life-threatening situation necessitating use of the test article; (2) the subject is unable to provide effective consent; (3) there is insufficient time in which to obtain consent from the subject's legal representative; and (4) there is no available alternative method of approved or

generally recognized therapy that provides an equal or greater likelihood of saving the subject's life.

If, in the investigator's opinion, immediate use of the test article is necessary to save the life of the subject and there is insufficient time to obtain the independent certification required before using the test article, the investigator is to make his or her own written determinations as outlined above, and within five (5) working days after the use of the test article, obtain the written review and evaluation of a physician who is not participating in the clinical investigation.

- Documentation, in both instances, must be submitted to the IRB Coordinator within (5) working days after the use of the test article. The ETSU/VA IRB Chair reviews this report using the ETSU/VA Form 100 checklist and determines whether the use of the exception for informed consent requirements complied with regulatory requirements. If the use meets the regulatory requirements, the investigator is notified of this determination in writing. If the use does not meet the regulatory requirements, the use is handled according to the IRB non-compliance policy.

VI. Regulations

When there is an emergency use of an investigational drug, the FDA considers the use to be a clinical investigation and the patient to be a subject. However, under DHHS or VA regulations this emergency use is not considered to be research and the patient is not a subject. Therefore, the outcome such care or data analysis may not be included in any report of a research activity subject to DHHS or VA regulations pertaining to research involving human subjects. Neither the FDA nor the DHHS or VA considers the emergency use an investigational device to be research or a clinical investigation and the patient is not a subject.

References:

21 CFR 56.101 (d)

45 CFR 46.103(b)

45 CFR 46. 116 (f)

OHRP Guidance

OHRP Compliance Activities: Common Findings and Guidance