

I7 PR1 Emergency Use of an Investigational Drug or Device

Overview

Clinicians should follow the procedures noted below when seeking to use an investigational drug or device in a therapeutic or diagnostic manner in an emergency.

Note: Emergency use of a test article, as defined by FDA regulations, is not considered research under DHHS nor VA regulations and the outcome of such care may not be included in any report of a research activity subject to DHHS nor VA regulations.

I7A Emergency Use of Investigational Drugs

The emergency use of an investigational drug requires an IND unless the intended patient does not meet the criteria of an existing study protocol, or if an approved study protocol does not exist. In such cases, the clinician will need to contact the manufacturer to determine if the drug can be made available for the emergency use under the company's IND. If circumstances do not allow time for an IND submission, the FDA may authorize use of the drug in advance of the IND submission. A clinician's request for FDA authorization may be transmitted to FDA by telephone or other rapid communication means (21 CFR 312.36).

Requirements for IRB Consideration of Emergency Use of IND

The clinician presents the following information to the Chair of the University Biomedical IRB for the single use of an investigational drug:

- assurance from the prescribing clinician that this use is NOT part of a project that is currently awaiting IRB approval;
- assurance that the use of the drug(s) or biologic is primarily to treat a patient with a specific, clinically urgent condition, and that the patient is not a research subject;
- brief written statement explaining the rationale for the use of the investigational drug;
- a copy of the consent form that will be used by the prescribing clinician to obtain informed consent from the patient or the patient's legally authorized representative or surrogate; and
- a formal statement that the prescribing clinician has received from the manufacturer (or distributor) of the investigational drug approval for its use for the purpose outlined in the consent document.

Exemption from Prospective IRB Approval

In order to use a test article in a life threatening situation without prior IRB review, the following criteria must be met:

- The subject is in a life-threatening or severely debilitating situation.
- No standard acceptable treatment is available.
- There is not sufficient time to obtain IRB approval.
- The use is reported to the IRB or EC within five working days.
- Any subsequent use* of the test article is subject to IRB review.

Note: The IRB can determine 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.

Informed Consent Requirements

Standard requirements for informed consent apply to emergency research (i.e., informed consent will be obtained from subjects or patients, or a legally responsible representative and documented unless the requirement for signed consent is waived) with the exception described below.

Both the investigator and a physician who is not otherwise participating in the clinical investigation must certify in writing all of the following:

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

Within five working days after the use of the test article, a physician who is not otherwise participating in the clinical investigation must certify in writing that the conditions listed below applied to the emergency use.

- The subject is confronted by a life-threatening situation necessitating the use of the test article.
- Informed consent cannot be obtained from the subject because of an inability to communicate with, or obtain legally effective consent from, the subject.
- Time is not sufficient to obtain consent from the subject's legal representative.

- There is available no alternative method of approved or generally recognized therapy that provides an equal or greater likelihood of saving the life of the subject.

The external physician's written certification must be submitted to the IRB within five working days after the use of the test article.

The Chair or Vice Chair of the Biomedical IRB will review the exceptions to the requirement to obtain consent and the five-day report of the emergency use to determine whether the circumstances met FDA regulations.

I7B Emergency Use of Unapproved Devices

Emergencies may arise where an unapproved device may offer the only possible lifesaving alternative, but an Investigational Device Exemption (IDE) for the device does not exist, or the proposed use is not approved under an existing IDE, or the clinician or institution is not approved under the IDE.

The clinician may use an unapproved device to treat a patient under the following conditions:

- The patient is faced with a seriously debilitating or an immediate life-threatening situation or disease.
- No generally acceptable alternative for treatment or diagnosis is available.
- The immediate need to use the device precludes the use of existing of procedures to get FDA approval for the emergency.

The clinician must also assess the potential for benefits from the unapproved use of the device, and have substantial reason to believe that benefits will exist.

The clinician must follow as many subject protection procedures as possible including:

- obtaining an independent assessment by an uninvolved physician;
- obtaining informed consent from the patient or her or his legally authorized representative or surrogate;
- notifying the Institutional Review Board (IRB) and obtaining the IRB Chair's concurrence; and
- obtaining authorization from the IDE holder, if an approved IDE for the device exists.

Prior approval for shipment or emergency use of an investigational device is not required, but within five working days from the time the sponsor holding the IDE learns of the emergency use, the sponsor must provide FDA with a written summary of the conditions constituting the emergency, subject protection measures used, and results of the use. If no IDE exists, the physician must report the emergency use to the FDA.