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Subject: Types of IRB Review
Division: IRB
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IRB Policy 105.3: EMERGENCY USE OF AN INVESTIGATIONAL ARTICLE

Policy

The IRB acknowledges that there are rare circumstances in which the normal review process must be circumvented. These are instances where unforeseeable urgent clinical needs or opportunities in individual patients require immediate action. A request for emergency approval may be made by calling the IRB office.

The attending physician must discuss the request for emergency use with FRI's Medical Director. The attending physician is the individual who will be held responsible for fulfilling the requirements for follow-up reporting to the IRB.

An investigational article may be used in an emergency prior to IRB review, provided that the patient is 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. Such emergency use must be reported to the IRB within 5 working days, and any subsequent use of the test article is subject to prior review (21 CFR 56.104 (c).

The emergency use provision of the FDA regulations is an exemption from prior review and approval by the IRB and allows for one emergency use of an investigational drug or biologic product without prospective IRB review.

Informed Consent for Emergency Use

Even for an emergency use, the investigator is required to obtain informed consent of the subject or the subject's legally authorized representative unless both the investigator and a physician who is not otherwise participating in the clinical investigation certify in writing all of the following (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, in the investigator's opinion, immediate use of the test article is required to preserve the subject's life, and if time is not sufficient to obtain an independent physician's determination that the four conditions

above apply, the clinical investigator should make the determination and, within 5 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 clinical investigation. In this event, a copy of the independent review must be submitted to the IRB within 5 working days after the use of the test article.

Responsibility

The responsibilities, which accompany use of an investigational drug or device on an emergency basis include the following:

1. An investigational drug or device can only be dispensed on an FDA-approved protocol, held either by a sponsor or an individual physician. If a sponsor is willing to allow a physician to use an investigational drug or device on an emergency basis via their FDA-approved protocol, the sponsor still requires approval from an IRB. Agreement by the sponsor to ship a drug is usually accompanied by paperwork detailing the justification for use of the drug and outlining reporting requirements after the patient has been treated.

2. The IRB Chairperson or designee (using consultants as appropriate, such as FRI's Medical Director) may issue a letter acknowledging notification of emergency use of the test article, on a case-by-case basis. The investigator should generate a letter to the IRB Chairperson describing the emergency-use situation, documenting compliance with the specific FDA requirements for emergency use. The notification to the IRB must occur prior to or within five days of use of the test article. The IRB Chairperson or designee will review the letter and confirm that an emergency situation exists and there is not sufficient time to convene a full-board IRB meeting. A written report is to be submitted for full IRB information within 10 working days of the Emergency Request. Acknowledgement by the IRB Chairperson should not be construed as IRB approval. Its purpose is to initiate a follow up file to ensure that the required notification/report is submitted.

3. The patient must understand the investigational nature of the test article. Informed consent must be obtained; however, the consent form is not a standard research consent form. In most cases, the sponsor will supply a consent form. The IRB is not involved in the review or approval of the consent form if the situation meets the criteria for emergency use.

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DHHS Regulations

DHHS does not provide for an emergency exception to IRB review. Whenever emergency care is initiated without prior review and approval, the patient may *not* be considered to be a research subject. HHS regulations do not permit research activities to be started, even in an emergency, without prior IRB review and approval.

For DHHS-supported or conducted research, the physician may, without prior IRB approval, treat the patient/subject using a test article (if the situation meets the FDA requirements), but the subject may not be considered a research subject and data derived from use of the test article may not be used in the study. The FDA does allow the data from an emergency-use situation to be used as part of a research study.

Applicable Regulations and Guidelines

21 CFR 56.102(d)
21 CFR 56.104(c)
21 CFR 50.23(a)
21 CFR 50.23(c)
FDA Guidance: Emergency Use of an Investigational Drug or Biologic - Information Sheet