

**Nova Southeastern University
Institutional Review Board
Policies and Procedures**

Emergency Use of Unapproved Medical Devices

Effective: 10/14/2010, 09/16/2011

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Purpose:

To establish policy that addresses the use of unapproved medical devices.

Definitions:

1. Unapproved medical device means a device that is used for a purpose or condition for which the device requires, but does not have, an approved application for premarket approval under section 515 of the Federal Food, Drug, and Cosmetic Act.

Policy:

An unapproved device may be used in human subjects only if it is approved for clinical testing under an approved application for an Investigational Device Exemption (IDE) under section 520(g) of the Act (*21 U.S.C. 360(i)(g)* and *21 CFR part 812*). Medical devices that have not received marketing clearance under section 510(k) of the FD&C Act are also considered unapproved devices which require an IDE.

The Food and Drug Administration (FDA) recognizes that emergencies arise where an unapproved device may offer the only possible life-saving alternative, but an IDE for the device does not exist, or the proposed use is not approved under an existing IDE, or the physician or institution is not approved under the IDE. Using its enforcement discretion, FDA has not objected if a physician chooses to use an unapproved device in such an emergency, provided that the physician later justifies to FDA that an emergency actually existed.

Each of the following conditions must exist to justify emergency use of an unapproved medical device:

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

FDA expects the physician to determine whether these criteria have been met, to assess the potential for benefits from the unapproved use of the device, and to have substantial reason to believe that benefits will exist. The physician may not conclude that an “emergency” exists in advance of the time when treatment may be needed based solely on the expectation that IDE approval procedures may require more time than is available. Physicians should be aware that FDA expects them to exercise reasonable foresight with respect to potential emergencies and to make appropriate arrangements under the IDE procedures far enough in advance to avoid creating a situation in which such arrangements are impracticable.

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In the event that a device is to be used in circumstances meeting the criteria listed above, the device developer should notify the Center for Devices and Radiological Health (CDRH) Program Operation Staff by telephone (301-594-1190) immediately after shipment is made. [**Note** - an unapproved device may not be shipped in anticipation of an emergency.] Nights and weekends, contact the FDA Office of Emergency Operations (HFA 614) 301-443-1240.

FDA expects physicians to follow as many subject protection procedures as possible. These include:

- obtaining an independent assessment by an uninvolved physician
- obtaining informed consent from the patient or a legal representative
- notifying institutional officials as specified by institutional policies
- notifying the Institutional Review Board (IRB) and
- obtaining authorization from the IDE holder if an approved IDE for the device exists

IRB Requirements

FDA regulations and NSU IRB policy permit an exception to the requirement for prior IRB review and approval for purposes of “emergency use” if all the following conditions are met:

- It is the use of a test article;
- On a human subject in a life-threatening situation;
- No standard acceptable treatment is available; AND
- There is not sufficient time to obtain IRB approval

This exemption is allowed only for a **one-time institutional use** of a test article without prospective IRB review. Any subsequent use of the investigational product must have prospective IRB review and approval. If there is uncertainty as to whether emergency use of a particular investigational drug or device has occurred at NSU, or at another facility by an NSU student or staff member, relevant information should be sought from the NSU IRB office prior to the “emergency use.”

If possible prior to an “emergency use”, the physician seeking to provide the life-saving treatment should notify the NSU IRB of this intent by any available means.

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This notification must include, and be in writing:

- A description of the circumstances that warrant the administration of a test article without IRB approval.
- A statement that the subject is confronted with a life-threatening situation that requires immediate medical intervention before the IRB can be convened
- Confirmation that no alternative method of approved or generally recognized therapy is available to provide an equal or greater likelihood of saving the subject's life.
- A description of how the test article will be used.
- A copy of the informed consent document to be used; or

A statement that the informed consent document cannot be obtained because of difficulty in communication with the subject and/or insufficient time to contact the subject's legal representative. Both the primary physician and a physician who is **not participating** in the clinical administration of the test article must sign this document.

The IRB office shall forward the physician's notification to the IRB chair or designee who will review the circumstances of the "emergency use" to verify whether it meets the conditions of the federal regulation and he/she, or the IRB office, shall so notify the physician in writing either by postal mail, electronic mail, or interoffice mail of the results of that review. This notification should not be construed as IRB approval. Rather, the IRB office shall use this prior report to initiate tracking to ensure that the investigator files a report within the five day time-frame required by federal regulation and this policy. A copy of this report shall also be provided to the signatory official (VP for Institutional Effectiveness) and the director of clinical operations.

Physicians authorizing the "emergency use" of the test article should follow as many subject protection procedures as possible including:

- Obtaining an independent assessment by an uninvolved physician
- Obtaining authorization from the IND/IDE holder (as appropriate)
- Notifying institutional officials as specified by clinical/institutional policies
- Obtaining informed consent from the patient or a legal representative
- Notifying the IRB

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Within five (5) working days following the emergency use of a test article, the physician must notify the IRB in writing of the emergency use of a test article pursuant to FDA regulations at *21 CFR 56.104(c)*. This report should include an explanation of the use, how and when the use took place, and justification based on FDA criteria for “emergency use” including why prospective IRB review was not possible, the informed consent process, and, if applicable, how IND/IDE requirements were met. This report should include a copy of the properly executed (signed) informed consent document or a statement that informed consent document could not be obtained because of difficulty in communication with the patient and/or insufficient time to contact the patient’s legal representative. The report should also include follow-up information on the condition of the patient in the days after the test article has been administered. The report is to be submitted in writing and must include a copy of the consent form that was (or is about to be) signed by the subject or the subject’s authorized representative.

If further uses of a test article are anticipated, a study application must be submitted for review and approval by the convened IRB in addition to the submission of the 5-day report. Subsequent use of the test article is contingent upon this IRB approval and an FDA-approved IND/IDE.

There are two options available to applications for further uses of a test article.

- Not collecting data for research: If the test article use does not include collecting data for research purposes, a treatment IND/IDE should be obtained from the FDA and a corresponding study application should be submitted for IRB approval. IRB approval is **required** for the use of a treatment IND even if the use does not involve research.
- Collecting data for research: if research data is collected pursuant to the use of the test article, a research IND/IDE should be obtained from the FDA and a corresponding study application should be submitted for IRB approval.

Note - FDA acknowledges that it would be inappropriate to deny emergency use of an investigational drug or biologic considered necessary for the treatment of a second individual if the use was unexpected and the only obstacle is that the IRB has not had sufficient time to convene a meeting to review the issue. Subsequent emergency use the unapproved article may not occur unless the physician or another person obtains approval of an IND/IDE. If the application for subsequent is disapproved by the FDA, the article may not be used even if the circumstances constituting an emergency exist. Manufacturers or developers of investigational articles that could be used in emergencies should anticipate the likelihood of emergency use and should obtain an IND/IDE for such uses.

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FDA regulations do not permit expedited IRB approval in emergency situations and terms such as “interim,” “compassionate,” or “temporary,” may not be used to authorize an expedited approval process. IRB approval of an emergency use requires review by the convened panel or, if the conditions outlined above are met and it is not possible to convene a quorum within the time available, the emergency use may proceed without an IRB approval (providing all requirements are met).

Exception From Informed Consent Requirement

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:

- (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. The investigator must notify the IRB within 5 working days after the use of the test article.

Exception from Informed Consent for Planned Emergency Research

The conduct of planned research in life-threatening emergent situations where obtaining prospective informed consent has been waived, is provided by federal regulation. The research plan must be approved in advance by FDA and the IRB, and publicly disclosed to the community in which the research will be conducted. Such studies are usually not eligible for the emergency approvals described above. The information sheet "Exception from Informed Consent for Studies Conducted in Emergency Settings: Regulatory Language and Excerpts from Preamble," is a compilation of the wording of 21 CFR 50.24 and pertinent portions of the preamble from the October 2, 1996 Federal Register.

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References:

45 CFR 46.101(b)
45 CFR 46.110(a – c)
21 CFR 50.23(a)
21 CFR 50.23(c)
21 CFR 50.24
21 CFR 56.104(c)
21 CFR 56.108(a)(1) and 56.110(a - c)
21 CFR 56.111
21 U.S.C. 360(e)

Procedures:

1. Prior Use Procedure

If possible, the physician who will be using the unapproved device should notify the IRB office that an emergency use of an unapproved device has occurred or will occur. Notification does not constitute IRB approval and notification initiates tracking to insure that the investigator files a report within the five day time frame noted in #2 of this section.

2. After-use Procedures

After an unapproved device is used in an emergency, the physician must:

A. Report to the IRB within five days and otherwise comply with provisions of the IRB regulations. That report is to be made in writing to the IRB office and is to include the items listed in 1C. If immediate use of the test article was required to preserve the subject's life, and if time was not sufficient to obtain an independent physician's determination that (a) the subject was confronted by a life-threatening situation necessitating the use of the test article; (b) informed consent could not be obtained because of an inability to communicate with, or obtain legally effective consent from, the subject; (c) time was not sufficient to obtain consent from the subject's legal representative; and (d) no alternative method of approved or generally recognized therapy was available that could provide an equal or greater likelihood of saving the subject's life; then the investigator must secure within 5 working days after use of the test article the determination and evaluation by an independent physician of items a-d. Once that report is secured it must also be transmitted to the IRB office. A copy of this report shall also be provided to the signatory official (VP for Institutional Effectiveness) and the director of clinical operations. Hardcopy records of the report and any additional documentation will be retained by the IRB office.

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- B. Evaluate the likelihood of a similar need for the device occurring again, and if future use is likely, immediately initiate efforts to obtain IRB approval and an approved IDE for the device's subsequent use; and
- C. If an IDE for the use does exist, notify the sponsor of the emergency use, or if an IDE does not exist, notify FDA of the emergency use (CDRH Program Operation Staff 301-796-5640) and provide FDA with a written summary of the conditions constituting the emergency, subject protection measures, and results.

Subsequent emergency use of the device may not occur unless the physician or another person obtains approval of an IDE for the device and its use. If an IDE application for subsequent use has been filed with FDA and FDA disapproves the IDE application, the device may not be used even if the circumstances constituting an emergency exist. Developers of devices that could be used in emergencies should anticipate the likelihood of emergency use and should obtain an approved IDE for such uses.

The Office for Human Research Protections does not permit patients to be considered research subjects without prior IRB review and approval. Emergency care may not be claimed as research, nor may the outcome of such care be included in any report of a research activity.

- 3. The after-use report will be provided to the IRB at its next convened meeting after submission of the report. The IRB will report its review of the after-use report in the minutes of the convened meeting as well as in writing either electronically or via hardcopy to the principal investigator.