

EMERGENCY USE OF UNAPPROVED MEDICAL DEVICES

(From FDA Information Sheets)

For the purpose of this information sheet, an unapproved medical device is defined as 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 [21 U.S.C. 360(e)]. 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(j)(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.

Requirements for Emergency Use

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.

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.

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-615) 301-443-1240.

FDA would expect the physician to follow as many subject protection procedures as possible. These include:

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

After-use Procedures

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

1. report to the IRB within five days [21 CFR 56.104(c)] and otherwise comply with provisions of the IRB regulations [21 CFR part 56];
2. 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
3. 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 301-594-1190) 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.

NOTE: The National Institutes of Health's Office For Human Research Protections (OHRP) 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.

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 [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. The investigator must notify the IRB within 5 working days after the use of the test article [21 CFR 50.23(c)]. **The documentation of this determination shall be submitted to the IRB within 5 working days after the use of the test article [21 CFR 50.23(c)].**

Notification/Reporting to Upstate IRB:

1. If possible, the physician who will be using the unapproved device should notify the IRB Chairperson that an Emergency Use of an unapproved medical device has occurred or will occur.

(a) Notification does **not** constitute IRB approval.

(b) Notification initiates tracking to insure that the investigator files a report within the 5-day time frame required by 21 CFR 56.104(c).

2. **Within 5 working days**, the emergency use must be reported to the IRB.

- a. The *Emergency Use Report Form* (available on IRBNet) may be used to fulfill this requirement.
- b. A copy of the completed consent form or a copy of the written determination/certification required for exception from informed consent (described above).