

Department: UAMS Institutional Review Board
Policy Number: 18.4
Section: Drugs and Devices
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SUBJECT: Emergency Use of an Unapproved Medical Device (Source *FDA Information Sheets Guidance for Institutional Review Boards and Clinical Investigators 1998 Update*)

An unapproved medical 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 520g of the Federal Food, Drug, and Cosmetic Act [21USC360(j,g) and 21CFR812;]. Medical devices that have not received marketing clearance under section 510k of the FD&C Act are also considered unapproved devices that 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.

Unapproved Medical Device. An unapproved medical device is 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 [21USC360(e)].

FDA Requirements for Emergency Use of Devices. 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 (Sponsor or Manufacturer) 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 Division of Emergency and Epidemiological Operations (202-857-8400).

FDA expects 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.

The physician's letter to the IRB should include the following information:

- Diagnosis
- Proposed treatment
- Date of treatment
- Drug or device names, if applicable
- Patient's name and age
- Hospital number
- Hospital name
- Date of verbal approval
- A copy of the signed consent form

After-use Procedures. After an unapproved device is used in an emergency, the physician should:

1. Report to the UAMS IRB within five days [21 CFR 56.104(c); 45 CFR] and otherwise comply with provisions of the IRB regulations (21 CFR part 56; 45 CFR 46);
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, the physician should notify the sponsor of the emergency use, or if an IDE does not exist, notify the 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. The physician should also immediately inform the IRB Chair who will refer the matter to the Office of Research Compliance.

The physician should inform the IRB prior to emergency use when possible or as soon as practical thereafter. However, this notification should not be construed as an IRB approval. Notification will be used by the IRB to initiate tracking to ensure that the investigator files a report within the five day time-frame required by 21 CFR 56.104c; 45 CFR. 46. The documentation required shall be submitted to the IRB within 5 working days after the use of the test article. (21 CFR 50.23(c)).

Neither the common rule or the FDA regulations provide for expedited IRB approval in emergency situations. Therefore “interim”, “compassionate”, “temporary” or other terms for an expedited approval process are not authorized. The IRB must either convene and give “full board” approval of the emergency use or, if it is not possible to convene a quorum with the time available, the use may proceed without IRB Approval. When this situation exists, the IRB may issue an acknowledgement letter that they have been made aware of the use.

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.

Exception for Informed Consent during Emergency Use of an unapproved device. 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 requirements of exception for consent in emergency research detailed in section 15.2 of this manual.

If immediate use of the test article is, in the investigator's opinion, required to preserve the life of the subject, and time is not sufficient to obtain the independent physician's determination that the four conditions above apply, the physician should make the determination and in within 5 working days after the use of the article, have the determination reviewed and evaluated in writing who is not participating in the clinical investigations. Data From emergency use of a test article should not be used as research.