Issuing Department: Human Subjects Protection Office
Policy Number: 2011-021.1
Policy Title: Investigational Device –Single Emergency Use

Purpose

The purpose of this policy is to set forth the requirements that Principal Investigators (PI), sponsors and Institutional Review Boards (IRB) must fulfill when using investigational devices in a therapeutic manner in an unplanned emergency situation.

Definitions

See policy 2011-007.0 for definitions of the following terms:

Device, Investigational Legally Authorized Representative	Emergency Use	Immediate Life-threatening Disease

Policy

Treatment use of an investigational device includes the use of a device for diagnostic purposes. An individual treated through emergency use is considered a research subject as defined in Food and Drug Administration (FDA) regulations, but may not be considered a research subjects as defined in Department of Health and Human Services regulations unless IRB approval is obtained prior to the use.

In order to use a test article for emergency treatment without prior IRB approval, and when there is not time to obtain such approval, each of the following conditions must exist:

- the patient is faced with a an immediate life-threatening condition or disease ;
- 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.

The physician must determine whether these criteria have been met, assess the potential for benefits from the unapproved use of the device, and 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. In the event that an investigational device is to be used in this situation the device developer should notify the Center for Devices and Radiological Health (CDRH), Program Operation Staff by telephone (301-796-5640) immediately after shipment is made. Nights and weekends contact the FDA Office of Emergency Operation s (HFA-615)301-443-1240

The physician 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 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.

If possible, a prospective review from the IRB Chair determining the single emergency use complies with the FDA regulations allowing an exemption from the requirement of IRB review should be sought.

Subsequent emergency use of the device should 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.

Consent: Consent will be obtained in accordance with FDA regulations, unless the circumstances meet the exception to the requirement for consent in FDA regulations.

Unless exemption criteria are met, informed consent will be sought from each prospective participant or the participant's legally authorized representative, in accordance with and to the extent required by 21 CFR 50 and consent will be documented in accordance with and to the extent required by 21 CFR 50.27.

Criteria for exceptions are as follows: both the investigator and a physician who is not otherwise participating in the clinical investigation certify in writing all of the following:

- the subject 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 legally authorized representative, and
- 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 regarding consent have been met, 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 treating clinician must notify the IRB within 5 working days after the use of the test article.

Procedure

If possible (i.e. time permits), the PI is to request a prospective review from the IRB Chair to determine that the single emergency use complies with the FDA regulations allowing an exemption from the requirement of IRB review. The material submitted to the Chair from the PI is to include:

- assurance from the prescribing person that the use is NOT part of a project that is currently awaiting IRB approval;
- that the use of the device is to treat/diagnose a patient with a seriously debilitating or immediate life-threatening condition or disease
- assurance that there is no generally acceptable alternative for treating/diagnosing the subject available

- a written statement explaining the rationale for the use of the investigational device(e.g. reason to believe there will be benefit from use of the device); and
- a copy of the consent form that will be used

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

- report to the IRB Chair within five days and otherwise comply with provisions of the IRB regulations;
- 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
- 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 (Center for Devices and Radiological Health Program Operation Staff 301-594-1190) and provide FDA with a written summary of the conditions constituting the emergency, subject protection measures, and results.

If consent cannot be obtained prior to the emergency use both the investigator and a physician who is not otherwise participating in the clinical investigation must certify in writing to the IRB Chair that the four conditions for not obtaining consent noted above in the policy section have been satisfied. 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 have been met, 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 and submit the material to the IRB Chair.

After review, the IRB Chair will submit a letter to the prescribing clinician, indicating that the clinician has complied with the internal policy and FDA regulations regarding the emergency treatment use of an investigational device. Designated IRB staff will also place a copy of the letter in the IRB Office files for emergency use.

- If in the course of conducting a retrospective review the Chair determines that the investigator was not compliant with policy and regulations, the matter will be considered an instance serious non-compliance. The Chair will inform the investigator and the DHSPO via letter and the DHSPO will follow through with reporting to institutional officials and external agencies.

Related Policies

2009-002 – Reporting Non-compliance to the IRB
2009-004 – Reporting Non-compliance to Institutional Officials and External Agencies
2011-007.0 – Definitions Applied to Policy
2011-008.5 – Informed Consent – Obtaining and Providing

Basis

21 CFR 812
FDA Information Sheet Guidance for IRBs, Clinical Investigators, and Sponsors: Frequently Asked Questions About Medical Devices (available at http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM127067.pdf)

Document Attributes

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Reviewed and Approved By:

Signed Richard Simon **8/20/2013**

Richard Simon, MD **Date:**

Director Human Subjects Protection Office