**IDE Early/Expanded Access for Medical Devices**

*Information contained in FDA Guidance*

An unapproved medical device may normally only be used on human subjects through an approved clinical study. However, there may be circumstances in which a physician may wish to use an unapproved device on a patient with a life-threatening condition or to help a patient suffering from a serious disease or condition for which no alternative therapy exists. Under these circumstances there are four main mechanisms in which the FDA may make an unapproved device available to patients/physicians.

•Emergency Use

•Compassionate Use (or Single Patient/Small Group Access)

•Treatment Use

•Continued Access

This document will focus on the 2 most common types: Emergency Use and Compassionate Use

**What is Emergency Use?**

Emergency situations may arise in which there will be a need to use an investigational device in a manner inconsistent with the approved investigational plan or by a physician who is not part of the clinical study. Emergency use of an unapproved device may occur before an FDA IDE application is approved. The sponsor must notify the FDA of the emergency use **within 5 days** through a submission of an Investigational Device Exemption (IDE) report describing the details of the case and the patient protection measures that were followed. The local IRB must also be notified within 5 days.

Criteria:

* Life-threatening or serious disease or condition
* No alternative
* No time to obtain FDA approval

A device can be used in an emergency situation when:

* There is no Investigational Device Exemption (IDE)
* Physician wants to use the device in a way not approved under an existing IDE
* A physician is not part of the IDE study

**What is Compassionate Use (Single Patient) Access?**

The compassionate use provision allows access for patients who do not meet the requirements for inclusion in the clinical investigation but for whom the treating physician believes the device may provide a benefit in treating and/or diagnosing their disease or condition. This provision is typically approved for individual patients but may be approved to treat a small group.

Criteria:

* Serious disease or condition
* No alternative

Time-frame:

* FDA recognizes that there are circumstances in which an investigational device is the only option available for a patient faced with a serious, albeit not life-threatening, disease or condition. In these circumstances, FDA uses its regulatory discretion in determining whether such use of an investigational device should occur.
* Prior FDA approval is needed before compassionate use occurs. In order to obtain Agency approval, the sponsor should submit an IDE supplement requesting approval for a compassionate use under section §812.35(a) in order to treat the patient.
* The physician should not treat the patient identified in the supplement until FDA approves use of the device under the proposed circumstances. In reviewing this type of request, FDA will consider the above information as well as whether the preliminary evidence of safety and effectiveness justifies such use and whether such use would interfere with the conduct of a clinical trial to support marketing approval.

**3). What is Required for Submission of Expanded Access Use of Medical Devices (UNC Investigator Request).**

* Physician must contact device manufacturer/distributor of the device for permission to access device on behalf of their patient. If the manufacturer/distributor has filing at the FDA, they will need to file UNC physician request as a supplement to their file at FDA. Device manufacturer/distributor will need to give UNC physician a letter of authorization to access their FDA file on behalf of the UNC investigator. Unless otherwise specified by the device manufacturer/distributor the UNC will be the sponsor of the IDE request they submit to the FDA.

Emergency Use: If an IDE exists, the sponsor (holder) of the IDE will report emergency use to the FDA. Investigator will need to check with sponsor as to what information will be required from them

* Physician will need to check with UNC Office of Clinical Trials (OCT) to ensure there is a master agreement in place with the company providing the product. If one does not exist, the investigator will need to request a Confidentiality Disclosure Agreement (CDA) from the company. OCT can assist with this. The CDA allows the physician to receive confidential information (Investigator Brochure, safety language, etc.) from the company. Contact OCT at 919-843-2698
* UNC IRB review is required for **all** expanded use requests. If physician is submitting a non-emergency request, prospective IRB review is required before patient can be treated. Unless otherwise specified, patient or patient’s legal authorized representative will be required to sign informed consent for treatment.
* If not Emergency Use, the IRB and FDA IDE application can be submitted in tandem. However, the UNC IRB will not give final approval until the FDA clears the request.
* Submission to the FDA should include the following (physician should contact the FDA before sending request to ensure they have provided all materials, as some divisions may require more information):
	+ A description of the patient's condition and the circumstances necessitating treatment
	+ A discussion of why alternatives therapies are unsatisfactory and why the probable risk of using the investigational device is no greater than the probable risk from the disease or condition
	+ An identification of any deviations in the approved clinical protocol that may be needed in order to treat the patient
	+ The patient protection measures that will be followed. (Informed consent, concurrence of IRB chairperson, clearance from the institution, independent assessment from uninvolved physician, authorization from IDE sponsor)
	+ Independent assessment by a physician who is not participating in the investigation

**Note**: Patient should not be charged for investigational device. If you are charging patient, you will need ask for permission from FDA and provide a rationale in your IDE request. You will also need to document this in your IRB submission.

* Physician should inquire within specified FDA division as to how they wish to receive IDE request. Some will let you fax or e-mail the request, while others require the standard hard copy submission in triplicate. If you faxed or e-mailed the request you must follow up with the FDA to ensure it was received. Once submission is received by FDA, the agency has 30 days to respond, if not sooner. The request will be assigned its own IDE number. All subsequent submissions to the IDE must include this number. Unless otherwise specified, the UNC physician will be considered the sponsor (holder) of the IDE. All communications will go to the physician, so it is best practice to provide an additional contact person in the body of the cover letter. This person may also act on behalf of the IDE.

For questions about expanded access for emergency use for medical devices, contact CDRH at phone: 301-796-5640; or fax 301-847-8120.

**After hours (after 4:30 pm EST weekdays and all day on weekends)**

All questions about and requests for expanded access for emergency use for drugs, biologics and medical devices should be directed to the FDA Emergency Call Center, telephone: 866-300-4374.

Summary:

* Physicians can use unapproved devices in emergency situations
* IRBs must receive reports within five working days
* Subsequent emergency use-needs IDE
* Compassionate use requires prior FDA and IRB concurrence before use

**Additional Resources**

1). IDE Early/Expanded Access

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/ucm051345.htm>

2). Expanded Access (Compassionate Use)

<http://www.fda.gov/NewsEvents/PublicHealthFocus/ExpandedAccessCompassionateUse/default.htm>

3). UNC IRB Contact

Mike Matamoros, (919) 966-3113

matamoro@email.unc.edu