

IDE Early/Expanded Access for Medical Devices

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

Emergency Use

Emergency situations may arise in which there will be a need to use an investigational device in a manner not consistent with the approved clinical protocol. Emergency use of an unapproved device may occur before an IDE is approved.

Criteria:

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

Compassionate Use

The compassionate use provision allows access for patients who do not meet the requirements for inclusion in a clinical investigation but 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

Prior FDA approval is required before compassionate use can occur. In order to obtain Agency approval, the sponsor should submit an IDE supplement requesting approval for a protocol deviation under section §812.35(a) in order to treat the patient. The IDE supplement should include:

- A description of the patient's condition and the circumstances necessitating treatment

- A discussion of why alternative 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 deviation 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 for the institution, independent assessment from uninvolved physician, authorization from IDE sponsor)

The physician should not treat the patient identified in the supplement until FDA approves use of the device under the proposed circumstances. If the request is approved, the attending physician should devise an appropriate schedule for monitoring the patient, taking into consideration the investigational nature of the device and the specific needs of the patient.

Treatment Use

An approved IDE specifies the maximum number of clinical sites and the maximum number of human subjects that may be enrolled in the study. During the course of the clinical trial, if the data suggests that the device is effective, then the trial may be expanded to include additional patients with life-threatening or serious diseases.

Criteria:

- Life-threatening or serious disease
- No alternative
- Controlled clinical trial
- Sponsor pursuing marketing approval

Continued Access

FDA may allow continued enrollment of subjects after the controlled clinical trial under an IDE has been completed in order to allow access to the investigational medical device while the marketing application is being prepared by the sponsor or reviewed by FDA.

Criteria:

- Public health need or
- Preliminary evidence that the device will be effective and there are no significant safety concerns

The following site provides more information about the IDE Early/Expanded Access for Medical Devices:

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