1. PURPOSE

The purpose of this document is to define criteria for use of FDA's Expanded Access Program.

2. FDA EXPANDED ACCESS CRITERIA

2.1 Expanded Access to Investigational Drugs

FDA regulations (21 CFR 312 Subpart I) define the circumstances under which investigational drugs can be made available to patients with serious diseases or conditions when there is no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the patient's disease or condition. To be eligible, the FDA must determine that:

(1) The patient or patients to be treated have a serious or immediately life-threatening disease or condition, and there is no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the disease or condition;

(2) The potential patient benefit justifies the potential risks of the treatment use and those potential risks are not unreasonable in the context of the disease or condition to be treated; and

(3) Providing the investigational drug for the requested use will not interfere with the initiation, conduct, or completion of clinical investigations that could support marketing approval of the expanded access use or otherwise compromise the potential development of the expanded access use.

To seek access to an investigational drug, a physician must submit an Investigational New Drug (IND) application or amend an existing IND.

2.2 Expanded Access to Investigational Medical Devices

FDA regulations (21 CFR 812.36) define the circumstances under which an investigational device may be used to treat, diagnose, monitor, or prevent the patient's condition. To be eligible, the FDA must determine:

(1) The device is intended to treat or diagnose a serious or immediately life-threatening disease or condition;

(2) There is no comparable or satisfactory alternative device or other therapy available to treat or diagnose that stage of the disease or condition in the intended patient population;

(3) The device is under investigation in a controlled clinical trial for the same use under an approved IDE, or such clinical trials have been completed; and

(4) The sponsor of the investigation is actively pursuing marketing approval/clearance of the investigational device with due diligence.

To seek access to an investigational device, a physician must submit an emergency use/compassionate use of an unapproved medical device request submit a supplement to an existing Investigational Device Exempton (IDE) application.