Expanded access to a drug or device

Overview
Expanded access is the use of investigational drugs, biological product, or device where availability is limited when the primary purpose is to diagnose, monitor, or treat a patient's disease or condition. Expanded access many times is also referred to as 'compassionate use.' The aim is to facilitate the availability 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 (See 21 CFR 312.300 (Subpart I)).

In November 2014, the State of Arizona passed Proposition 303. Proposition 303 says a manufacturer may make available a drug, biological product or device to an eligible terminally ill patient. It exempts a physician from regulatory action based solely on the physician's recommendation of the drug, biological product or device, as a class 1 misdemeanor.

Determination
Prior approval from the FDA is required for every expanded access request. The submission may be a new submission to the FDA or a protocol amendment to an existing submission.

In addition, all expanded access requests require prior IRB review and approval, with the exception of Emergency Use. See HSPP Guidance, Emergency Use, for more information.