SOP IRB 1003
Compassionate Use: Investigational Drugs and Devices

may be unexpected serious adverse effects and to take appropriate measures to ensure that this is understood by the patient or their LAR and to monitor for safety.

1.0 Expanded Access to Investigational Drugs and Biologics

The FDA's expanded access rule for investigational drugs, including biologics classified as drugs, is intended to improve access to investigational drugs for patients with serious or immediately life-threatening diseases or conditions who lack other therapeutic options and may benefit from the investigational agent. Expanded access is sometimes referred to as compassionate use or treatment use.

For the purposes of expanded access to investigational drugs, immediately life-threatening disease or condition means a stage of disease in which there is reasonable likelihood that death will occur within a matter of months or in which premature death is likely without early treatment. Serious disease or condition means a disease or condition associated with morbidity that has substantial impact on day-to-day functioning. Short-lived and self-limiting morbidity will usually not be sufficient, but the morbidity need not be irreversible, provided it is persistent or recurrent. Whether a disease or condition is serious is a matter of clinical judgment, based on its im

Physicians seeking access to investigational drugs under expanded access should work closely with the sponsor or manufacturer, the FDA, and the USAIRB Office, to determine the appropriate access mechanism and ensure that proper regulatory procedures are followed. The FDA provides information about the procedures and requirements for expanded access on a website, including a link to FDA's contact information.

Expanded access to investigational drugs may be sought under an "Access Protocol" or an "Access IND". FDA generally encourages Access INDs, which are managed and submitted by the sponsor of an existing IND, because it facilitates the review of safety and other information. However, Access INDs for the treatment of individual patients are also available and commonly used when: (1) a sponsor holding an existing IND declines to be the sponsor for the individual patient use (e.g., because they prefer that the physician take on the role of sponsor-investigator); or (2) there is no existing IND.

1.1 Sponsor or Manufacturer Approval:

Prior to submitting to the FDA or IRB, physicians seeking expanded access to an investigational drug should contact the sponsor (e.g., for investigational drugs un1Tw 1.28 7.1 (

When there is an emergency situation and insufficient time to submit a written

6. A copy of the draft informed consent document.

The IRB may review the expanded access application prior to FDA approval being receivedbut will not finalize approval until documentation of FDA approval is provided. The IRB will provide the investigator with written documentation of its review.

USA IRB will consider reliance upon an external IRB for expanded access when the IND is held b

- Clearance from the institution as specified by their policies (see b

Related Documents:

SOP 1002: Emergency Use: Investigational Drugs, Biologics or Devices

History:

Effective Date:
Revisions: November, 2018

Responsible Office:

Office of Research Compliance and Assurance