Investigator's Brochures

SOP 119
Created February 11, 2014

Purpose

This document describes the standard operating procedures (SOP) on how to submit investigator's brochures to the University of Hawai'i (UH) Institutional Review Board (IRB).

Definitions

Research protocols developed by industry typically evaluate the safety and efficacy of Investigational New Drugs (INDs). In addition to the protocol, sponsors are required to develop an **Investigator's Brochure (IB)**. FDA regulations state that IBs must contain the following information[1]:

1. A brief description of the drug substance and the formulation;
2. A summary of the pharmacological and toxicology effects of the drug in animals and, to the extent known, in humans;
3. A summary of the pharmacokinetics and biological disposition of the drug in animals and, to the extent known, in humans;
4. A summary of the information relating to safety and effectiveness of the drug in humans obtained from prior clinical studies;
5. A description of possible risks and side effects to be anticipated on the basis of prior experience with the drug under investigation or with related drugs, and/ or precautions or special monitoring to be done as part of the investigational use of the drug.

Procedures

On Submitting Investigator's Brochures with New IND Protocols

Applications for IRB approval of a new IND protocol should include a copy of the most current IB from the sponsor. Preferably, IBs should be submitted on a CD. Please do not submit paper copies of these documents.

On Submitting Amended Investigator's Brochures

During the course of the study, the sponsor may issue amended IBs to investigators. When the amended IB includes information on risks to participants that was previously not known or recognized by the IRB, it should be provided to the IRB for review. The investigator is required to summarize the new information and provide a recommendation to the IRB on appropriate follow-up actions to be taken in order to protect study participants. As applicable, an amended protocol and consent form(s) must also be provided to the IRB for review and approval.

[1] Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance, April 1996, http://www.fda.gov/downloads/Drugs/Guidances/ucm073122.pdf

If an IB is revised for reasons unrelated to items 1 through 5 above and includes no new (to the IRB) information on risks to study participants, investigators should not submit the revised IB to the IRB.

References

- The IRB has and follows written policies and procedures to conduct reviews by the convened IRB or Ethics Committee (**AAHRPP Element II.2.D**.).
    - Element II.2.D.1. – Initial review