Grand Valley State University Institutional Review Board (IRB)	
Title: *Requirements for Research Involving Investigational New Drugs*	
Section: 930	
Approved by IRBPPC: 03/31/2020	Approved by AIO/RIO: 04/06/2020
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Related documents: *900: IRB Protocol Review*	

Policy

1. Clinical investigations testing the safety or efficacy of drug products approved by the IRB will comply with the FDA Investigational New Drug (IND) Application regulation at 21 CFR 312.

2. Investigators are responsible for submitting the IND Application to the IRB for review, or for providing documentation supporting an IND exemption. The IRB will review the submitted information for the proposed study and modify the determination if the IRB disagrees with the sponsor.

3. If the sponsor, sponsor-investigator, or IRB determines an IND Application is required, then the sponsor or sponsor-investigator must have an approved IND Application before IRB approval can be granted.

Procedures

1. Types of Drug Studies

The IND regulations describe two types of drug studies: those that require an approved IND application and those that are exempt from the IND requirements.

A. IND Exempt

i. Under 21 CFR 312.2(b), the following studies are exempt from requirements to submit an IND Application to the FDA:

1. A clinical investigation of a drug product is exempt from the IND regulations if all of the following criteria are met:

a. The investigation is not intended to be reported to FDA as a well-controlled study in support of a new indication for use nor intended to be used to support any other significant change in the labeling for the drug;

b. If the drug that is undergoing investigation is lawfully marketed as a prescription drug product, the investigation is not intended to support a significant change in the advertising for the product;

c. The investigation does not involve a route of administration or dosage level or use in a patient population or other factor that

significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the drug product;

d. The investigation is conducted in compliance with the requirements for institutional review set forth in 21 CFR 56 and with the requirements for informed consent set forth in 21 CFR 50; and
e. The investigation is conducted in compliance with the requirements of 21 CFR 312.7.

2. A clinical investigation involving an in vitro diagnostic biological product if (a) it is intended to be used in a diagnostic procedure that confirms the diagnosis made by another, medically established, diagnostic product or procedure and (b) it is shipped in compliance with 21 CFR 312.160.
3. A drug intended solely for tests in vitro or in laboratory research animals is exempt if shipped in accordance with 21 CFR 312.160.

ii. The investigator will submit documentation supporting the applicable exempt category for IRB review.

iii. Determination of IND exemption can be completed by expedited review or at a convened IRB meeting. If the determination is made at a convened IRB meeting, the determination will be documented in the meeting minutes.

B. <u>IRB Assessment of Clinical Investigation Requiring an IND</u>

i. The IRB will determine whether the clinical investigation can use an investigational drug product after reviewing the following information provided by the investigator:
   1. When the research requires an approved IND Application, a copy of the FDA IND acknowledgement letter or confirmation from the sponsor of a valid IND including the IND number;
   2. A description of the drug product;
   3. Reports of prior investigations with the drug product, investigator's brochure (or package insert) and other risk evaluations presented by the sponsor or investigator;
   4. Description of subject selection criteria;
   5. Description of monitoring procedures; and
   6. Any other information that the IRB requires in order to conduct its review and make a determination.

ii. If an IND application is or has been submitted to the FDA, but final approval has not been granted, the IRB can proceed with the review of the study. Final approval will not be granted until documentation of the FDA IND approval is submitted.

iii. If there is a question as to whether an IND is required, the IRB may require, as part of the review and approval process, that an investigator contact the FDA to discuss the proposed research in an effort to help determine if an IND application is required. The IRB may also direct the investigator to submit a formal IND application to the FDA in cases where it is not clear whether an IND is required, or there is not enough evidence to support an IND exemption determination.

2. Dietary Supplements
    A. When a lawfully marketed dietary supplement is being studied for its effects on diseases (i.e., to cure, treat, mitigate, prevent, or diagnose disease including its associated symptoms), it is an investigational new drug and is subject to the 21 CFR 312 IND requirements. However, investigators may request an exemption from 21 CFR 312 directly from the FDA.
    B. When a lawfully marketed dietary supplement is being studied for its dietary supplement use (i.e., structure and/or function claims), it is not an investigational new drug and is not subject to the 21 CFR 312 IND requirements. Structure and function claims are statements that describe the effect a dietary supplement may have on the structure or function of the human body.

Background

1. Definition of Drug

    Per Section 201(g) of the Food, Drug, and Cosmetic Act, a drug is:
    A. A substance recognized by an official pharmacopoeia or formulary.
    B. A substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease.
    C. A substance (other than food) intended to affect the structure or any function of the body.
    D. A substance intended for use as a component of a medicine but not a device or a component, part or accessory of a device.