

Investigational and Marketed Drugs (HRPP 6.1)

Description:

This policy describes UNMC's requirements for research involving investigational and marketed drugs.

Definitions:

Investigational Drug: (a) a drug or biologic used in a clinical investigation under an Investigational New Drug (IND) application, or (b) a marketed drug being studied for an unapproved or approved use in a clinical trial.

Clinical Investigation: any experiment that involves a test article and 1 or more human subjects, and that either must meet the requirements for prior to submission to the FDA under Section 505(i) or 520(g) of the Food, Drug, and Cosmetics Act or need not meet the requirements for prior submission to the FDA under these sections of the Act but the results of which are intended to be later submitted as part of an application for a research or marketing permit.

The terms research, clinical research, clinical study, and clinical investigation are deemed to be synonymous.

Investigational New Drug (IND) Application: application submitted to the FDA (by the sponsor of the research) to conduct a clinical investigation with an investigational new drug subject to 21 CFR 312.2(a).

Marketed Drug: drug or biologic approved by the FDA for marketing and is generally in use for treatment purposes.

Sponsor: a person or organization who takes responsibility for and initiates a clinical investigation. The sponsor may be a pharmaceutical company, governmental agency, academic institution, private organization, or an individual investigator.

Sponsor-Investigator: an individual that both initiates and conducts an investigation. Additionally, the sponsor-investigator directs the administration or dispensing of the investigational drug. An investigator who also serves as a sponsor must comply with all FDA requirements applicable to both an investigator and a sponsor.

Expanded Access: the use of an investigational agent outside of a clinical trial. The terms *expanded access* and *treatment use* are used interchangeably to refer to the use of an investigational drug when the primary purpose is to diagnose, monitor, or treat a patient's disease or condition. The term *compassionate use* is also occasionally used in the context of the use of an investigational drug to treat a patient.

Procedures:

- All contracts between sponsors and **UNMC, NM, and BMC for investigational drug studies** must be reviewed and approved by UNMC Sponsored Programs Administration (SPA) or UNeHealth.
- All contracts between sponsors and **Nebraska Childrens for investigational drug studies** must be reviewed and approved by UNMC SPA, UNeHealth, or by Nebraska Childrens Administration.
 - If reviewed by Nebraska Childrens Administration, it must also be reviewed by UNMC SPA.
- The IRB will review the application to ensure the investigational drugs are securely stored and dispensed:
 - UNMC or NM-stored and dispensed in accordance with Investigational Drug Policies (I380 and MS05)
 - Nebraska Childrens- stored and dispensed in accordance with Nebraska Childrens Policy 204.00
 - External site- copy of the policy of external site(s) which satisfies the requirements of the FDA regulations must be submitted to the ORA
- Any PI that had the study audited by a sponsor, a CRO or the FDA must immediately notify the designated IRB analyst and the UNMC Chief Compliance Officer.
 - The IRB must be provided a copy of the report.
- If a study is audited by the Fred & Pamela Buffett Cancer Center Protocol Review Monitoring System (PRMS) Audit Committee, a copy of the report must be provided to the IRB.
- The PI must inform the IRB and Investigational Drug Pharmacist when a study involving an investigational drug is terminated.

Studies Requiring an IND:

- An IND is required for studies involving:
 - An unapproved drug
 - A marketed drugs that is being studied:
 - in support of a new indication for use or any other significant change in the labeling for the drug; or
 - in support a significant change in the advertising for the product; or
 - involves 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
 - There may be other situations in which an IND is required; please contact the ORA early in the process.
- The IND may be held by the sponsor, or by the investigator
- If the investigator is also the holder of the IND, the PI must:
 - Comply with FDA-mandated sponsor requirements (21 CFR 312.50)
 - Certify compliance by submitting Addendum O which specifies all responsibilities of a Sponsor-Investigator
- If there is a question about whether a drug requires an IND, the PI may be asked by the IRB to obtain a written determination from:
 - FDA Center for Drug Evaluation and Research (CDER)
 - Center for Biologics Evaluation and Research (CBER)