Study Drugs and Supplements

Definitions:

Biological Product: a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein (except any chemically synthesized polypeptide), or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings. (42 U.S.C. 262(i)) Biological products include, among other products, bacterial vaccines, allergenic extracts, gene therapy products, growth factors, cytokines, and monoclonal antibodies.

Dietary Supplement: defined by Dietary Supplement Health and Education Act of 1994 (DSHEA), as a product (other than tobacco) intended to supplement the diet that bears or contains one or more dietary ingredients. The dietary ingredients in these products can include vitamins, minerals, herbs and other botanicals, amino acids, other dietary substances intended to supplement the diet, and concentrates, metabolites, constituents, extracts, or combinations of the preceding types of ingredients. Dietary supplements are taken by mouth and can be found in many forms such as tablets, capsules, softgels, liquids, gelcaps, or powders.

Dispense:
the interpretation, evaluation, and implementation of a prescription drug order, including the preparation and delivery of a drug or device to a patient or patient's agent in a suitable container appropriately labeled for subsequent administration to, or use by, a patient. Dispense necessarily includes a transfer of possession of a drug or device to the patient or the patient's agent. (LA R.S. 37:1164). Louisiana law requires that dispensing may only be done by a licensed pharmacist or a physician who is registered with the board as a dispensing physician. (LA R.S. 37:1201).

Distribute or Distribution: means the delivery of a drug or device other than by administering or dispensing.

Drug: articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease and articles (other than food) intended to affect the structure or any function of the body of man or other animals.

All study drugs must be ordered by the investigator or other qualified individual and kept in a locked area with limited access. For research participants, responsibility for the storage, monitoring, dispensing, and accounting of study drugs shall be the responsibility of the investigator under the direction and oversight of the Pharmacy.
The Pharmacy Director must be notified via e-mail or invoice within 24 hours after the arrival of a shipment of study drugs. The e-mail should state the name of the study, the name of the study drug, strength and dosage form, lot number, and expiration date.

Dispensing or Distribution of Study Drugs

The study staff or pharmacy must document the dispensing or distribution of study drugs to subjects. The documentation shall include patient name, date, medication name, lot number, quantity dispensed, and name of person or entity dispensing or distributing. Refer to WHF Pharmacy policies for additional requirements.

Dispensing Controlled Substances

Controlled substances must be securely stored and must be dispensed by a duly licensed pharmacist.

Drug Accountability Record

The Investigator must maintain records of the product's delivery to the study site, the inventory at the site, the use by each subject, and the return to the sponsor or alternative disposition of unused product. These records should include:

- dates
- quantities
- batch/serial numbers
- expiration dates
- the unique code numbers assigned to the investigational products and trial subjects

The Investigator should maintain records that document adequately that the subjects will provide the doses specified by the protocol and reconcile all investigational products received from the sponsor. The investigational drug supply is subject to audit by the IRB.

In regard to the use by each subject, Investigators should maintain drug accountability records that document adequately which subjects received the drug; when the subjects received the drug; the specific dosage the subjects received; and any returned amount of the dispensed investigational drug.

Drug Storage - Investigational products should be stored as specified by the Sponsor and in accordance with applicable regulatory requirements. Storage guidelines include:

- Storage area is large enough for the supply of study drug.
- Storage area can be locked with access only by appropriate personnel
- Investigational drug is stored separately from other compounds.
- Non-dispensed drug is stored separately from returned dispensed drug.
- All environmental controls are maintained.

If the study protocol requires the subject to return the empty investigational drug container or any amount of the unused investigational drug, it is the Investigators responsibility to store the returned dispensed Investigational drug separately from the non-dispensed investigational drug.

It is the responsibility of the Investigator to deliver the returned dispensed investigational drug to the pharmacy.

Drug Labeling for Investigational Drugs

The following labeling requirements are required for investigational new drugs:

- The immediate package of an investigational new drug intended for human use shall bear a label with the statement, Caution: New Drug – Limited by Federal or U.S. law to investigational use (FDA 21 CFR 312.6).
- The label or labeling of an investigational new drug shall not bear any statement that is false or misleading in any particular way and shall not represent that the investigational new drug is safe or effective for the purposes for which it is being investigated (FDA 21 CFR 312.6).
- Participant Identifier
- Protocol number or name
- Strength of drug
- Dose
- Directions for use or administration
- Quantity dispensed

Dietary Supplements

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.

Investigational New Drug (IND) requirements for dietary supplements

Dietary supplements may be considered drugs and may be subject to FDA requirements for INDs or IND exemptions. A dietary supplement is not considered a drug and is not subject to the premarket approval requirements for drugs if the intended use for which it is marketed is only to affect the structure or any function of the body (i.e., not intended to be used for a therapeutic purpose).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. However, if the clinical investigation is intended to evaluate the dietary supplement's ability to diagnose, cure, mitigate, treat, or prevent a disease,17 an IND is required under part 312.

Woman's IRB requires that all research studies involving the use of dietary supplements must include either proof of an approved IND from the FDA, or a statement from the FDA certifying that an IND is not required. Investigators using dietary supplements in a clinical trial are required to register the study on clinicaltrials.gov.

Additional information and FDA guidance on INDs for dietary supplements:
https://www.fda.gov/media/79386/download