SUPPLYING AND HANDLING INVESTIGATIONAL PRODUCTS
IN HUMAN SUBJECTS RESEARCH

POLICY

Investigational products (drugs, biologics, and devices) may be administered to study participants during the course of a research study if the following criteria are met:

1. Principal Investigators (PIs) must be aware of, and compliant with, the relevant regulations (Food and Drug Administration (FDA) and Office of Human Research Protections (OHRP) regulations and university policy) regarding the identification, storage, administration, disposal, handling and control of investigational products;

2. Prior to the start of the research study the PI is responsible for and must be aware of the research unit’s Standard Operating Procedures (SOPs) for receipt, distributing, storing, inventory, and distribution of investigational products including arranging with the Investigational Drug Service as appropriate;

3. The PI must have assurances from the study sponsor indicating that the manufacture and formulation of the product comply with federal regulations;

4. The products must be administered in accordance with an IRB approved protocol;

5. The researchers must be appropriately licensed under state and federal law to administer the investigational product.

RESPONSIBILITIES

1. The PI of the research study is responsible for the inventory, storage, management, administration, and disposition of investigational products in accordance with the approved protocol, the sponsor’s instruction, FDA, and the policy of the institution where the research is conducted.

2. The PI must ensure that appropriate records of receipt, inventory, distribution, storage and disposition of investigational products are kept.

3. Researchers will maintain current licenses required by federal, state, and local law and by UC policy for managing, storing, or supplying investigational drugs, biologics or devices.
4. When the product is an implantable device, the PI must include in study records the specific device used with a specific research participant.

5. Each clinical research unit project using an investigational product will follow the unit’s Standard Operating Procedures (SOPs) for receipt, distributing, storing, inventory, and distribution of the product and for preventing unauthorized use of the product.

6. Researchers storing, handling or disposing of hazardous investigational products must follow guidance provided by the Institutional Biosafety committee.

7. Researchers’ compliance with policies and procedures for investigational drugs, biological products, and medical devices is subject to audit. Researchers shall cooperate with auditors.

Applicable Regulations, Documents:

21 CFR 312.61
21 CFR 312.62
21 CFR 312.69
21 CFR 812.110

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<td>L. Harpster</td>
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<td>M. Linke</td>
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