Policy
Department: HUMAN RESEARCH PROTECTIONS PROGRAM
Policy Number: XI.A
Section: Investigational Drugs, Biologics, and Devices
Review Responsibility: HRPP Policy and Procedure Committee
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Subject: Storage, Handling, and Dispensing of Investigational Drugs, Agents, and/or Biologics in Clinical Trials

Definitions:
1. **Investigational Agents**: A pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial. This includes products with a marketing authorization when used or assembled (formulated or packaged) in a way different from the approved form, products used for an unapproved indication, or products used to gain further information about an approved use.

2. **Investigational Drugs/Investigational Biologics (Test Articles)**: A new drug/agent or biologic that is used in a clinical investigation. The term investigational biologic also includes a biological product that is used in vitro for diagnostic purposes. Investigational drugs or biologics may include:
   a. Products that are not generally recognized as being safe and effective for any use under the conditions prescribed, recommended, or suggested by the FDA; or
   b. Products already approved by the FDA as safe and effective for specific indications that are being studied for new indications (or doses, strengths, or frequency).

3. **Investigational Drug Service (IDS)**: A division of the VUMC Pharmacy Department that provides support for clinical drug studies including Institutional Review Board consultation and dispensing services for investigational drugs, agents, or biologics. This division actively supports all Departments and Investigators involved in research.

4. **Joint Commission on Accreditation of Healthcare Organizations (JCAHO)**: A national accrediting body for hospitals and other health care delivery organizations.

Policy:
It is the policy of the Human Research Protections Program (HRPP), in its role as the Privacy Board for Research for Vanderbilt University Medical Center (VUMC), that research data be used, stored and/or disclosed according to current HIPAA regulations.

I. Storage of Investigational Drugs, Agents, or Biologics.
   A. It is the responsibility of the Investigator to comply with all institutional, state and federal regulations in regards to storage of investigational drugs, agents, or biologics.
   B. Investigational drugs, agents, or biologics used in the context of research, may be stored in areas other than the IDS under the direct supervision of the Investigator and is in accordance with the sponsor, if applicable.
   C. Controlled substances may not be stored outside of the pharmacy department.
   D. Investigational agent storage facilities outside of the IDS must be in compliance with institutional, state, federal [Food and Drug Administration (FDA)], and Joint Commission on Accreditation of Hospital Organizations (JCAHO) requirements. Pharmacy monitoring may be incorporated into the IRB auditing process as needed to assure compliance.

II. Dispensing of Investigational Drugs, Agents, or Biologics.
   A. All investigational drugs, agents, or biologics administered to inpatients should be dispensed in accordance with IDS policies and procedures.
   B. If IDS is not utilized for the dispensing of investigational drugs, agents, or biologics, it is the responsibility of the Investigator to assure that dispensing is in accordance with all institutional, state, federal, and JCAHO requirements.
C. The Pharmacy must prepare and dispense controlled substances for all inpatients and outpatients.
D. Compounding of oral and intravenous drugs must be handled by the Pharmacy. The Pharmacy must prepare and dispense such medications for all inpatients and outpatients.

III. Investigations of issues related to the potential mishandling of investigational drugs, agents, or biologics will be conducted by the IDS and promptly reported to the IRB.

References:
21 CFR 50, 56, 312, 812
FDA Information Sheets
Investigational Drug Service Pharmacy Policies and Procedures