Subject: Procedure for the Storage, Handling, and Dispensing of Investigational Drugs, Agents, and/or Biologics in Clinical Trials

Procedure:
This procedure outlines the appropriate storage, handling, and dispensing of investigational drugs, agents and/or biologics used in human subjects research.

I. Investigator Responsibilities.
   A. The Investigator will work directly with the Investigational Drug Service (IDS) regarding the appropriate storage, handling (compounding), and dispensing of investigational drugs, agents, or biologics. In addition, the Investigator must comply with all IDS policies and procedures regarding investigational drugs, agents, and biologics.
   B. With the exception of controlled substances, an investigational drug, agent, or biologic utilized in a clinical trial may be stored in an area other than the IDS under the direct supervision of the PI. If storage, handling, and dispensing will be managed outside the IDS, the Investigator will provide, in the IRB Application, details regarding the storage, handling, and dispensing of investigational drugs, agents, and biologics used in the context of the research.
   C. When storing investigational drugs, agents, or biologics outside of the IDS Pharmacy, it is the Investigator’s responsibility to work with the IDS pharmacy to assure that the planned storage, handling, and dispensing of the investigational drug, agent, or biologic is in compliance with institutional, state, federal (FDA), and JCAHO requirements.
   D. The Investigator will assure that investigational drugs, agents, and biologics to be given to inpatients are dispensed in accordance with the IDS procedures/recommendations and the IRB approved protocol. This includes all inpatient beds in the Vanderbilt University Medical Center, Clinical Research Center, Stallworth Rehabilitation Hospital and the Psychiatric Hospital at Vanderbilt.
   E. The Investigator is responsible for working directly with the IDS regarding the costs for the storage, handling (compounding), and dispensing of investigational drugs, agents, and biologics. The Investigator and the IDS will work in conjunction to assure adequate funding for these pharmacy costs is incorporated into the grant, contract proposal, or from other internal sources.

II. IDS Responsibilities.
   A. As part of its role in assuring proper labeling, storage, distribution, and control of all investigational agents, the Investigational Drug Service (IDS) will be available to assist Investigators.
   B. The IDS will investigate issues of potential PI non-compliance of the proper storage, handling, and dispensing of investigational agents in clinical trials. If a potential safety issue is suspected, the IDS will promptly notify the HRPP Director who will notify the appropriate Committee Chair to determine if enrollment needs to be suspended, or the administration of the drug, agent, or biologic needs to stop pending the investigation. All determinations will be reported at the next convened IRB Committee meeting.
   C. Investigation findings will be reported to the assigned IRB Committee by the IDS pharmacy representative for the assigned Committee.
D. All inpatient and outpatient research protocols involving either FDA approved or investigational agents (including radioactive agents used therapeutically or diagnostically) will receive review by the IDS pharmacy representative for the assigned IRB Committee. The IDS pharmacy representative’s review for appropriateness will include an assessment of the source, purity, quality, method of preparation, and delivery.

III. Regulatory Compliance Analyst (RCA) Responsibilities.
A. The RCA will assure that the IDS pharmacy representative for the assigned Committee receives appropriate information which includes a protocol, IRB application, consent form, and if applicable, an Investigator’s brochure.
B. When applicable, the RCA will assure that each study that includes an investigational drug, agent, or biologic has a pharmacy reviewer comment form completed by the IDS pharmacy representative.
C. The RCA will update the HRPP database accordingly with information regarding the storage, handling, and dispensing of investigational drugs, agents, and biologics.