Standard Operating Procedure Number: 1-4
The University Hospital Investigational Drug Service
Adopted: 02/2005 **Revised: 07/2009**
Page: 1 of 2

THE UNIVERSITY HOSPITAL
INVESTIGATIONAL DRUG SERVICE (IDS)

POLICY

All studies conducted in University Hospital facilities in which investigation drug will be administered to patients will utilize the Investigational Drug Service (IDS) provided by the hospital's pharmacy department.

INVESTIGATIONAL DRUG SERVICE

Location: University Hospital, Room B-200
Hours: 7:00 a.m.- 3:30 p.m., Monday-Friday
7:00 a.m.- 12:00 p.m., Saturday and Sunday, Closed Holidays
Telephone: 513-584-1766
In-House Page: 0091
Fax: 513-584-8810
E-mail: IDS-Pharmacy@healthall.com

Shipping: The University Hospital
Department of Pharmacy Services
234 Goodman Street, ML# 0740
Cincinnati, Ohio 45219-2316
Attn: Investigational Drug Service

RESPONSIBLE PERSON(S)

IDS Personnel
Principal Investigator
Research Coordinator
Regulatory Manager

PROCEDURE

1. The documentation to be sent to the IDS includes the approved protocol and amendments; the Investigator Brochure, including subsequent safety reports;, the IRB approval letter and any IRB approval notifications for amendments and progress reports.

2. In preparation for commencement of study, the IDS will prepare nursing fact sheets and pharmacy dispensing guidelines. Each study is assigned an IDS number by the IDS staff.

This number must be used in any written or verbal orders or communications with the pharmacy staff.

3. Each prescription or physician order should be written according to protocol guidelines and should include study case number and IDS number. The IDS will maintain drug accountability using the standard drug accountability record form. Any unused study drug will be returned or destroyed by the IDS.

4. Notification of the clinical trial to the IDS is not required if the study is being conducted outside the University Hospital unless the research group prefers the IDS to mix or prepare the investigational product.

5. If the investigator will not be using the IDS, he/she must demonstrate understanding of the handling and control of investigational test articles, to the IRB, by reviewing the research unit's Standard Operating Procedures (SOPs) for receipt, distributing, storing, inventory, and distribution of the product and for preventing unauthorized use of the product.

Applicable Regulations:

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

Date _____ **Signature** _____