

Pharmacy's Role in Clinical Research

Helping to Support Clinical Research from Protocol to Patient



An Information Guide to Get You Started

Vanderbilt University
Medical Center
Investigational Drug Service
Pharmacy Department

CHECKLIST OF ITEMS NEEDED FOR PROTOCOL SETUP

The principal investigator should ensure that the following items are in the IDS prior to study participant enrollment.

1. Copy of the protocol and any amendments
2. Copy of the FDA 1572 or list of approved prescribers whichever is applicable.
3. IRB approval letter
4. Copy of all consent forms
5. Investigator Brochure

WHAT SHOULD THE INVESTIGATOR EXPECT?

Drug appropriately secured and stored

CPOE order files setup in physician order entry system (if inpatient study)

copy of pre-printed outpatient prescription (where applicable)

dedicated pharmacy binder that includes enrollment logs, drug accountability logs, patient worksheets if applicable, and protocol procedures

Drug inventory /compliance monitoring

Dispensing according to protocol

WHO WE ARE?

The Investigational Drug Service (IDS) of the Department of Pharmaceutical Services provides administrative and clinical services to investigators involved in drug related research throughout the medical center and campus.

1. We provide the following benefits to investigators and their research team:
2. Administrative workload is decreased relative to drug management
3. Enhanced drug accountability systems
4. Serve as the un-blinded study personnel to maintain study integrity
5. Ensure compliance with FDA, JCAHO and all applicable state and local standards
6. Stream-line drug distribution processes
7. Timely delivery of research medication to the patient
8. Research staff are allowed to focus on patient care and not drug management
9. Costs are reduced by integrating drugs into established pharmacy systems

WHO WE ARE?

Our goal is to provide timely and efficient support for clinical studies. We offer pharmacy support for investigators 24/7 and provide the following services:

1. Drug Procurement
2. Drug Storage
3. Drug Distribution
4. Study Design/Randomization
5. Inventory Control
6. Drug Information
7. Patient Counseling
8. Special Formulations/Compounding Services
9. Labeling and Packaging
10. Sterility testing, including bacteriostasis, fungistasis and bacterial endotoxin (LAL)
11. Other services

WHAT WILL IT COST?

To accurately project a budget, a copy of the protocol should be submitted to the IDS as soon as it is available.

A budget will then be provided to the investigator, for inclusion in the sponsor budget. Budgets generally have two fees:

- Protocol management
- Dispensing fees.

The protocol management fee covers the cost of storage, inventory management, inservicing of pharmacy staff and computer file maintenance.

Dispensing fees include the cost of preparation of the drug including any supplies used to dispense the study medication.

For investigators conducting investigator initiated research, the IDS can also assist with drug acquisition and special formulation compounding

Give us a call today. Let us see how we can help.

Call 343-6537

HELPFUL WEBSITES

- www.fda.gov
- www.mc.vanderbilt.edu/irb
- www.mc.vanderbilt.edu/rss
- www.jcaho.com

FOR MORE INFORMATION CONTACT

Hope Campbell, PharmD, BCPS

Coordinator, Investigational Drug Services
hope.campbell@vanderbilt.edu
615-343-5146 (o) 615-835-9066 (Pager)

Geri Foster, DPh

IDS/Compounding Pharmacist
geri.foster@vanderbilt.edu
615-343-6537 (O) 615-835-1797 (Pager)

Christal Stephens, CPhT

Investigational Pharmacy Technician III
christal.stephens@vanderbilt.edu
615-343-0834 (O) 615-835-9067 (Pager)

Sheri Malone, CPhT

Investigational Pharmacy Technician II
sheri.malone@vanderbilt.edu
615-343-0834 (O) 615-835-1795 (Pager)

Vanderbilt University Medical Center

Dept of Pharmaceutical Services

Investigational Drug Service

1211 Medical Center, Room B101 VUH
Nashville TN 37232-7610
Phone: (615) 343-6537
Fax: (615) 322-6643
Hours of operation: 7AM -4:30 PM