**Investigational Medication**

Modified: January 2017

**Background:**

It is the responsibility of the Principal Investigator (PI) at the site of a clinical trial to ensure accurate and complete accountability and proper storage of investigational drugs/products used in a clinical trial.

**Q: What is required by the FDA regarding investigational drug storage and accountability?**

For studies conducted under an Investigational New Drug (IND) application, FDA regulations charge investigators with the responsibility document the receipt, use and disposition of all investigational agents including dates, quantity and use by subjects; maintain accountability, secure storage, proper dispensing and dispensing records, and proper disposal of waste and return of all unused drug.

**Q: Must the Investigational Drug Service of the UFHealth Shands Gainesville or UFHealth Shands Jacksonville control the investigational drug inventory?**

Yes. For investigational drugs for inpatient research studies must be dispensed by the Pharmacy. The Investigational Drugs Service (IDS) will provide security, inventory control, and integration of drug dispensing and administration with the standard medication process within the hospital.

Investigational Drugs for outpatient research studies may be dispensed by the Pharmacy or by the Investigator. When the Pharmacy controls the Investigational Drugs for a study, all necessary drug control and recordkeeping functions are conducted for the investigator by the Pharmacy. If an investigator wishes to retain control of an Investigational Drugs, the investigator is responsible to ensure the security and accuracy of the investigational device.

**Q: How is the IDS contacted, and what services do they provide?**

Investigators who wish to have the Pharmacy control Investigational Drugs in research studies should contact the IDS staff at either UFHealth Shands or UFHealth Shands Jacksonville. Services provided include:

- Coordinate and dispense study medication;
- Prepare randomization lists;
- Blind study medication;
- Assist with development of matching placebo; drug information; patient counseling; adherence monitoring; and
- Obtaining drug supplies.

The Pharmacy can provide inventory management for a drug study. Inventory management includes:
• Recordkeeping requirements;
• Tracking of the running balance for the study drug supply: and
• Accounting for all doses dispensed.

The Pharmacy can prepare and dispense study drug. The Research Pharmacy does charge a fee for administrative set up, inventory management, and dispensing. Please contact the IDS staff for fee information.