ROLE OF AN IDS PHARMACY IN DRUG STUDIES

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Why Investigational Product Processes Need To Be Strictly Governed

OBJECTIVES

- Describe Good Clinical Practice (GCP) guidelines as they pertain to study drugs
- Describe national and state standards and laws applicable to study drugs
- Explain how the Investigational Drug Service (IDS) can help Investigators/Study Coordinators fulfill these requirements

STANDARDS

"JCAHO standards make specific statements related to the control of high-risk and investigational drugs[1]"

- MM.06.01.05: the hospital safely manages investigational medications[5]
  - Second element of performance: states the hospital's written process for the use of investigational medications specifies that the pharmacy controls the storage, dispensing, labeling, and distribution of investigational medications

LAWS AND REGULATIONS

- State Regulations
  - NYS laws still apply when dispensing investigational drugs directly from an outpatient clinic setting (i.e. controlled drugs)
- Hospital Regulations
  - Strong Memorial Hospital regulations regarding dispensing of medications to inpatients/outpatients must be followed

HANDLING OF CONTROLLED SUBSTANCES

- 21 CFR 312.69
  - If the investigational drug is subject to the Controlled Substances Act, the investigator will take adequate precautions, including storage in a securely locked, substantially constructed cabinet, to which access is limited, to prevent theft or diversion into illegal channels of distribution
  - **NY State requires that the site/PI obtain a Class 4 Researcher's license**

Good Clinical Practice (GCP) Guidelines

DRUG RECEIPT AND STORAGE

- Study drug should be shipped directly to the attention of the responsible/designated person (i.e. IDS pharmacy)
- Study drug will be stored in a secure, locked location under conditions specified by the sponsor
- Access to the study agent will be restricted only to those authorized by the investigator and/or sponsor

DRUG RECEIPT AND STORAGE CONT.

- Copies of all drug receipt invoices will be maintained in a study file
- Periodic inventory checks are performed by the study staff member responsible for control of the drug product(s)
- Controlled drug products are inventoried on a weekly basis

DRUG RECEIPT AND STORAGE CONT.

- Used product(s) will be stored in a location separate from unused supplies
- Expired product(s) will be quarantined and stored in a separate location until either returned, or destroyed, as per sponsor instructions

TEMPERATURE MONITORING

- Temperatures must be monitored on a daily basis with continuous monitoring preferred
  - IDS has continuous monitoring system in place
    - Records temperature every 15 minutes
    - Alerts IDS staff members in the event of temperature excursions
- Temperature records are readily available to study monitors upon request
- Secondary monitoring system should be in place
- Alternate storage plans in the event of failure (i.e. refrigerator/freezer)

DESTRUCTION/RETURN OF INVESTIGATIONAL DRUG PRODUCT(S)

- IDS will dispose of investigational drug products in accordance to guidelines for destruction
- IDS will return drug product to sponsor if requested
- Copies of all drug return/destruction records will be maintained in the study file
- SOP's for destruction of medicines will be on file and available for sponsor approval
- Destruction of controlled substances will follow NYS and Federal regulations

WHAT IS AN "INVESTIGATIONAL DRUG SERVICE" (IDS)?

An IDS exists to assist the Investigator in the conduct of research studies involving pharmaceutical agents.

OUR MISSION

The mission of the IDS is to provide clinical research scientists and investigators with investigational drug management practices that are compliant with Good Clinical Practices (GCP), Federal and State regulations, Joint Commission (JC) standards[1,5], as well as per the recommendations for the American Society of Health-System Pharmacists (ASHP)[2-4]

THE INVESTIGATIONAL DRUG SERVICE (IDS)

- Services Provided:
  - Drug and Record Storage
    - Archiving via Iron Mountain study files (pharmacy)
  - Inventory Control
    - Receipt
    - Returns
    - Quality Assurance
  - Patient Randomization
  - Dose Calculation/Preparation/Delivery

THE INVESTIGATIONAL DRUG SERVICE (IDS) CONT.

- Services Provided:
  - Regulatory forms
  - Study Meetings
    - Eval/SIV/Monitoring/Close Out
    - Planning/design (in-house)
  - Miscellaneous
    - Randomization Schemes
    - Odd dosage form preparations
    - Drug packaging/shipping (with limitations)

RISKS ASSOCIATED WITH STUDIES NOT UNDER IDS OVERSIGHT

- Lack of drug security if access to study supply is not properly limited (i.e. drug stored in office accessible to non-study personnel)
- Potential for improper storage temperature of drugs
- Potential for preparation of sterile products in a non-sterile environment

RISKS ASSOCIATED WITH STUDIES NOT UNDER IDS OVERSIGHT CONT.

- Potential for unblinding of blinded personnel when sharing office space with study personnel who are designated as unblinded
- Increased potential for dosing errors due to lack of order review by staff outside of IDS
- Potential for inappropriate disposal of used/unused drug

SUMMARY

Benefits of establishing greater IDS control over studies include:

- 20+ years of experience in GCP
- GCP trained via CITI program
- Established track record
- Assurance of secure and proper drug storage
  - Including expired and/or used supplies
- Maintenance of proper blinding
- Order/Rx verification by a pharmacist
- Class 4 Researcher's license (institutional)

SUMMARY CONT.

- IDS pharmacist as a source of drug information
- Proper disposal/destruction of investigational drug
- Emergency plan in place in the event of equipment failure
- USP797 compliant IV room for sterile dose preparation
- 24/7/365 on call coverage, via pager, by IDS pharmacist

DEDICATED SUPPORT TEAM

- Staff and Contact Information:
  - Steve Bean PharmD, Supervisor
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