Human Research Seminar Series

Handling/Administration/Documentation of Study Drugs

Friday, May 3, 2013

Presented by:
Clemencia Solorzano, PharmD
Clinical Pharmacy Manager, Investigational Drug Service
The Role of Pharmacy in Clinical Research

May 3, 2013

Clemencia Solorzano, PharmD
Clinical Pharmacy Manager, Investigational Drug Service
Moses Division

Goals and Objectives

- Describe the Investigational Drug Service (IDS)
- Describe scope of pharmacy services
- Review MMC Guidelines and Policies
  - Investigational Drug Service (PH-I-5)
  - Patient Care Manual (M-2)
  - Administrative Policy (PH-I-4)
- Current Dilemmas
- Miscellaneous points to consider
Investigational Drug Service (IDS)
Pharmacy Staff

Moses Campus

- Pharmacy Manager*
- Pharmacist*
- Technician (P/T)*

Einstein Campus

- Director of Operations
- Pharmacist*
- Technician (P/T)

Wakefield Campus:
- Director of Operations / main pharmacy

5/22/2013

Contact Information – Moses

E-mail: mmcids@montefiore.org

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<thead>
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Beeper # 917 641-5616

Tel# 718 920-6546

Fax# 718 653-1905

Off-hour / emergency contact information:
- Pharmacy Office 920-2940 (Day time only M – F)
- Main Pharmacy 920-4103 (Evenings, midnights, weekends & holidays)
Contact Information – Einstein
IDS Tel #718 904-2422

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Tel#718 904-2825
Tel#718 904-2422
Fax# 718 904-2158

Off-hour contact information: Main pharmacy 718 904-2838

Omit the name of the Principal Investigator

Wakefield Pharmacy contact information: Laura Alfieri, MS, RPh 718 920-9452
Main pharmacy 718 920-9008

IDS Pharmacy Satellite - Moses

- **Location**
  - Foreman Pavilion, 6th floor, Silver Zone

- **Shipping Address**
  - Attn: Clemencia Solorzano
    Pharmacy Department,
    111 East 210th, Bronx, NY 10467
  - Omit the name of the Principal Investigator

- **Hours of Operation**
  - 8:30am – 5:00pm (general)
  - 24-hr service available
Types of Studies

- 50% - 60% of the 159 studies are routinely active
- > 25 clinical departments
- Complexity
  - Outpatient vs Acute care
  - 24 hr service
  - Controlled substances

Pharmacy Services

- Consulting
- Administrative
- Preparation, dispensing, accountability
Pharmacy Services - Consults

- Protocol design
- Placebo design
- Execution and logistics
- Drug cost estimation
- Drug information
- Preliminary data collection of drug use
- Pharmacokinetic dose adjustments

Pharmacy Services - Administrative

- IRB reviews
  - Pharmacist - members of IRB
- BRANY* reviews
  - Pharmacist - IRB Chair
- IRB application
  - Signature approval
  - Storage Waiver
- Adverse Drug Event Reviews

*Biomedical Research Alliance of New York
Pharmacy Services – Administrative…

- Quality Improvement Initiatives
  - Storage QI
  - Participate in internal/external audits

- Carecast entries / pyxis storage

- Site initiation and monitoring visits

- Budget preparation/ Billing

Budget

- Required for each study
  - Investigator initiated
    - Consider inpatient/outpatient trial
    - Resources required
    - Placebo preparation/blinding/randomization tables
  - Sponsored Trials
    - Defined research fee schedule
    - Use as initial guide for negotiation
    - Final budget must be approved by pharmacy

- Typical fee schedule
  - Initiation/start-up fees
  - Per patient or per unit dispensing fee
  - Drug costs if applicable
  - Close-out fees
Billing

- Initiation fee
  - One-time fee billed at study initiation
- Dispensing fee
  - Billed quarterly
- Close-out fee
  - End of study
- Payments
  - Fund-Fund transfer (Sponsored trials)
  - Check paid directly to pharmacy (Investigator initiated or Government funded trials)
  - Einstein fund #s do not work at Moses

Pharmacy Services - Dispensing

- Drug procurement and storage
- Drug preparation (IV, Capsule)
- Randomization & Blinding
- Drug accountability
- Inpatient/Outpatient dispensing
- Patient Counseling
- Drug information
Role of Pharmacy in Research

To achieve safe and responsible handling of research drugs within the institution

Good Clinical Practice

- **Standards** by which all clinical trials are designed, implemented, conducted and reported so that there is public assurance that the data are complete, correct and accurate and that the rights, welfare and confidentiality of the subjects are protected.
Pharmacy Standards

- State Board of Pharmacy
- Joint Commission (JCAHO)
- USP 797
- DEA
- FDA
- MMC policies

MMC Policies

- Administrative Policy (PH-I-5)
  - How research is to be conducted
- Investigational Drug Service (PH-I-4)
  - Role of pharmacy in research
- Patient Care Manual (M-2)
  - Responsibility of physician, nurse, pharmacist
- Research specific policies
  - Cross-campus transportation
  - Destruction
  - Chain of Custody
  - Temperature Monitoring
  - Unblinding
PH-I-5

Investigational Drug Administration Policy and Procedure

Policy (PH-I-5)

It is hospital policy that the pharmacy department inventory and store all investigational drugs
(PH-I-5) - Storage Waiver (SW)

- Must be requested at each site
- Must be requested by PI
- Approvals granted:
  - Intravenous medications:
    - Emergency administration
    - Prepared and used within 1 hour of compounding
    - Administration time cannot exceed 12 hours
  - Oral medications:
    - Patient specific kits or prescription vials
    - Impractical for pharmacy to store or dispense the medication
    - Appropriately labeled for outpatient dispensing

Use of “Standard of Care” Drugs

- Definition
  - Commercially available formulary medications that are used in a research context for an appropriate FDA approved indication in an approved population and dose.
  - Must be routinely available for ordering and administration
  - “Study” CIS entry not required
- Drug supply not managed by the IDS
  - Subject to shortages, recalls, unavailability
  - Lot#s and expiration dates not managed
- Storage waiver required?
Labeling Requirements (SW)

- Identifying drug name and protocol #
- Instructions for use
- Subject name, initials, ID#
- PI contact/Sponsor information
- “Investigational Use Only”

Inventory Maintenance (SW)

- Accurate balance
- Temperature logs
  - Ambient (59 - 86 °F or 25 – 30 °C)
  - Refrigerated (36 – 46 °F or 2 – 8 °C)
  - Freezer ( -15 - -25 °C)
- Storage site – locked and separated
- Expired inventory properly stored
Patients admitted to hospital already on investigational drug (PH-I-5)

- A 6 year old transferred to MMC from Columbia Children’s with an intravenous study drug being administered
  - Physician provides written drug information to pharmacy, nursing and medical staff
  - Pharmacy IRB representative evaluates safety
  - Formal IRB approval not required
  - Processed as per non-formulary policies (pharmacy re-labeling)
  - Consent / Re-consent?

Guidance for Institutional Review Boards and Clinical Investigators
www.FDA.gov/oc/ohrt/irb/investigational.html

Emergency Use of Investigational Drugs (PH-I-5)

- A 9 y/o developed DIC from current chemo regimen. Patient is in crisis. MD brings you a box of ampules and writes an order to administer 1 ampule q6h.
  - No standard acceptable treatment available for a patient’s condition
  - The patient does not meet inclusion criteria of an existing protocol
  - Not sufficient time to obtain IRB approval
Emergency Use Policy

- Signed informed consent
- IRB notification of use within 5 working days
- Physician to provide necessary drug information
- Limited to that one time use

PH-I-4

Investigational Drug Service
(PH-I-4) Study Drug Disposal

- Destruction Policy
  - PI/sponsor notification of study discontinuation

- Disposal Methods
  - Returned to sponsor
  - Destruction on premises
  - Third party disposal

- Witnessed and signed
- Documentation

(PH-I-4) Cross-campus Transportation

- Prepared intravenous solutions or intact vials
- Properly labeled
- Properly packaged (cool packs) to maintain refrigerated temperature
- Only legitimate study personnel
- Transfer and receipt documented on accountability record at both sites
It is the policy of the medication center that all orders for investigational drugs must be:

- Written by an attending physician or his designee
- Verified by pharmacy prior to dispensing
- Reviewed by nursing staff prior to administration
PCM M-2
Required Chart Information (PI)

- Signed consent with current IRB approval stamp
- A protocol or “Use of Investigational Drug Form”
- Order placed in Carecast
  - Customized
  - Miscellaneous

Placing Orders in Carecast

- Click on “meds by category” tab
- Click on “non-chemo” investigational tab
- Choose the specific pre-built study order
  OR
- Choose the “miscellaneous investigational order” (PO, IVPB or continuous infusion)
- Choose frequency, # of doses or duration*

* Duration is important since these orders automatically default to 24hrs. cEMR orders?
PCM M-2
Acute Care Dispensing

- Drugs must be logged, stored, prepared, and labeled according to protocol requirements.
- Must be dispensed from the pharmacy
- Includes all investigational drugs brought from home or dispensed by the principal investigator
- Clearly identify all investigational drugs with the words “Investigational Use Only”

PCM M-02
Acute Care Administration

- Administer IVs intact
- Dedicated IV lines unless otherwise allowed by protocol
- Pediatric age< 3 yrs, administer ONLY by a syringe pump
- Attach administration sets as close to cathether site as possible
- Flush cathether with appropriate diluent as specified by protocol
- ANM/PCC should be notified
Other Policies - IDS

- **Cold Chain Transfer policy**
  - Transport of study medication from one location to another
  - Covers transport by non-study personnel

- **Un-blinding policy**
  - Conditions under which pharmacy can un-blind
  - When to notify IRB
  - Whom should be un-blinded

- **Temperature monitoring policy**
  - Automated monitoring by engineering
  - Frequency of monitoring
  - Out of range temperatures

Current Dilemmas

- **Study related activities of “non-research” nursing personnel**
  - Staff qualified by education, training, experience, licensure
    - Delegation of task falls within the scope of the individual’s professional licensure
    - Nursing administrator signature
    - Nurse must be informed about protocol
    - Protocol and consent in chart
    - Not collecting research data
Current Dilemmas cont’d…

- “Dispensing activities?” of non-clinical research personnel
  - Staff qualified by education, training, experience, licensure
  - No standard job description for research associate (RA)
  - Only qualified research personnel licensed to dispense
  - RA can hand the medication to the patient after it is checked by licensed research personnel

Miscellaneous points to consider

- Controlled substance studies
  - Must be dispensed by pharmacy
  - DEA registration of each study is required

- Gene therapy / OR studies
  - Special study supplies may be required

- 24-hr protocols
  - The most successful 24hr protocols are those in which there is a strong clinical study team committed to enrollment & nursing staff training
Miscellaneous points to consider

- Drug delivery process:
  - RECEIPT @ receiving dock
  - DELIVERY directly to Pharmacy storeroom (orange zone)
  - Delivery is usually at 9am, 3pm
  - Pick up from the storeroom by IDS staff
  - IVR or IXR Acknowledgement in the PM that day or next day

- BRANY not familiar with specific MMC policies. Your duty is to know enough to tell them what you can or can’t do.

Re-cap

- Application process
  - signature
  - Storage waiver
  - Protocol review
    - Assess pharmacy involvement
  - Budget

- IRB approval
  - Communication w/ PI re execution & logistics
  - Drug receipt / Electronic web access
  - Site initiation
  - Set start date

5/22/2013