INVESTIGATIONAL DRUG ACCOUNTABILITY

Joyce Lee, Pharm.D, BCOP, BCPS
Clinical Research Training Program 2011
June 24, 2011
Disclaimer

- The information herein is not intended to replace any in-depth personal review of the Code of Federal Regulations, ICH GCP Guidelines, or any other applicable IRB, federal, state, or local rules, laws, or guidelines applicable to the conduct of clinical research at this site.
Objectives

- Discuss role of investigator in management and accountability of study drug
- Review the requirements for drug storage
- Discuss information needed for documentation of drug accountability
IDS Pharmacy Team

Joyce Lee (Pharmacist)
Nadir Sarwary (IDS Tech)
Dennis Steindorf (Pharmacist)
Nikki Cargill (IDS Tech)
Smiley Hom (Pharmacist)
Ashley Bryant (Pharmacist)
Marie Disho-Andrada (Pharmacist)

6/9/11
Drug Accountability

- General Principle:
  - Procedures for drug accountability, administration, and evaluation are more complex in research than in clinical practice.
Drug Accountability

Sponsor responsibilities

- Determination of:
  - storage conditions
  - shelf life
  - diluents / reconstitution procedures
  - records of receipt, shipment & disposition
Drug Accountability

Investigator responsibilities

• Adherence to:
  ◦ storage requirements
  ◦ dispensing per protocol
  ◦ accurate records for receipt, dispensing, return & final drug disposition
Drug Accountability

Pharmacist responsibilities

• Establish a Policies and Procedures (P&P)
  ◦ a copy for Sponsor
  ◦ a copy for Investigator’s file

• Proper storage conditions
  ◦ Temperature logs
  ◦ Documentation of excursions.

• Segregate study agents by protocol

• Isolate expired and damaged study agents
Drug Shipment

Required regulatory documents:

- Signed protocol
- Completed protocol title page
- IRB approval of protocol and consent
- Signed FDA 1572 form with CVs of investigators

For INDUSTRY Sponsored studies
- a signed contract must be in place

For INVESTIGATOR INITIATED Studies
- an IND Application (FDA Form 1571) must have been completed
- an IND Number assigned (unless exempt)
Drug Shipment

- Drug received directly from sponsor – Investigator or designee
  - must conduct inventory of study drug received
  - must maintain records regarding receipt and disposition of study drug
UCD Policy (P&P #1508)

- “Exception to the requirements for the distribution of investigational drugs must be approved by the IDS and IRB at the time of submission. Receipt and storage of investigational drugs at any location outside the IDS must be approved and monitored by the IDS”

- Investigational drug shipments will be sent to IDS rather than the Principle Investigator (PI)

- IDS will maintain drug accountability logs for the PI and the sponsor
Drug Storage

- All study drugs, vaccines or devices must be stored in accordance with protocol guidelines
  - With appropriate labeling
  - In a secure area with limited access
  - Under appropriate environmental conditions
  - Temperature Logs to be maintained by IDS
Prescribing

- Only the Principal Investigator and sub-investigators listed on the FDA Form 1572 may write orders for study agents.

- The exception -- those listed on an “Authorized Prescribers List” – those clinicians on the “IRB Research Personnel List”

- Prescription must contain all information currently required by state, federal and institutional laws and policies
Drug Dispensing

- Instruct subject in proper use of medication (21 CFR 312.61)

- Maintain adequate records of the dispensing of study drug in:
  - Medication dispensing record
  - Source document
  - Case report form(s)
    - Record Kit Numbers when appropriate
    - Attach tear-off labels when provided
Drug Compliance

• Accurate drug accountability is important
  ◦ To assess compliance
  ◦ To assess subject’s understanding of dosing regimen
  ◦ To demonstrate efficacy of study medication
Drug Compliance

- Actual # taken = # dispensed - # returned

- Predicted # taken = amt per day \times # of days

- Compliance % = \frac{Actual}{Predicted} \times 100%

- # missed doses = predicted - actual
Unblinding of Drug Treatment

- Treatment should not be unblinded except under emergency conditions.
- Emergency unblinding procedures are described in the protocol.
- Unblinding should be discussed with the sponsor if possible.
- Safety of the subject is paramount.
Drug Return

- All study drug must be accounted for
- Follow sponsor’s written directions
- Alternative disposition may be authorized
Services Provides from IDS

- Security and storage meeting Good Clinical Practice (GCP) guidelines
- Controlled temperature with monitoring
- Drug preparation and dispensing meeting local, state and federal guidelines
- Enrollment, randomization and blinding/un-blinding when needed
IDS – Drug Accountability – Compliance - Documentation

- Receipt of Drug
  - Date shipped/received
  - Quantity, batch/lot, expiration etc
  - IVRS confirmation of receipt of drug

- Drug preparation and dispensing

- Drug returns and destruction per protocol
Documentation in the EMR

- After patient has signed the consent, study personnel will document in the EMR
- UCD Hospital P & P # 2317
- Open the “PROBLEM LIST” in the patients medical record
- Enter the code V70.7
Problem List in EMR

Enter V70.7 code

Change the display to “RESEARCH PATIENT” instead of “Exam-Clinical Research”

Complete the Comment Section
EMR – Comments Section

- IRB identification number
- Title of the study
- Phone Contact information
  - Principal Investigator
  - Study Coordinator
- Add any information that would help the non-study clinician in an emergency
Compliance

- Use sponsor monitor visits to your advantage.
- Use local quality assurance (QA) review committee audits when available.
- Make appropriate corrections before an audit.
Drug Accountability - Summary

- All study drug must be accounted for!
- Do the numbers add up?
IDS Contact

- **Location:**
  - 2315 Stockton Blvd, Rm DT 0762, Sacramento, CA 95817
- **Phone:** (916) 703-4093
- **Pager:** (916) 762-3929
- **Email:** IDS@ucdmc.ucdavis.edu
Thank you!

ACCORDING TO SOME WEBSITES I’VE FOUND I’VE GOT ALL THESE DISEASES! HOW MANY TRIALS CAN YOU GET ME ON?