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INVESTIGATIONAL DRUGS

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Howard University Cancer Center

Department of Pharmacology

Objectives

- Explain the requirements of the research pharmacy and roles of an investigational pharmacist
- List the procedures of receiving, handling and storing investigational drugs
- Compare the requirements of industry sponsored, cooperative groups, FDA and internal audits

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Outline

Receipt
Storage
Dispensing/Accountability
Study Drug Ordering
Sponsor Visits
Records
Standard Operating Procedures

Goals and Objectives

Goal: To be familiarized with the products of handling investigational products (IPs)

Objectives:

Understand the requirements of research pharmacy and the roles of an investigational pharmacist.

Procedures of receiving, handling, and storing investigational drugs.

Compare requirements of industry sponsored, cooperative groups, FDA and internal audits.

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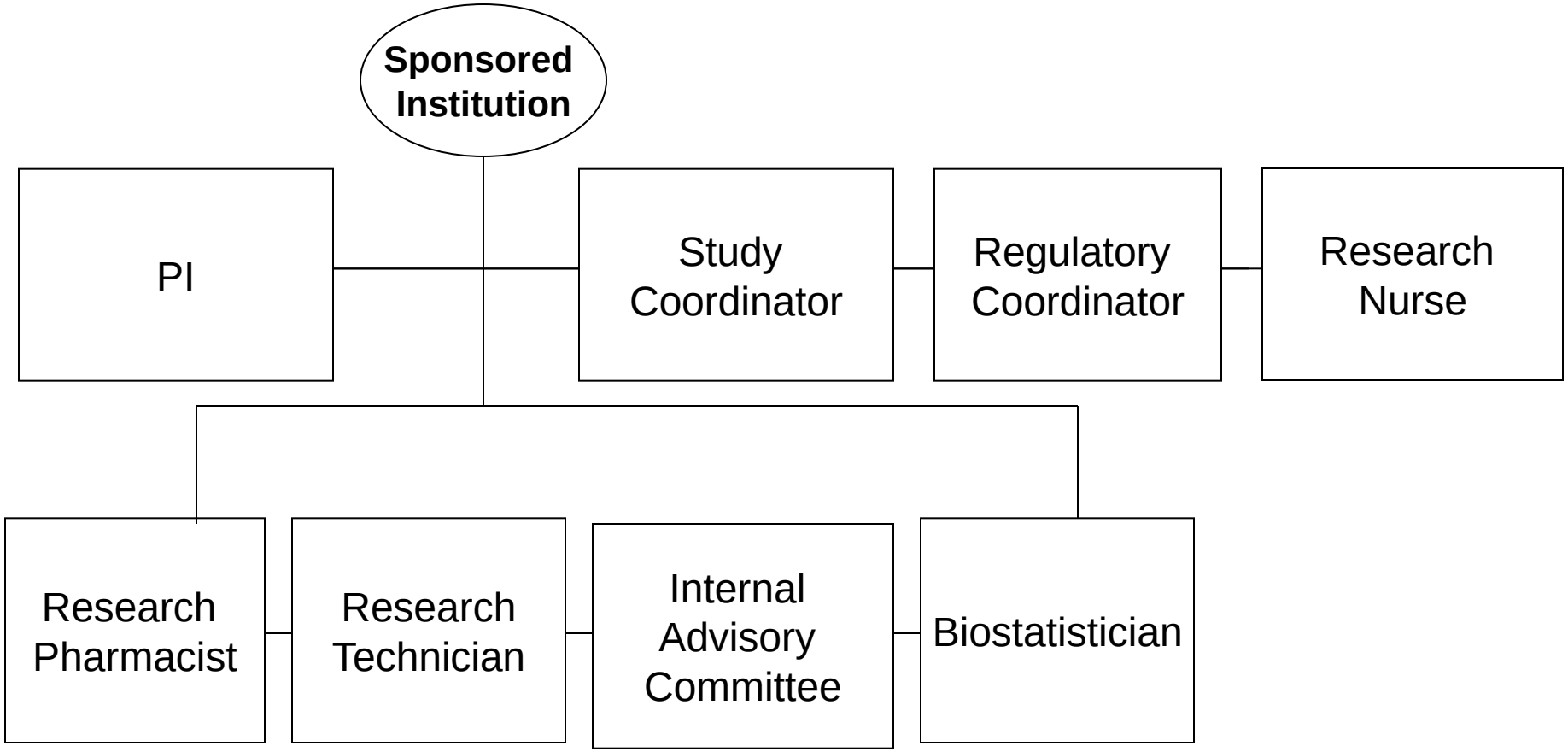
General Research Team



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General Background Information

- HUH Research Pharmacy
- Over 100 active protocols
- Over 50 active drug protocols
- Howard University Cancer Center, diabetes, sickle cell, prostate and breast cancer, melanoma, psychotic disorders, and PI initiated studies
- Two research pharmacist and one technician

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FDA General Provisions for Clinical Investigators

U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

Most Popular Searches

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CFR - Code of Federal Regulations Title 21

FDA Home ▸ Medical Devices ▸ Databases

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[Code of Federal Regulations]
[Title 21, Volume 1]
[Revised as of April 1, 2013]
[CITE: 21CFR50]

TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER A--GENERAL
PART 50 PROTECTION OF HUMAN SUBJECTS

Subpart A--General Provisions

Sec. 50.1 Scope.

(a) This part applies to all clinical investigations regulated by the Food and Drug Administration under sections 505(i) and 520(g) of the Federal Food, Drug, and Cosmetic Act, as well as clinical investigations that support applications for research or marketing permits for products regulated by the Food and Drug Administration, including foods, including dietary supplements, that bear a nutrient content claim or a health claim, infant formulas, food and color additives, drugs for human use, medical devices for human use, biological products for human use, and electronic products. Additional specific obligations and commitments of, and standards of conduct for, persons who sponsor or monitor clinical investigations involving particular test articles may also be found in other parts (e.g., parts 312 and 812). Compliance with these parts is intended to protect the rights and safety of subjects involved in investigations filed with the Food and Drug Administration pursuant to sections 403, 406, 409, 412, 413, 502, 503, 505, 510, 513-516, 518-520, 721, and 801 of the Federal Food, Drug, and Cosmetic Act and sections 351 and 354-360F of the Public Health Service Act.

(b) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21, unless otherwise noted.

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FDA Regulations

- FDA Requirements
  - 21CFR205.50(c) (revised April 1, 2012)
- Cold Chain Management
  - "Uninterrupted flow of temp. controlled shipment from manufacturing through delivery to end user"

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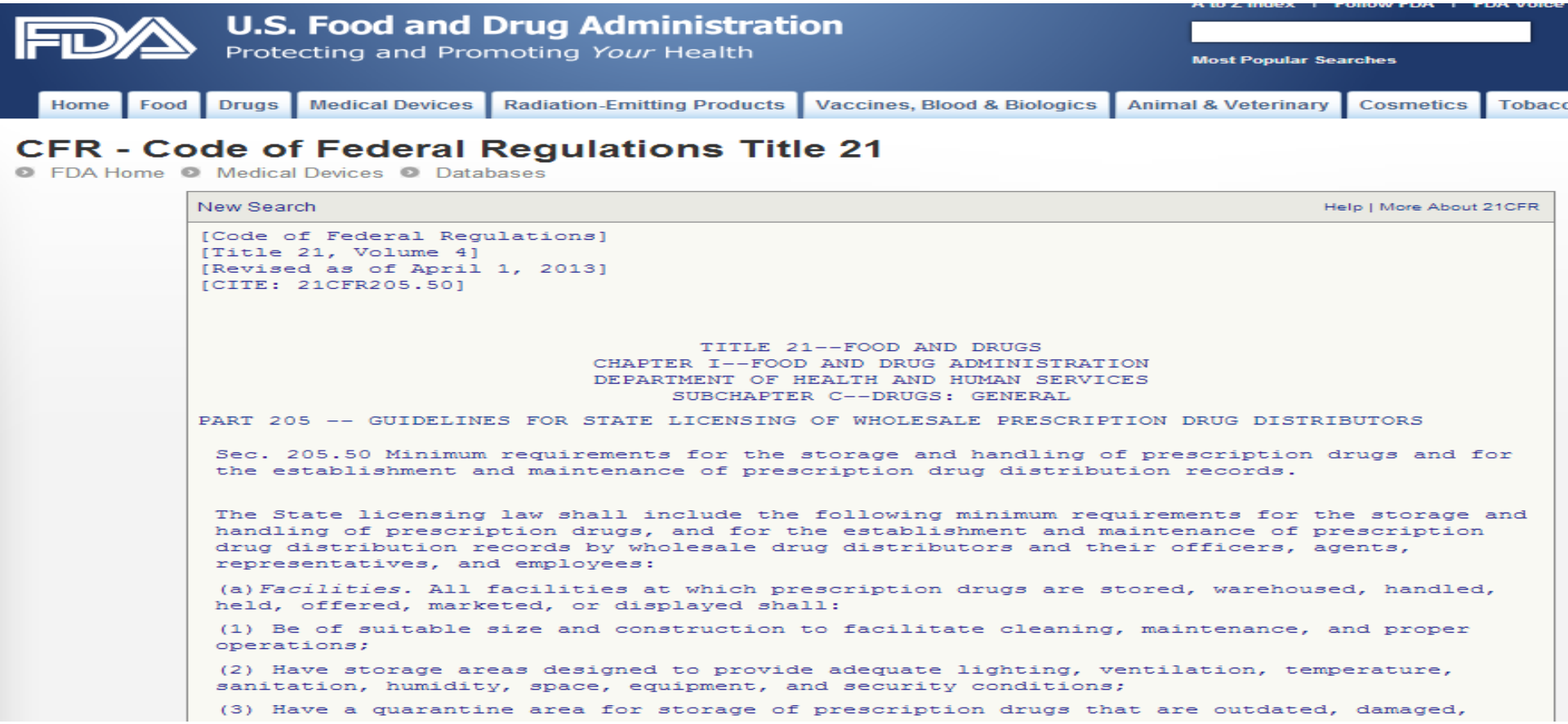
FDA Requirements and Guidelines for Drug Storage



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Shipping/Receipt

Insulated Storage Containers
TempTale, FreezeTag,
Temperature Datalogger

Invoice / Shipping Form
Confirmation/Acknowledgement

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Storage

Security / Restricted Access

Equipment:

Subzero (-20°C) and UltraLow Freezers (-70°C)

Liquid Nitrogen Freezer (-180°C)

Refrigerator (2-8°C)

Controlled Room Temperature (15-30°C)

Temperature Monitoring Devices

Min. and Max.

Temp. Datalogger with Alarm System

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Drug Storage

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Room Temperature Drug Storage-Example

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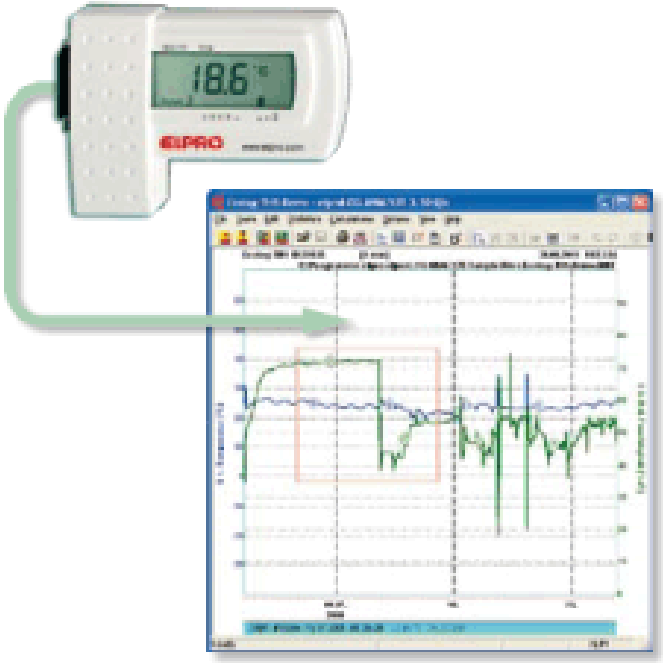
Temperature Monitoring Devices - Example



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Temperature Devices- Example

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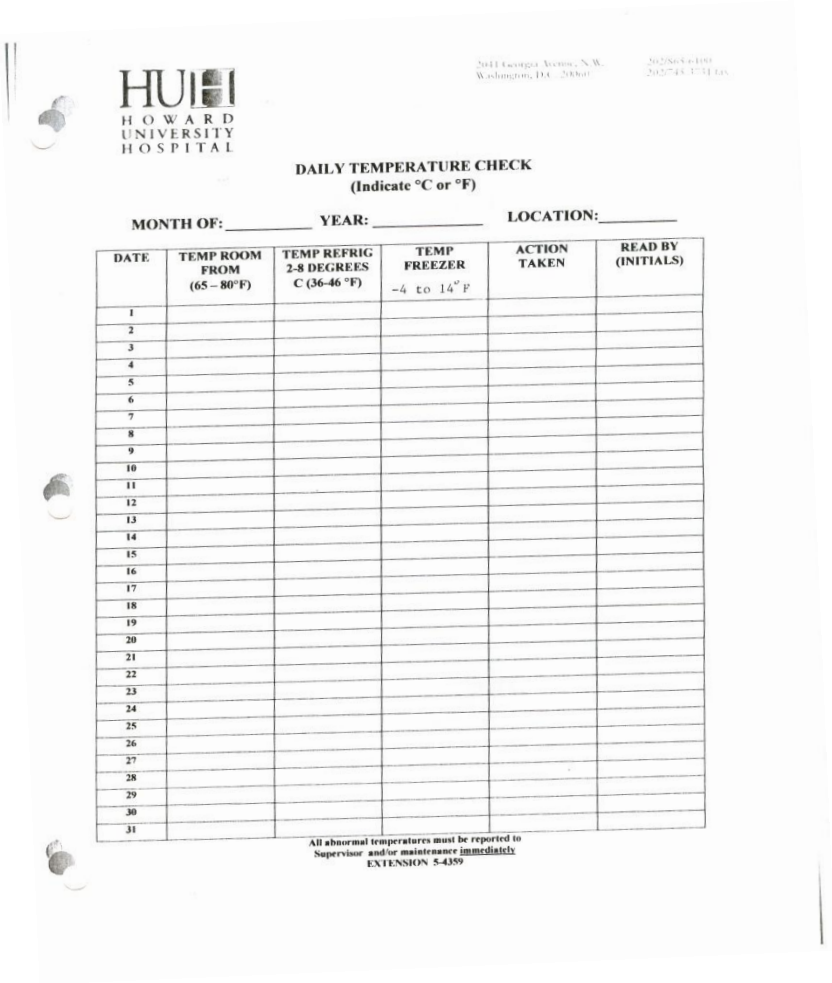
Temp Monitor Log

- List Room Temperature
- Refrigerator Temperature
- Freezer Temperature
- Action Taken



HUH
HOWARD UNIVERSITY HOSPITAL

DAILY TEMPERATURE CHECK
(Indicate °C or °F)

MONTH OF:_____ **YEAR:** _____ **LOCATION:**_____

DATE	TEMP ROOM FROM (65 – 80°F)	TEMP REFRIG 2-8 DEGREES C (36-46 °F)	TEMP FREEZER -4 to 14°F	ACTION TAKEN	READ BY (INITIALS)
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					
14					
15					
16					
17					
18					
19					
20					
21					
22					
23					
24					
25					
26					
27					
28					
29					
30					
31					

All abnormal temperatures must be reported to Supervisor and/or maintenance immediately
EXTENSION 5-4359

Dispensing / Accountability

- Pre-Printed Study Drug Order Form
- Accountability Forms
  - NCI / CTEP
  - ACTG / DAIDS
  - Industry Provided
  - Own Form

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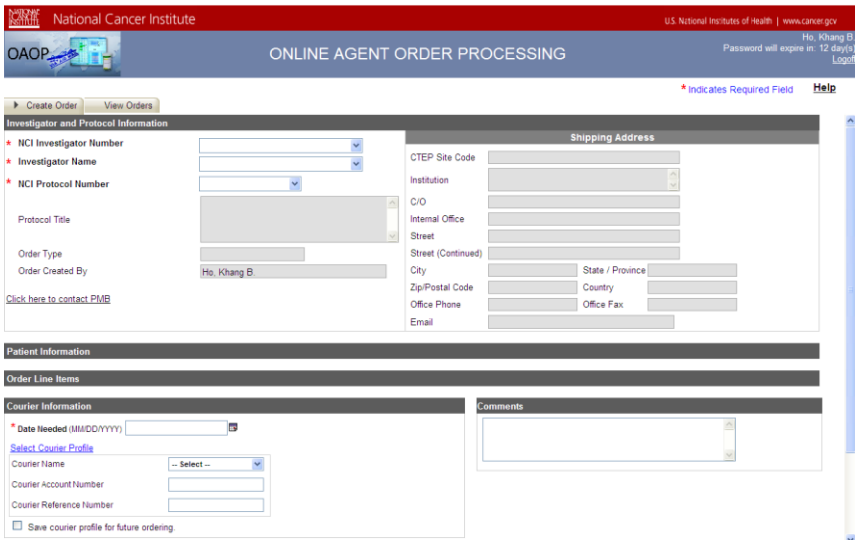
Study Drugs Ordering

- NCI / CTEP / IAM
- ACTG / DAIDS
- Industry / Sponsor Specific Procedures
  - IVRS / IWRS
  - RAMOS
  - Email / Fax



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Accountability Forms
NCI and DAIDS

OMB No. 0925-0240
Expires: 02/28/2011
NIH 2584

National Institutes of Health
National Cancer Institute

Division of Cancer Treatment and Diagnosis
Cancer Therapy Evaluation Program

PAGE NO.
CONTROL RECORD ☒
SATELLITE RECORD ☐

Investigational Agent Accountability Record

Name of Institution: The Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins	NCI Protocol No.: J1124
Agent Name: GSK2118436	Dose Form and Strength: 75mg capsule
Protocol Title: A Phase II Study Of The Selective BRAF Kinase Inhibitor GSK2118436 In Subjects With Advanced Non-Small Cell Lung Cancer And BRAF Mutations	Dispensing Area: Weinberg Pharmacy
Investigator Name: Charles Rudin, MD	NCI Investigator No.: N/A

Line No.	Date	Patient's Initials	Patient's ID No.	Dose	Quantity Dispensed or Received	Balance Forward / Balance	Kit #	Lot/Batch#	Recorder's Initials
1.									
2.									
3.									
4.									
5.									
6.									
7.									
8.									
9.									
10.									
11.									
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16.									
17.									
18.									
19.									
20.									
21.									
22.									
23.									
24.									

Study Product Accountability Record
Division of AIDS (DAIDS)
National Institutes of Allergy and Infectious Diseases (NIAID)

PAGE ____ OF ____

Clinical Research Site Name: Georgetown University Hospital			Clinical Research Site Number: 1008	
Investigator of Record Name: Joseph Timpone,MD			Investigator Number: 30743	
Protocol Number: A5257	Study Product Name: Emtricitabine Tenofovir DF(FTC/TDF)		Strength and Dosage For: 200mg/300mg	NSC Number: 900158
Package Size: 30 /Btl	Manufacturer: GSI	Lot Number: 02009254	Storage Temperature: Room Temperature	Expiration Date*: 11-2014

*Note: Expiration dates may not be available for all study products.

	Rx Number	Date	SID	PID	Quantity Dispensed or Received	Balance Balance Forward	R.Ph. Initials	Comments
1								
2								
3								
4								
5								
6								
7								
8								
9								
10								
11								
12								
13								
14								
15								
16								
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18								
19								
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22								
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29								
30								
31								
32								

All entries must be made in ink. Corrections may be made by drawing a line through the incorrect entry, then enter the correct entry and initial the correction.
This is a standard form used for all DAIDS sponsored studies. Photocopying is authorized. F-1
Revised July 2008

Dispensing / Accountability Cont'

- Monthly Reconciliation
- Expiry Tracking
- Quarantine
- Dispensing of Standard of Care Meds
  - Lots
  - Expiration
  - Manufacturer

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DRUG ACCOUNTABILITY RECORDS

- Accurate records of all study drug received at, dispensed from, returned to and disposed of by the study site should be recorded by using the Drug Inventory Log. The log can be provided to you if you do not have your own standard format.
- Inspections of the study drug supply for inventory purposes and assurance of proper storage should be conducted as necessary. Any significant discrepancy should be recorded and reported to the sponsors IDS or their designee and a plan for resolution should be documented.

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DRUG ACCOUNTABILITY RECORDS, cont'd.

- Temperature records for drug must be made available to the sponsored IDS or other Sponsor nominated monitoring teams for verification of proper study drug storage.

- Only completely unused study drug vials should be retained by the site until a representative from the main sponsors IDS or other sponsored IDS-designated personnel have completed an inventory.

DRUG ACCOUNTABILITY RECORDS, cont'd.

- Partially used and completely used drug vials should be destroyed according to the site's guidelines, and their disposition should be recorded on the Investigational Drug Accountability Record Form.
- All returned medication is to be documented on the Drug Accountability Record From per institutional policy.

Drug Destruction Policy, cont'd

- If the study site chooses to destroy study drug, the method of destruction must be documented and the sponsored IDS must evaluate and approve the study site's drug destruction standard operating procedure prior to the initiation of drug destruction by the study site.

- WHAT IS YOUR SITE'S DRUG DESTRUCTION POLICY? _____

Documentations / Records

- Shipping Documents / Invoices
- Accountability Logs
- Temperature Logs
- Correspondences
  - Emails, Faxes, Letters
- Memos To File (MTF)
- Destruction or Drug Return Forms

Standard Operating Procedures (SOPs)

- SOPs
  - Storage Procedures
  - Temperature Monitoring
  - Destruction of Study Drugs or Investigational Products
  - Storage of Records

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Sponsor Visits / Audits

- Pre-Qualification / Site Selection Visit
- Site Initiation Visit
- Routine Monitoring Visit (RMV)
- Close Out Visit
- Audits
  - Internal
  - Sponsor
  - FDA

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Questions?