SARASOTA MEMORIAL HOSPITAL
CANCER RESEARCH DEPT. POLICY

TITLE:	**STANDARD OPERATING PROCEDURE FOR INVESTIGATIONAL DRUG ACCOUNTABILITY, STORAGE, TRANSPORT, DISPENSING AND RETURN**	**POLICY #:**	256.001
		EFFECTIVE DATE:	April 28, 2010
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		POLICY TYPE:	
		PAGE:	☐ DEPARTMENTAL ☐ INTERDEPARTMENTAL ☐ DEPARTMENTS PROVIDING NURSING CARE 1 of 10

Job Title of Reviewer: Sandy Davis, RN, MSN, CCRP

PURPOSE: This standard operating procedure (SOP) describes the processes at this investigative site for the receipt, storage, dispensing, reconciliation and return or authorized destruction of the investigational drug (study drug).

POLICY STATEMENT: This SOP applies to all procedures related to all clinical studies subject to investigational new drug (IND) regulations for drugs and biologics during all investigational phases of development. It describes the steps followed by this clinical research site from the time the study drug is received on-site until it is either returned to the sponsor or destroyed on-site at the sponsor's request.

DEFINITIONS: Standard Operating Procedures (SOP), Investigational new drug (IND), Principle Investigator (PI), Sub-Investigator (Sub-I), Food and Drug Administration (FDA), Institution Review Board (IRB), Standard of Procedures (SOP), Adverse Events (AE), Serious Adverse Events (SAE)

PROCEDURE:

A. RECEIPT AND INVENTORY OF STUDY DRUG

1. All study drugs are received at Florida Cancer Specialist Office location of 1970 Golf Street, Sarasota, FL 34236 from the sponsors. Upon subject enrollment, study drug will be transported via secure courier to the location where the patient will receive treatment. All locations will be documented on the FDA form 1572.
2. Upon receipt of the study drug, delegated research staff at Florida Cancer Specialist will contact the Sarasota Memorial Health Care System Research/Pharmacy Coordinator at 941-917-2227. The SMH Research/Pharmacy Coordinator will inventory the shipment, ensuring that the information on the packing slips matches exactly with what has been sent to the site to include the amount, lot numbers, quantity per carrier / container, etc.
3. The Research/Pharmacy Coordinator will promptly bring any discrepancies to the attention of the sponsor.
4. If the sponsor includes a form in the shipment to acknowledge receipt, obtain the appropriate signature and forward the form to the sponsor/CRO.
5. A copy of the shipping receipt should be maintained with the pharmacy files and at study close with the regulatory documents

6. Ensure that if unblinding supplies are provided that they are kept stored with the pharmacy files.
7. Receipt of study drug is recorded on the NIH Drug Accountability Form (Attachment A), indicating date, units received, lot number, and receiver's initials.

B. STORAGE

1. Study drug will be stored in a secure environment with access limited to essential research personnel, according to the storage requirements detailed in the protocol or supplied by the sponsor in a supplementary document. The Research/Pharmacy coordinator will ensure that study drug is stored at the appropriate temperature (Attachment B), maintaining a storage area temperature log.
2. All Sarasota Memorial Health Care System study drugs, that are received at Florida Cancer Specialist,1970 Golf Street, Sarasota, FL 34236 are stored in an SMH owned and monitored refrigerator or freezer. Temperature control logs are recorded routinely and are available for monitors to review.
3. On occasion, Sarasota Memorial Health Care System study drugs are received at Florida Cancer Specialist, 1970 Golf Street, Sarasota, FL 34236 and can be stored among Florida Cancer Specialist study drugs. SMH Study drugs will remain in their own container with proper labeling attached. This is most likely to occur for drugs not requiring refrigeration or freezing temperatures. Drug accountability records are kept by SMH Research staff and will be available for monitors review.
4. Ensure that the randomization code, if appropriate, has been received.
5. All drug receipts are filed and kept in the drug manual and shipments are logged on the NIH Drug Accountability Form.

C. DISPENSING OF STUDY DRUG

1. The SMH Research/Pharmacy Coordinator will ensure that each time study medication is dispensed, the NIH Drug Accountability Record Form. http://ctep.cancer.gov/forms/accountability.pdf) or comparable accountability record is completed at the Florida Cancer Specialist office location of 1970 Golf Street, Sarasota, FL 34236. The SMH Research Coordinator will ensure that the documentation occurs at the every location the drug is dispensed (for example a satellite site listed on the 1572 for that study). Documentation will include at a minimum:

    - Amount (and lot number, if appropriate) dispensed,
    - Initials of individual dispensing study drug,
    - Subject's number,
    - Subject's initials,
    - Date (and time, if appropriate) of dispensing,
    - Date (and time, if appropriate) amount of and amount of study drug returned, if applicable

2. When requested by study sponsor, empty, partial, and unused oral and IV medication containers will be returned to the research pharmacy via courier for

drug accountability purposes.

3. The drug accountability records are maintained at Florida Cancer Specialist, 1970 Golf Street, Sarasota, FL 34236. At the request of the study monitor, drug accountability records can be brought to Sarasota Memorial Health Care System for the monitoring visits but then will return to the Florida Cancer Specialist office since this is the site of drug storage. All drug accountability records will be at Sarasota Memorial Health Care System at study closure in the Cancer Research office.
4. All investigational drug monitoring visits will be scheduled in advance and will be conducted with the research pharmacy coordinator at the Florida Cancer Specialist Office at 1970 Golf Street, Sarasota, FL 34236. Monitors are not permitted to perform drug inventory without the presence of an SMH Research Staff. All monitoring visits must be scheduled in advance by contacting the SMH Research Staff at 941-917-2227.
5. The SMH study research/pharmacy coordinator will ensure that study drug supplies are adequate and within an appropriate expiration date. The study research/pharmacy coordinator will monitor any extension of study drug expiration.
6. The SMH study research/pharmacy coordinator will personally deliver the study drug to the pharmacy if any mixing, IV tubing preparation, or bags are required for administration. The SMH study research/pharmacy coordinator will provide a pharmacy manual from the sponsor to the pharmacy mixing the study drug. SMH study staff will be present for the patient's infusion to monitor and document any adverse events for the sponsor. Chemo infusion nurses are not responsible for reporting adverse events to the study sponsor.
7. The SMH study research/pharmacy coordinator will notify the sponsor when additional supplies will be required.

D. TRANSPORT OF STUDY DRUG

1. Upon enrollment of subjects and as needed study drug will be transported to the satellite sites where patients will receive treatment. All investigational drug will be placed inside clear plastic bags with drug dispensing tracking forms (Attachment C) for transport and will be transported to the various sites via appropriately labeled coolers.
2. Drugs requiring refrigeration will always be transported in coolers with cold packs and will be monitored with thermometers to ensure drug is maintained at temperature specified by the protocol. Temperature in the cooler is documented on the drug dispensing form at the time the drug is placed in the cooler at the central drug storage location (Florida Cancer Specialist Office, 1970 Golf Street, Sarasota, FL 34236) and upon removal from the cooler in the satellite site.
3. When the drug is received at the satellite site, a designated SMH staff member will sign, date and time when drug is removed from the cooler on the Drug Dispensing Form and place form in drug accountability binder.
4. The time that is required delivering investigational drugs from the central drug storage location (Florida Cancer Specialist Office, 1970 Golf Street, Sarasota, FL 34236) to satellite sites should not exceed 3 hours. Specific courier route is subject to change.

E. RETURN/DESTRUCTION OF STUDY DRUG

1. All empty intravenous bags and tubing or syringes will be destroyed in chemo safety buckets according to the policy and procedure for drug disposal at the individual sites.
2. At the conclusion of the study, the SMH research pharmacy coordinator will ensure that all documentation regarding receipt, storage, dispensing, and return of used investigational drug containers is complete, accurate, and ready for review at the sponsor's termination visit.
3. The SMH Research/Pharmacy Coordinator will ensure that the study drug is available for the monitor to inventory and prepare for return shipment to the sponsor/CRO if applicable.
4. Destruction of study drug at the research sites, upon written authorization from the sponsor to do so, may be undertaken so long as such procedures are permitted by the site's OSHA and biohazard materials policies.
5. Provide the sponsor with written documentation of the destruction of the study drug per institutional policy.
6. Maintain a copy in the Regulatory Binder. Please see attachment D.

RESPONSIBILITY:

This SOP applies to those members of the clinical research team involved in inventorying, storing, dispensing, or arranging for the return/destruction of study drug in connection with all clinical studies carried out at this investigative site. This includes the following:

Principal Investigator
Sub-Investigator
Site Project Manager
Research/Pharmacy Coordinator
Research Assistant
Regulatory Coordinator
All other applicable research staff
Study Monitors/ Sponsors

It will be the responsibility of the Sarasota Memorial Health Care System directors to ensure that the Cancer Care Service Department Research Staff is aware of, and adhere to, this policy.

REFERENCES:

1.APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 312.50	General responsibilities of sponsors
21 CFR 312.56	Review of ongoing investigations
21 CFR 312.59	Disposition of unused supply of investigational drug
21 CFR 312.60	General responsibilities of investigators
21 CFR312.61	Control of the investigational drug

21 CFR 312.62	Investigator recordkeeping and record retention
21 CFR 312.68	Inspection of investigator's records and reports
21 CFR 312.69	Handling of controlled substances
November 1998	Guidelines for the Monitoring of Clinical Investigations
December 8, 2008	FDA Internal Compliance Program Guidance Manual 7348.811: Clinical Investigators
May 1997	International Conference on Harmonization; Good Clinical Practice: Consolidated Guideline
2006	FDA Inspections of Clinical Investigators

2. Selected Regulations and Guidance for Drug Studies (2004). Philadelphia, PA: Clinical Research Resources.

3. FCS Investigative Site SOP: PM 305: SOP for Investigative Drug Accountability, Storage, Transport, Dispensing, and Return, Version date 15OCT2009. FCS: Author.

REVIEWING AUTHOR(S):

SMH: Tamela Fonseca, RN, CCRC, Site Project Manager; SMH: Yulonda Greene, RN, BSN, Director ; First Physicians Group: James Fiorica, MD; FCS: Katie Goodman, Research Director

ATTACHMENT(S):

Attachment A - NIH Drug Accountability Record
Attachment B- Temperature Log
Attachment C- Drug Dispensing Sheet
Attachment D- Drug Destruction Log

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:	NCI Protocol No.:
Agent Name:	Dose Form and Strength:
Protocol Title:	Dispensing Area:
Investigator Name:	NCI Investigator No.:

Line No.	Date	Patient's Initials	Patient's ID No.	Dose	Quantity Dispensed or Received	Balance Forward / Balance	Manufacturer and Lot No.	Recorder's Initials
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FLORIDA CANCER SPECIALISTS
DRUG STORAGE TEMPERATURE LOG
OFFICE:______________________________

Date	Temperature (Celsius)	Staff Initials	Date	Temperature (Celsius)	Staff Initials	Date	Temperature (Celsius)	Staff Initials

Refrigerators must maintain temperatures between
2 degrees Celsius and 8 degrees Celsius.
Notify the research department if temperature out of range.

Sarasota Memorial Health Care System: Research Trials

Dispensing Sheet

Protocol Title:_____

Drug to be Dispensed from Central Drug Storage
FCS 1970 Golf Street; Sarasota, FL 34236.

Date :_____ Drug: _____
Transferred to location: _____
Patient: _____Subject ID: _____

Vials sent: _____ Lot # _____ Temp _____(° C)

_____ _____
Signature of Research Nurse Responsible for drug transport Date

Receipt of Drug at Satellite Site

_____ (° C)
Temperature of Drug on Receipt (if applicable)
Store in refrigerator (2C-8C) protected from freezing. Do not shake. Protect from light.

_____ _____
Signature of Research Nurse Delivering & Logging Drug Date

Place original of this form in your Research Drug Accountability Log.

Sarasota Memorial Health Care System
Cancer Care Services-Research Trials

Drug Destruction Note to File:

Protocol:_____

Investigational Drug Name: _____

Batch# _____ Container# _____

Drug destroyed at _____, according to protocol guidelines.

Amount destroyed_____.

Drug destroyed by _____, on this date _____.

Per protocol guidelines the above referenced drug was destroyed. Sponsor and/or study monitor was made aware that drug was being destroyed at site.

_____ _____
Signature of Research Nurse responsible for drug destruction Date

APPROVALS:

Signatures indicate approval of the new or reviewed/revised policy	**Date**
Signature: **Title:**	
Signature: **Title:**	
Signature: **Title:**	
Committee/Sections (*if applicable*):	
Department and Site Project Manager **Signature:** **Title:** Tamela Fonseca, RN, BSN, CCRC, Site Project Manager **,** Sarasota Memorial Health Care System	
Vice President/Administrative Director (*if applicable*): **Signature:** **Title:** Yulonda M. Greene, RN, BSN, OCN, Director, PT. Care Services Institute for Cancer Care, Sarasota Memorial Health Care System	
First Physicians Group Physician **Signature:** **Title:** James Fiorica, MD, GYN Oncologist	
Florida Cancer Specialist **Signature:** **Title:** Katie Goodman, Research Director	