S.O.P. IV TRANSPORT of Study Medications to Satellite Pharmacies

I. PURPOSE

A. To clarify the responsibilities and procedures of the Investigational Pharmacy in the transportation of study medications to respective pharmacy satellite within University Hospitals Case Medical Center hospital system.

B. As University Hospitals expands to meet the needs of patients in a larger area of Northern Ohio, satellite locations of the University Hospitals Health System have been opened. Patients who have been enrolled in UH investigational protocols may be treated at other sites that are a part of University Hospitals Case Medical Hospital system.

C. This outlined procedure is intended to meet Good Clinical Practices (GCPs) in handling and transport of Investigational Product (IP) between the IDS Pharmacy (Room B052, 11100 Euclid Avenue, Cleveland, Ohio 44106) to respective satellite pharmacies (listed in Appendix I in this document).

D. Transfer of Study Articles to satellite pharmacies within university hospital system will be subject to final approval of the protocol sponsor.

E. Where the standards set out in this document are not acceptable to a given protocol sponsor, additional efforts will be made to comply with the particular protocol and sponsor requirements. If such efforts still fall short or sponsor requirements, study IP will not be transferred to pharmacy satellite and study IP storage, preparation and dose administration will be performed on UHCMC main campus, with drug handling directly overseen by IDS Pharmacy.

II. SCOPE

This procedure applies to the transport of study investigation product (IP) between IDS Pharmacy and respective system pharmacy satellites (referred to in Appendix I).
III. DEFINITIONS

INVESTIGATIONAL PRODUCT (IP): "Investigational product" is defined as any unapproved drug, medical device, or biologic undergoing clinical trials to provide evidence to regulatory authorities that the product is safe and efficacious. Synonymous with term INVESTIGATIONAL DRUG, further defined as "...a pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial, including a product with a marketing authorization when used or assembled (formulated or packaged) in a way different from the approved form, or when used for an unapproved indication, or when used to gain further information about an approved use." *(ICH GCP E6, section 1.33)*

DELIVERY MANIFEST: A summary of the specific investigational agents included in a shipment. The manifest includes the investigational drug description, associated protocol study name/number, quantity, and lot number. Included on this form is a place for the responsible pharmacist to sign and date as acknowledgement of receipt of IP. This document should be faxed back to UHCMC IDS (216-844-1445) once the shipment has been verified.

PATIENT TREATMENT RECORD: A patient-specific form for each investigational agent. This document includes the drug description, dose (if available at time of shipping), quantity, lot number, and anticipated date of treatment. Included on this form is a place for the responsible pharmacist to sign and date. This document should be faxed back to UHCMC IDS (216-844-1445) at the time that the investigational agent is actually prepared or dispensed. The original (signed) Patient Treatment Record should be stored in the appropriate site protocol study binder along with the signed physician’s order that supports the use of that investigational agent.

DRUG ACCOUNTABILITY RECORD FORM (DARf): This is a document on which all transactions for a specific investigational agent are recorded, including receipt, dispensing, return, and waste of the investigational agent. A separate DARf must be used for each investigational agent in each protocol. Requests for additional blank forms should be requested by the satellite pharmacist from the UHCMC IDS pharmacy.
PROTOCOL STUDY BINDER: This is a satellite-specific, study-specific binder that is a central storage place for all documentation that pertains to that specific study. Each protocol binder will contain the following:
   a. Patient enrollment form
   b. Drug Accountability Record form (for each investigational agent)
   c. Pharmacy Synopsis
   d. Protocol
   e. Storage area for all documentation associated with the protocol including, but not limited to shipment receipts, Patient Treatment Records, notes to file.

IV. RESPONSIBILITIES

A. Investigational Site Responsibilities
   1. The IDS Pharmacy is responsible for accurate and timely transport of IP between the IDS Pharmacy and respective pharmacy satellites, as outlined in procedures section of this SOP.

B. Sponsor Responsibilities
   1. The Sponsor is responsible acceptance of the transport of IP as outlined in this SOP, OR providing details of additional requirements necessary to meet the sponsor specified requirements.
   2. If the additional requirements and procedures are created and accepted by both the IDS Pharmacy and study sponsor, a letter to file document should be created listing the accepted procedures and placed within the respective study protocol pharmacy binder.
   3. If established procedures are not acceptable, a memo or email should be provide detailing that the sponsor has not granted permission for transport of IP to associated pharmacy satellites.
V. PROCEDURES

A. Study articles will be transferred to the appropriate satellite pharmacy with a written request for the appropriate study coordinator. If possible, the Investigational Pharmacy will be given adequate notice to ensure timely delivery of the study article to the satellite pharmacy. The written notice can be FAXED to the Investigational Pharmacy in the form of a study prescription that includes the study name, Patient name, Patient Study ID, assigned study medication or medication kit number, patient directions. The request should include the date and satellite location the study medication will need to be available.

B. Study articles/medication will be prepared and labeled as patient specific prescriptions. A patient delivery sheet will be created that includes information on the transport request. (Patient initials, Patient Study ID Number, Study Identification, Study article name, and the name of the satellite pharmacy.)

C. Each transport record will provide a summary of all study articles being transported to a particular satellite pharmacy (DELIVERY MANIFEST).

D. The investigational pharmacy and satellite pharmacy staff will be responsible for maintaining drug accountability records and ensuring that the drug is available at the satellite location when needed. Please refer to IDS Pharmacy SOP VII: IDS Satellite Procedures for more details.

E. Drug is transported under study article storage requirements. (ie: in cooler with ice pack(s) if refrigeration required). Transportation from the Investigational Pharmacy location to the various satellite pharmacy locations listed above will generally take less than one hour (but up to 2 hour time frame is allowed).

F. TRANSPORT of IP requirement of being frozen during transport will not be eligible for transport to a satellite pharmacy.

G. Drug is transported by local courier service and is a direct delivery between the IDS Pharmacy and respective satellite pharmacy.
H. Upon receipt of study articles at the satellite pharmacy, the responsible pharmacist will reconcile the shipment, sign the delivery receipt of the shipment and then faxed a copy of the signed delivery receipt to the Investigational Drug Pharmacy as proof that the items were successfully transported to the satellite pharmacy. The original signed acknowledgement of receipt will be maintained within the satellite protocol binder.

I. Transportation of the study articles is performed by a local courier services (Bonnie Speed Delivery Services). Associated charges for the courier services are the responsibility of the respective study grant.

J. Good communication between the investigational pharmacy staff and study nurses, and between pharmacy staff at various locations will help serve the needs of enrolled study patients.

SIGNATURE PAGE

I have reviewed and approved this SOP:

[Signature]

IDS Pharmacy Signature

[Date]

MICHAEL J BANCHY R.Ph.

PRINTED NAME
APPENDIX 01

II. Satellite Locations (include, but are not limited to the following locations):

Chagrin Highlands Medical Center
Seidman Cancer Center Pharmacy
Suite 1100, Room 1156
3909 Orange Place
Orange Village, OH 44122
216-896-1826

Firelands Seidman Cancer Center
Seidman Cancer Center Pharmacy (Firelands)
701 Tyler Street, Professional Building #1
Sandusky, OH 44870
419-557-7311

GEAUGA (University Hospitals)-Geauga Medical Center
Pharmacy-Geauga Medical Center
Chardon Ohio 44024
(440) 285-6365

Lake University Seidman Cancer Center
9485 Mentor Avenue
Suite #3, Room L39
Mentor, OH 44060
440-205-5711

Monarch (Landerbrook) SCC
SCC Pharmacy (Monarch)
5885 Landerbrook Drive, Suite 100
Mayfield Heights, OH 44124
440-995-2702

Sharon Health Center Seidman Cancer Center
Seidman Cancer Center Pharmacy (Sharon)
5133 Ridge Road
Wadsworth Ohio 44281
(330) 239-7215

Southwest General Hospital
Seidman Cancer Center Pharmacy (Southwest)
18697 Bagley Road
Middleburg Heights, OH 44136
440-816-6072

St. John's Medical Center/UH Seidman Cancer Center
Seidman Cancer Center Pharmacy (St. Johns)
29325 Health Campus Drive Suite #1
Westlake, Ohio 44145
(440) 617-4674

Westlake Seidman Cancer Center
SCC Pharmacy (Westlake)
960 Clague Road
Westlake, OH 44145
440-250-2014