

	POLICY TITLE: Investigational Product Management
MANUAL NAME: Clinical Operations	POLICY NUMBER: CR 1.2.1 <input type="checkbox"/> Addendum to Corporate Policy <input type="checkbox"/> Form Available In I-REPP System
SECTION (as applicable): Clinical Research	POLICY OWNER: Tedd Adair, Vice President of Clinical Operations and Chief Clinical Officer
ORIGINATION DATE: 01/01/2011	FINAL APPROVAL DATE: April 30, 2016

POLICY:

Management of investigational drugs and any other investigational products/agents. To protect patient safety by ensuring proper management of investigational drugs and other products (IP), including IP accountability, storage, dispensing, transfer, and return of the product.

SCOPE:

This procedure applies to investigational products used in any clinical trial conducted at any IASIS facility.

DEFINITIONS:

Investigational Agent/Product (IP): An investigational agent or product is any packaged medication, device, other treatment, consumer product, or supplement (including active, placebo, labeled in double-blind, single blind or open format) that is intended for administration to subjects as part of a study protocol to test the effects of the product.

IP Dispensing: In most health care settings, dispensing means the pouring or placing of drugs from stock supplies into bottles or containers for use by individual patients and the labeling of these containers with the medication and dosage. This is the role of the pharmacist. In the conduct of clinical trials, study medication from stock supplies is placed into containers and labeled by the sponsor (or a sponsor's agent). When a site has been approved by the sponsor to begin enrolling patients into a study, the sponsor ships the study medication, which has been prepared for use by individual subjects, to the research site. Thus, in clinical trials, IP dispensing refers to the process of assigning the prepared IP to research participants under the supervision of a physician who is an investigator for the given study. This assignment process may be performed by any properly trained and authorized member of the investigator's research team.

IP Administration: In clinical trials, as in other health care settings, administration refers to the action of giving a dose of medication or applying some other treatment, product, or supplement to a patient to whom that IP had been assigned. This administration process may be performed by any properly trained and/or licensed clinician.

PROCEDURE:

IP Accountability:

- IP disposition (receipt, dispensing, and return of IP by the subject) is documented on the *Investigational Agent Accountability Record* below.
- IP is accounted for separately by protocol.
- If the same IP is used for more than one protocol, a separate *Investigational Agent Accountability Record* is maintained for each protocol.
- If a protocol uses more than one sponsor-supplied agent or more than one strength or formulation of the same agent, a separate *Investigational Agent Accountability Record* is maintained for each agent, strength, and formulation.
- In the event of a change in the study coordinator, a complete IP Accountability is performed by the new study coordinator under observation by one other employee from either Operations or the Quality Management department.
- The study coordinator performs a complete IP accountability on all of his/her studies (until all IP has been returned to the sponsor or destroyed according to sponsor instructions) according to the following frequency:
 - o Monthly for studies involving controlled substances
 - o Quarterly for studies that do not involve controlled substances

This IP accountability is performed by an authorized member of the study team or the study monitor and observed by an ICARE employee from either Operations or Quality Management. The only exception to this IP accountability procedure is when it would break the study blind, in which case the sponsor's plan for IP accountability is followed.

Forms: If the sponsor provides a form for IP accountability and storage, dispensing, return of medication by the subject, IP transfer, or IP return, that form may be used in place of the relevant form included in this Guideline.

Storage:

- Investigational agents supplied by the sponsor are stored in a secure location which is only accessible to authorized personnel
- An *Investigational Agent Accountability Record* is maintained at each location where IP is stored (e.g., main pharmacy, satellite pharmacy, physician's office, ICARE site office)
- IP is stored per the sponsor's specifications in regard to temperature, handling, light, etc.
- IP supplies are checked for expiration and damage prior to their use
- In addition to the above requirements, the following requirements must also be met for each study in which the investigational agent is a controlled substance:
 - o A study and site-specific plan for controlling access is developed prior to receiving the first shipment of the IP. This plan is documented using the *Storage and Access Plan for Controlled Substances* form and filed in the regulatory binder. Controlled substances requiring DEA 222/223 forms are always stored at the address listed on the DEA form.
 - o In the event a controlled investigational agent needs to be delivered to a patient who is in a different location than where the IP is stored, the delivery takes place the same day the agent is removed from its storage location.

Dispensing:

- IP is counted/measured to confirm the proper amount is assigned to the patient
- The *Investigational Agent Accountability Record* is initialed by the person assigning the IP and the following information is documented:
 - o Patient initials
 - o Patient number
 - o Dose (if applicable)
 - o Quantity dispensed
 - o Balance
 - o Recorder's initials
- The patient is advised about proper dosage administration and/or is given written dosage instructions if self-administered.
- The patient is reminded about the importance of returning unused study and/or empty containers if self-administered.

Administering:

- IP administration is documented in the source documents, including:
 - o Who administered the IP
 - o The date and time of administration
 - o The number of units and dose
 - o The route of administration

Return of IP by the Subject:

- The IP is counted/measured to confirm proper amount returned.
- The *Investigational Agent Accountability Record* is completed by documenting the following information.
 - o Date returned
 - o Patients initials
 - o Patient's ID number
 - o Dose
 - o Amount returned
 - o Balance
 - o Amount lost or wasted
 - o Initials
- If a patient fails to return the IP as requested, this will be documented on the *Investigational Agent Accountability Record*.
- All investigational agents are returned to their original secure location immediately upon the patient's return of the study agent to research personnel.
- The *Investigational Agent Accountability Record* is retained with the Regulatory/Essential Documents or the subject's CRF as instructed by the sponsor.

IP Transfer to a New Storage Location:

In some instances, the investigational agent may need to be transferred from one storage location to another. In these cases, designated study coordinators will have the authority to transfer the investigational agent from one storage location to another provided that all institutional approvals are obtained prior to the transfer.

- The person performing the transfer signs the *Return/Transfer Agent Form* and specifies what supplies are being transferred.
- IP supplies and/or other study supplies are transferred in accordance with the sponsor's specifications regarding handling and transport.

- IP supplies are stored in a limited access area at an approved site per sponsor's specifications in regard to temperature, handling, light, etc.
- Supplies checked for expiration and damage prior to their use

IP Return to the Sponsor:

- IP may be returned to the Study Sponsor for the following reasons:
 - o The agent is no longer required because the study is completed or discontinued.
 - o Agent is outdated. Investigators/designees should only return outdated agents with a firm expiration date or if they have received written notification from Sponsor that an agent has expired and should be returned.
 - o The IP is damaged or unfit for use. Investigators/designees should contact the Sponsor prior to returning investigational agents because of stability concerns; (e.g. loss of refrigeration or exposure to elevated temperatures). Broken vials are not returned. Broken vials are destroyed at the clinical site and the appropriate IP accountability guidelines are followed.
- The *Return/Transfer Agent Form* is completed. All information must be accurate and complete, (e.g. protocol numbers and investigator numbers).
- Quantities and lot numbers are double checked prior to shipment.
- All instructions on the *Return/Transfer Agent Form* are followed.
- The *Return/Transfer Agent Form* is enclosed with the return IP, and a copy is maintained in with the regulatory/essential documents.
- The IP is packaged securely to prevent breakage. Breakage of vials en route to the sponsor is a potential health hazard. To minimize the risk to couriers and staff, it is required that all returns follow the HAZMAT protocol.
- IP returns are shipped at room temperature unless otherwise required.
- IP returns are sent to the address indicated on the *Return/Transfer Agent Form*
- IP returns are sent next day air and documented with delivery confirmation
- Confirmation of IP return delivery is placed in the regulatory binder
- Controlled substances: All controlled substances are returned by the sponsor

IP Destruction:

IP may be destroyed per the sponsor's written instructions using the sponsor's written guidelines or the facility guidelines for destruction where the IP is stored. All information regarding lot #s, bottle #s, package #s, etc. should be documented as being destroyed.

Responsibility:

- Only authorized personnel have access to investigational products.
- All study personnel who are authorized to store, dispense, transfer, and return IP are responsible for following this Guideline.
- The study coordinator is responsible for ensuring IP accountability is performed according to the above procedures.
- The PI is responsible for ensuring that the IP is administered properly and only to those authorized to receive it.

FORM REFERENCES:

Not Applicable

REFERENCES:

Food and Drug Administration Title 21 CFR 312.62 and 812.140

Storage and Access Plan for Controlled Substance

STUDY INFORMATION

Sponsor: _____ Protocol Number: _____
Principal Investigator: _____ IASIS/ICARE Site: _____

STORAGE AND ACCESS PLAN

Location of IP Storage
Office address: _____
Room: _____
Type of cabinet/container for IP: _____

Check to verify that IP cabinet/container is:
 securely locked
 substantially constructed

List of all people who have access to the key (including PI, IASIS/ICARE employees, and others if applicable):

Comments: _____

Signature and date by the ICARE Research Supervisor or Site Director indicating that he/she has reviewed, verified, and endorsed the above plan:

ICARE Research Supervisor/Site Director Date

Signature and date by the PI or organization under whose controlled substance license the drug is shipped (if the latter, the person signing must be a licensed pharmacist who works for that organization) indicating that he/she has reviewed, verified, and endorsed the above plan:

Principal Investigator or Licensed Pharmacist Date

IASIS/ICARE Return/Transfer Agent Form Investigational Agent Accountability				Name of Institution			FOR ICARE USE ONLY:			
INSTRUCTIONS FOR RETURNS: 1. Properly complete all sections to receive credit for the return/transfer 2. Type or Print all information – one item, lot, or protocol per line 3. Enter Investigator signature or signature of individual preparing this form 4. Pack the agent(s) well to minimize breakage and leakage for returns 5. All agents may be returned via room temperature shipment unless otherwise required, but must be transferred per sponsor specifications for handling/transport 6. Enclose the completed list with the agent(s) and enter return to address where indicated.				Street Address			Airbill/Carrier No.:			
				City/State/Zip Code			Signature of Authorizing Official:			
				<input type="checkbox"/> Check here if returned receipt should be mailed to the above address, OR fill in a fax number below			Date of Authorization:			
The agents listed below were ordered by (one investigator per form only): Dr.				Investigator No.:						
Sponsor	Agent Name	Protocol No.	Strength, Unit, & Dose (specify vials, capsules, or tablets)	Lot No. (or Bottle No. for blinded trial)	Manufacturer	Quantity	Monitor Initials	CRC Initials		
1										
Reason for return/transfer <input type="checkbox"/> Agent Outdated <input type="checkbox"/> All patients off treatment <input type="checkbox"/> Protocol complete <input type="checkbox"/> Other:				Signature of Person Receiving		Signature of Person Transferring				
2										
Reason for return/transfer <input type="checkbox"/> Agent Outdated <input type="checkbox"/> All patients off treatment <input type="checkbox"/> Protocol complete <input type="checkbox"/> Other:				Signature of Person Receiving		Signature of Person Transferring				
3										
Reason for return/transfer <input type="checkbox"/> Agent Outdated <input type="checkbox"/> All patients off treatment <input type="checkbox"/> Protocol complete <input type="checkbox"/> Other:				Signature of Person Receiving		Signature of Person Transferring				
4										
Reason for return/transfer <input type="checkbox"/> Agent Outdated <input type="checkbox"/> All patients off treatment <input type="checkbox"/> Protocol complete <input type="checkbox"/> Other:				Signature of Person Receiving		Signature of Person Transferring				
5										
Reason for return/transfer <input type="checkbox"/> Agent Outdated <input type="checkbox"/> All patients off treatment <input type="checkbox"/> Protocol complete <input type="checkbox"/> Other:				Signature of Person Receiving		Signature of Person Transferring				
6										
Reason for return/transfer <input type="checkbox"/> Agent Outdated <input type="checkbox"/> All patients off treatment <input type="checkbox"/> Protocol complete <input type="checkbox"/> Other:				Signature of Person Receiving		Signature of Person Transferring				
Transport Specifications:				LOCATION RECEIVING AGENT						
Signature/Printed Name Investigator of Preparer		Date		Date Received		RETURN RECEIPT: To obtain a return receipt by fax, provide your number in the space below.				
Title		Phone No.		Street Address						
				City/State						
				Zip Code						

Review/Revised Date:	Title:	Description of Change or Location of Change in Document:
04/30/2016	Tedd Adair VP Clinical Operations & CCO	Scheduled review; converted to ISO Policy Template