

Study Management SM 307.01

STANDARD OPERATING PROCEDURE Investigational Product Management

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1. INTRODUCTION AND PURPOSE

Management of investigational products used in clinical trials is of scientific, clinical, and ethical significance for the clinical trial, study subjects, and Investigators conducting clinical trials. Research Network site Investigators are responsible for management of investigational products at the site.

The purpose of this SOP is to describe the responsibilities of Georgia CORE staff and consultants to monitor the Research Network sites for documentation and accuracy in the ordering, receipt, storage, dispensing, reconciliation, and disposal or authorized destruction of the investigational product (study drug) at the completion of the study.

2. SCOPE

This SOP applies to all Georgia CORE staff and consultants involved monitoring, investigational product management used in clinical studies subject to investigational new drug (IND) regulations for drugs and biologics or those eligible for investigational new drug (IND) exemption during all phases of development. The SOP applies from the time that the investigational product is ordered and received at the Research Network site until the drug is either returned to the protocol-designated location as specified in the protocol or destroyed.

3. APPLICABLE REGULATIONS AND GUIDELINES

The Code of Federal Regulations and the International Conference on Harmonization, Good Clinical Practice: Consolidated Guideline and selected program and guidance documents apply to this SOP (Appendix A).

4. REFERENCES TO OTHER APPLICABLE SOPS

GA - 102	Sponsor Responsibility and Delegation of Responsibility
SM - 204	Site Initiation Visit
SM - 303	Documentation and Records Retention
SM - 304	Routine Monitoring Visits
SM - 305	Closeout Visits
DM- 401	Data Management

5. ATTACHMENTS

- A. Sample Investigational Product Accountability Log
- B. Sample Subject Investigational Product Dispensing Log
- C. CTEP PMB Investigational Product Information/Management
- D. Management of Investigational Products in a Satellite Pharmacy

6. RESPONSIBILITY

This SOP applies to those members of Georgia CORE involved in involved in monitoring the Research Network site management of investigational products, including the following:

- President and CEO
- Georgia CORE staff and consultants
- Site Research Network site Investigator and staff

7. DEFINITIONS (See GA Appendix A Glossary of Terms)

Binding/Masking
Investigational Product
Randomization
Source Documents

8. PROCESS OVERVIEW

- A. Receipt and inventorying of the investigational product

- B. Storage of the investigational product
- C. Dispensing of the investigational product
- D. Disposition of the investigational product

9. PROCEDURES

A. Receipt and Inventorying of Investigational Product

Georgia CORE staff
and consultants

Confirm that an investigational product is ordered and shipped to the Research Network site only after initiation visit training and applicable regulatory requirements, including IRB approval and contracts, have been fulfilled by the site.

Confirm that the Research Network site has supplies required for the blinding of the investigational product (if applicable).

Review with the Research Network site Investigator and staff that if the investigational product is blinded, the blind will not be broken except in the case of an emergency or a protocol-defined situation. Review that the protocol should be consulted for explicit directions about breaking the blind for the investigational product.

Confirm that upon receipt of the investigational product, the Research Network site staff has inventoried the shipment, ensuring that the information on the packing slip matches exactly with what has been sent to the site. Staff should check the following:

- Amount
- Lot numbers
- IP study assignment numbers (if applicable)
- Quantity per carrier/container (if applicable)
- Maintenance of temperature stability (if applicable)

Determine if the Research Network site staff promptly brought any discrepancies to the attention of the supplier of the investigational product.

Confirm that upon receipt of the investigational product, the Research Network site staff has checked that the product has been packaged properly and the labels and/or labeling provided the information that is required by the applicable regulations. The information required on the investigational product label or in accompanying labeling may include, but is not limited to the following:

- Study name and number
- Drug name (unless blinded)
- Dosage and formulation

- Lot number
- Sponsor name and place of business
- FDA required statement *Caution: New Drug – Limited by US law to Investigational Use*, if applicable
- Subject numbers and/or visit numbers
- Special instructions regarding dosage or storage
- Expiration date
- Quantity in container
- Any other information required in the applicable investigational product labeling regulations

Confirm that the Research Network site staff documents the order and receipt of the investigational product on the Investigational Product Accountability Log (Attachment A) or the applicable CTEP-PMB form.

Confirm that if a form was included in the shipment to acknowledge receipt, that the Research Network site staff obtained the appropriate signature and forwarded the form to the appropriate address.

Confirm that the Research Network site staff retained a copy of the ordering and receipt forms for the regulatory file.

B. Storage of the Investigational Product

Georgia CORE staff and consultants Confirm that the investigational product is stored in a secure environment with access limited to essential personnel, according to the storage requirements detailed in the protocol or supplied in a supplementary document.

Confirm that the Research Network site staff is following any special requirements for controlled substances required by the protocol in addition to those specified by the state and federal regulations.

Confirm with the Research Network site staff that the randomization code has been received, if applicable.

C. Dispensing the Investigational Product

Georgia CORE staff and consultants During routine monitoring visits and the study closeout visit, verify that the investigational product documentation has been accurate and complete throughout the study.

that each time the investigational product is dispensed, the Investigational Product Accountability Form is completed (Attachment A). Documentation will include:

- Amount (and lot number, if appropriate) dispensed,
- Initials of individual dispensing investigational product,
- Subject's number,
- Subject's initials,
- Date (and time, if appropriate) of dispensing,
- Date (and time if appropriate) of investigational product return,
- Amount of investigational product returned.

Confirm that the Investigational Product Accountability Form is maintained with the investigational product during the course of the study and included in the regulatory file at the conclusion of the study.

Confirm that the Research Network site staff is maintaining a Study Subject Investigational Product Dispensing Form (Attachment B) on each subject including:

- Visit number
- Date
- Lot number
- Amount dispensed
- Amount returned
- Amount lost

Confirm that after the study subject returns all used containers/units, if required by the protocol, that the Research Network site staff returns the containers/ units to the location designated in the protocol. Also check that if any containers/units are missing, the reasons are documented by the site staff.

Confirm that the Research Network site staff notes any discrepancies between amounts used by subjects and amounts expected to be returned and documents the reasons.

Confirm that the investigational product supplies at the Research Network site are adequate and within an appropriate expiration date.

Review with the Research Network site staff that they are to alert the investigational product supplier when additional product or supplies will be required.

Review with the Research Network site Investigator and staff that if emergency breaking of the investigational product blind is medically necessary, all circumstances are documented appropriately in the study file, including the exact manner in which the code was broken and the rationale.

Review with the Research Network site Investigator and staff that if the blind is broken, they are to notify the Investigator who initiated the study (if applicable), the IRB, and Georgia CORE.

D. Disposition of the Investigational Product

Georgia CORE staff
and consultants

Confirm that at the conclusion of the study, all documentation regarding ordering, receipt, storage, dispensing, return of used containers, and disposition of the investigational product is complete and accurate.

Review with the Research Network site staff that they must prepare the investigational product and containers for return shipment to the product supplier as noted in the protocol.

Review with the Research Network site staff that the destruction of investigational product at the site may be undertaken so long as such procedures are permitted by the OSHA and biohazard materials policies of the site and as specified in the protocol.

Review with the Research Network site staff that they must provide the Georgia CORE with written documentation of the destruction of the investigational product. Check that the site has maintained a copy in the site regulatory files and sent a copy to Georgia CORE.

Note: Procedures addressing the accountability for and management of investigational products in a Satellite Pharmacy are included in Attachment D: Management of Investigational Products in a Satellite Pharmacy

10. HISTORY

Version Number	Section Number	Modification	Approval Date
307.00	All	Original Version	
307.00	9A	Added steps for checking formation on packing slips on investigational products (Bullets 3 and 5)	09 March 2012
307.00	All	No change necessary	01 June 2014
307.00	3, 5C, 9A	Changes include CTEP-PMB information for NCTN trials	17 March 2017
307.01	All	Edits for clarification and consistency, Addition of Attachment D: Satellite Pharmacy Accountability, Addition to Attachment C: Management of Investigational Products during COVID-19 Pandemic	30 June 2020

ATTACHMENT A:
Sample Investigational Product Accountability Log

Protocol #: _____

Protocol title: _____

Name of Investigational product received: _____

Investigational product received:

Bottles _____ Blister packs _____ Capsules _____

Ampules _____ Patches _____ Other (describe) _____

Date of receipt: __/__/__ Received by: _____

Amount: _____ Lot number: _____

Amount: _____ Lot number: _____

Sample Investigational Product Dispensing Record

Date	Subject No./ Initials	Number Dispensed	Number Used	Number Returned	Lot #	Dispensed by (Initials)	Comments

For investigational product not returned or accounted for, complete the following:

Date	Subject No./ Initials	Recorder's Initials	Reason

Date that all investigational product was returned to: _____ Date __/__/__

(location designated in protocol)

Signature of person completing this form: _____ Date __/__/__

ATTACHMENT B:
Sample Study Subject Investigational Product Dispensing Log

Protocol #: _____

Protocol title: _____

Name of Investigational product received: _____

Investigational product received:

Bottles _____ Blister packs _____ Capsules _____

Ampules _____ Patches _____ Other (describe) _____

Date of receipt: __/__/__ Received by: _____

Amount: _____ Lot number: _____

Amount: _____ Lot number: _____

Sample Investigational Product Dispensing Record

Date	Subject No./ Initials	Number Dispensed	Number Used	Number Returned	Lot #	Dispensed by (Initials)	Comments

For investigational product not returned or accounted for, complete the following:

Date	Subject No./ Initials	Recorder's Initials	Reason

Date that all investigational product was returned to: _____ Date __/__/__

(location designated in protocol)

Signature of person completing this form: _____ Date __/__/__

ATTACHMENT C:
CTEP PMB Investigational Product Information/Management

1. Investigational Drug Accountability Training Videos for CTEP NCTN Trials:
https://ctep.cancer.gov/branches/pmb/drug_training_videos.htm
(Updated 10/19/16)
2. Investigational Drug Forms: Accountability, Return, Destruction, Transfer
<https://ctep.cancer.gov/forms/>
(Updated 01/27/20)
3. Interim Guidance for Shipping Oral IND Agents to Clinical Trial Subjects during the COVID-19 Pandemic
[Updated Interim Guidance for Shipping Oral IND Agents to Clinical Trial Subjects during the COVID-19 Pandemic \(PDF\) \(03/23/20\)](#)

ATTACHMENT D:
Management of Investigational Products in a Satellite Pharmacy

1. The Satellite Dispensing Area receives study-supplied agent from a Control Dispensing Area.
2. The Satellite Dispensing Area is under the direct responsibility and oversight of the Control Dispensing Area.
3. The Satellite Dispensing Area is responsible for:
 - Receiving study-supplied agent from the Control Dispensing Area
 - Appropriate storage, accountability and security of study-supplied agent
 - Dispensing study-supplied agent to patients/study participants as prescribed by authorized study-eligible physician investigators with an active investigator registration status and as dictated by the protocol
 - Timely returning non-dispensed study-supplied agent to the Control Dispensing Area for further or final disposition
 - Physical destruction of patient returned study-supplied agents per applicable regulations and institutional policies and procedures

Reference:

https://ctep.cancer.gov/branches/ctmb/clinicalTrials/docs/ctmb_audit_guidelines.pdf#search=%22records%20in%20satellite%20pharmacies%22

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