1. Purpose

To establish and describe the Office of Sponsor and Regulatory Oversight's (OSRO) Oversight of Investigational Product Shipments policy for shipping Investigational Product (IP) from a Principal Investigator (PI) to various destinations.

2. Scope

2.1. OSRO in the Center for Cancer Research (CCR), National Cancer Institute (NCI) shall establish and control the policy.

2.2. Investigators, research team members, other departmental personnel, and external NIH collaborators and contractors when they are working on studies conducted under a CCR-held Investigational New Drug (IND) application or Investigational Device Exemption (IDE), participating in a CCR-supported Non-Significant Risk Device Study (NSR) or supported by a CCR-held Master File under OSRO oversight shall comply with the policy.

2.3. OSRO oversees IP shipments to authorized recipients of CCR clinical studies to minimize risk to human safety and comply with applicable collaborator agreements and regulatory agencies.

2.4. Limitations

2.4.1. This policy does not apply to personnel working on studies that are not under a CCR-held IND, IDE, or is an NSR device study and/or when no OSRO oversight or interdepartmental collaboration is required.

2.4.2. Nothing in this policy will supersede NCI, National Institutes of Health (NIH) or Health and Human Services (HHS) requirements.

3. Responsibilities

3.1. The Center for Cancer Research Management is committed to providing resources to meet the requirements for implementing an Oversight of Investigational Product Shipments policy within OSRO and supporting its continual improvement.

3.2. OSRO personnel are responsible for understanding and using the Oversight of Investigational Product Shipments policy.

3.3. The OSRO Director is responsible for establishing and maintaining the Oversight of Investigational Product Shipments policy.

3.4. OSRO Sponsor and Regulatory Oversight Support (SROS) Contractor staff assisting OSRO Functional Groups are responsible for understanding the Oversight of Investigational Product Shipments policy.

4. References

4.1. ICH E6(R2) Good Clinical Practice: Integrated Addendum to ICH E6(R1) Guidance for Industry (FDA), March 2018

4.2. ICH E6(R3) Good Clinical Practice (GCP) draft Guidance for Industry (FDA), May 2023

4.3. 21CFR Part 312 – Investigational New Drug Application

4.4. 203 Clinical Trial Records

5. Definitions

Refer to the OSRO Lexicon.

6. Policy

6.1. OSRO shall oversee the shipping of IP assigned to CCR clinical studies according to Good Clinical Practice (GCP, References 4.1 and 4.2) and applicable regulatory requirements.

6.2. While the PI is responsible for compliance with the Institutional Review Board (IRB) approved protocol and applicable guidelines and federal regulatory requirements, the PI may delegate authority for shipping IP to qualified study personnel including the pharmacy.

6.3. IP management plans for shipping, inventory control, and stability studies (if applicable) should be described in the clinical study protocol.

6.3.1. These plans will be reviewed during the OSRO protocol review beginning in 2024.

6.4. When IP shipment is required for executing the protocol, then a shipping plan should be included in the protocol design. Examples of predetermined shipments include but are not limited to the following.

6.4.1. Shipments to/from external sites (multi-center trials),

6.4.2. Shipments to enrolled study participants,

6.4.3. Shipments to authorized, non-study healthcare facilities, and

6.4.4. Shipments to stability testing facilities.

6.5. PIs may not ship IP between locations until OSRO has provided written authorization.

6.5.1. If shipments listed in Steps 6.4.2 – 6.4.4 are identified in the OSRO-accepted protocol, then pre-authorization is not required.

6.5.2. PIs are encouraged to contact OSRO at OSROStudyAgent <OSROStudyAgent@nih.gov> to determine if a shipment may be exempt from pre-authorization.

6.6. Prior to granting authorization, OSRO Pharmaceutical Management will ensure that 1.) IP has been stored under appropriate conditions of temperature, humidity, and exposure to light (if applicable), 2.) the IP is within its shelf life, 3.) sufficient inventory is available to fulfill the request, and 4.) manufacturer/supplier authorization has been obtained, if required per contract.

6.7. Shipment of IP outside of the United States will be allowed only in rare cases and with appropriate justification as an emergency.

6.7.1. The PI is responsible for confirming and attesting to OSRO that all laws of the foreign country receiving IP will be met.

6.7.2. The PI is responsible for requesting authorization from the applicable government agency (e.g., Ministry of Health (MOH)) of the foreign country where the shipment will be delivered, where required.

6.7.3. OSRO will not permit shipment without written authorization from the appropriate MOH or government agency.

6.7.4. The OSRO Director shall approve all requests for international shipments of IP.

6.8. The PI and receiving institution, if applicable, should keep appropriate documentation to support the transportation activity (Reference 4.4).

6.8.1. Examples of supporting documentation include but are not limited to the following:

6.8.1.1. OSRO authorization to ship the IP which identifies the

- IP name, strength, dosage form, lot number, quantity, and expiration date
- protocol number,
- the PI's name,
- the recipient's name and location, and
- the reason for the transfer.

6.8.1.2. Packing slip/bill of lading

6.8.1.3. Chain of Custody

6.8.1.4. Proof that the cold chain was maintained during the shipment, i.e., temperature monitoring data

6.8.1.5. Proof of IP container relabeling including a sample label

6.8.1.6. Updated Drug Accountability Record showing the change in IP inventory

6.8.1.7. Any correspondence regarding the shipment

6.8.2. Source documents or exact copies should be filed in the site study file.

6.8.3. The documentation is subject to review by OSRO Pharmaceutical Management and/or OSRO Operations during clinical site monitoring visits.

6.9. OSRO Pharmaceutical Management shall approve shipments related to the disposition of all unused supplies of IP from a clinical trial.

7. Change Summary

Revision Number	Effective Date	Description of Change
1	08NOV2023	New Document