1. Purpose

The Office of Sponsor and Regulatory Oversight (OSRO) has established procedures to ensure appropriate authorization is granted for shipments of investigational product (IP) and confirmation that no shipping excursions occurred.

2. Scope

2.1. OSRO authorizes the shipment or transfer of IP assigned to Center for Cancer Research (CCR) Investigational New Drug application (IND) studies, Investigational Device Exemption (IDE) studies, or Non-Significant Risk Device (NSR) studies conducted under OSRO oversight.

2.2. Limitations

2.2.1. Activities performed by non-OSRO staff are given only to provide context around the OSRO activities. OSRO assumes no control over these personnel and their actions.

3. Responsibilities

3.1. OSRO Pharmaceutical Management (PM) approves the

3.1.1. Shipment of IP from the NIH Clinical Center (CC) Pharmacy to external entities such as authorized non-study healthcare facilities, collaborators, and enrolled study participants, and

3.1.2. Disposition of unused IP.

3.2. OSRO PM reviews shipping documents.

3.3. Manufacturers/suppliers provide written authorization for IP shipments or transfers per contract or agreement.

3.4. OSRO Sponsor and Regulatory Oversight Support (SROS) contractor staff assist OSRO Functional Groups as needed.

3.5. The Principal Investigator (PI) is responsible for requesting authorization from

3.5.1. OSRO PM,

3.5.2. Appropriate authorities (domestic and international), ethics committees, and/or federal organizations and forwarding these authorizations to OSRO PM.

3.6. The CC Pharmacy is responsible for ensuring that the correct IP is shipped under the correct conditions to the correct destination.

4. References

4.1. 503 Oversight of Investigational Product Shipments

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

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 ICH E6(R3) Good Clinical Practice (GCP) draft Guidance for Industry (FDA), May 2023

5. Definitions

Refer to the OSRO Lexicon.

6. Procedure

6.1. OSRO PM oversees IP shipping events per Reference 4.1.

6.2. The degree of OSRO PM oversight of a shipping event is risk-based and considers patient safety, impact to IP identity, strength, quality, and purity, and IP inventory and expiration date.

6.2.1. Common shipping events are to the following destinations.

- External clinical site, i.e., in a multi-center trial
- Enrolled study participant
- Authorized non-study healthcare facility
- Analytical laboratory (IP testing)
- Manufacturer / Supplier
- Principal Investigator (change in protocol)
- Non-clinical research laboratory
- Authorized disposal facility

6.3. OSRO PM approves shipments or transfers of IP from one responsible party to another party before the shipping or transfer event occurs and with the following exceptions.

6.3.1. Regular periodic shipments to enrolled study participants, authorized non-study healthcare facilities and analytical testing laboratories which are disclosed in the study protocol do not require pre-authorization.

6.3.1.1. Non-disclosed, unplanned shipments to these destinations require pre-authorization.

6.3.1.2. OSRO PM makes final determination on whether a shipment may be exempt from pre-authorization.

6.4. Requests for shipping IP are received from the study PI via email to OSROStudyAgent <OSROStudyAgent@nih.gov>.

6.4.1. PI and CC Pharmacy collaboration on the IP shipping request is recommended.

6.4.1.1. The IP must be properly labeled; all units have been in proper storage conditions and are intact, and the expiration date covers the entire duration of treatment, when applicable.

6.4.1.2. The quantity of IP for shipment is determined by the clinical study protocol and in accordance with institutional policy.

6.4.1.3. Any exceptions to Steps 6.4.1.1 and 6.4.1.2 are handled on a case-by-case basis and are approved by OSRO PM.

6.4.2. Required supporting records should either accompany the request or be submitted as soon as possible. The necessary records depend on the destination and are identified in Table 1. Some supporting documentation is controlled by the CC Pharmacy.

6.4.2.1. Common requester-provided documentation includes a completed F01-501-S08 Investigational Product Transfer Authorization (refer to Step 7.1), the Drug Accountability Record (DAR), any records on excursions in storage conditions, and/or an IP stability report.

6.5. OSRO PM reviews the request and supporting documentation to confirm that sufficient inventory is available, data supports the IP being active and stable, and within its shelf life.

6.6. OSRO PM obtains authorization from the manufacturer or supplier if required per contract.

Table 1. Supporting Documentation Required for Obtaining Authorization to Ship IP to Various Destinations.

Destination	Requester Submitted Records			Obtained by OSRO PM
External clinical site	F01-501-S08*	DAR**	Storage temp logs, Stability trends	Manufacturer/Supplier Authorization
Enrolled study participant (ad-hoc)		DAR		
Authorized non-study healthcare facility (ad-hoc)		DAR		
Analytical laboratory (ad-hoc)		DAR		Manufacturer/Supplier Authorization (if applicable)
Manufacturer / Supplier		DAR		
Principal Investigator (protocol change)	F01-501-S08	DAR	Storage temp logs, Stability trends	Manufacturer/Supplier Authorization
Non-clinical research laboratory	F01-501-S08	DAR	Sample label	Manufacturer/Supplier Authorization
Authorized disposal facility		DAR		Manufacturer/Supplier Authorization

*F01-501-S08 Investigational Product Transfer Authorization
**Drug Accountability Record (DAR)

6.7. OSRO PM notifies the requester of its decision by one or more of the following documents: a signed F01-501-S08 Investigational Product Transfer Authorization, memo, and/or email.

6.8. The CC Pharmacy ships the IP as ordered by the PI and per institutional policies.

6.8.1. The shipper ensures that the IP is shipped under required controlled conditions such as temperature, humidity, exposure to light and agitation.

6.9. At the conclusion of the shipping event, OSRO PM reviews the shipping documentation, i.e., temperature monitoring data, packing slips (bills of lading), chain of custody forms, to ensure that the IP shipment occurred as intended.

6.9.1. The required shipping documentation depends on the destination of the IP, the purpose of the shipping, and is identified in Table 2.

Table 2. Supporting Documentation for Assessing Successful Shipment/Transfer of IP to Various Destinations.

Destination	Reviewed Shipping Records			
External clinical site	Packing slip	Temperature data	DAR	
Enrolled study participant (ad-hoc)	Packing slip		DAR	
Authorized non-study healthcare facility (ad-hoc)	Packing slip	Temperature data	DAR	
Analytical laboratory (ad-hoc)	Packing slip	Temperature data	DAR	
Manufacturer / Supplier	Packing slip		DAR	
Principal Investigator (protocol change)			DAR	Confirmation of relabeling
Non-clinical research laboratory			DAR	Confirmation of relabeling
Authorized disposal facility			DAR	Confirmation of disposal

6.10. Transfer to a non-clinical research laboratory requires relabeling/over labeling of the IP containers.

6.10.1. OSRO PM does not manage relabeling operations.

6.10.2. The PI or designee should provide a sample label to OSRO PM for review with the request.

6.10.3. The PI or designee should provide confirmation of relabeling after the IP containers have been relabeled.

6.11. External clinical sites in a multi-center trial are expected to maintain an accountability of IP for the duration of the study or until all material is either used by study participants, destroyed on site, or returned to a designee.

6.11.1. Upon reconciliation, any discrepancies in accountability between shipment quantity and clinical site(s) are to be investigated and documented.

6.12. Orally administered IP may be shipped directly to a study participant.

6.12.1. The shipping address must be that of the enrolled study participant's address on file.

6.12.2. The study team should provide instructions and verify that participants fully understand how to self-administer the IP.

6.12.3. If a shipping plan is described in the protocol, then OSRO authorization for each shipping event is not necessary.

6.13. Authorized, non-study healthcare facilities may include a hospital or a pharmacy where a study participant may pick up the drug shipment.

6.13.1. Authorized healthcare facilities are expected to maintain accountability of IP for the duration of the study or until all material is either destroyed on site or returned to a designee.

6.13.2. Upon reconciliation, any discrepancies in accountability between shipment quantity and the authorized, non-study healthcare facility are to be investigated and documented.

6.13.3. If a shipping plan is described in the protocol, then OSRO authorization for each shipping event is not necessary.

6.14. OSRO PM authorizes IP shipping to analytical laboratories for performing IP stability testing.

6.14.1. OSRO PM does not manage IP stability programs.

6.15. Disposition options for unused IP include but are not limited to:

6.15.1. Clinical sites returning or destroying unused IP.

6.15.2. Transfer of unused IP to another clinical study or to a non-clinical research laboratory.

6.15.3. Return of unused IP to the manufacturer or supplier.

6.15.4. Destruction of unused IP by the CC Pharmacy.

6.16. The Office designation of OSRO shall refer both to the Office of Sponsor and Regulatory Oversight staff and the OSRO Sponsor and Regulatory Oversight Support contractor staff.

7. Associated Documents

7.1. F01-501-S08 Investigational Product Transfer Authorization

8. Change Summary

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