1. Purpose

The Office of Sponsor and Regulatory Oversight (OSRO) shall review and approve the transfer of investigational products (IP) between different protocols, clinical sites, or for non-human research use.

2. Scope

2.1. This SOP applies to Center for Cancer Research (CCR) Investigational New Drug application (IND) studies conducted under OSRO oversight.

3. Responsibilities

3.1. OSRO Pharmaceutical Management (PM) approves the reassignment of IP from its currently authorized protocol and/or clinical site.

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

3.3. The transferring Principal Investigator (PI), receiving PI, and Pharmacy are responsible for submitting required documentation to OSRO.

4. References

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

4.2. 21CFR Part 312 – Investigational New Drug Application

5. Definitions

Refer to the OSRO Lexicon.

6. Procedure

6.1. Any request to transfer IP between protocols or clinical sites, or to a laboratory for non-human research use shall be approved by OSRO PM prior to transfer.

6.1.1. Transfer of IP between clinical sites can only occur in multi-center trials in which the product plan clearly states this is allowed, provided that no federal or states laws would be violated and appropriate documentation is maintained.

6.1.2. Requests are made using F01-501-S08 Investigational Product Transfer Authorization form.

6.1.3. Completed forms should be sent to OSROStudyAgent <OSROStudyAgent@nih.gov> for approval.

6.1.3.1. Signatures from the originating PI and the receiving PI are required.

6.2. OSRO PM or its designee will review the request for appropriateness and feasibility.

6.2.1. The provided reason for the transfer is reviewed to determine that the transfer is appropriate, i.e., protocol is closing or the IP has expired.

6.2.2. Drug accountability logs are reviewed to ensure the correct quantity is being requested.

6.2.3. Authorization from the IP supplier and/or manufacturer, as applicable, must be received by OSRO PM before the transfer will be approved.

6.2.4. For transfers between protocols or clinical sites, temperature excursions in IP storage, stability or other storage issues must be assessed by OSRO PM before the request will be approved.

6.3. OSRO PM approves the transfer by signing the F01-501-S08 Investigational Product Transfer Authorization.

6.4. The signed F01-501-S08 Investigational Product Transfer Authorization is sent to the IP storage site, e.g., Clinical Center Pharmacy, to authorize the transfer process.

6.5. Upon receipt of the signed F01-501-S08 Investigational Product Transfer Authorization, an authorized site staff member should verify the accuracy of the transfer form against the current physical inventory.

6.5.1. In instances where there is a discrepancy, the site staff member is responsible for reconciling the inventory before proceeding.

6.6. For transfers for non-human research use, an authorized site staff member is responsible for over-labeling the IP containers to indicate that the material is not authorized for human use.

6.7. The site staff member should file appropriate documentation to support the transportation activity, such as:

6.7.1. Signed F01-501-S08 Investigational Product Transfer Authorization and any correspondence or supporting documentation regarding the transfer

6.7.2. Date of IP Transfer

6.7.3. Protocol Number

6.7.4. PI's name

6.7.5. IP name, strength, dosage form, lot number, quantity, and expiration date

6.7.6. Transfer and receipt individuals' names and signatures

6.7.7. Chain of Custody

6.7.8. Cold Chain maintenance

6.7.9. Updated Drug Accountability Record reflecting the change in IP inventory

6.7.10. Container over-labeling for transfers for non-human research use

7. Associated Documents

7.1. F01-501-S08 Investigational Product Transfer Authorization

8. Change Summary

Revision Number	Effective Date	Description of Change
1	16JUN2023	New Document