1. Purpose

The process by which requests for Investigational Product (IP) disposition are reviewed and approved by the Office of Sponsor and Regulatory Oversight (OSRO) Pharmaceutical Management is given.

2. Scope

Investigational Products (IPs) listed on an Investigational New Drug application (IND) under OSRO oversight are within scope. This may include commercially available products.

3. Responsibilities

3.1. OSRO Pharmaceutical Management reviews and approves requests for IP disposition and obtains authorization from IP manufacturer/supplier as required.

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

3.3. Principal Investigators and Clinical Center pharmacy staff (or site pharmacy staff for a multi-center study) are responsible for submitting requests for IP disposition per OSRO process.

3.4. Clinical Center pharmacy staff (or site pharmacy staff for a multi-center study) are responsible for disposing of IPs according to local regulations.

4. References

4.1. 503 Oversight of Investigational Product Shipments

4.2. 503-S01 Shipment of Investigational Drug Products

5. Definitions

Refer to the OSRO Lexicon.

6. Procedure

6.1. Unused investigational product may be destroyed, returned to the product manufacturer/supplier, transferred to another protocol or clinical site, or transferred to a non-clinical research laboratory.

6.1.1. Allowable disposition options should be confirmed by consulting the manufacturer/supplier agreement, protocol, and/or manual of procedures (MOP).

6.2. Requests for IP transfer to another protocol or clinical site are covered in 503-S01 Shipment of Investigational Drug Products (Reference 4.2).

6.3. Requests for IP destruction, return to IP manufacturer/supplier, or transfer to a non-clinical research laboratory should be submitted to OSROStudyAgent@NIH.gov.

6.3.1. The request should include the protocol number, Principal Investigator name, IP name, lot number (manufacturer, IDMS), quantity of IP impacted, the quantity of IP in inventory, expiration date, the desired disposition, and reason.

6.3.2. Requests for destruction or return to IP manufacturer/supplier typically occur at the end of a study or upon IP expiration.

6.3.3. Requests for transfer to a non-clinical research laboratory may be made at any time during the study or upon IP expiration.

6.4. Destruction of Unexpired IP

6.4.1. Requests for destruction of full inventory of unexpired IP will be approved only for protocols which have no participants on study receiving treatment or no additional enrollment planned.

6.4.2. OSRO PM looks up the protocol status in the electronic Trial Master File (eTMF). The protocol status must be one which indicates that no current or future participants will receive the IP.

6.4.3. OSRO PM must confirm a request for destruction of unexpired IP with the Principal Investigator if the request was not submitted by the Principal Investigator.

6.4.4. OSRO PM obtains authorization from the manufacturer/supplier to destroy the IP per agreement, if necessary.

6.4.5. OSRO PM emails the Clinical Center Pharmacy or site pharmacy and requests IP destruction.

6.4.5.1. The Clinical Center Pharmacy should provide confirmation and an updated Drug Accountability Record (DAR) showing an inventory balance of zero (0).

6.4.6. OSRO PM may approve requests for destruction of dispensed IP, e.g., patient returns or similar without manufacturer/supplier and/or Principal Investigator approval at its discretion.

6.4.6.1. IP destruction is documented on the pharmacy DAR or equivalent inventory control system. The DAR is reviewed on the next pharmacy monitoring visit.

6.5. Return of Unexpired IP to Manufacturer/Supplier

6.5.1. Requests to return the full inventory of unexpired IP to the manufacturer/supplier follows the same process as for destruction of unexpired IP. See Steps 6.4.1 to 6.4.5.

6.6. Transfer of Unexpired IP to a Non-Clinical Research Laboratory

6.6.1. Requests to transfer the full inventory of unexpired IP to a non-clinical research laboratory follows the same process as for destruction of unexpired IP. See Steps 6.4.1 to 6.4.5.

6.6.2. The Clinical Center Pharmacy relabels the IP containers as not for human use per its procedure.

6.7. Disposition of Expired IP

6.7.1. The IP storage facility, e.g., the Clinical Center Pharmacy, notifies OSRO PM of IPs nearing expiration.

6.7.2. OSRO PM informs the Principal Investigator of the IP expiration.

6.7.2.1. OSRO PM will request permission from the manufacturer/supplier to transfer expired IP to a non-clinical research laboratory upon request by the Principal Investigator.

6.7.3. OSRO PM contacts the manufacturer/supplier of the IP to request authorization to dispose of the IP per agreement, if necessary.

6.7.4. OSRO PM emails the Clinical Center Pharmacy and requests disposition.

6.7.5. The Clinical Center Pharmacy should provide confirmation.

7. Associated Documents

7.1. 503-S02-W01 Disposing of Investigational Product

8. Change Summary

Revision Number	Effective Date	Description of Change
1	21AUG2024	New Document