1. Purpose

To establish and describe the Office of Sponsor and Regulatory Oversight's (OSRO) Investigational Product Management policy.

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. Limitations

2.3.1. 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.

2.3.2. 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 Investigational Product Management policy within OSRO and supporting its continual improvement.

3.2. OSRO personnel are responsible for understanding and using the Investigational Product Management policy.

3.3. The OSRO Director is responsible for establishing and maintaining the Investigational Product Management policy.

3.4. OSRO Sponsor and Regulatory Oversight Support (SROS) Contractor staff assisting OSRO Functional Groups are responsible for understanding the Investigational Product Management 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 ICH E6(R3) Good Clinical Practice (GCP) draft Guidance for Industry (FDA), May 2023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. 21 CFR Part 312 – Investigational New Drug Application

4.4. 21 CFR Part 812 – Investigational Device Exemptions

5. Definitions

Refer to the OSRO Lexicon.

6. Policy

6.1. OSRO, as sponsor, follows sponsor responsibilities recommended in applicable regulations and good clinical practices (see Section 4 for reference list).

6.2. The investigational product is characterized as appropriate to the stage of development of the product.

6.3. The investigational product is manufactured in accordance with applicable good manufacturing practices (GMP).

6.4. The investigational product labeling complies with applicable regulatory requirement(s).

6.5. Instructions for handling, storing, and dispensing the investigational product is available to the pharmacy.

6.6. The investigational product will be analyzed per an approved stability study to ensure that it is stable over the period of use.

6.7. The investigational product will be used according to a signed agreement between the manufacturer and sponsor or sponsor's proxy.

6.8. An Investigator's Brochure should be available for the investigational product.

6.8.1. For an investigational product without an Investigator's Brochure, product information (e.g., safety, storage, handling) required for study management must be provided in another document.

6.9. The disposition and transfer of unused investigational products are authorized by OSRO.

7. Change Summary

Revision Number	Effective Date	Description of Change
1	11JUL2024	New Document