1. Purpose

The Office of Sponsor and Regulatory Oversight (OSRO) shall receive and review copies of investigational product (IP) and investigational device (ID) labels for applicable investigational products.

2. Scope

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

2.2. IP/ID labels for product/device dispensed by the NIH Clinical Center Pharmacy for inpatient administration, product/device shipped to health care providers caring for Subjects in the community, and product/device dispensed for study Subject at home self-administration are within the scope of this SOP.

2.3. IP/ID labels for multi-site studies are within the scope of this SOP.

3. Responsibilities

3.1. OSRO Pharmaceutical Management is responsible for review of IP/ID labels and communication with product/device suppliers or manufacturers, and the NIH Clinical Center Pharmacy.

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

4. References

4.1. 21 CFR 312.6 – Investigational New Drug Application – Labeling of an investigational new drug

4.2. 21 CFR 812.5 – Investigational Device Exemption – Labeling of investigational devices

5. Definitions

Refer to the OSRO Lexicon.

6. Procedure

6.1. Prior to IND submission, OSRO Regulatory will receive a representative IP/ID label from the supplier or manufacturer.

6.2. OSRO Pharmaceutical Management or its SROS contractor designee will review the IP/ID label for completeness and adequacy. When problems are identified, OSRO Pharmaceutical Management will contact the supplier or manufacturer for resolution. OSRO Pharmaceutical Management will work with the supplier or manufacturer to resolve any issues.

6.3. OSRO Pharmaceutical Management or its SROS contractor designee will review any updates of the IP/ID label provided by the supplier or manufacturer for completeness and adequacy. When problems are identified, OSRO Pharmaceutical Management will contact the supplier or manufacturer for resolution.

6.4. OSRO Pharmaceutical Management or its SROS contractor designee will provide a copy of the approved IP/ID label to the Clinical Center Pharmacy or other dispensing pharmacy as appropriate.

6.5. The IP/ID label will be filed in the electronic Trial Master File (eTMF).

7. Change Summary

Revision Number	Effective Date	Description of Change
1	05JUN2020	New Document
2	01DEC2022	Step 3.2 – added Section 4 – added hyperlinks Steps 6.2, 6.3 and 6.4 – added "or its SROS Contractor designee" Step 6.6 – removed Title and sections 1, 2, 3, and 6 – added investigational device (ID) references Updated language as needed