1. **Purpose**

The Office of Sponsor and Regulatory Oversight (OSRO) shall receive copies of investigational product (IP) 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 labels for product dispensed by the NIH Clinical Center Pharmacy for inpatient administration, product shipped to health care providers caring for Subjects in the community, and product dispensed for study Subject at home self-administration are within the scope of this SOP.

2.3. IP labels for multisite studies are within the scope of this SOP.

3. **Responsibilities**

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

4. **References**

4.1. 21 CFR 312.6 – Labeling of an investigational new drug

4.2. 21 CFR 812.5 – Labeling of investigational devices

5. **Definitions**

Refer to the OSRO Lexicon.

6. **Procedure**

6.1. Prior to IND submission, OSRO Regulatory will receive the proposed IP label from the supplier or manufacturer.

6.2. OSRO Pharmaceutical Management will review the IP 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 will review any updates of the IP 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. A copy of the OSRO Pharmaceutical Management approved IP label will be provided to the Clinical Center Pharmacy or other dispensing pharmacy as appropriate.

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

6.6. This document shall be reviewed periodically and updated as necessary.
7. Change Summary

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<thead>
<tr>
<th>Revision Number</th>
<th>Effective Date</th>
<th>Description of Change</th>
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<tbody>
<tr>
<td>1</td>
<td>05JUN2020</td>
<td>New Document</td>
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