1. Purpose

To summarize the process for the Office of Sponsor and Regulatory Oversight (OSRO) Pharmaceutical Management receipt and review of investigational product (IP) and investigational device (ID) quality and materials agreements for applicable investigational products and devices.

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. Investigational product(s)/device(s) used in accordance with an OSRO approved protocol.

2.3. Agreements associated with the use of IP/ID governing quality, supplies and reporting.

2.4. Limitation:

2.4.1. Licensed commercially available products/devices used per the product/device label.

3. Responsibilities

3.1. OSRO Pharmaceutical Management is responsible for reviewing the IP/ID quality and materials agreements.

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

4. References

4.1. N/A

5. Definitions

Refer to the OSRO Lexicon.

6. Procedure

6.1. Prior to final execution, OSRO Pharmaceutical Management will receive the protocol and IP/ID-specific quality and materials agreements.

6.2. OSRO Pharmaceutical Management will review the agreements for scope, completeness and adequacy.

6.3. Any issues or concerns from OSRO Pharmaceutical Management will be documented and sent to the appropriate party for resolution.

6.4. OSRO Pharmaceutical Management will review any subsequent proposal for changes to the agreement(s) for appropriateness and adequacy and follow up with the appropriate party until all issues have been resolved.

6.5. Approved, executed Quality Agreements/Materials Agreements and amendments 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 Step 6.6 – removed Title and sections 1, 2, 3, and 6 – added reference to investigational device(s)