1. Purpose

The Office of Sponsor and Regulatory Oversight (OSRO) shall receive and review copies of Certificates of Analysis (COAs) 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.

3. Responsibilities

3.1. OSRO Regulatory is responsible for communicating with suppliers and manufacturers.

3.2. OSRO Pharmaceutical Management is responsible for reviewing COAs.

3.3. 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. Receipt of COA from the Supplier or Manufacturer

6.1.1. Prior to IND submission OSRO Regulatory will receive a representative COA from the collaborator or NIH supplier or manufacturer.

6.1.2. OSRO Pharmaceutical Management will review the representative COA for completeness and adequacy. Where problems are identified, OSRO Pharmaceutical Management will communicate issues to the supplier or manufacturer, copying OSRO Regulatory.

6.1.3. When the manufacturer is NIH, OSRO Pharmaceutical Management and OSRO Regulatory may interact with the manufacturer to jointly determine the specifications of the COA.

6.1.4. OSRO Regulatory will receive COAs from the supplier or manufacturer for lots of applicable investigational product used in CCR IND studies.

6.1.5. OSRO Pharmaceutical Management will review any update to a COA provided by the supplier or manufacturer for completeness and adequacy. Where problems are identified, OSRO Pharmaceutical Management will communicate issues to the supplier or manufacturer, copying OSRO Regulatory.

6.1.6. The COA will be filed in the electronic Trial Master File (eTMF).

6.2. Verification of COA

6.2.1. Upon receipt of the actual investigational product' COA, OSRO Pharmaceutical Management will ensure that the product meets all release criteria, and the COA provided with the supply matches the representative COA in the eTMF.

6.2.2. If the product does not meet all the release criteria, or there is concern about the expiration date, or a need for retesting, then OSRO Pharmaceutical Management will:

6.2.2.1. Notify the dispensing pharmacy that the product must be quarantined and not used; and

6.2.2.2. Notify the supplier or manufacturer, copying OSRO Regulatory.

6.2.3. OSRO Pharmaceutical Management and OSRO Regulatory will jointly decide on the suitability for use of the product following receipt of information from the supplier or manufacturer.

6.2.4. The COA and all formal communications regarding the COA will be filed in the eTMF.

7. Associated Documents

7.1. N/A

8. Change Summary

Revision Number	Effective Date	Description of Change
1	05JUN2020	New Document
2	01DEC2022	Step 3.3 – added Step 6.3 – removed Step 7.1 – removed Updated language as needed