1. **Purpose**

The Office of Sponsor and Regulatory Oversight (OSRO) shall receive 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 or manufacturers.

3.2. OSRO Pharmaceutical Management is responsible for reviewing COAs.

4. **References**

4.1. N/A

5. **Definitions**

Refer to the OSRO Lexicon.

6. **Procedure**

6.1. Receipt of Sample COA from the Supplier or Manufacturer

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

6.1.2. OSRO Pharmaceutical Management will review the sample 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 will interact with the supplier or manufacturer to jointly determine the appropriate composition of the COA.

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

6.1.5. OSRO Pharmaceutical Management will review any update of sample 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 sample COA will be filed in the electronic Trial Master File (eTMF).
6.2. Verification of COA

6.2.1. Upon receipt of the COA, OSRO Pharmaceutical Management will ensure that the product meets all release criteria, and the COA matches the COA sample on file.

6.2.2. If the product does not meet all the release criteria, or there is an effect on 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 usability of the product following receipt of information from the supplier or manufacturer. OSRO Pharmaceutical Management will instruct the dispensing pharmacy using Form F01-501-S01 Investigational Product Dispensation Form whether to use, destroy or return the product.

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

6.3. This document shall be reviewed periodically and updated as necessary.

7. Associated Documents

7.1. F01-501-S01 Investigational Product Dispensation Form

8. Change Summary

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<th>Revision Number</th>
<th>Effective Date</th>
<th>Description of Change</th>
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<td>1</td>
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<td>New Document</td>
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