1. Purpose

The process for testing and retesting of Investigation Products (IP), including applicable ancillary products and intermediate products is outlined.

2. Scope

2.1. This SOP applies to Center for Cancer Research (CCR) Investigational New Drug application (IND) studies conducted under the Office of Sponsor and Regulatory Oversight (OSRO) oversight for the following instances:

2.1.1. CCR serves as the manufacturer, i.e.,

- IP is manufactured internally at a CCR or other NIH Intramural facility
- Intermediary product or IP is manufactured externally to CCR specifications

2.1.2. IP is manufactured by a manufacturer in a process independent from CCR central resources.

2.2. Limitation

2.2.1. This SOP does not apply to protocols where CCR is not the manufacturer, for example, when the IP is manufactured by a commercial partner.

3. Responsibilities

3.1. OSRO serves as the Sponsor for CCR clinical studies for which it oversees.

3.2. OSRO Pharmaceutical Management is responsible for overseeing the process.

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

4. References

4.1. ICH E6(R2) Good Clinical Practice: Integrated Addendum to ICH E6(R1) Guidance for Industry (FDA), March 2018

5. Definitions

Refer to the OSRO Lexicon.

6. Procedure

6.1. At the concept stage, the responsible party for primary IP oversight will be determined.

6.2. Prior to IND submission:

6.2.1. The testing/retesting plan spanning the entire expected use of the IP will be developed.

6.2.1.1. For protocols where the Principal Investigator (PI) or designee is the responsible party for primary IP oversight, the PI or designee will develop the plan and submit it to OSRO for review and approval.

6.2.1.2. For protocols where OSRO is the responsible party for primary IP oversight, OSRO Pharmaceutical Management will develop the testing/retesting plan.

6.2.2. The testing/retesting plan will include the following elements:

6.2.2.1. Manufacturer and contact information.

6.2.2.2. Laboratory conducting the testing/retesting and contact information.

6.2.2.3. The applicable attributes to be tested for the IP (examples include, but are not limited to, appearance, moisture, potency/activity, purity, sterility and stability) and the time intervals for testing, allowing for future retest dates to precede future expiration dates so that a product may be used for patient treatment without interruptions.

6.2.2.4. The tests that will be conducted to assess the applicable attributes including success/failure criteria for those tests.

6.3. In case of a change in the laboratory conducting the testing/retesting or in the testing procedures, the responsible party for primary IP oversight, i.e., the PI, must notify the Sponsor 30 days prior to any change implementation.

6.4. The results of each test/retest should be:

6.4.1. Presented as official reports of the testing laboratories; and

6.4.2. Compiled as one report, with a summary of all testing; and

6.4.3. Signed and dated by the responsible party for primary IP oversight; and

6.4.4. Provided to the Sponsor at least 7 days prior to the retest/expiration date of the product.

6.4.5. Preliminary results may be provided to Sponsor (OSRO Pharmaceutical Management) as they are received but do not substitute an official report.

6.5. Based on the testing results, the Sponsor will notify the pharmacy and the PI of the approval/disapproval for continued use of the IP as well as the next retest date.

7. Associated Documents

7.1. N/A

8. Change Summary

Revision Number	Effective Date	Description of Change
1	09DEC2020	New Document
2	10JUN2021	1. Step 6.2.2.3: Added phrase, “allowing for future retest dates to precede future expiration dates so that a product may be used for patient treatment without interruptions.” 2. Step 6.4.4: Changed 30 days to 7 days. 3. Added Step 6.4.5 Preliminary results may be provided to Sponsor (OSRO Pharmaceutical Management) as they are received but do not substitute an official report.

Revision Number	Effective Date	Description of Change
3	10MAY2023	Biennial review Steps 3.2 and 3.3 – added Step 4.1 – added hyperlink Step 6.6 – removed Updated grammar and process as needed