1. Purpose

To establish that each National Cancer Center (NCI) Center for Cancer Research (CCR) study investigational product (IP) has preparation procedures to be followed.

2. Scope

2.1. This procedure applies to clinical studies conducted under CCR-held Investigational New Drug Applications (INDs) under Office of Sponsor and Regulatory Oversight (OSRO) oversight.

3. Responsibilities

3.1. OSRO Pharmaceutical Management manages the process of IP preparation procedures.

3.2. The OSRO Sponsor and Regulatory Oversight Support (SROS) Contractor assists OSRO Pharmaceutical Management 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. Completing the CCR/OSRO Sponsor Investigational Product Preparation form (F01-501-S07)

6.1.1. OSRO Pharmaceutical Management or its SROS Contractor designee will complete F01-501-S07 CCR/OSRO Sponsor Investigational Product Preparation.

6.1.2. If information is not available to fully complete the form, TBD (to be determined) will be used.

6.1.3. The completed form will be stored in the electronic Trial Master File (eTMF).

6.2. Sharing the CCR/OSRO Sponsor Investigational Product Preparation form (F01-501-S07)

6.2.1. The completed F01-501-S07 CCR/OSRO Sponsor Investigational Product Preparation will be emailed to OSROMonitoring and the site at least 5 business days prior to the initiation visit for the protocol.

6.2.2. F01-501-S07 CCR/OSRO Sponsor Investigational Product Preparation will be introduced at the initiation visit and reviewed during subsequent monitoring visits to ensure site preparation procedures are consistent with the form.

6.3. Updating the CCR/OSRO Sponsor Investigational Product Preparation form (F01-501-S07)

6.3.1. With each Institutional Review Board (IRB)-approved protocol amendment and/or updates in investigator's brochure, pharmacy manual, or manual of procedures, OSRO Pharmaceutical

Management or its SROS Contractor designee will review the updated document(s) to determine if a change has been made to the IP preparation procedure.

6.3.2. If no applicable changes are determined, no changes will be made to the form.

6.3.3. If applicable changes are determined, OSRO Pharmaceutical Management or its SROS Contractor designee will update the form and email it to OSROMonitoring and the site within 5 business days of discovery.

7. Associated Documents

7.1. F01-501-S07 CCR/OSRO Sponsor Investigational Product Preparation

8. Change Summary

Revision Number	Effective Date	Description of Change
1	03JAN2022	New Document
2	10MAY2023	Steps 6.2.1 and 6.3.3 – added email hyperlink for OSROMonitoring Step 6.3.1 – revised