	Office of Sponsor and Regulatory Oversight	Document #: F01-501-S07
	CCR/OSRO Sponsor Investigational Product Preparation	Revision #: 4
		Effective Date: 29APR2024

Instructions: The form must be completed for each Investigational Product and on file with the clinical pharmacy. The form must be revised as applicable information is updated, e.g., Investigator’s Brochure, package insert, Pharmacy Manual. For each revision, update the completion date and form version number below and summarize the updates in Section 4.

Form Revision Number: _____ Form Revision Date: _____

Protocol Number: _____ IND Number: _____

Protocol Title: _____

Investigational Product:

Drug Name: _____

Manufacturer: _____

Supplier: _____

1. How is the investigational product supplied?

Oral Formulation	Parenteral Formulation	Topical Formulation	Other (specify):
Tablet	Solution	Cream	
Capsule	Lyophilized powder	Lotion	
Suspension		Ointment	
Solution		Other (specify):	
Powder for Reconstitution			


Auxiliary Label Information (e.g., “Do Not Refrigerate,” “Use In-line Filter,” “For Intrathecal Use Only”):

At what temperature(s) will the investigational product be stored?

What are the temperature requirements for storing this product? Describe the permissible temperature range (highest/lowest/duration).

2. How will the investigational product be administered?

Enteral	Parenteral	Topical	Other (specify):
By mouth	IV Infusion		
By peg tube/J-/NG- /NJ-tube/etc.	IV push		
	Injection (e.g., SC, IM, IT, etc.)		
	Line Type:		

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Dose/Dose Calculation:

Drug Strength, as supplied: _____

Drug Package/Unit Size, as supplied: _____

Diluent Name: _____

Preparation Instructions, in sequential steps:

3. How will the investigational product be destroyed?

Document & Destroy (per Site SOP)

Email OSROStudyAgent@NIH.gov for approval

Document & Destroy (per manufacturer/supplier agreement)



NATIONAL CANCER INSTITUTE
Center for Cancer Research

Office of Sponsor and Regulatory Oversight

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4. Revision History

Rev. #	Rev. Date	Comment	Preparer Signature	Approval Signature
		New document		