	Office of Sponsor and Regulatory Oversight	Document #: F01-504-S01
	Investigational Product Temperature Excursion Report	Revision #: 1
		Effective Date: 15JUL2024

Instructions: Please complete this form as soon as possible after discovering a temperature excursion in a controlled temperature storage unit or shipping event. Email the completed, digitally signed form and supporting documentation to OSROStudyAgent@nih.gov.

Note: All IP involved in a temperature excursion *must immediately be quarantined* under storage conditions indicated by the Protocol/Manual of Procedures (MOP)/Pharmacy Manual/Investigator’s Brochure/product label until further notice from OSRO.

Instructions for the disposition of affected IP will be sent after OSRO reviews the provided information.

TEMPERATURE EXCURSION DETAILS		
Date of Notification:		
Date of Excursion:		
IP Storage Condition:		
Storage Unit Identification Number:		
Storage Unit Location:		
Highest / Lowest Exposure Temperature (°C):		
Cumulative Time Out-of-Range:		
Temperature monitor report attached to this report:	Yes	No
Affected IP has been quarantined at its specified storage temperature:	Yes	No

DESCRIPTION AND CAUSE OF EXCURSION

IMMEDIATE ACTIONS TAKEN



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AFFECTED INVESTIGATIONAL PRODUCT DETAILS

IP Name & Strength	Lot Number	Expiration / Retest Date	Quantity of Units Affected	Protocol Number	Previous Temperature Excursion ¹		Dispensed to Study Participant ²		Comment
					Yes	No	Yes	No	
					Yes	No	Yes	No	
					Yes	No	Yes	No	
					Yes	No	Yes	No	
					Yes	No	Yes	No	
					Yes	No	Yes	No	
					Yes	No	Yes	No	
					Yes	No	Yes	No	
					Yes	No	Yes	No	
					Yes	No	Yes	No	

¹ If yes, provide the date(s) the affected IP was subjected to a temperature excursion in the Comment cell.

² If yes, provide the date(s) the affected IP was given to a study participant in the Comment cell.


INFORMATION COMPLETED BY

By signing below, I attest that the information on this form is accurate.

Signature:

Name/Credential:

Email:

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SPONSOR RESPONSE	
<p>Quality of IP has not been compromised and it may continue to be used in the clinical trial. IP may be released from quarantine.</p> <p>IP is not approved for further use. IP may be</p>	
Signature:	Email: