

INVESTIGATIONAL PRODUCT TEMPERATURE EXCURSION (FORM L)

This form needs to be filled out for each product affected.

Date:		Protocol Number:		Investigator of Record Name:	
Clinical Research Site Name:				Clinical Research Site Number:	
Investigational Product Name:				Strength and Dosage Form:	
Package Size:	Manufacturer:	Lot Number(s):	Required Storage Temperature:	Box number(s) affected:	

Hereby we would like to inform you about a temperature excursion that occurred at site indicated above, that was reported on date: _____ and occurred on date: _____.

Temperature excursion description	
Temperature exposed to & for how long	
Did any enrolled subjects received affected IP?	<input type="checkbox"/> Yes <input type="checkbox"/> NO If Yes, Please provide details: _____
Comments	

DAIT PM and PS need to evaluate the temperature excursion and urgently inform the site of the need to quarantine the affected product(s) or if dispensing is granted to continue.

Please attach the site manual or electronic temperature log with this form.

<i>NIAID/DAIT/CPDC Use Only</i>		
Date Received:	Project Manager Name:	Project Manager Signature:
Date Finalized:	DAIT Pharmacist Name & Signature:	Name & Signature of Reviewing CPDC Official:

<p style="text-align: center;">SIGNATURE – Pharmacist of Record</p> <p>The PoR attests that the information on this form is accurate.</p> <p>Print Name: _____</p> <p>Signature: _____</p> <p>Date _____ (MM-DD-YY)</p>	<p style="text-align: center;">SIGNATURE – DAIT Authorized Monitor</p> <p>The DAIT Authorized Monitor attests that temperature excursion was identified during a monitoring visit.</p> <p>Print Name: _____</p> <p>Signature: _____</p> <p>Date _____ (MM-DD-YY)</p>
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