INVESTIGATIONAL PRODUCT TEMPERATURE EXCURSION FORM

(FORM L)

Division of Allergy, Immunology, and Transplantation
National Institute of Allergy and Infectious Diseases (NIAID)

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	
Comments	

1. 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.
2. Please attach the site manual or electronic temperature log with this form.

SIGNATURE — Pharmacist of Record	**SIGNATURE — DAIT Authorized Monitor**
The PoR attests that the information on this form is accurate. Print Name: _____ Signature: _____ Date _____(MM-DD-YY)	The DAIT Authorized Monitor attests that temperature excursion was identified during a monitoring visit, if applicable. Print Name: _____ Signature: _____ Date _____(MM-DD-YY)

NIAID/ DAIT/ CPC Use Only		
Date Received:	**Project Manager Name:**	**Project Manager Signature:**
Date Finalized:	**DAIT Pharmacist Signature:**	**Signature of Reviewing CPC Official, if applicable:**