

CHANGES TO THE DAIT PHARMACY GUIDELINES AND FORMS

2015 to 2016 (v2 to v3)

1. Main Pharmacy Guidelines

The DAIT Pharmacy Guidelines

<https://www.niaid.nih.gov/sites/default/files/pharmacy.pdf> underwent a high level edit to ensure consistency throughout the document, clarify and correct procedures, correct spelling and grammatical errors, and update URLs.

The major changes between the May 2015 version 2 guidelines and May 2106 version 3 guidelines are listed below:

Note: Throughout the document:

- Clinical Products Distribution Center (CPDC) renamed Clinical Products Center (CPC)
- Principal Investigator replaced term Investigator of Record

Page (v3)	Section	Section Title	Changes from v2
4	N/A	Appendices (Forms & Instructions For Completion)	Updated URLs
6	1.1	Background	Updated DAIT home page URL
6	1.2.1	Overview of DAIT Pharmacist Responsibilities, Clinical Research Operations Program	Included DAIT Medical Officers in list of staff working with the DAIT pharmacist
8	1.3.4	NIAID DAIT Clinical Research Networks/Consortia	Updated several URLs
12	2.1.14	Supervision and Training of Pharmacy Staff	Clarified procedure: all documents related to training pharmacy staff to be placed in the Pharmacy Binder, not the "files."
12	2.1.15	Protection of Pharmacy Staff	Clarified procedure: All training related to protection must be documented
21	2.3.5	Reports to the Principal Investigator (PI) and Institutional Review Board (IRB)	Changed nomenclature: Investigator of Record (IoR) to Principal Investigator (PI)

21	2.3.5.2	Reports to DAIT Staff Members	Modified procedure: Pharmacy Specialist and Regulatory Officer removed recipient list
Page (v3)	Section	Section Title	Change from v2
25/26	2.3.6.4	Document Archiving	Changed names of Forms E through L by replacing “Study” with “Investigational.”
27	2.4.1	Ordering (of IP)	Clarified process for PoR to follow for requesting subsequent orders of drugs or supplies from the CPC.
27	2.4.2	Receipt (of IP)	Modified paperwork requirement for shipment: require “product receipt form” instead of IP manufacturer’s “Certificate of Analysis”
30	2.4.6.2	Accidental Unblinding (of PI)	Modified notification: PoR notifies the DAIT Project Team (PM, MO, Regulatory Affairs Officer and PS – all from DAIT) instead of PI, PM and CPC.
31	2.4.7	Dispensing/Preparation and Authorized Prescribers	Clarified that IP was for an IND exempt study
31/32	2.4.7.1	Investigational Product Order Form or Prescription	Modified procedure: PI needs to sign only Form FDA 1572, not the DAIT IoR Form
33	2.4.7.4	Dose Calculation and Preparation Process	Clarified procedure: 1) any change in delegation must be documented in the “Delegation Log” and 2) specifies the use of the “IP dispensing and administration” manual.
35	2.4.8	Refill/Repeats	Clarifies procedure by also referencing the IP Dispensing and Administration manual as a source of information
36	2.4.11	Obtaining Investigational Product from a Source other than the CPC	Clarified procedure by adding “Generally, the site is asked to write a report and submit to the “DAIT Project Team” or a deviation might be filed in the study files.”
36	2.4.13.2	On-Site Investigational Product Destruction.	Clarified the entire procedure
42-44	4	Glossary	Added or modified definitions: CPC, DAIT CRO, DAIT Project Team, ICH
48	5	References	Updated URL for Reference 8

2. PHARMACY GUIDELINES FORMS

Form	Changes (v3 compared to v2)
A	<ol style="list-style-type: none"> 1. Changed Clinical Research Products Management Center (CPDC) to Clinical Products Center (CPC)
B	<ol style="list-style-type: none"> 1. Shortened title of the form to “Change in Pharmacist of Record” 2. Clarified “Instructions to the NEW PoR.” Of note: <ol style="list-style-type: none"> a. Specified filing the original form in the Pharmacy Binder b. Removed the option to return the form by FAX 3. Changed “To Return by” section <ol style="list-style-type: none"> a. Provided mail and email return addresses b. Changed “Study Project Manager” to “DAIT Project Manager” c. Changed “Note” to inform the PoR that DAIT PM will send form to DAIT PS and the CPC.
C	<ol style="list-style-type: none"> 1. Clarified “Instructions to the New Back-up PoR.” Of note: <ol style="list-style-type: none"> a. Specified filing the original form in the Pharmacy Binder. b. Removed the FAX option to return the form and the CV 2. Changed “To Return by” section <ol style="list-style-type: none"> a. Provided mail and email return address b. Changed “Study Project Manager” to “DAIT Project Manager” c. Changed “Note” to inform the PoR that DAIT PM will send form to DAIT PS and the CPC.
D	<ol style="list-style-type: none"> 1. Clarified “Instructions to the Pharmacist.” Of note: <ol style="list-style-type: none"> a. Specified filing the original form in the Pharmacy Binder b. Removed the FAX option to return the form 2. Changed “To Return by” section <ol style="list-style-type: none"> a. Provided mail and email return addresses b. Changed “Study Project Manager” to “DAIT Project Manager” c. Changed “Note” to inform the PoR that DAIT PM will send form to DAIT PS and the CPC.
E	<ol style="list-style-type: none"> 1. Clarified “Instructions to the Pharmacist.” Of note: <ol style="list-style-type: none"> a. Specified filing the original form in the Pharmacy Binder 2. Changed the “Email, FAX or Express Mail to” section to specify the completed form is to be returned to only the CPC (Eminent) 3. Increased the column width of “Comments” 4. Changed the “NIAID/DAIT USE ONLY” section <ol style="list-style-type: none"> a. Included DAIT Pharmacy Specialist (with the DAIT PM) as signer for subsequent orders
F	<ol style="list-style-type: none"> 1. Changed title of the form to “Study Product Receipt”(previously “Shipment Receipt Acknowledge”)

	<ol style="list-style-type: none"> 2. Redesigned the layout of the form 3. Required the temperature data and the completed form be returned to Eminent. 4. Specified filing the completed form and the temperature data in the Pharmacy Binder
G	No changes
H	<ol style="list-style-type: none"> 1. Clarified “Instructions to Complete This Form.” Of note: <ol style="list-style-type: none"> a. Added the DAIT Pharmacy Specialist, in addition to DAIT PM, as recipient of completed form b. Specified filing the completed form and the temperature data in the Pharmacy Binder 2. “Transfer From/Transfer To/Ship To” section <ol style="list-style-type: none"> a. Provided the Name and Address where investigational product to be shipped
I	<ol style="list-style-type: none"> 1. Modified the “Instructions to the Pharmacist of Record” section <ol style="list-style-type: none"> a. Specified returning the form to Eminent Services b. Specified filing the completed form in the pharmacy binder 2. Changed “Return To” section <ol style="list-style-type: none"> a. Provided Eminent contact information 3. Moved section about the pharmacy to above the section about the investigational product 4. Changed the name of the bottom section to “<i>CPC Use Only</i>” (previously <i>NIAID/DAIT/CPDC Use Only</i>) <ol style="list-style-type: none"> a. Changed “Return Drug (RD) Number” to “Eminent Receipt Number” b. Removed information about Project Manager
J	<ol style="list-style-type: none"> 1. Page 1, General Instructions <ol style="list-style-type: none"> a. Changed CPDC throughout the form to CPC (Eminent). b. Specified the “pharmacy binder” as the “pharmacy files” c. Removed the need for “within 21 days of the date of signing” (#3) 2. Page 2, Numbered instructions <ol style="list-style-type: none"> a. Reordered some instructions to follow the layout on page 3 b. Removed instruction about IP Identification Number (#7, v2) 3. Page 3 <ol style="list-style-type: none"> a. Removed “IP identification” column from table b. Technician no longer permitted to initial form (#15), only the pharmacist 4. Page 4, New page, to list new IP for destruction
K	<ol style="list-style-type: none"> 1. Only the pharmacist may log in the temperature and initial the form
L	<ol style="list-style-type: none"> 1. In the second section, removed row “Did any enrolled subjects received affected IP?” 2. Reversed the order of the bottom two sections

