

Instructions for Completing an Investigational Product Destruction (Form J)

As a sponsor of clinical studies, the Division of Allergy, Immunology, and Transplantation of the National Institute of Allergy and Infectious Diseases (NIAID) of the National Institutes of Health (NIH) must comply with the U.S. Food and Drug Administration (FDA) regulations governing the proper disposition of investigational products being investigated in clinical trials. DAIT has the responsibility of assuring that all clinical research sites establish and maintain adequate records of investigational product disposition to comply with FDA regulations and the standards of research involving the use of investigational products.

General Instructions

1. Prior to destroying any DAIT sponsored funded investigational products and/or protocol designated investigational products, the Pharmacist of Record (PoR) must complete the Investigational *Product Destruction Form (Form-J)* for all investigational products designated for destruction. If a protocol specific destruction form is provided within a specific protocol, that form takes precedence.
2. The Investigational Product Destruction Form should be submitted for verification and approval to the PM at least two weeks in advance of the scheduled destruction visit. Forms can be submitted via email to the protocol specific PM. The non-approved original Investigational Product Destruction Form should be retained in the pharmacy files. The project manager and regulatory officer (RO) will verify and the Investigational Product Destruction Form and return the form, in PDF format to the PoR via email. The approved Investigational Product Destruction Form must be used during the destruction visit.
3. The approved Investigational Product Destruction Form must be signed by the PoR and the DAIT PM, RO at the conclusion of the destruction visit. The approved Investigational Product Destruction Form with the original signatures and any copies of destruction certificates or memos must be couriered to the CPDC by the PoR within 21 days of the date of signing with a copy to the PM and RO.
4. Keep copies of the signed approved Investigational Product Destruction Form for your records.

Instructions for Completing an Investigational Product Destruction Form

- A separate form is required for each network or consortium, protocol, site and investigator.
- Type or print legibly all information on the form.
- Never use pencil, white-out or obliterate entries that require correction.
- Make all entries in black or dark blue ink.
- Cross out errors with a single line. Date and initial any corrections.
- Each line item should list a single lot number.
- When investigational product returns for destruction are from the same lot number, they may be totaled and listed on one line. For example, if a patient returns 3 full bottles of investigational product that have the same lot number. This can be entered as a total of 3 full bottles on one line of the Investigational Product Destruction Form.
- Additional comments may be entered on the back of the form with the line number as reference.
- Cross out any blank lines remaining on the completed Investigational Product Destruction Form.

1. **Clinical Research Site Name and Site Number:** Enter the *complete* name of the registered clinical research site and the clinical research site identification number.
2. **Investigator of Record Name:** Enter the name of the investigator who signed the Form FDA 1572 or the clinician directly responsible to the investigator of record as stated on the Form FDA 1572 for IND studies. For non-IND studies, enter the name of the investigator who signed the “*Investigator of Record Agreement*.”
3. **Network:** Enter the name of the applicable network for the investigational products. Only **ONE** network should be listed for each Investigational Product Destruction Form completed.
4. **Protocol Name and Number:** Enter the protocol name and number associated with the investigational products for destruction.
5. **For NIAID/ DAIT/ CPDC Use Only:** Do not complete this section (to be completed by the project manager and/or CPDC Pharmacist).
6. **Date:** Enter the date that the investigational product is being added to this form and quarantined from active stock in a MM/DD/YY format.
7. **IP Identification Number:** Enter the investigational product unique identification number (if applicable). If you have more drugs to return, use the 3rd page.
8. **Investigational Product Name / Package Size:** Enter the name and package size of the investigational product.
9. **Investigational Product Strength:** Enter the strength of the investigational product including units (e.g., mg, IU, %, etc.), if applicable.
10. **Investigational Product Dosage Form:** Enter the dosage form of the investigational product designated for destruction (e.g., tablet, vial, capsule, gel, etc.).
11. **Lot Number:** Enter the lot number for the investigational product (if available).
12. **CPDC Lot Number Verification:** CPDC should verify the previously shipped investigational products to the requesting site.
13. **Quantity Full:** Enter the quantity of containers (vials/syringes/bottles/kits) to be destroyed. Sealed containers (vials/syringes/bottles/kits) are considered full if the seal is intact. For example, if returning 6 unopened/sealed bottles enter “6 bottles.” The quantities entered on this form must match quantities entered on other forms/logs used.
14. **Quantity Partial:** Enter the actual number of units remaining for destruction and indicate the type of units. For example, if returning 3 partial bottles each containing 5 capsules, enter “15 capsules;” Partial quantity count and destruction is for patient compliance measurement based on a specific protocol guidance.
15. **Reason for Destruction:** Indicate the reason for the IP being destroyed. Choose from the following codes to indicate the reason for IP destruction. More than one code may be used.
 - A = Partial containers remaining after preparation (e.g., partial vial, partial bottle, partial tube, etc.). Only applies if a specific protocol indicates to destroy empty or partial IP containers after preparation.
 - E = Expired
 - L = Quarantined supply
 - P = Dispensed (e.g., patient returns, returns from clinic staff) only if a specific protocol indicates to measure patient compliance.
 - S = Can no longer be safely used (e.g., damaged, stored improperly, temperature excursion)
 - X = Study closed
 - O = Other (must write comment)
16. **Pharmacist Initial:** Include the name of the pharmacist completing the entry.
17. **Comments:** This section is for providing additional information regarding the IP being destroyed. When the code “O” is used in the Reason for Destruction section, this field must be completed.
18. **Destruction Occurred:** This section is to be completed in its entirety if destruction of investigational products occurred during the “DAIT-Authorized Monitoring Visit.” If further documentation to show proof of destruction will be provided to the PoR by the destruction company, a copy of this documentation must be sent along with the signed/approved “Investigational Product Destruction Form” to the CPDC and PM or submitted to the CPDC and/or PM upon receipt by the Pharmacist of Record at the site.
19. **Packaged for Destruction:** This section is to be completed if destruction did not occur during the “DAIT-Authorized Monitoring Visit” and the IPs were packaged for destruction to occur at a later date or to be to send back to CPDC. A copy of the “Certificate of Destruction” must be emailed, faxed, or mailed along with the signed/approved “Investigational Product Destruction Form” to the CPDC and PM or submitted to the CPDC and/or PM upon receipt by the PoR at the site.
20. **Signature - Pharmacist of Record or Back-Up Pharmacist of Record:** The PoR or the Back-Up PoR is to print and sign his/her name in this section. Each page must be signed and dated. *The PoR and the DAIT authorized monitor are to sign and date the Investigational Product Destruction Form on the same day.*
21. **Signature – DAIT Authorized Monitor:** The DAIT-authorized monitor verifying IPs for destruction is to print and sign his/her name in this section. By signing this form, the DAIT-authorized monitor is confirming that s/he has notified the PoR on the additional steps required and that the PoR has been instructed that the certificate of destruction or other similar document needs to be received upon completion of destruction. *The PoR and the DAIT-authorized monitor are to sign and date the “Investigational Product Destruction” form on the same day.*

INVESTIGATIONAL PRODUCT DESTRUCTION FORM
 Division of Allergy, Immunology, and Transplantation (DAIT)
 National Institutes of Allergy and Infectious Diseases (NIAID)
 National Institutes of Health (NIH)

FOR NIAID/ DAIT/ CPDC USE ONLY⁵

R.D. NUMBER: _____

CPDC PHARMACIST SIGNATURE/DATE: _____

SIGNATURE OF DAIT REVIEWING OFFICIAL/ DATE: _____

Clinical Research Site Name¹:	Clinical Research Site Number²:
Investigator of Record Name²:	Network/Consortium/ Program/Grant³:
Protocol Name and Number⁴:	

	Date ⁶	IP Identification Number ⁷	IP Name/ Package Size ⁸	IP Strength ⁹	Study Product Dosage Form ¹⁰	Lot Number ¹¹	CPDC Use Only: Lot # Verified ¹² (Yes/No)	Quantity		Reason For Destruction ¹⁵ (A, E, L, P,S, X, O)	Pharmacist/Tech Initials ¹⁶	Comments ¹⁷ (when the code "O" is used)
								Full ¹³	Partial ¹⁴ (Only if protocol indicate to measure patient compliance)			
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THE SECTIONS BELOW TO BE COMPLETED BY THE DAIT AUTHORIZED MONITOR AND PHARMACIST OF RECORD

DESTRUCTION OCCURED¹⁸

1. Did IP destruction occur during a monitoring visit? Yes, date: _____ No
2. Were IPs destroyed on site? Yes No
 - a. If no, please name facility at which the IPs were destroyed: _____
 - b. Will the destruction company provide further documentation such as a certificate of destruction or a receipt of the IPs for destruction?
 Yes – copy attached No Yes – will submit a copy upon receipt to CPDC and/or PM.

PACKAGED FOR DESTRUCTION¹⁹

1. Will the IPs "packaged for destruction" be destroyed on site? Yes No
 - a. If no, please name the facility at which the products will be destroyed:

 - b. Will the destruction company provide further documentation such as a certificate of destruction or a receipt of the IPs for destruction?
 Yes – will submit a copy upon receipt to the CPDC and/or PM. No
2. What is the scheduled destruction date (if known)?

SIGNATURE – Pharmacist of Record²⁰

The PoR attests that the information on this form is accurate and is in accordance with the pharmacy site's destruction SOP for destruction of IPs on site or packaged for destruction at an outside facility.

Print Name: _____

Signature: _____ Date _____ (MM-DD-YY)

SIGNATURE – DAIT Authorized Monitor²¹

The DAIT Authorized Monitor attests that the verified IPs were destroyed on site or packaged for destruction at an outside facility, in accordance with the pharmacy site's destruction SOP for destruction of IPs.

Print Name: _____

Signature: _____ Date _____ (MM-DD-YY)

PLEASE USE THIS PAGE, IF YOU HAVE MORE IPs TO DESTROY

	Date ⁶	IP Identification Number ⁷	IP Name/ Package Size ⁸	IP Strength ⁹	Study Product Dosage Form ¹⁰	Lot Number ¹¹	CPDC Use Only: Lot # Verified ¹² (Yes/No)	Quantity		Reason For Destruction ¹⁵ (A, E, L, P,S, X, O)	Pharmacist/Tech Initials ¹⁶	Comments ¹⁷ (when the code "O" is used)
								Full ¹³	Partial ¹⁴ (Only if protocol indicate to measure patient compliance)			
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