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-funded/sponsored unused or expired 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. This form should be submitted via email for verification and approval to the protocol-specific PM. If there is a study close-out visit scheduled, the PoR must submit the destruction form to the PM at least two weeks prior to the scheduled visit. The original Investigational Product Destruction Form should be retained in the pharmacy binder. The "DAIT Project Team" will verify and return the form, in PDF format, to the PoR via email. The approved form must be used during the destruction visit.

3. The approved form must be signed by the PoR and the DAIT monitor (if a close-out visit is scheduled). The approved form with the original signatures and any copies of destruction certificates or memos must be kept in the pharmacy files and a copy sent to the PM within 21 days of destruction.

4. The PoR should retain copies of the signed, approved "Investigational Product Destruction" form in the pharmacy files.

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.

Instructions for Completing an Investigational Product Destruction Form J

1. **Protocol Name and Number:** Enter the protocol name and number associated with the investigational products for destruction.

2. **Primary Investigator (PI):** Enter the name of the investigator who signed the Form FDA 1572 or the clinician or the Co PI 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. **Clinical Research Site Name and Site Number:** Enter the *complete* name of the registered clinical research site and the clinical research site identification number.

4. **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.

5. **For NIAID/ DAIT/ CPC Use Only:** Do not complete this section (to be completed by the project manager and/or CPC Personnel).

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. **Investigational Product Name / Package Size:** Enter the name and package size of the investigational product.

8. **Investigational Product Strength:** Enter the strength of the investigational product including units (e.g., mg, IU, %, etc.), if applicable.

9. **Investigational Product Dosage Form:** Enter the dosage form of the investigational product designated for destruction (e.g., tablet, vial, capsule, gel, etc.).

10. **Lot Number:** Enter the lot number for the investigational product (if available).

11. **CPC Lot Number Verification:** CPC should verify the lot number with the previously shipped product(s) to the requesting site. This will not apply to those IPs obtained from other sources.

12. **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.

13. **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.

14. **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 (for reasons other than expiration date)
    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)

15. **Pharmacist Initial:** Include the name or the initials of the pharmacist completing the entry.

16. **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.

17. **On-site Destruction:** This section is to be completed if destruction of investigational products is granted by DAIT PM during the "DAIT-Authorized Monitoring Visit." A copy of the "certificate of destruction" from the destruction company, along with the signed/approved "Investigational Product Destruction" form must be submitted to the DAIT PM to show proof of destruction by the Pharmacist of Record at the site.

18. **Packaged for Destruction:** This section is to be completed if destruction did not occur during the "DAIT-Authorized Monitoring Visit" and the IPs are to be packaged for destruction to occur at a later date or to be sent back to the CPC for destruction. A signed/approved "Investigational Product Destruction" form must be submitted by the site PoR to the DAIT PM for further processing and approval.

19. **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.

20. **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 on-site destruction, if approved. The PoR and the DAIT-authorized monitor are to sign and date the "Investigational Product Destruction" form.

INVESTIGATIONAL PRODUCT DESTRUCTION FORM J

Division of Allergy, Immunology, and Transplantation (DAIT)
National Institute of Allergy and Infectious Diseases (NIAID)
National Institutes of Health (NIH)

Protocol Name and Number[1]:	**Principal Investigator Name[2]:**
Clinical Research Site Number[3]:	**Clinical Research Site Name[3]:**
Network/Consortium/ Program/Grant[4]:	

FOR NIAID/ DAIT/ CPC USE ONLY[5]

CPC PERSONNEL SIGNATURE (IF APPLICABLE):

DATE _____

SIGNATURE OF DAIT PM:

_ DATE _____

SIGNATURE OF DAIT RO AND/OR PS:

_ DATE _____

	Date[6]	IP Name/ Package Size[7]	IP Strength[8]	IP Dosage Form[9]	Lot Number[10]	CPC Use Only: Lot # Verified[11] (Yes/No)	Quantity		Reason For Destruction[14] (A, E, L, P,S, X, O)	Pharmacist's Initials[15]	Comments[16] (when the code "O" is used)
							Full[12]	Partial[13] (Only if protocol indicate to measure patient compliance)			
1											
2											
3											
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6											

THE SECTIONS BELOW TO BE COMPLETED BY THE PHARMACIST OF RECORD AND THE DAIT AUTHORIZED MONITOR (IF APPLICABLE)

ON-SITE DESTRUCTION[17]

1. IP destruction to occur during a monitoring visit? ☐ Yes, date: _____ ☐ No

2. IPs to be destroyed on site? ☐ Yes ☐ No

a. If no, please name facility to which the IPs will be sent for destruction : _____

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 DAIT PM ☐ No (you must not destroy on-site, contact your PM)

PACKAGED FOR DESTRUCTION[18]

1. Received permission from DAIT PM ☐ Yes ☐ No

2. Received packaging material and instructions from the CPC? ☐ Yes ☐ No

3. Did a DAIT-authorized monitor verified IPs to be destroyed? ☐ Yes ☐ No

4. What is the scheduled destruction date (if known)? _____

SIGNATURE – Pharmacist of Record[19]

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 Monitor (If Applicable)[20]

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