

Standard Operating Procedure for DEA Registration, Controlled Substance Use & Disposal

Purpose: To ensure compliance, security, and consistency in the use of controlled substances in research.

Procedure: Step 1:

PI applies for a Drug Enforcement Agency (DEA) controlled substances license.

- To obtain a license application, go online to:
<https://www.deadiversion.usdoj.gov/webforms/jsp/regapps/common/newAppLogin.jsp>
- Complete the application and submit it with the registration fee. A state license is not required. In the field on the application that relates to an NH license, do not click the box or input anything into that field.
- Keep a copy for your files.
- Upon receipt of your DEA certificate, contact EHS for an inspection of your facility. A copy of your license must be uploaded to the “Documents” section on BioRAFT. Select file type “DEA Authorizations.”

Step 2:

Upon receipt of your license certificate, the DEA licensee agrees to the following compliance elements:

- Establish a logbook or notebook for controlled substances. Schedule I substances must have their own logbook. A separate log sheet must be maintained for each substance. This log sheet must include date received, quantity, and drug name. See *Drug Tracking Form*, attached. The logbook should be kept in a lockable space within the lab (desk drawer, safe, etc.).
 - Electronic files are acceptable if stored securely and electronic signatures are not used (e.g. sign and scan).
 - Save all receipt and disposal documents for at least 2 years.
- Keep controlled substances in locked storage. For Schedule I-II

EHS Approved By:	<i>Jason Angell</i>	Approval date:	1/20/2026
Revision #	0	Revision date:	
		Pages#	3

substances, the storage must comply with 21 CFR 1301.72. For Schedule III-V substances, the locked storage must be attached to the wall or be sufficiently heavy to prevent it from being carried off, or otherwise comply with 21 CFR 1301.72. Schedule I-II substances must not be kept in the same storage location as Schedule III-V substances.

- Limit access to controlled substances.
 - For Schedule I substances:
 - Access is limited to the registrant and the specifically DEA-authorized personnel who are named in the DEA-approved research protocol.
 - For Schedule II-V substances
 - Restrict access to only authorized members of your lab.
 - To authorize additional users, the *Controlled Substances Screening Guidance and Questionnaire* (attached) must be completed and saved.
 - Anyone in a lab may be authorized at the PI's discretion, with the exception of minors.
- Perform an initial controlled substance inventory form (attached) when you are DEA-approved, and before receiving any controlled substances
- Perform an inventory audit biennially (required minimum frequency) and annually (if desired). The biennial inventory **MUST** be taken on May 1 of each odd-numbered year. If May 1 falls on a weekend, inventory must be taken on the closest business day preceding May 1. Ensure that your stock matches what is stated in your logbooks. See controlled substances inventory forms (attached).
 - Separate inventory forms must be maintained for Schedule I-II and Schedule III-V substances, with initial and biennial (and annual if desired) inventories required for each category.
 - If your actual inventory does not match your logs, you must follow the steps detailed in the *Inventory Discrepancy Investigation Guidance* form (attached).
- Renew your license annually if you plan to continue using controlled substances.
- **BEFORE you allow your license to expire, please contact EHS immediately for disposal of any controlled substances in your inventory. Disposal of any controlled substance must occur prior to license expiration.**
- The DEA may inspect you at any time. Contact EHS when you become aware of a DEA inspection.

Step 3:

If you have old, unused, or outdated controlled substances, disposal will be by double-witnessed chemical deactivation. The lab should schedule a time for EHS to dispose of the controlled substance in the lab, and one authorized user must be present for disposal to sign as a second witness on the *Registrant Record of Controlled Substances Destroyed Form DEA- 41* (attached).

- Chemical deactivation will be done by a New Hampshire-certified Hazardous Waste Coordinator and witnessed by the DEA registrant or another authorized user.
- Form DEA-41 will be signed by both parties.
- EHS will email a copy of DEA-41 to the registrant, which should be saved in the lab's logbook
- EHS will save a copy of DEA-41 to the EHS DEA shared file
- EHS will send the original DEA-41 form to the DEA at:
324 South River Road
Bedford, NH 03110
- Please contact EHS if you have any questions about this disposal process.

Environmental Health & Safety

37 Dewey Field Road, Suite 6216
Hanover, New Hampshire 03755
Tel: 603-646-1762
environmental.health.and.safety@dartmouth.edu
<http://www.dartmouth.edu/~ehs/>

(Complete one form for each container)

Name of PI

Date Received _____ Expiration Date _____

Drug Name _____ Serial/Lot/Tracking# _____

[illegible]

Date Container Emptied or Disposed: _____

Controlled Substances Screening Guidance and Questionnaire

The following is based on 21 CFR § 1301.90 and § 1301.76 (2025).

For each person wishing to use controlled substances in the lab, the DEA license holder (typically the PI) must ask the following questions, the answers to which should not be recorded.

If an individual answers affirmatively to Question 1, they shall not be allowed to work with controlled substances. If an individual answers affirmatively to Questions 2 or 3, it is not necessarily disqualifying, but up to the registrant's discretion.

If the licensee feels it prudent, a background check may be performed, but written consent from the screened individual is required. The maintenance of fair employment practices, the protection of the person's right of privacy, and the assurance that the results of such inquiries will be treated by the employer in confidence will be explained to the employee.

Questions:

1. Have you ever been convicted of a felony offense relating to controlled substances, or had an application for registration with the DEA denied or revoked, or have you ever surrendered a DEA registration for cause?
2. Within the past five years, have you been convicted of a felony, or within the past two years, of any misdemeanor or are you presently formally charged with committing a criminal offense? (Do not include any traffic violations, juvenile offenses or military convictions, except by general court-martial.) If yes, furnish details of conviction, offense, location, date and sentence.
3. In the past three years, have you ever knowingly used any narcotics, amphetamines or barbiturates, other than those prescribed to you by a physician? If the answer is yes, furnish details.

Names, signatures, and dates should only be completed for screened individuals who are approved for controlled substance use. For those approved to work with controlled substances, this form must be signed and retained for at least 2 years past the individual's employment end date.

Screened Individual Name:

Signature:

Date:

PI Name:

Signature:

Date:

Controlled Substances Initial Inventory
~~X~~ Schedule I-II (Exact Count Required) **_____ Schedule III-V (Estimates OK)**

Initial inventory should always be zero. Separate sheets should be created and maintained for Schedule I-II controlled substances and Schedule III-V controlled substances. Inventory should be taken either at the beginning or end of the business day.

Registrant Information			
Registrant's Name: Jason Angell	DEA #: RR1234567	Registered Address: 37 Dewey Field Rd. Ste 6216 Hanover, NH 03755	
Date of Inventory: 1/12/2026	Time Inventory Taken: X Beginning of Day _____ End of Day	Inventoried by (Print and Sign): Jason Angell <i>Jason Angell</i>	Witnessed by (Print and Sign): Annette Chism <i>Annette Chism</i>

Complete Physical Inventory for ALL Schedule III-V Controlled Substances on hand at the time of inventory							
	Name of Substance	Concentration/ Strength	Initial Volume/ Quantity of Container	Number of Containers	Total Quantity/Volume on Hand per Concentration/Strength	Open/ Unopened	Active/Expired
1							
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3							
4							
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20							

Controlled Substances Initial Inventory
_____Schedule I-II (Exact Count Required) _____Schedule III-V (Estimates OK)

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Registrant's Name:	DEA #:	Registered Address:	
Date of Inventory:	Time Inventory Taken: ____ Beginning of Day ____ End of Day	Inventoried by (Print and Sign):	Witnessed by (Print and Sign):

Complete Physical Inventory for ALL Schedule III-V Controlled Substances on hand at the time of inventory							
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Controlled Substances ☒ Annual Inventory ☐ Biennial Inventory
☒ Schedule I-II (Exact Count Required) ☐ Schedule III-V (Estimates OK)

Separate sheets should be created and maintained for Schedule I and II controlled substances and Schedule III-V controlled substances. Inventory should be taken either at the beginning or end of the business day. Biennial inventory **MUST** be taken on May 1 of each odd year, or if this day is on the weekend, the closest business day preceding May 1.

Registrant Information							
Registrant's Name: Jason Angell		DEA #: RR1234567		Registered Address: 37 Dewey Field Rd. Ste 6216 Hanover, NH 03755			
Date of Inventory: 1/12/2026		Time Inventory Taken: ☒ Beginning of Day ☐ End of Day		Inventoried by (Print and Sign): Jason Angell <i>Jason Angell</i>		Witnessed by (Print and Sign): Annette Chism <i>Annette Chism</i>	
Complete Physical Inventory for ALL Schedule III-V Controlled Substances on hand at the time of inventory							
	Name of Substance	Concentration/ Strength	Initial Volume/ Quantity of Container	Number of Containers	Total Quantity/Volume on Hand per Concentration/Strength	Open/ Unopened	Active/Expired
1	<i>Psilocybin</i>	<i>10 mg</i>	<i>50 tablets</i>	<i>1</i>	<i>50 tablets</i>	<i>Unopened</i>	<i>Active</i>
2	<i>Psilocybin</i>	<i>10 mg</i>	<i>50 tablets</i>	<i>1</i>	<i>24 tablets</i>	<i>Open</i>	<i>Active</i>
3	<i>Psilocybin</i>	<i>10 mg</i>	<i>50 tablets</i>	<i>1</i>	<i>50 tablets</i>	<i>Unopened</i>	<i>Expired</i>
4	<i>Fentanyl Citrate</i>	<i>50 mcg/mL</i>	<i>10 mL</i>	<i>2</i>	<i>20 mL</i>	<i>Unopened</i>	<i>Active</i>
5	<i>Fentanyl Citrate</i>	<i>50 mcg/mL</i>	<i>10 mL</i>	<i>1</i>	<i>5 mL</i>	<i>Open</i>	<i>Active</i>
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Controlled Substances _____ Annual Inventory _____ Biennial Inventory
_____ Schedule I-II (Exact Count Required) _____ Schedule III-V (Estimates OK)

Separate sheets should be created and maintained for Schedule I and II controlled substances and Schedule III-V controlled substances.
 Inventory should be taken either at the beginning or end of the business day. Biennial inventory **MUST** be taken on May 1 of each odd year, or if
 this day is on the weekend, the closest business day preceding May 1.

Registrant Information							
Registrant's Name:		DEA #:		Registered Address:			
Date of Inventory:		Time Inventory Taken: ____ Beginning of Day ____ End of Day		Inventoried by (Print and Sign):		Witnessed by (Print and Sign):	
Complete Physical Inventory for ALL Schedule III-V Controlled Substances on hand at the time of inventory							
	Name of Substance	Concentration/ Strength	Initial Volume/ Quantity of Container	Number of Containers	Total Quantity/Volume on Hand per Concentration/Strength	Open/ Unopened	Active/Expired
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Inventory Discrepancy Investigation Guidance

Any inventory reconciliation that identifies a discrepancy should document the issue using the following guidance. If there is any inventory discrepancy, contact EHS.

1. Internal Investigation

- Double-check and reconcile
 - Recount the controlled substances and review all associated records including:
 - Drug Tracking Form
 - Controlled Substances Annual Inventory Reconciliation form
 - Ordering records
 - DEA Registrant Record of Controlled Substances Destroyed (DEA-41, provided to you by EHS)
 - Any notes or records of spills, accidental destruction, etc.
- Identify the Cause
 - Common causes can include:
 - Recordkeeping error: A simple mistake in a log entry, such as a transcription error or a misplaced zero.
 - Calculation error: An incorrect calculation of remaining stock.
 - Spills or waste: A dose was accidentally spilled or wasted and not properly documented.
 - Manufacturer overfill or underfill: For multi-dose vials, slight variations in volume due to manufacturer overfill or underfill.
 - Dead space: The small amount of liquid that remains in the needle and syringe hub can cause minor discrepancies.
 - Theft or diversion: This is the most serious possibility and must be considered if other explanations are ruled out. Look for signs of tampering, broken seals, or suspicious activity.
- Document Everything:
 - Document every step of the investigation. Note who conducted the recount, when it was done, what was found, and the suspected cause. This documentation is crucial for both internal records and, if needed, for the DEA.

2. Determining "Significant Loss"

The DEA requires the reporting of any "theft" and "significant loss." A "significant loss" is not defined by a specific quantity but is determined by a set of factors. The registrant, must use their professional judgment to decide if the loss is significant. Factors to consider include:

- The actual quantity of the controlled substance lost.

- The specific controlled substance lost. Is it a substance with a high potential for abuse (e.g., fentanyl, cocaine)?
- The reason for the loss. Can the loss be attributed to a specific individual, a new process, or a trend?
- A pattern of losses. Is this an isolated incident, or is it part of a recurring pattern?
- Local trends or indicators of diversion.
 - Even a small amount, such as a single dose, may be considered significant if it is a potent drug with a high potential for diversion or if it is part of a pattern of missing doses. When in doubt, it is recommended to err on the side of reporting.

3. Reporting to the DEA

If the lab determines the discrepancy constitutes a theft or a significant loss, they must take the following actions:

- Immediate notification: The DEA registrant must notify the nearest DEA Field Division Office in writing within one business day of the discovery. This can be done via email or a formal letter (as long as it's received within one business day).
- DEA Form 106: The registrant must then complete and submit DEA Form 106, "Report of Theft or Loss of Controlled Substances."
- This form must be submitted electronically through the DEA's secure network application.
 - It must be completed and submitted within 45 days of the discovery of the theft or loss.

4. Internal and Local Reporting

If the lab determines the discrepancy constitutes a theft or a significant loss, they must take the following actions:

- Report to Dartmouth EHS if this has not already been done.
- Contact the Dartmouth Department of Safety and Security, who may involve local law enforcement.

5. Important Considerations

Do Not Obliterate Records: When correcting a recordkeeping error, do not use white-out or completely erase entries. Instead, draw a single line through the incorrect entry, write the correct information, and initial and date the change. This maintains a clear audit trail.

Proactive Measures: After an investigation, the lab should review its procedures to prevent future discrepancies. This may include:

- Increasing the frequency of inventory checks.
- Reviewing security measures for the controlled substance storage.
- Providing additional training to all personnel with access to controlled

substances.

- Ensuring that two people are involved in inventory counts as a check and balance.

U. S. DEPARTMENT OF JUSTICE – DRUG ENFORCEMENT ADMINISTRATION
REGISTRANT RECORD OF CONTROLLED SUBSTANCES DESTROYED
FORM DEA-41

A. REGISTRANT INFORMATION

Registered Name:	DEA Registration Number:
Registered Address:	
City:	State: Zip Code:
Telephone Number:	Contact Name:

B. ITEM DESTROYED**1. Inventory**

Examples	National Drug Code or DEA Controlled Substances Code Number	Batch Number	Name of Substance	Strength	Form	Pkg. Qty.	Number of Full Pkgs.	Partial Pkg. Count	Total Destroyed
	16590-598-60	N/A	Kadian	60mg	Capsules	60	2	0	120 Capsules
	0555-0767-02	N/A	Adderall	5mg	Tablet	100	0	83	83 Tablets
	9050	B02120312	Codeine	N/A	Bulk	1.25 kg	N/A	N/A	1.25 kg
1.									
2.									
3.									
4.									
5.									
6.									
7.									

2. Collected Substances

Examples	Returned Mail-Back Package	Sealed Inner Liner	Unique Identification Number	Size of Sealed Inner Liner	Quantity of Packages(s)/Liner(s) Destroyed
	X		MBP1106, MBP1108 - MBP1110, MBP112	N/A	5
		X	CRL1007 - CRL1027	15 gallon	21
		X	CRL1201	5 gallon	1
1.					
2.					
3.					
4.					
5.					
6.					
7.					

C. METHOD OF DESTRUCTION

Date of Destruction:	Method of Destruction:	
Location or Business Name:		
Address:		
City:	State:	Zip Code:

D. WITNESSES

I declare under penalty of perjury, pursuant to 18 U.S.C. 1001, that I personally witnessed the destruction of the above-described controlled substances to a non-retrievable state and that all of the above is true and correct.

Printed name of first authorized employee witness:	Signature of first witness:	Date:
Printed name of second authorized employee witness:	Signature of second witness:	Date:

E. INSTRUCTIONS

- Section A. REGISTRANT INFORMATION:** The registrant destroying the controlled substance(s) shall provide their DEA registration number and the name and address indicated on their valid DEA registration, in addition to a current telephone number and a contact name, if different from the name on the valid DEA registration.
- Section B. (1) Inventory:** This part shall be used by registrants destroying lawfully possessed controlled substances, other than those described in Section B(2). In each row, indicate the National Drug Code (NDC) for the controlled substance destroyed, or if the substance has no NDC, indicate the DEA Controlled Substances Code Number for the substance; if the substance destroyed is in bulk form, indicate the batch number, if available. In each row, indicate the name, strength, and form of the controlled substance destroyed, and the number of capsules, tablets, etc., that are in a full package (pkg. qty.). If destroying the full quantity of the controlled substance, indicate the number of packages destroyed (number of full pkgs.). If destroying a partial package, indicate the partial count of the capsules, tablets, etc. destroyed (partial pkg. count). If destroying a controlled substance in bulk form, indicate that the substance is in bulk form (form) and the weight of the substance destroyed (pkg. qty.). In each row, indicate the total number of each controlled substance destroyed (total destroyed).
- Section B. (2) Collected Substances:** This part shall be used by registrants destroying controlled substances obtained through an authorized collection activity in accordance with 21 U.S.C. 822(g). In each row, indicate whether registrant is destroying a mail-back package or an inner liner. If destroying a mail-back package, enter each unique identification number separated by a comma and/or as a list in a sequential range and total quantity of packages being destroyed. If destroying an inner liner, enter each unique identification number separated by a comma and/or as a list in a sequential range based on the size of the liners destroyed and the total quantity of inner liners being destroyed. In the case of mail-back packages or inner liners received from a law enforcement agency which do not have a unique identification number or clearly marked size, include the name of the law enforcement agency and, if known, the size of the inner liner or package. **DO NOT OPEN ANY MAIL-BACK PACKAGE OR INNER LINER; AN INVENTORY OF THE CONTENTS OF THE PACKAGES OR LINERS IS PROHIBITED BY LAW AND IS NOT REQUIRED BY THIS FORM.**
- If additional space is needed for items destroyed in Section B, attach to this form additional page(s) containing the requested information for each controlled substance destroyed.
- Section C. METHOD OF DESTRUCTION:** Provide the date, location, and method of destruction. The method of destruction must render the controlled substance to a state of non-retrievable and meet all applicable destruction requirements.
- Section D. WITNESSES:** Two authorized employees must declare by signature, under penalty of perjury, that such employees personally witnessed the destruction of the controlled substances listed in Section B in the manner described in Section C.
- You are not required to submit this form to DEA, unless requested to do so. This form must be kept as a record of destruction and be available by the registrant for at least two years in accordance with 21 U.S.C. 827.

Paperwork Reduction Act Statement: The information collected on this form is necessary for DEA registrants to record controlled substances destroyed in accordance with the Controlled Substances Act (CSA). The records that DEA registrants maintain in accordance with the CSA must be kept and be available, for at least two years, for inspection and copying by officers or employees of the United States authorized by the Attorney General. 21 U.S.C. 827. DEA estimates that it will take approximately 30 minutes to complete this form, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. The completion of this form by DEA registrants that destroy controlled substances is mandatory in accordance with 21 U.S.C. 827. Please note that an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Comments regarding this information collection, including suggestions for reducing the burden estimate, should be directed to the Drug Enforcement Administration, DEA Federal Register Representative/ODL, 8701 Morrisette Drive, Springfield, Virginia 22152.

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