



INDIANA UNIVERSITY

Laboratory Safety Guideline

Controlled Substances Guidelines for Research (Non-Practitioners)

Introduction

The following procedure describes the instructions to ensure that Indiana University research is in compliance with both State and Federal regulations concerning the use and handling of controlled substances. It applies to Indiana University staff who utilize controlled substances while teaching or conducting research. Compliance will be accomplished by proper licensing with the Indiana State Board of Pharmacy and the U.S. Department of Justice, Drug Enforcement Administration (DEA), proper record keeping, inventory, and handling by University research staff.

To ensure that annual monitoring and inspections are performed, new or existing researchers who utilize controlled substances must notify the University by providing the following information on the [Indiana University Drug Enforcement Administration \(DEA\) License Information Survey](#) found in Appendix C.

Questions concerning controlled substances may be directed to the Chemical Hygiene Officer, (812) 855-6311 or the Regional DEA Office located in Indianapolis, IN, at (317) 226-7977.

Monitoring and Inspections

Inspections will be performed during annual laboratory audits for chemical safety, storage, and handling and included on the audit inspection checklist found in the Laboratory Chemical Safety Plan.

Instructions

The following instructions are provided to assist the users with management of their controlled substances programs.

Appendix A – How to Register

Appendix B – Schedules of Controlled Substances

Appendix C – Recordkeeping

Appendix D – Disposal and Spillage



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Appendix A How to Register

Individuals must first notify the Chemical Hygiene Officer (812-855-6311) of their intentions and then register with the State of Indiana for the use of controlled substances.

The following instructions and forms can be used to register.

Indiana State Board of Pharmacy Instructions and Forms:

- Instructions for Indiana Controlled Substances Registration (CSR)

(<http://www.in.gov/pla/2361.htm>)

Note: In most instances researchers are considered “Non-Practitioners” and will follow the links to Applications and Requirements, Controlled Substances Registration, and then to Instructions and Applications for Non-Practitioners.

DEA Registration Form:

- Instructions and Application for Registration (DEA Form 225)

(www.mcq.edu/research/animal/pdf/225_form.pdf)

Registration Tips:

1. Ensure the information that you are providing is legible. Complete the DEA Form 225 registration form.
2. Obtain your Indiana Controlled Substance Registration (CSR) first. The CSR will be needed to complete the DEA application and if filing electronically, will not let you advance without filling in the CSR. Make sure you remind the Indiana State Board of Pharmacy inspector to include your name on the CSR. This inspector will make a site visit to your lab prior to issuing the State CSR.

Note: The State does not inform the DEA Office when you are registered. There is no need to attach a copy of your state CSR with the DEA registration form. This must be available and provided to the Diversion Investigator assigned to the pre-registration investigation.



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Appendix A

How to Register

Only researchers using Schedule 1 substances need to list the drug code numbers for the DEA application. Make sure you have the proper controlled substance schedule listed for the drug(s) you will be using. Also make sure you have listed the proper drug codes. They **must** coincide with the schedules requested.

CAUTION: The Indiana controlled substance schedules are the reverse of the Federal schedules! The drug schedule license you apply for on the Federal application must correspond to the drug schedule you are licensed for in Indiana (e.g. if your Indiana license shows you are licensed for Schedule 2N you would request a Schedule 2 license on the Federal application).

4. When completing the DEA registration form, make sure the name and address are identical to those on the Indiana State license.
5. Schedule 1 Controlled Substances registrations require specific application instructions: Contact the Chemical Hygiene Officer (812-855-6311) for instructions.
6. Complete the "Fee Exemption" Section (section 10) on the DEA 225 form. Exemption from payment of application fee is limited to federal, state or local government operated hospitals, institutions and officials. The applicant's superior (i.e. your Department Head) or agency officer must certify exempt status. The signature, authority title, and telephone number of the certifying official (other than the applicant) must be provided.
7. The registrant must send the DEA application form to:

Drug Enforcement Administration
United States Department of Justice
Central Station
P.O. Box 28083
Washington, D.C. 20038-8083

Note: If an application has to be reviewed by DEA headquarters (such as an application for use of a Schedule 1 controlled substance) the review might add up to 6 weeks to the approval time frame. Every package sent to the DEA Washington location, especially bulky application packets, is subjected to a hazard analysis scan process. Send only the printed application; do not include other required information (see section 8 below) at this time.

8. Once your application request has been entered into the DEA database, an agent from the Indianapolis Regional DEA Office will contact you to request that you mail or fax to them the additional required documentation that will include:



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Appendix A

How to Register

- Controlled Substance Authorized User Signature List listing all staff who will have access to controlled substances.
 - Copy of your research protocol and/or a completed DEA research protocol information sheet (www.deadiversion.usdoj.gov/21cfr/cfr/1301/1301_18.htm).
 - Curriculum vitae.
 - Narrative covering how you will secure the controlled substances and how you will conduct inventories.
10. Send all forms and documentation by registered mail. Keep a copy for your records.
11. Upon receipt of the DEA license, the investigator must complete and submit the Indiana University Drug Enforcement Administration (DEA) License Information Survey (Appendix C) to the Chemical Hygiene Officer.

DEA License Scope

Practitioner means a physician, dentist, veterinarian, scientific investigator, pharmacy, hospital, or other institution or individual licensed, registered, or otherwise permitted to distribute, dispense, conduct research with respect to, or administer a controlled substance in the course of professional practice or research in Indiana. Note: a practitioner may conduct research as a coincident activity.

A non-practitioner, in Indiana, would be anyone that performs research and does not have a practitioner's license. A researcher is classified as a non-practitioner and can only be registered as such. A non-practitioner cannot dispense or write prescriptions with a researcher registration, but can purchase and/or administer controlled substances. A researcher works under a protocol, which directs the specific actions and the specific drugs that may be used in the research protocol.

Agents are authorized employees or lab staff who act on behalf of the registrant. The requirement of registration is waived for any agent or employee of a person who is registered to engage in any group of independent activities, if such agent or employee is acting in the usual course of his/her business or employment.

Power of attorney; any purchaser may authorize one or more individuals, whether or not located at the registered location of the purchaser, to obtain and execute order forms on his/her behalf by executing a power of attorney for each such individual. The authorization forms and further information can be found in Title 21, Code of Federal Regulations, Section 1305.07 (21 CFR 1305.07) found at the following website:

- www.deadiversion.usdoj.gov/21cfr/cfr/1305/1305_05.htm



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DEA Controlled Substances Schedules

Controlled substances are designated as Schedule I - V (C-I, C-II, C-III, C-IV and C-V) according to their medical use, potential for abuse, and safety or dependence liability. Each controlled substance, or basic class thereof, has been assigned an "Administration Controlled Substances Code Number."

The Certificate of Registration (DEA form 223) will contain the name, address, and registration number of the registrant, the activity authorized by the registration, the schedules and/or administration controlled substances code number of the controlled substances which the registrant is authorized to handle, the amount of fee paid (or exemption), and the expiration date of the registration.

The code number may not appear on any DEA forms. Typically, the approved drug schedules will be on the certificate of registration and DEA 222 order form with the exception of GHB, carfentanil, etorphine hydrochloride, and diprenorphine which require additional record keeping and handling requirements.

The Certificate of Registration will be issued by the Administration pursuant to:

21 CFR 1301.35 (www.deadiversion.usdoj.gov/21cfr/cfr/1301/1301_35.htm)

DEA 222 forms may be filled in accordance with special procedures pursuant to:

21 CFR 1305.05 (www.deadiversion.usdoj.gov/21cfr/cfr/1305/1305_07.htm).

And maintained separately pursuant to:

21 CFR 1305.17 (www.deadiversion.usdoj.gov/21cfr/cfr/1305/1305_17.htm)

For the schedules of controlled substances refer to:

21 CFR 1308 (www.deadiversion.usdoj.gov/21cfr/cfr/2108cfrt.htm)

Schedule I Controlled Substances

The Indiana State Board of Pharmacy must recommend placement of a substance in Schedule I if it finds that:

1. The substance has high potential for abuse; and
2. The substance has no accepted medical use in treatment in the United States or lacks accepted safety for use in treatment under medical supervision.

Examples of Schedule I substances include heroin, lysergic acid diethylamide (LSD), marijuana, and methaqualone.

The board may recommend placement of a substance in schedule I under this chapter if it finds that the substance is classified as a controlled substance in schedule I under federal law.



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Schedule I Controlled Substances can be found in:

21CFR 1308.11 (www.deadiversion.usdoj.gov/21cfr/cfr/1308/1308_11.htm)

The Indiana list of Schedule I Controlled Substances can be found in the:

Indiana Code 35-48-2-4 (www.ialegis.gov/ic/code/title35/ar48/ch2.html#IC35-48-2-4)

Schedule II Controlled Substances

The Indiana State Board of Pharmacy must recommend placement of a substance in Schedule II if it finds that:

1. The substance has high potential for abuse;
2. The substance has currently accepted medical use in treatment in the United States , or currently accepted medical use with severe restrictions; and
3. The abuse of the substance may lead to severe psychological or physical dependence.

Examples of Schedule II substances include pentobarbital, morphine, phencyclidine (PCP), cocaine, methadone, and methamphetamine.

The board may recommend placement of a substance in schedule II under this chapter if it finds that the substance is classified as a controlled substance in schedule II under federal law.

Schedule II Controlled Substances can be found in:

21 CFR 1308.12 (www.deadiversion.usdoj.gov/21cfr/cfr/1308/1308_12.htm).

The Indiana list of Schedule II Controlled Substances can be found at:

Indiana Code 35-48-2-6 (www.ialegis.gov/ic/code/title35/ar48/ch2.html#IC35-48-2-6)

Schedule III Controlled Substances

The Indiana State Board of Pharmacy must recommend placement of a substance in Schedule III if it finds that:

1. The substance has a potential for abuse less than the substances listed in schedule I and II under this chapter;
2. The substance has currently accepted medical use in treatment in the United States and
3. Abuse of the substance may lead to moderate or low physical dependence or high psychological dependence.



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Ketamine, anabolic steroids, codeine and hydrocodone with aspirin or Tylenol[®], and some barbiturates such as phenobarbital are examples of Schedule III substances. The list of anabolic steroids can be found at:

21 CFR 1300.01 (a)(4) (www.deadiversion.usdoj.gov/21cfr/cfr/1300/1300_01.htm)

The board may recommend placement of a substance in schedule III under this chapter if it finds that the substance is classified as a controlled substance in schedule III under federal law.

Schedule III Controlled Substances can be found in:

21 CFR 1308.13 (www.deadiversion.usdoj.gov/21cfr/cfr/1308/1308_13.htm)

The Indiana list of Schedule III Controlled Substances can be found at:

IC 35-48-2-8 (www.ai.org/legislative/ic/code/title35/ar48/ch2.html#IC35-48-2-8)

Schedule IV Controlled Substances

The Indiana State Board of Pharmacy must recommend placement of a substance in Schedule IV if it finds that:

1. The substance has a low potential for abuse relative to substances in schedule III under this chapter;
2. The substance has currently accepted medical use in treatment in the United States and
3. Abuse of the substance may lead to limited physical dependence or psychological dependence relative to the substances in schedule III under this chapter.

Examples of drugs included in schedule IV are all the benzodiazepines, such as alproazolam and diazepam, etc. (otherwise known as Valium[®], and Xanax[®]).

The board may recommend placement of a substance in schedule IV under this chapter if it finds that the substance is classified as a controlled substance in schedule IV under federal law.

Schedule IV Controlled Substances can be found in:

21 CFR 1308.14 (www.deadiversion.usdoj.gov/21cfr/cfr/1308/1308_14.htm)

The Indiana list of Schedule IV Controlled Substances can be found at:

IC 35-48-2-10 (www.ai.org/legislative/ic/code/title35/ar48/ch2.html#IC35-48-2-10).



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Schedule V Controlled Substances

The Indiana State Board of Pharmacy must recommend placement of a substance in Schedule V if it finds that:

1. The substance has low potential for abuse relative to the controlled substances listed in schedule IV under this chapter;
2. The substance has currently accepted medical use in treatment in the United States; and
3. The substance has limited physical dependence or psychological dependence liability relative to the controlled substances listed in schedule IV under this chapter.

Cough medicines with codeine are examples of Schedule V drugs.

The board may recommend placement of a substance in schedule V under this chapter if it finds that the substance is classified as a controlled substance in schedule V under federal law.

Schedule V Controlled Substances can be found in:

21 CFR 1308.15 (www.deadiversion.usdoj.gov/21cfr/cfr/1308/1308_15.htm).

The Indiana list of Schedule V Controlled Substances can be found at:

IC 35-48-2-12 (www.ai.org/legislative/ic/code/title35/ar48/ch2.html#IC35-48-2-12).



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Appendix C Recordkeeping

Records of Non-Practitioner Registrants

All records must be maintained for at least two years from the date of such inventory or records, for inspection and copying by authorized employees of the DEA. Retaining records for five years is advisable due to the statute of limitations. These records must be in conformance with the record keeping and inventory requirements of federal law. This includes all purchasing records, all administering and dispensing records, all Schedule I and II Order Forms (DEA Form 222), and all physical inventories.

Schedules I and II must be maintained separately from all other records of the registrant, and Schedule III, IV, and V must be maintained either separately from all other records of the registrant or in such form that the information required is readily retrievable from the ordinary business records of the registrant. The phrase "*readily retrievable*" means they can be separated out from other records in a reasonable time.

Note: Records must be made available within five (5) working days after a request by the Indiana Board of Pharmacy for such records or information on controlled substances transactions.

Purchasing Records

Purchasing records can be:

- A copy of the invoice.
- A copy of the shipping document.
- A copy of the packing slip.

Note: These are acceptable records for Schedules III, IV, and V controlled substances but DEA Form 222 is the only approved receipt record for Schedule I and II controlled substances.

Purchasing records must contain:

- The name, address, and DEA number of the company from which the controlled substance was purchased.
- The name of the controlled substance purchased.
- The size and strength of the controlled substance purchased.
- The amount purchased (which should match the amount received).

The purchasing record (invoice, shipping document, or packing slip) must be annotated with the handwritten date of receipt.



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Dispensing Records

Dispensing records must contain:

- The name and address of person (research subject) or identification numbers of animal subjects to whom it was dispensed.
- The date dispensed.
- The initials of person dispensing on behalf of registrant.
- The name of the controlled substance.
- The strength and size of the controlled substance.
- The amount dispensed (number of units or volume).

Note: There are special recordkeeping requirements for Gamma Hydroxybutyric Acid (GHB).

Inventory Records

Controlled substance inventory is one of the most important aspects of the DEA program. The dispensing records and the inventory records can be the same and is acceptable to the State Pharmacy Board. An initial inventory is required a) when first registered with the DEA or b) when the registrant first engages in research activity. A biennial inventory (every two years) is required thereafter and can be performed whenever necessary as long as it is within the two year increment.

This can be a “perpetual” inventory with the starting amount and a running log of what is dispensed and when (see above under "Dispensing records"). Inventory maintenance is the key to the loss detection, theft, and the diversion of controlled substances. Complete inventory requirements can be found at the following website:

- www.deadiversion.usdoj.gov/21cfr/cfr/1304/1304_11.htm



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Security

Security depends greatly on the type, quantity, and form of controlled substances being used in the research project. Schedule I, II, III, IV, and V controlled substances must be stored in a *securely* locked substantially constructed cabinet. Controlled substances should not be located near a glass panel where they can be visible from the outside.

Researchers must provide effective controls to guard against theft of controlled substances. This includes limiting the distribution of the lock combinations, the number of keys, and the number of employees who will have access to these keys or lock combinations. Developing an accountability standard operating procedure for keys, combinations and/or changing lock combinations is recommended.

Note: Always ask visitors or individuals entering these areas for identification and why they are there. When maintenance work is done in the controlled substance storage area the research staff must maintain adequate observation.

DEA Ordering Forms

To order a controlled substance you must first have a DEA license. The Schedule I and II Controlled Substance Order Form (DEA Form 222) is a paper-based form that comes in triplicate and is used to order controlled substances. It is requisitioned directly from the DEA and is required to be filled out in triplicate. The DEA Form 222 also allows the exchange of controlled substances from the registrant to another party registered with the DEA (typically used when a controlled substance is sent to a reverse distributor for credit or disposal).

Schedule I or II registrants can request official DEA Form 222 on-line at the following website:

- <https://www.deadiversion.usdoj.gov/webforms/orderFormsRequest.jsp>

You will receive the maximum number of order form books allowed for your business activity.

Schedule III, IV, and V drug orders do not require a DEA Form 222. These drugs can be ordered directly from the manufacturer. However, you may be asked to provide a copy of your DEA Registration before your order will be prepared and shipped.

Note: If the registration of any purchaser terminates (because the purchaser dies, ceases legal existence, discontinues business or professional practice, or changes his name or address as shown on his registration) or is suspended or revoked as to all controlled substances (Schedules I through V) for which he/she is registered must relinquish all unused controlled substances and order forms for such substances to the Indiana University Police Department (812-855-4111). The Chemical Hygiene Officer (812-855-6311) can facilitate this.



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Appendix C Recordkeeping

Theft of or Missing Controlled Substances Reporting

The DEA license holder must have complete accountability of all controlled substances stored or used in their area. This makes keeping good records essential so that any shortages or missing controlled substances will not go unnoticed. Theft or misuse of a controlled substance is a criminal act that must be reported to the following agencies:

- Indiana State Board of Pharmacy: (317) 234-2067
- Nearest DEA office within one (1) day of discovery:
INDIANAPOLIS DISTRICT OFFICE
575 N. Pennsylvania, Room 408
Indianapolis, IN 46204
Diversion Number: (317) 226-7977
Diversion Fax: (317) 226-7703
- Indiana University Police Department: (812) 855-4111
- Indiana University, Chemical Hygiene Officer: (812) 855-6311

In addition to the immediate phone reporting, a Report of Theft or Loss of Controlled Substances (DEA Form 106) must be completed and submitted to the Indiana DEA office to report *any* theft or a *significant* loss.

Reporting is also necessary if small quantities of controlled substances become unaccounted for on a re-occurring basis and must be investigated which may lead to reporting on a DEA Form 106. Keep copies of DEA Form 106 in your inventory records.

Other Pertinent Record Information

- Maintain current, complete and accurate records to reflect substances:
 - * Received (Purchased).
 - * Sold (Administered & Dispensed).
 - * Delivered to another registrant.
 - * Otherwise disposed.
 - * Theft or loss.
- Separate records are required for each location.
- Separate records are required for each independent activity for which he/she is registered.

When recording dates of receipt, importation, distribution, exportation, or other transfers, the date on which the controlled substances are actually received, imported, distributed, exported, or otherwise transferred must be used as the date of receipt or distribution on any documents of transfer (e.g. invoices or packing slips).



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Forms

These forms will be used to log the purchasing, administering, dispensing, and inventory of controlled substances possessed by DEA registrants.

- Indiana University Drug Enforcement Administration (DEA) License Information Survey
Below on page C-6
- Registrants Inventory of Drugs Surrendered (DEA Form 41)
http://www.deadiversion.usdoj.gov/21cfr_reports/surrend/41/41_form.pdf
- Report of Theft or Loss of Controlled Substances (DEA Form 106)
http://www.deadiversion.usdoj.gov/21cfr_reports/theft/index.html
- DEA On-Line Forms and Applications
http://www.deadiversion.usdoj.gov/online_forms.htm
- DEA Order Forms Request (for DEA Form 222)
<https://www.deadiversion.usdoj.gov/webforms/orderFormsRequest.jsp>

Controlled Substance Links

- Code of Federal Regulations Schedule of Controlled Substances
<http://www.deadiversion.usdoj.gov/schedules/index.html>
- Indiana Administrative Code, Title 856 Indiana Board of pharmacy
http://www.in.gov/legislative/iac/iac_title?iact=856
- Indiana Administrative Code, Title 35, Article 48 Controlled Substances
<http://www.in.gov/legislative/ic/code/title35/ar48/>
- Indiana State Board of Pharmacy
<http://www.in.gov/pla/2361.htm>
- U.S. Department of Justice Drug Enforcement Administration Office of Diversion Control
<http://www.deadiversion.usdoj.gov/index.html>
- DEA Security Regulation (21 CFR 1301.71 thru 21 CFR 1301.76)
<http://www.deadiversion.usdoj.gov/21cfr/cfr/2101cfrt.htm>



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Appendix C

Recordkeeping

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DRUG ENFORCEMENT ADMINISTRATION (DEA)
LICENSE INFORMATION SURVEY

The use of controlled substances in University research must be in compliance with the requirements of both the Indiana Code and the Federal Drug Enforcement Administration (DEA). Please complete the following information for the use of controlled substances. The purpose of this information is to ensure that all users and locations of controlled substances in research are known and that the proper controls are in place to provide compliance with the regulatory requirements and safe authorized use of these materials.

1. NAME (AS IT APPEARS ON THE DEA LICENSE): _____
2. DEPARTMENT/SCHOOL: _____
3. OFFICE STREET ADDRESS: _____
4. BUILDING AND ROOM NUMBER: _____
5. LOCATION OF THE RESEARCH: _____
6. EMAIL: _____ PHONE: _____
7. LICENSE NUMBER: _____ EXPIRATION DATE: _____

Please send this form via campus mail to the Chemical Hygiene Officer, University Office of Environmental Health and Safety, 1514 E. Third St., Bloomington, IN 47405.



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Appendix D

Disposal or Spillage

To minimize waste, DEA registrants should only purchase quantities they intend to use. Damaged, expired, unwanted, unusable, or non returnable Controlled Substances must be accounted for, retained, and disposed of in accordance with applicable State and Federal regulations.

A Registrants Inventory of Drugs Surrendered, DEA Form 41 found at the following website:

- http://www.deadiversion.usdoj.gov/21cfr_reports/surrend/41/41_form.pdf

must be completed prior to disposing of any DEA controlled substance. Two (2) copies of the form must be sent to the local Indiana DEA branch and one (1) copy should be retained by the registrant for at least 2 years.

Disposal records must contain:

- Your DEA number, name, and address.
- The reverse distributor's DEA number, name, and address.
- The number of units (in finished forms and/or commercial containers) disposed of in any manner, including the manner of disposal.

The disposal record must be dated to reflect when the products were sent for destruction and left your inventory.

There are three disposal options for expired or unwanted controlled substances recommended by the Chemical Hygiene Officer. The Chemical Hygiene Officer (812-855-6311) should be contacted to help determine the correct disposal method.

1. Contact the Supplier:

Some suppliers will take back pharmaceuticals for credit. If possible, this is the best means of controlled substance disposal.

2. On-Site Disposal:

Small quantities (less than 1 pound) can be disposed onsite by the DEA registrant using the following six-step controlled substance disposal procedure:

- i. Contact the Chemical Hygiene Officer (812-855-6311) with a controlled substance disposal request.
- ii. Complete the Registrants Inventory of Drugs Surrendered, DEA Form 41 found at http://www.deadiversion.usdoj.gov/21cfr_reports/surrend/41/41_form.pdf prior to disposal.
- iii. Inform the Chemical Hygiene Officer (812-855-6311) when the DEA Form 41 has been completed and is ready for review.



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Appendix D

Disposal or Spillage

- iv. The Chemical Hygiene Officer will forward this form to the DEA with a projected two week disposal date.
- v. At the end of the waiting period arrangements will be made for an IU Police Officer and the Chemical Hygiene Officer to be present to witness the disposal, verify the DEA Form 41 and inventory records.
- vi. The Chemical Hygiene Officer will forward two copies of the DEA Form 41 to the Agent in Charge of Indiana DEA, and provide one copy to the researcher for their inventory records.

Attn: Agent in Charge, Diversion
Drug Enforcement Administration
Indianapolis District Office
575 N. Pennsylvania, Room 408
Indianapolis, IN 46204

2. Reverse Distribution:

For large quantities (greater than 1 pound), contact a Reverse Distributor. This option transfers ownership of the controlled substance to a DEA-approved Pharmaceutical Returns Processor for re-use, re-sale or destruction at a hazardous waste incinerator. This process may involve the completion of DEA Form 222 or DEA Form 41. Contact information for three reverse distributors is listed below.

- * MedTurn: (317) 867-2552
- * National Notification Center: (800) 636-9826
- * Guaranteed Returns: (800) 729-3279

Spills

Breakage, spills, or other witnessed controlled substance losses do not need to be reported as lost. This type of loss must be documented by the registrant and witness on the inventory record. Controlled substances that can be recovered after a spill, but cannot be used because of contamination (tablets), must be placed in the disposal/destruction waste stream. If the spilled controlled substance is not recoverable (liquids); the registrant must document the circumstances in their inventory records and the witnesses must sign.