MARIAN UNIVERSITY
Indianapolis
Research and Scholarship Administration

# Controlled Substances in Research

## Scope:

This policy applies to all research and other scholarly activities performed on the campuses of Marian University (herein the "University") by faculty, staff, students and/or other persons. The workplace includes, but is not limited to, University owned and controlled buildings, real estate, and vehicles.

## Policy Statement:

As a recipient of federal funds, the University complies with the Drug Free Workplace Act of 1988 requiring all employees be notified that the unlawful manufacture, distribution, dispensing, possession, or use of controlled substances is prohibited at Marian University. Prohibited drugs are defined as illegal substances, including controlled substances as defined in the Controlled Substance Act (21 U.S.C. 8120) and the Code of Federal Regulations (21 C.F.R. 1308.11-1308.15) and prescription controlled substance which have not been prescribed by a licensed physician or dentist for specific treatment purposes for the employee. Violation of this prohibition by an employee shall result in the University taking appropriate personnel action against the employee, up to and including discharge, or requiring the employee to participate satisfactorily in drug abuse assistance or rehabilitation program approved for such purposes by a federal, state, or local health, law enforcement, or other appropriate agency.

As an exception to the above, the University recognizes that certain research projects and/or other scholarly activities may involve substances that are regulated by the United States Drug Enforcement Administration DEA or state agencies as "controlled substances." The policy detailed below is designed to assist researchers with 1) seeking approval from the University for a research-use exception to the Drug Free Workplace Policy and 2) registration and compliance with applicable state and federal regulations.

Compliance will be the responsibility of the DEA Registrant and will be accomplished through annual inspection of controlled substance storage location by the University; proper licensing and registration with the Indiana State Board of Pharmacy and the U.S. Department of Justice, DEA; and proper recordkeeping, inventory, storage and handling.

## Definitions:

- **Practitioner:** 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.

- **Non-practitioner:** In Indiana, is anyone that performs research involving a controlled substance who 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 research protocol, which specifies the exact procedures and drugs that may be used.

- **Agents**: 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 at the URL below:

  https://www.ecfr.gov/current/title-21/chapter-II/part-1305/subpart-A/section-1305.07

**Authority and Responsibilities:**

- The Marian University Research & Scholarship Administration (inclusive of the MU Chemical Hygiene Officer and the Institutional Biosafety Committee) shall be responsible for:

  - Initial approval of research use of controlled substance and annual inspection of the security and recordkeeping requirements of the DEA Registrant;
  - Providing guidance for controlled substance registration;
  - Providing assistance with compliance; and
  - Providing guidance (and assistance when appropriate) regarding disposal of expired or unwanted substances.
  - For controlled substances used in biological settings (such as cell culture), providing consultation and oversight for mitigation of biohazard risk.

- Faculty, Staff, Students, and/or Volunteers utilizing controlled substances in research shall be responsible for:

  - Providing MU Research & Scholarship Administration the following information:
    - PI name, e-mail, phone number, DEA registration number (upon registration), expiration date, school/department, room number of research.
    - A brief research plan describing the intended use of the controlled substance(s) in research.
    - A plan for addressing accidental spills of the controlled substance and, if applicable, disposal of biohazardous waste (liquid and/or solid).
    - A plan limiting access to the controlled substance storage, including names of persons who will be utilizing the material(s) in research, who will be responsible for ordering and/or receiving said materials, and who will be issued keys and/or combinations to the secure storage site.
  - Obtaining proper state and federal registrations prior to the possession of controlled substances;
  - Compliance with all requirements of those registrations in accordance with the applicable state and federal regulations;
  - Maintaining all records for inventory, dispensing, and reporting;

**Procedure:**

**1. Initial Approval for Research Use of Controlled Substance(s)**

New or existing researchers who intend to utilize controlled substances in research must receive approval from the University prior to initiating said project or approval process external to the University. The purpose of this approval is to 1) issue an express exception to the Drug Free Workplace Policy for the intended research use and 2) ensure that all users, specific controlled substances being utilized, and locations of controlled substances storage are known to all pertinent units of the University (Research & Scholarship Administration, Chemical Hygiene Officer, Campus Police, Campus Operations, etc.) and 3) to ensure that the proper procedures are in place to provide compliance with the regulatory requirements and safe authorized use of these materials. Failure to adhere to this approval process will be considered a violation of the Drug Free Workplace Policy and may result in any and all penalties described therein.

**2. Monitoring and Inspections**

Management of controlled substances, inventory and dispensing records are the responsibility of the registrant. The security and recordkeeping requirements of the controlled substances will be visually inspected annually by the University. Failure to maintain accurate and complete inventory and dispensing records is a violation of federal law by the registrant (see Appendix B). Additionally, non-compliance with requirements for security safeguards, management, and/or inventory and dispensing records may result in disciplinary actions by the University.

**3. Security, Storage and Transport**

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 behind two differently-keyed locks (e.g. in a lockbox in a substantially constructed cabinet that is mounted to the wall, floor, or bench). Controlled substances shall not be located near a glass panel where they can be visible from the outside. Information on specific, approved locations and methods for storage of controlled substances on Marian University campuses is available from the Research & Scholarship Administration.

Transport of controlled substances between the storage location and the location of research use must be in a leak-proof, durable container with a tight-fitting lid that is used to provide an additional level of containment around a primary container of the material.

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

Dispensing records must be maintained accurately and continually to verify loss or theft.

**4. Registration**

As described above, individuals must first notify the MU Research & Scholarship Administration

of their intentions for using a controlled substance in research. After receiving approval for such use, individuals may then register with the State of Indiana 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 procedures are in place to provide compliance with the regulatory requirements and safe authorized use of these materials. In most instances research scientists are considered "non-practitioners" and must complete the applications for Non-Practitioners. The following instructions and forms can be used to register.

### 3.1 Indiana State Board of Pharmacy Registration

To begin the registration process, instructions for Indiana Controlled Substances Registration (CSR) are found at the following URL:

http://www.in.gov/pla/3027.htm

Note: Do not move your inventory without notifying the State Board of Pharmacy and DEA. To move or relocate your inventory to a different location (or room), change the ownership, or change your name, you must notify the State Board of Pharmacy (first) using the same application form above. Then you must notify the federal DEA once you have received an approved state license.

### 3.2 DEA Registration

Instructions for the Drug Enforcement Agency (DEA) Office of Diversion Control registration can be found at the following URL:

http://www.deadiversion.usdoj.gov

Follow the link and select New Applications or Renewal Applications as necessary.

New applications may be submitted electronically or on paper forms. Renewals may only be completed electronically.

- Research scientists use DEA Form 225 for Non-Practitioners.
- Physicians and veterinarians use DEA Form 224 for Practitioners.

Electronic forms and downloadable paper forms are found at the URL below. Forms are occasionally updated. Check for the most recent version.

http://www.deadiversion.usdoj.gov/drugreg/index.html

Note: To report inventory location changes, name or address changes, or drug code and schedule changes follow the Registration Changes link at the website above after receiving an approved state license for the change.

### 3.3.3 Registration Guidelines:

1. Obtain your Indiana Controlled Substance Registration (CSR) first. The CSR will be

needed to complete the DEA application and if filing electronically, the DEA 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.

2. Complete the DEA Form 225 application after you have received the state CSR. When completing the DEA registration form, make sure the name and address are identical to those on the state CSR.

3. 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 narcotic/non-narcotic designations in Indiana are the reverse of the federal Schedules! The designation “N” refers to a narcotic in Indiana, whereas the designation “N” refers to a non-narcotic according to the DEA. The drug Schedule registration you apply for on the federal application must correspond to the drug schedule you are registered for in Indiana (e.g. if your Indiana registration shows you are registered for Schedule 2N you would request a Schedule 2 registration on the federal application as shown below).

   Indiana 2N= DEA 2
   Indiana 2 = DEA 2N
   Indiana 3N= DEA 3
   Indiana 3 = DEA 3N

4. Schedule 1 Controlled Substances registrations require specific application instructions: Contact MU Research & Scholarship Administration for assistance.

5. Complete the "Fee Exemption" section (Section 6) on the paper DEA 225 form (Section 1 of the electronic application). Exemption from payment of application fee is limited to federal, state or local government operated hospitals, institutions and officials.

   Enter the word “Exempt” into the appropriate space on the form to indicate the fee exempt status. MU Research & Scholarship Administration can also certify the tax/fee exempt status. If so, the signature, authority title, and telephone number of the certifying official (other than the applicant) must be provided. Please contact the MU Research & Scholarship Administration for information.

6. If not completing an on-line form, the registrant must send the DEA application form to:

   DEA HEADQUARTERS
   ATTN: Registration Section/ODR
   P.O. Box 2639

Springfield, VA 22152-2639

Note: If an application must 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, especially bulky application packets, is subjected to a hazard analysis scan process. Send only the printed application; do not include other required information (see item 9. below) at this time.

7. 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:

    - Controlled Substance Authorized User Signature List listing all staff that will have access to controlled substances.
    - Copy of your research protocol and/or a completed DEA research protocol information sheet.
    - Curriculum vitae.
    - Narrative covering how you will secure the controlled substances and how you will conduct and maintain dispensing records and inventories.

8. Send all forms and documentation by registered mail. Keep a copy for your records.

9. Upon receipt of the DEA registration, the investigator must report the registration to the MU Research & Scholarship Administration.

### 3.3.4 Registration Renewal

Federal DEA renewal applications are mailed to the registered location 60 days prior to the expiration. On-line renewal information and applications are found at the following URL:

http://www.deadiversion.usdoj.gov/drugreg/index.html#regapps

Click on “Renewal Applications” and you will be directed to the proper DEA Registration Renewal Form Login. You will need the following information as it appears on your original registration:

- DEA registration number;
- Last name or business name and first name;
- Social security number and/or tax identification number;
- Registration expiration date; and
- State and zip code.

Note: Information from your original application will be filled in for you including the tax/fee exempt status of the University. Enter your name as the certifying applicant/official upon completion of the application.

## 3.4 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."

Specific controlled substances, regulated chemicals, and scheduling actions are listed alphabetically and by code number at:

http://www.deadiversion.usdoj.gov/schedules/index.html

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

DEA 222 forms may be filled in accordance with special procedures pursuant to: 21 CFR 1305.05

And maintained separately pursuant to: 21 CFR 1305.17

### 3.4.1 Schedule I Controlled Substances

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

- The substance has high potential for abuse; and
- 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.

DEA Schedule I Controlled Substances can be found in: 21 CFR 1308.11
Indiana Schedule I Controlled Substances can be found in: IC 35-48-2-4 (Version b)

### 3.4.2 Schedule II Controlled Substances

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

- The substance has high potential for abuse;
- The substance has currently accepted medical use in treatment in the United States, or currently accepted medical use with severe restrictions; and
- 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.

DEA Schedule II Controlled Substances can be found in: 21 CFR 1308.12 Indiana Schedule II Controlled Substances can be found in: IC 35-48-2-6

### 3.4.3 Schedule III Controlled Substances

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

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

Ketamine, anabolic steroids, codeine and hydrocodone with aspirin or Tylenol®, and some barbiturates such as phenobarbitol are examples of Schedule III substances.

The list of anabolic steroids can be found at: 21 CFR 1300.01 (a)(4)

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.

DEA Schedule III Controlled Substances can be found in: 21 CFR 1308.13
Indiana Schedule III Controlled Substances can be found in: IC 35-48-2-8

### 3.4.4 Schedule IV Controlled Substances

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

- The substance has a low potential for abuse relative to substances in Schedule III under this chapter;
- The substance has currently accepted medical use in treatment in the United States; and

- 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.

DEA Schedule IV Controlled Substances can be found in: 21 CFR 1308.14
Indiana Schedule IV Controlled Substances can be found in: IC 35-48-2-10

### 3.4.5 Schedule V Controlled Substances

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

- The substance has low potential for abuse relative to the controlled substances listed in Schedule IV under this chapter;
- The substance has currently accepted medical use in treatment in the United States; and
- 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.

DEA Schedule V Controlled Substances can be found in: 21 CFR 1308.15
Indiana Schedule V Controlled Substances can be found in: IC 35-48-2-12

## 3.5 Recordkeeping

Records must be made available to the University within five (5) working days of such request. Failure to comply with said request may result in disciplinary action by the University. Records must be in conformance with the recordkeeping and inventory requirements of federal law. This includes all purchasing records, all administering and dispensing records, all Schedules 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.

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.

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.

### 3.5.1 Purchasing Records

Purchasing records can be:

- A copy of the invoice;
- A copy of the shipping document; or
- 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; and
- The amount purchased (which must match the amount received).

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

### 3.5.2 Dispensing Records

Dispensing records must contain:

- The name and address of person (research subject) or identification numbers of animal subjects (or groups of animals) 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; and
- The amount dispensed (number of units or volume). An example dispensing record form is found in Appendix A.

Title 21 of the Code of Federal Regulations, Section 1304.22 (c) Records for dispensers and researchers, states that:

“Each person registered or authorized to dispense or conduct research with controlled substances shall maintain records with the same information required of manufacturers pursuant to paragraph (a)(2)(i), (ii), (iv), (vii), and (ix) of this section. In addition, records

shall be maintained of the number of units or volume of such finished form dispensed, including the name and address of the person to whom it was dispensed, the date of dispensing, the number of units or volume dispensed, and the written or typewritten name or initials of the individual who dispensed or administered the substance on behalf of the dispenser."

Researchers using animal subjects, and not humans, must use the animal species and identification (ID) instead of the requirement for recording the name and address of the person receiving the controlled substance.

### 3.5.3 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 (at least 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 and dispensing record 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

### 3.5.4 Theft of or Missing Controlled Substances Reporting

The DEA registration 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 within one (1) day of discovery:

- Indiana State Board of Pharmacy: (317) 234-2067
- Nearest DEA office:

  INDIANAPOLIS DISTRICT OFFICE
  575 N. Pennsylvania, Room 408
  Indianapolis, IN 46204
  Diversion Number: (317) 226-7977
  Diversion Fax: (317) 226-7703

- Marian University Police Department: (317) 955-6789
- Marian University Research & Scholarship Administration

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.

### 3.5.5 Other Pertinent Record Information

- Maintain current, complete and accurate records to reflect substances:
    - Received (Purchased);
    - Sold (Administered & Dispensed);
    - Delivered to another registrant;
    - Otherwise disposed; and
    - 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).

### 3.5.6 DEA Ordering Forms

University funds (including extramural funds issued to the University on behalf of the Investigator) shall not be used for purchasing controlled substances for research without the express, written approval by the MU Research & Scholarship Administration. Failure to adhere to this policy may result in disciplinary action by the University.

To order a controlled substance you must first have a DEA registration. 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 is suspended or revoked as to all controlled substances (Schedules I through V) for which he/she is registered, they must return all unused substances and their order forms to the Indiana Board of Pharmacy or their authorized agent (such as Marian University Police Department) or place all substances under seal. The MU Research & Scholarship Administration can facilitate this.

### 3.6 Disposal

To minimize waste, DEA registrants must 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 University, state, federal regulations.

The Registrant must provide the MU Research & Scholarship Administration with a plan for addressing disposal of controlled substances in biohazardous material.

A Registrants Inventory of Drugs Surrendered, DEA Form 41, is necessary to document proper disposal.

DEA Form 41 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 must 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; and
- 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. The MU IBC contact for your respective campus (Section 3.8) must 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. Reverse Distribution:

   Large quantities (greater than 1 pound) must utilize a Reverse Distributor for disposal. 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 the Reverse Distributors is listed below.

- Stericycle: (800) 636-9826
- Guaranteed Returns: (800) 729-3279

3. 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 MU Chemical Hygiene Officer with a controlled substance disposal request.

ii. Prior to disposal complete DEA Form 41, the Registrants Inventory of Drugs Surrendered.

iii. Inform the MU Chemical Hygiene Officer when the DEA Form 41 has been completed and is ready for review.

iv. The MU Chemical Hygiene Officer will forward a copy of 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 MU Police Officer and the MU Chemical Hygiene Officer to be present to witness the disposal and verify the DEA Form 41 and inventory shown on the form. The DEA registrant or their authorized agent must bring the controlled substance to the disposal site. The MU Chemical Hygiene Officer will not take possession of controlled substances at any point in the disposal process.

vi. The MU Chemical Hygiene Officer will forward two copies of the DEA Form 41 to the Agent in Charge of the regional office of the 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

### 3.7 Spills

The Registrant must provide the MU Research & Scholarship Administration with a plan for addressing spills involving controlled substances alone and controlled substances in biohazardous material.

Breakage, spills, or other witnessed controlled substance losses do not need to be reported as lost to the DEA, however, this type of loss must be documented by the

registrant and witnessed 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 appropriate 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.

### 3.8 MU Contacts

Questions concerning controlled substances may be directed to the MU Research & Scholarship Administration, the MU Chemical Hygiene Officer, or the MU IBC.

## APPENDIX A – RECORDKEEPING FORMS

The links and forms detailed below will provide additional information and be used to log the purchasing, administering, dispensing, and inventory of controlled substances possessed by DEA registrants.

- Registrants Inventory of Drugs Surrendered (DEA Form 41)

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

- Report of Theft or Loss of Controlled Substances (DES Form 106)

  https://www.deadiversion.usdoj.gov/21cfr_reports/theft/index.html

- DEA Order Forms Request (for DEA Form 222)

  https://apps.deadiversion.usdoj.gov/webforms2/spring/orderFormsLogin?execution=e1s1

- 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://iac.iga.in.gov/iac//iac_title?iact=856

- Indiana Administrative Code, Title 35, Article 48 Controlled Substances

  http://iga.in.gov/legislative/laws/2022/ic/titles/001

- Indiana State Board of Pharmacy

  https://www.in.gov/pla/professions/indiana-board-of-pharmacy/

- U.S. Department of Justice Drug Enforcement Administration Office of Diversion Control

  http://www.deadiversion.usdoj.gov/index.html

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## APPENDIX B: CONTROLLED SUBSTANCE DISPENSING RECORD

PRINCIPAL INVESTIGATOR: _____

CONTROLLED SUBSTANCE: _____ CONCENTRATION: _____

STARTING AMOUNT: _____ STARTING DATE: _____

| DATE | AMOUNT USED | AMOUNT LEFT | ANIMAL ID | USER INITIALS |
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**Revision History:**

1. Assistant Provost for Research & Scholarship:

Signed: Jonathan Lowery Date: 9/16/2022

Provost:

Signed: Alan J Sylvan Date: 9/20/2022