DEPAUL UNIVERSITY

Controlled Substances Program

Environmental Health & Safety

January 2023

TABLE OF CONTENTS

1. INTRODUCTION

1.1 PURPOSE

This program outlines the requirements and responsibilities for the possession and use of controlled substances for authorized research or instructional activities at DePaul University. The University must comply with Federal and State laws and regulations regarding the use, storage and disposal of controlled substances, including relevant US Drug Enforcement Administration (DEA) regulations at 21 CFR Parts 1300-1321 and the Illinois Department of Financial and Professional Regulation (IDFPR) regulations at Ill. Admin. Code Title 77 § 3100.

Controlled substances are divided into five schedules (Schedules I-V) based on their usefulness in medicine as a drug, their relative abuse potential and likelihood of causing dependence when abused. A complete list of the schedules is published annually in **21 CFR 1308.11-1308.15**. Examples of substances in each schedule are included below.

Schedule I Controlled Substances

Schedule I substances have no currently accepted medical use, a lack of accepted safety for use under medical supervision and a high potential for abuse.

Examples: heroin, lysergic acid diethylamide (LSD), marijuana (cannabis), peyote, methaqualone, and 3,4-methylenedioxymethamphetamine ("Ecstasy").

Schedule II/IIN Controlled Substances (2/2N)

Schedule II/IIN substances have a high potential for abuse which may lead to severe psychological or physical dependence.

Examples of Schedule II narcotics: hydromorphone (Dilaudid®), methadone (Dolophine®), meperidine (Demerol®), oxycodone (OxyContin®, Percocet®), and fentanyl (Sublimaze®, Duragesic®), morphine, opium, codeine, and hydrocodone.

Examples of Schedule IIN stimulants: amphetamine (Dexedrine®, Adderall®), methamphetamine (Desoxyn®), and methylphenidate (Ritalin®).

Other Schedule II substances: amobarbital, glutethimide, and pentobarbital.

Schedule III/IIIN Controlled Substances (3/3N)

Schedule III/IIIN substances have less potential for abuse than Schedule I and II substances and abuse may lead to moderate or low physical dependence or high psychological dependence.

Examples of Schedule III narcotics: products containing not more than 90 milligrams of codeine per dosage unit (Tylenol with Codeine®), and buprenorphine (Suboxone®).

Examples of Schedule IIIN non-narcotics: benzphetamine (Didrex®), phendimetrazine, ketamine, and anabolic steroids such as Depo®-Testosterone.

Schedule IV Controlled Substances

Schedule IV substances have a low potential for abuse relative to substances in Schedule III.

Examples: alprazolam (Xanax®), carisoprodol (Soma®), clonazepam (Klonopin®), clorazepate (Tranxene®), diazepam (Valium®), lorazepam (Ativan®), midazolam (Versed®), temazepam (Restoril®), and triazolam (Halcion®).

Schedule V Controlled Substances

Schedule V substances have a low potential for abuse relative to substances in Schedule IV and consist primarily of preparations containing limited quantities of certain narcotics.

Examples: cough preparations containing not more than 200 milligrams of codeine per 100 milliliters or per 100 grams (Robitussin AC®, Phenergan with Codeine®), and ezogabine.

1.2 SCOPE AND APPLICATION

Individuals who manufacture, distribute, dispense, import, export, conduct research or instructional activities with a controlled substance are subject to DEA and IDFPR regulations. Possession and use of controlled substances at DePaul is restricted to registrants and authorized individuals working under the direct supervision of registrants in accordance with their registration and in compliance with all applicable Federal, State and University requirements. Failure to comply with this policy may be grounds for disciplinary action or research termination.

2. ROLES AND RESPONSIBILITIES

2.1 UNIVERSITY ADMINISTRATION

The University administration has overall responsibility for instituting policies and programs, establishing systems, and providing resources to help ensure that research or instructional activities involving controlled substances are in accordance with all applicable requirements. Certain responsibilities have been delegated as outlined below.

2.2 REGISTRANT

1. Maintain DEA registration and Illinois license for controlled substances.
2. Follow all applicable Federal, State and University requirements for authorization, acquisition, security, use, handling, storage, transfer or disposal, reporting and recordkeeping for controlled substances maintained by the laboratory.
3. Notify EHS if additional personnel need to work with controlled substances under the registrant's direction (i.e. become an authorized individual).
4. If needed, provide training for authorized individuals to use or access controlled substances on the requirements of this program and applicable regulations.
5. Conduct an annual inventory of controlled substances.
6. Notify the local DEA field office, Public Safety, EHS, the relevant department chair and Dean upon discovery or report of theft or loss of controlled substances.
7. Perform investigation of reported or suspected thefts of controlled substances, working with law enforcement, Public Safety and other University parties as appropriate.
8. Complete and submit DEA Form 106 if it is determined that theft or significant loss of a controlled substance has occurred.
9. Maintain all documentation required by this program.
10. Notify EHS when controlled substances are ready for disposal and coordinate with local DEA field office for assistance if necessary.

2.3 AUTHORIZED INDIVIDUAL

1. Participate in authorization process and training prior to working with controlled substances.
2. Comply with Federal, State, and University requirements for controlled substances.
3. Maintain strict control and inventory of controlled substances.
4. Complete all required forms and recordkeeping.

5. Immediately report missing controlled substances to the registrant/PI, Public Safety, EHS, the relevant department chair and Dean.

2.4 ENVIRONMENTAL HEALTH & SAFETY (EHS)

1. Maintain the written Controlled Substances Program.
2. Provide guidance to campus units for registering with Federal and State agencies.
3. Provide guidance on storage and assist in disposal of controlled substances.
4. Include awareness information on controlled substances during annual Lab Safety Training if necessary.
5. Work with registrants as needed to correct any identified deficiencies related to controlled substances management.

2.5 PUBLIC SAFETY

1. Respond to reported thefts or missing controlled substances and coordinate with the registrant, law enforcement and EHS as applicable in the investigation.

3. REGISTRATION

Registration with both the State of Illinois and DEA is required to possess and use controlled substances for University research or instructional activities. Only the schedules of controlled substances identified on the registration may be used for the designated purposes listed. The registration certificate must be kept at the registered location and readily available at all times.

Prior to applying for a new controlled substances registration, employees must notify EHS and ensure that any other applicable project approvals are obtained from the appropriate University committee (e.g., IACUC).

3.1 APPLICATION

An Illinois Controlled Substance License must be obtained first in order to apply for a Federal DEA number. This can be done by registering with the IDFPR using the 097 Other Controlled Substances License Application.

New employees who already hold a Federal DEA number and a permanent license from another state must also apply for an Illinois Controlled Substance License in order to use their Federal DEA number in Illinois.

Once an Illinois Controlled Substance license is obtained, a DEA registration application must be submitted online: https://www.deadiversion.usdoj.gov/drugreg/index.html

Relevant types of DEA registration include:

- **Research:** DEA Form 225 is used for conducting research on narcotic and non-narcotic controlled substances in Schedules II-IV.
- **Laboratory Chemical Analysis:** DEA Form 225 provides authorization to conduct analysis with controlled substances listed in any schedule.
- **Dispenser of Controlled Substances (for Clinical Research):** DEA Form 224 is used by private practitioners (physicians, dentists, veterinarians, nurse practitioners, hospitals, and pharmacies) for clinical and hospital use.
- **Instructional Activity:** DEA Form 224 is used for instructional activity only, and covers controlled substances in Schedules II-V.

3.2 RENEWAL

The registrant is responsible for maintaining a current DEA registration and Illinois license by renewing as necessary (i.e., typically every 3 years for DEA and annually for Illinois).

3.3 TERMINATION

To terminate a registration/license, the registrant must notify the IDFPR and the local DEA field office in writing. They must also notify EHS.

4. AUTHORIZED INDIVIDUALS

If granted in the registration, registrants may authorize additional personnel to use the controlled substance(s) for approved activities. Authorization involves completion of a questionnaire and background screening. Registrants must initiate this process by contacting EHS well in advance of when they would like additional personnel to begin work with controlled substances.

No person who has been convicted of a felony offense related to controlled substances or had a DEA registration denied, revoked or surrendered for cause will be allowed to become an authorized individual.

4.1 TRAINING

Authorized individuals working under the direction of a registrant must receive information and training on the requirements applicable to their role. The registrant will coordinate this training. Training records must be forwarded to EHS.

4.2 AUTHORIZATION STATUS

Each registrant must maintain a list of their authorized individuals. EHS maintains a centralized list of registrants and their authorized individuals.

An authorized individual must be in good standing as far as required training and compliance in order to maintain their authorization status. In the event of repeated violations and failure to cooperate in addressing compliance deficiencies, individuals may lose their authorization status.

5. PURCHASE AND RECEIPT

5.1 PURCHASE

Controlled substances must be purchased under a DEA number. Schedules III-V can be purchased through standard procurement channels. Schedules I and II require the submission of DEA Form 222.

5.2 RECEIPT

Controlled substances are shipped to the registrant and address as indicated on the DEA registration. Once received, controlled substances must be picked up by the registrant or an authorized individual and should be opened to verify the contents so any discrepancies can be rectified with the supplier. If discrepancies cannot be readily addressed, the local DEA field office should be contacted for assistance.

Registrants must keep receipts (invoices or packing slips) that include the date any controlled substances were received.

6. USE, STORAGE AND SECURITY REQUIREMENTS

6.1 LABELING

Containers of controlled substances must be labeled with the designated symbol for the schedule to which they belong. Identifying labels must not be removed from the original containers. If the substance is converted or diluted, the new container must be labeled properly.

The designated symbols for each schedule of controlled substance are as follows:

- **Schedule I:** CI or C-I
- **Schedule II/IIN:** CII or C-II
- **Schedule III/IIIN:** CIII or C-III
- **Schedule IV:** CIV or C-IV
- **Schedule V:** CV or C-V

6.2 STORAGE AND SECURITY

Registrants must ensure effective controls and procedures are in place to guard against theft and diversion of controlled substances. This includes the following:

- Access to controlled substances must be limited to registrants and their authorized individuals.
- Controlled substances must be stored in a securely locked, substantially constructed cabinet.
- Controlled substances must never be left unattended.
- Inventories should be kept to a minimum.
- Key locks or combinations should be changed whenever personnel change.

The adequacy of security controls is determined based on a number of factors including the type of activity conducted, the type, form and quantity of controlled substances handled, the location of the premises and the relationship such location bears on security needs and the availability of local police protection.

6.3 REPORTS OF THEFT OR SIGNIFICANT LOSS

The DEA requires **immediate notification** of any theft or significant loss of controlled substances upon its discovery. When determining whether a loss is significant, a registrant should consider at least the following factors:

1. The actual quantity of controlled substances lost in relation to the type of business
2. The specific controlled substances lost
3. Whether the loss of the controlled substances can be associated with access to those controlled substances by specific individuals, or whether the loss can be attributed to unique activities that may take place involving the controlled substances
4. A pattern of losses over a specific time period, whether the losses appear to be random, and the results of efforts taken to resolve the losses; and, if known,
5. Whether the specific controlled substances are likely candidates for diversion
6. Local trends and other indicators of the diversion potential of the missing controlled substance

If circumstances surrounding the theft/loss are clear (e.g., quantities involved, etc.), the registrant must immediately complete DEA Form 106 and send a copy to IDFPR within 1 business day.

When the circumstances surrounding the theft/loss are unknown at the time of discovery, the DEA recommends providing initial written notice via a short statement to the local DEA field office. The registrant must then make efforts to determine the facts involved by conducting inventories, internal audits and/or investigations using internal or law enforcement resources as appropriate. DEA Form 106 should be submitted as soon as the circumstances are determined. The DEA Form 106 must document the circumstances of the theft or significant loss and the quantities of controlled substances involved. If an investigation takes more than two months, the registrant should provide updates to the DEA.

If it is later determined that there was no theft or significant loss, the registrant should inform the DEA that no DEA Form 106 will be filed.

6.4 BREAKAGE OR SPILLAGE

It is the DEA's position that witnessed breakage or spillage of controlled substances does not constitute a loss of controlled substances because the registrant can account for the controlled substances. These incidences do not require DEA notification.

If the controlled substances are recoverable, they should be disposed of and DEA Form 41 submitted if required (if a DEA approved on-site method of destruction is used) with signatures from two individuals who witnessed the breakage, spillage or damage along with an account of what they witnessed.

If the breakage or spillage is clearly observed but the controlled substances are not recoverable, the registrant must document the specific circumstances of the breakage/spillage in their inventory records. Two individuals who witnessed the breakage must sign the inventory records, indicating what they witnessed.

7. DISPOSAL

When a registrant wishes to dispose of controlled substances, they must be destroyed in compliance with all applicable laws and regulations and rendered non-retrievable. Registrants must notify EHS of their intent to dispose of a controlled substance and EHS will assist with coordinating the disposal.

Registrants may dispose of controlled substances using an on-site method of destruction that has been explicitly approved by the local DEA field office or through a DEA registered reverse distributor.

When Schedule I or II controlled substances are transferred to a reverse distributor, the reverse distributor must issue DEA Form 222 or the electronic equivalent to the registrant.

When Schedules III-V controlled substances are transferred to a reverse distributor, the registrant must maintain a record of distribution that lists the drug name, dosage form, drug strength, quantity, and date transferred. Reverse distributors are responsible for submitting a DEA Form 41 when the controlled substances have been destroyed.

7.1 ABANDONED CONTROLLED SUBSTANCES

Under no circumstances are controlled substances to be abandoned by a registrant. In the event that an employee leaves the University without appropriately transferring or disposing of all controlled substances from their possession, EHS must be contacted as soon as possible to arrange for appropriate disposal.

8. RECORDKEEPING

Registrants must maintain complete and accurate records. All records concerning controlled substances must be maintained for at least 2 years and must be readily available for inspection by the DEA, IDFPR, EHS or other University auditors.

Inventories and records of controlled substances listed in Schedules I and II must be maintained separately from all other registrant records. For Schedules III, IV, and V, these records can similarly be maintained separately, or in such a form that they are readily retrievable from all other registrant records.

Required records include:

- Executed official order forms (DEA Form 222) or the electronic equivalent
- Unexecuted official order forms (DEA Form 222)
- Power of Attorney authorization to sign order forms, if applicable
- Receipts and/or invoices for schedules III, IV, and V controlled substances
- Records of controlled substances distributed (i.e., sales to other registrants, returns to vendors, distributions to reverse distributors)
- Records of dispensing (dispensing log)
- All inventory records of controlled substances, including the initial and annual inventories, dated as of beginning or close of business
- Reports of Theft or Significant Loss (DEA Form 106), if applicable
- Inventory of Drugs Surrendered for Disposal (DEA Form 41), if applicable
- Training records for authorized individuals

8.1 ANNUAL INVENTORY

Illinois requires every licensee to conduct an annual inventory that includes an inventory with an actual count of the inventory on hand for all Schedule II controlled substances and approximate inventory for all Schedule III, IV and V controlled substances. These inventories must be maintained for a minimum of 5 years.

APPENDIX A: PROGRAM HISTORY

Date	Revision Number	Brief Description of Changes	Review Completed by
May 2015	1	Web/contact info	J. Graham
September 2016	2	Update links	J. Graham
January 2023	3	Restructured program	K. Abma