

## **CONTROLLED SUBSTANCE POLICY**

### **1.0 INTRODUCTION**

A controlled substance is a drug or chemical whose manufacture, possession, or use is regulated by a government, such as illicitly used drugs or prescription medications that are designated as a Controlled Drug under the Controlled Substances Act (CSA). An updated and complete list of the schedules is published annually in 21 Code of Federal Regulations (CFR) 1308. The federal regulations for controlled substances are 21 CFR 1300 – 1321 (<http://www.deadiversion.usdoj.gov/21cfr/cfr/2108cfrt.htm>). In addition, Massachusetts has its own CSA, which is implemented by 105 Code of Massachusetts Regulation (CMR) 700.000 (<http://www.mass.gov/eohhs/gov/laws-regs/dph/regs-cmr/public-health-regulations-105-cmr-700-799.html>).

In the United States (U.S.), the Drug Enforcement Administration (DEA) is responsible for suppressing illegal drug use and distribution by enforcing the U.S. CSA. In Massachusetts, the Massachusetts Department of Public Health (MADPH) enforces the MA CSA.

Controlled substances are used in laboratories and in Health Services at Simmons University (Simmons), which consists of two campuses:

|                             |                             |
|-----------------------------|-----------------------------|
| Academic Campus             | Residence Campus            |
| 300 The Fenway              | 54 Pilgrim Road             |
| Boston, Massachusetts 02115 | Boston, Massachusetts 02115 |

The laboratories are located on the Academic Campus and Health Services is located on the Residence Campus.

### **2.0 SCOPE AND PURPOSE**

To meet the regulatory and guideline requirements for controlled substances, Simmons' Director of Environmental Health and Safety (EH&S) has prepared this policy to assist Simmons' employees when investigating whether or not to use controlled substances and to provide guidelines and policies on how to ensure regulatory compliance when working with controlled substances within their departments.

### **3.0 SCHEDULES AND LISTED CHEMICALS**

Controlled substances under the U.S. CSA are divided into five schedules, which are followed by the MA CSA. Massachusetts also has a Schedule VI, which includes all prescription drugs, which are not included in any other schedule. Table 1 summarizes the description and provides examples of these controlled substances.

| <b>Table 1 – Schedules</b> |   |   |
|----------------------------|---|---|
| <b>Schedule</b>            | <b>Description</b>  | <b>Examples</b>   |
| I                          | Substances in this schedule have no currently accepted medical use in the United States, a lack of accepted safety for use under medical supervision, and a high potential for abuse.             | heroin, lysergic acid diethylamide (LSD), marijuana (cannabis), peyote, methaqualone, and 3,4-methylenedioxymethamphetamine ("Ecstasy")   |
| II                         | Substances in this schedule have a high potential for abuse which may lead to severe psychological or physical dependence.  | hydromorphone (Dilaudid®), methadone (Dolophine®), meperidine (Demerol®), oxycodone (OxyContin®, Percocet®), and fentanyl (Sublimaze®, Duragesic®), morphine, opium, codeine  |
| III                        | Substances in this schedule have a potential for abuse less than substances in Schedules I or II and abuse may lead to moderate or low physical dependence or high psychological dependence.      | products containing not more than 90 milligrams of codeine per dosage unit (Tylenol with Codeine®), and buprenorphine (Suboxone®), benzphetamine (Didrex®), phendimetrazine, ketamine, anabolic steroids such as Depo®-Testosterone |
| IV                         | Substances in this schedule have a low potential for abuse relative to substances in Schedule III.  | alprazolam (Xanax®), carisoprodol (Soma®), clonazepam (Klonopin®), clorazepate (Tranxene®), diazepam (Valium®), lorazepam (Ativan®), midazolam (Versed®), temazepam (Restoril®), and triazolam (Halcion®)                           |
| V                          | Substances in this schedule have a low potential for abuse relative to substances listed in Schedule IV and consist primarily of preparations containing limited quantities of certain narcotics. | cough preparations containing not more than 200 milligrams of codeine per 100 milliliters or per 100 grams (Robitussin AC®, Phenergan with Codeine®), ezogabine   |
| VI                         | Prescription drugs, which are not included in any other schedule  | isoflurane  |

The federal Chemical Diversion and Trafficking Act (CDTA) lists approximately 40 chemicals as part of a system of regulatory controls intended to address the diversion of chemicals important for illegal manufacture of controlled substances. The CDTA created two categories (called List 1 and List 2) which are precursor chemicals for making illicit drugs and substances. Under the federal regulations for DEA "Listed" chemicals, Distributors and Manufacturers (among others) of List 1 and 2 chemicals must obtain a specific license from the DEA. Laboratories that order these DEA Listed chemicals are NOT required to obtain the license; however, they may find that some of their chemical distributors may request additional information (e.g.: a "sign off" from a responsible official knowledgeable about the intended work with the precursor; a statement of why a precursor chemical has a legitimate research purpose; a signed Authorized Purchaser Form).

There is no strict or standard process for the distributors' due diligence so there are differing approaches used by precursor chemical distributors and manufacturers to satisfy themselves that they are not selling DEA Listed chemicals to clandestine drug labs or other improper actors. This additional

scrutiny rarely occurs in the course of ordering by Simmons' laboratories but, when it does, causes confusion with DEA Controlled Substance Requirements. There is no requirement for the laboratory to obtain a DEA Controlled Substance Registration to purchase, use or store DEA Listed Substances.

A list of the DEA Controlled Substances and Listed Substances is available at: <http://www.deadiversion.usdoj.gov/schedules/>.

## 4.0 RESPONSIBILITIES

In order to ensure compliance with Simmons' obligation under the controlled substances' regulations, registrations, and guidelines; it is important that affected faculty, laboratory staff, and department administrators understand their responsibilities associated with ordering, preparing, handling, using, and disposing of controlled substances.

This section also outlines the responsibilities for the Responsible Official, faculty, staff, adjuncts, department heads, and administrative departments, which assist departments with their controlled substances to ensure compliance with applicable regulations, registrations, and guidelines.

### 4.1 Responsible Official

The Responsible Official for Simmons is the Department Chair for Biology. This position oversees the program, orders controlled substances, and is responsible for the program.

### 4.2 Faculty, Staff, and Adjuncts

Faculty, staff, and adjuncts including Health Services will be responsible for:

- Contacting the Responsible Official about their intent to use controlled substances in their department prior to ordering the controlled substance.
- Managing the ordering, delivery, inventory, use, and disposal of controlled substances.
- Ensuring that controlled substances are registered with DEA and/or MADPH, as applicable.
- Maintaining and using controlled substances in accordance with their applicable registration(s), and this policy.
- Restricting access to the controlled substances only to users that are authorized to use controlled substances.
- Ensuring usage logs, purchase orders, and inventories are properly kept.
- Contacting the Director of EH&S to inform her that you need to dispose of controlled substances.
- Notifying Public Safety about unauthorized or suspicious persons; loss or compromise of keys, passwords, or combinations; loss or theft of controlled substances; and alteration of inventory records.

In the event that the faculty, staff, or adjuncts are on leave or are otherwise absent, they may designate another appropriate person within their department to assume these responsibilities.

### 4.2 Authorized Employees

Authorized employees are employees who are authorized to work with controlled substances or be in the area where controlled substances are in use. They will be responsible to adhering to the

requirements outlined in the applicable regulations, registrations, and this policy. At a minimum, authorized employees will:

- Review this policy.
- Report to Public Safety about unauthorized or suspicious persons; loss or compromise of keys, passwords, or combinations; loss or theft of controlled substances; and alteration of inventory records.

### **4.3 Department Heads**

Department Chairs, Directors, and/or Managers will assist employees in complying with the requirements provided in applicable regulation(s), the corresponding registration(s), and this policy.

### **4.4 Director of EH&S**

The Director of EH&S will:

- Conduct annual inspections of laboratories working with controlled substances.
- Provide inspection summary reports including corrective action recommendations to the applicable Department Chair, Director or Manager and the Director of Buildings and Grounds.
- Provide informational materials to assist Simmons' employees with their use of controlled substances.
- Assist with the disposal of controlled substances and providing options for proper disposal.
- Assist with notifications to regulatory agencies about reportable events.

### **4.6 Public Safety**

Public Safety will assess the laboratory in meeting the physical security requirements when working with controlled substances and assist the laboratory and Health Services in meeting these requirements. Examples of physical security include locked cabinets, safes, and locked doors. Public Safety will also assist in investigations.

In addition, they will help enforce this policy in laboratories and departments working with controlled substances and support investigations regarding theft or loss of controlled substances, and damaged or unknown packages.

### **4.7 Talent and Human Capital Strategy**

Talent and Human Capital Strategy, which is Simmons' Human Resource Department, will be responsible for conducting background checks on employees working with controlled substances or working in areas, where controlled substances are being stored and used at Simmons. Section 6.3 provides additional information regarding this background check.

## **5.0 REGISTRATIONS**

Registrations with the DEA and MADPH Drug Control Program is required if you are going to use a Controlled Substance, Schedules I – V. If working with Schedule VI, you are required to obtain a registration from the MADPH. The registration fee varies, and the license must be renewed annually. The approximate turnaround time for the registration process is between two and four weeks. Licenses are not granted automatically with the payment of the fee. In general, the applicant must be able to demonstrate a need for the controlled substance to conduct their business. Additionally, an applicant must demonstrate an internal control system that will account for usage control, secure access and

personnel training. Applicants' facilities are subject to inspection by DEA and/or MADPH. There are further requirements that must be fulfilled before licensure is permitted, and licenses can be suspended or revoked from a facility.

## 6.0 SECURITY REQUIREMENTS

This section provides the security requirements for Practitioners. Practitioners include physicians, dentists, veterinarians, researchers, hospitals, pharmacies, or other persons registered to do research, to dispense, or to use in teaching or chemical analysis a controlled substance in the course of professional practice. These requirements apply to Simmons.

Minimum security standards for practitioners are set forth in the regulations and are to be used in evaluating security. They may not necessarily be acceptable for providing effective controls and operating procedures to prevent diversion or theft of controlled substances.

Security controls for controlled substances will be evaluated by the Director of EH&S to determine if they meet the intent of the law and regulations to prevent theft or diversion.

### 6.1 Minimum Standards for Practitioners' Handling of Controlled Substances

Controlled substances must be stored in a securely locked cabinet of substantial construction.

Even though the regulations do not specifically define locked cabinet construction, the intent of the law is that controlled substances must be adequately safeguarded. Therefore, depending on other security measures, a wooden cabinet may or may not be considered adequate. In an area with a high crime rate, a strong metal cabinet or safe may be required. At Simmons, the controlled substances are stored in a double locked steel cabinet.

Some of the factors considered when evaluating a practitioner's controlled substances security include:

1. The number of employees, customers and/or patients who have access to the controlled substances.
2. The location of the registrant (high or low crime area).
3. The use of card access to restricted areas.
4. Periodic walk through by Public Safety.
5. Quantity of controlled substances to be kept on hand.
6. Prior history of theft or diversion.

Again, an overall evaluation of the security will be made by DEA and MADPH using the general and minimum security requirements as outlined in this policy to assure that the controlled substances are stored securely.

In order to minimize the opportunities for theft or diversion of controlled substances, we are required not only to provide effective physical security, but also to initiate additional procedures to reduce access by unauthorized persons as well as to provide alarm system where necessary.

To meet these security requirements, we have implemented the following:

- Card access to the floor.

- Limited access to cabinet, where the controlled substances are stored. Only authorized employees and the Department Chair, Director, or Manager will know the location of the keys to the controlled substances' cabinet(s).

### **6.3 Employees**

Employees, who will be working with controlled substances or working in an area where controlled substances are stored, are subject to a background check. This background check will include the following questions as required by DEA:

1. 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 charged (formally) with committing a criminal offence? Do not include any traffic violations, juvenile offences or military convictions, except by general court-martial. If the answer is yes, furnish details of conviction, offense location, date, and sentence.
2. 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.

DEA also recommends that an authorization, in writing, be completed by a person who is allowed to or is considered for work in a controlled substances area. This authorization should permit inquiries to be made of courts and law enforcement agencies concerning pending charges or convictions. Information on employees' criminal records should then be used as follows:

1. Locally by name, date and place of birth, and other identifying information, inquire at local courts and law enforcement agencies for records of pending charges and convictions; and
2. Nationally by the same identifying information make and inquiry at the appropriate DEA Field Office.

A necessary part of an overall employee security program is the reporting of employee drug theft or diversion in the workplace. Drug diversion, broadly defined, is when the legal supply chain of prescription analgesic drugs is broken, and drugs are transferred from a licit to an illicit channel of distribution or use. Employees who have knowledge of drug theft or diversion have an obligation to report such information to Public Safety. Public Safety, the Director of EH&S and/or University Counsel will report the drug theft or diversion to the DEA and MADPH.

Information obtained about employees will be kept as confidential and to take all reasonable steps to protect the confidentiality of the information and the identity of employees furnishing information. Failure to report drug theft or diversion information should be a critical factor in determining an employee's continued employment in a drug security area.

Employees who possess, sell, use or divert controlled substances not only subject themselves to state or Federal prosecution for any illicit activity, but should also become the subject of independent action regarding their continued employment.

### **6.4 Unauthorized Person**

Any unauthorized person, who gains access to controlled substances for the purpose of diversion or theft, may be reported to the Public Safety and may be subject to the disciplinary policies of Simmons.

### 6.5 Loss or Theft

Faculty, staff, and/or adjuncts will notify Public Safety and the Director of EH&S upon discovery if (s)he discovers that a controlled substance is missing. The Public Safety, the Director of EH&S and/or University Counsel will notify the nearest DEA Field Office of the theft or significant loss of any controlled substance upon discovery of such loss or theft. The Director of EH&S will promptly complete and submit DEA Form 106 regarding the theft or loss.

### 6.6 Blank prescriptions and DEA Order Forms

A practitioner should develop the practice of keeping blank prescription forms in locations which would preclude patients or casual visitors from stealing the forms for the purpose of falsification. Unused DEA Order Forms should also be kept in a secure location for the same reason.

## 7.0 PURCHASING

Before a controlled substance is purchased by an employee at Simmons, the person must provide the following information to the Responsible Official for approval. By providing this information, it will ensure that the proper security measures, registration, and license are in place for the controlled substances.

License Holder's Name:

Department:

Phone:

Email Address:

Substance Name:

Is it Generic? USP Grade?

DEA Schedule:

Is it a prescription drug?

Quantity            Number of Vials:            Amount per Vial:

Storage Location            Building:            Room:            Security Measures:

If you are purchasing a Schedule I or II Controlled Substance, then you are required to complete a DEA 222 Form, which is found on the following webpage:

<http://www.deadiversion.usdoj.gov/faq/dea222.htm>.

## 8.0 RECEIVING CONTROLLED SUBSTANCES

Once the license holder receives the controlled substance, it will be placed into the designated, secured location and the initial amount will be logged in the inventory log book.

The stocks of controlled substances should be kept to the smallest quantity needed for efficient operation to conduct the indicated experiment. It is strongly suggested that diluted mixtures be made in a timely manner, so that little, if any, non-diluted Schedule I-V controlled substances are maintained in the laboratory environment.

## 9.0 Training

The Department Chairs, Directors, and/or Managers must ensure that laboratory members and employees working with controlled substances are trained so they:

- Understand the regulatory requirements.
- Follow this policy.
- Ensure controlled substances are accounted for and not lost.
- Understand the reporting requirements for controlled substances.

Inexperienced staff requires direct oversight until they are able to demonstrate that they know the proper techniques to perform the activities associated with controlled substances.

The training will be conducted by the Director of EH&S or designee. Controlled substances' training must be document using a training form or an online program.

### 10.0 DISPOSAL

Controlled substances consumed in a reaction or converted into a hazardous waste mixture from which a Controlled Substance is not recoverable may be disposed of through routine waste disposal procedures from EH&S.

Animal carcasses that were injected with controlled substances must be disposed of through Simmons' Institutional Animal Care and Use Committee.

When controlled substances expire, authorized employees should request waste assistance from EH&S. Sometimes, at the conclusion of an experiment, a small amount of a controlled substance will remain in the vial or syringe. In this circumstance, in addition to requesting waste pick-up for those small remaining amounts, researchers may dispose of the substances by transferring the controlled substance to absorbent lab wipes and then arranging for disposal through EH&S. In any event, no materials should be disposed of through laboratory drains without the prior approval by EH&S. The authorized individual must remain in possession (secured) of expired or unwanted controlled substances, including diluted forms, until they have been properly destroyed.

### 11.0 RECORDKEEPING

Laboratories and Health Services are required to keep track of each Controlled Substance using log book or equivalent. A usage log book or sheets shall be numbered, bound, and, if the size of the cabinet permits, maintained at all times in the locked safe or cabinet along with the Controlled Substances. Usage Log sheets must be maintained for a minimum of three years after the complete use and disposal of Schedule I-V controlled substances and be readily available for inspection by the DEA, MADPH, or EH&S. Laboratories are not required to maintain usage logs for Schedule VI Controlled Substances.

All laboratories that work with Schedule I-V Controlled Substances and Health Services are to conduct self inspections on a quarterly basis to ensure that the laboratory's usage logs match the physical inventory. The results of those self-inspections shall be recorded in the usage log and shall be maintained by the license holder for a minimum of three years.

On a biennial institutional cycle starting in 2016, all laboratories licensed to work with controlled substances will be directed by the Director of EH&S in January to report their current inventory of controlled substances in order to comply with the federal requirement to conduct biennial inventories. For such biennial requirements, laboratories and Health Services may document the inventory checks in the usage log book or equivalent. License holders will sign this book in addition to the authorized



individuals who conducted the inventory. All records generated in connection with the controlled substances program should be maintained by the license holder for at least three years following termination of any license.

## 12.0 REFERENCES

The following documents were used and reviewed during the development of this SOP:

- Harvard University's EH&S Controlled Substance Webpage (<https://www.ehs.harvard.edu/programs/controlled-substances>)
- 21 CFR 1300 – 1321 (<http://www.deadiversion.usdoj.gov/21cfr/cfr/2108cfrt.htm>)
- 105 CMR 700.000 (<http://www.mass.gov/eohhs/gov/laws-regs/dph/regs-cmr/public-health-regulations-105-cmr-700-799.html>)