

# CONTROLLED SUBSTANCES MANUAL

## Table of Contents

<b>I.</b>	<b>Introduction</b> .....	1
	A. University Policy.....	1
	B. Vice President of Research.....	1
	C. Director of Environmental Health and Safety.....	1
	D. Principal Investigators (PI).....	2
	E. Director of Campus Security.....	2
	F. Director of Compliance.....	2
<b>II.</b>	<b>Acquisition</b> .....	3
	A. Procedures.....	3
	B. DEA Form 222.....	3
<b>III.</b>	<b>Custody</b> .....	4
	A. Requirements.....	4
	B. Custody and Custodian.....	4
	C. Safeguarding Duties.....	5
	D. Custody Records.....	5
<b>IV.</b>	<b>Storage Requirements</b> .....	6
	A. Requirements.....	6
	B. Cabinet Specifications.....	6
	C. Access.....	6
<b>V.</b>	<b>Disposal</b> .....	6
<b>VI.</b>	<b>Loss and Incidents of Diversion</b> .....	7
<b>VII.</b>	<b>Oversight</b> .....	7
<b>VIII.</b>	<b>Inventories</b> .....	8

# CONTROLLED SUBSTANCES MANUAL

## I. INTRODUCTION

A. University Policy. The University is committed to ensuring that its activities involving schedule II-V controlled substances are in compliance with applicable federal and state regulations and that the controlled substances are safeguarded to deter theft and diversion and to reduce accessibility to potential abusers. All University employees shall comply with the applicable law and this manual.

B. Vice President of Research. The Vice President of Research is the University official responsible for activities relating to clinical and basic science research, including research involving controlled substances. The Vice President of Research will ensure there are sufficient resources to comply with the requirements associated with safeguarding controlled substances.

C. Director of Environmental Health and Safety. The Director of Environmental Health and Safety is responsible for the day-to-day compliance with this manual and applicable government regulations. Specific responsibilities include:

1. Ensure timely compliance with government registration requirements.

- a. U.S. Drug Enforcement Administration (DEA) Registration.

- (1) Ensure timely application is made for renewal of registration (DEA Form 225a) with the federal government to conduct research with schedule II, III, IV, and V controlled substances between 45 and 60 days prior to expiration of current registration (note that, if application for renewal was filed and accepted at least 45 days before expiration date and the DEA has not denied the application, then the existing registration will continue to be in effect until the date the DEA takes action).

- (2) Maintain the Certificate of Registration (DEA Form 223).

- (3) When applicable, apply to modify existing federal registration to authorize the handling of additional controlled substances or change the name or address of the University by submitting a letter of request to the DEA Registration Unit and, once issued by the DEA, maintain the modified DEA Form 223 along with the existing DEA Form 223 until expiration.

- (4) Further information: [www.usdoj.gov/dea/](http://www.usdoj.gov/dea/)

- b. Illinois Department of Professional Regulation (IL DPR) Registration.

- (1) Ensure timely compliance with Illinois registration requirements with the Department of Professional Regulation.

- (2) Further information: [www.ildpr.com](http://www.ildpr.com)

## CONTROLLED SUBSTANCES MANUAL

2. Designate custodians, when qualified, and maintain list of custodians.
3. Maintain documents relating to controlled substances for at least five years.
4. Conduct inventories of controlled substances at least every two years.
5. Perform routine audits and monitoring measures.
6. Make an immediate verbal report of significant events to the Director of Compliance, such as any diversion or loss of controlled substances, any diversion or loss of blank DEA Forms 222, and any intentional or repeated negligent acts of failing to safeguard controlled substances or comply with this manual.
7. Ensure all persons with access to controlled substances read and acknowledge their obligations contained in this manual.
8. Forms and Templates. Develop and require the use of forms, templates, checklists, and other tools to enhance compliant activity.

D. Principal Investigators (PI). The PI is the individual responsible and accountable for the appropriate design, conduct, and monitoring of a research protocol. For protocols involving the controlled substances, the PI must acquire the designation of custodian and ensure that all activities involving controlled substances are in accordance with applicable law and this manual. The requirement for DEA and Illinois registration is waived for an individual practitioner (including scientific researcher) who is an agent or employee of the University so long as the University has a current and valid registration.

E. Director of Campus Security. Specific responsibilities of the Director of Campus Security regarding controlled substances include:

1. Coordinate activities with the Director of Environmental Health and Safety in the efforts to deter and detect instances of theft and diversion.
2. Establish and maintain liaison with local and federal law enforcement entities and seek periodic briefs on issues relating to controlled substances.

F. Director of Compliance. The Director of Compliance will make external reports to the DEA relating to significant loss, diversion, or theft of any controlled substance and loss, diversion, or theft of DEA Forms 222.

# CONTROLLED SUBSTANCES MANUAL

## II. ACQUISITION

### A. Procedures.

1. A PI seeking to acquire a schedule II-V controlled substance will submit a request to Director of Environmental Health and Safety per guidelines established by that Director.

2. The Director of Environmental Health and Safety will perform a review, to include ensuring the PI is designated as a custodian and ensuring all necessary documents have been prepared (such as a purchase order, a copy of DEA Form 223 certificate of registration, and, if a schedule II substance, a DEA Form 222). After review and approval, the Director of Environmental Health and Safety may sign the DEA Form 222 (when applicable and only if authorized by a power of attorney or as the person signing the application for DEA registration) and forward the documents to the Director of Purchasing.

3. The Director of Purchasing has authority to execute the acquisition of a controlled substance when the documentation is complete and accurate.

4. The Receiving or Mail Room Sections shall notify the PI upon receipt of a package and shall not open any package containing controlled substances.

5. Upon acquiring custody, the PI must make a notation of the number received and date received along with the PI's initials (and if a partial shipment, so note) and forward the documentation to the Director of Environmental Health and Safety. For schedule II controlled substances, this notation must be on Copy 3 of the DEA Form 222. For all other controlled substances, this notation must be on another document (such as the purchase order or acquisition correspondence). The PI will then generate a Custody Record.

### B. DEA Form 222.

1. DEA Form 222 will be utilized for each instance of acquiring a schedule II controlled substance from a source other than one acting under authority of the University's registration.

2. Blank DEA Forms 222 may be obtained by contacting the DEA Division Office (312-353-7889 or 312-353 8227) or submitting DEA Form 222a.

3. The Director of Environmental Health and Safety maintains custody of blank DEA Forms 222 and will ensure each form is logged in upon receipt, stored in a securely locked and substantially constructed cabinet, and logged out upon use.

4. Copy 3 of each DEA Form 222 that was used (including those voided or cancelled) will be maintained by the Director of Environmental Health and Safety for at least five years.

5. All incidents of diversion or loss of blank DEA Forms 222 will be reported to the Director of Compliance immediately upon discovery of the loss or diversion.

# CONTROLLED SUBSTANCES MANUAL

## III. CUSTODY

### A. Requirements.

1. All controlled substances acquired by the University must be in the custody of a custodian at all times.

2. Once custody of a controlled substance is acquired, that custodian is responsible for all safeguarding duties for that controlled substance until custody is accepted and documented by another custodian.

3. Safeguarding duties of the custodian include ensuring the controlled substances are handled only by persons with authorized access and in accordance with authorized activities, ensuring the controlled substances are properly stored, and ensuring the necessary reports and records are generated and processed as appropriate.

### B. Custody and Custodian.

1. Custody. Custody means the exercise of authority, charge, and control over the controlled substance.

a. Custody is acquired by a custodian when it is accepted in writing.

b. To maintain custody, the custodian must either:

(1) have physical possession of the controlled substance;

(2) when in the possession of another, ensure the controlled substance is handled in accordance with the written protocol and only by persons authorized in writing; or

(3) have properly stored the controlled substance.

2. Custodians. Custodians are designated in writing by the Director of Environmental Health and Safety when that person meets all of the following criteria:

a. is qualified to be a Principal Investigator in a research protocol;

b. has not been convicted of a felony relating to controlled substances;

c. has not had an application for DEA or state registration denied; has not had a DEA or state registration suspended or revoked; has not surrendered a DEA or state registration for cause; and

d. has disclosed information to the Director of Environmental Health and Safety, as required by the DEA and IL DPR.

## CONTROLLED SUBSTANCES MANUAL

C. Safeguarding Duties. The custodian is responsible for safeguarding duties for all controlled substances over which the custodian has custody. Those duties include:

1. ensuring access to the controlled substance is limited to persons designating in writing by the custodian (persons with authorized access may only be a scientific researcher who has not been convicted of a felony relating to controlled substances, has not had an application for DEA or state registration denied, has not had a DEA or state registration suspended or revoked, and has not surrendered a DEA or state registration for cause);

2. ensuring handling is limited to authorized activities (authorized activities are those activities articulated in an approved research protocol and other lawful activities expressed in this manual or applicable government regulations);

3. ensuring controlled substances are securely stored;

4. ensuring all necessary reports and records are generated and forwarded to the Director of Environmental Health and Safety, including an immediate verbal report of all instances of theft, loss, or diversion.

D. Custody Record. Certain events shall be recorded in a custody record for each controlled substance as follows:

1. Events that Must be Documented.

- a. obtaining custody.
- b. administering or consuming pursuant to protocol.
- c. loss or incident of diversion.
- d. breakage or spillage.
- e. disposal.
- f. relinquishing custody.

2. Entries for Each Event.

- a. event description and
  - (1) if obtaining custody, the name of the source (if the source is external to the University, use acquisition procedures)
  - (2) if disposal, description of method of disposal (DEA permission is required)
  - (3) if relinquishing custody, the name of the recipient (the recipient may not be external to the University except by specific permission from DEA).
- b. date.
- c. exact amount of controlled substance affected by the event.
- d. name and initials of custodian.

## CONTROLLED SUBSTANCES MANUAL

### IV STORAGE REQUIREMENTS

A. Requirement. Schedule II-V controlled substance shall be stored in a securely locked and substantially constructed cabinet and the custodian must ensure the following criteria are met.

B. Cabinet Specifications. The cabinet must meet the following specifications:

1. all doors and points of access have a locking mechanism using a key or combination;
2. the structure is such that disassembly or other forced entry is clearly detectable; and
3. the size and weight are such that it is not easily transportable or concealable.

C. Access.

1. Entry into Cabinet. The custodian shall maintain a key or combination control system so that access is limited to the custodian and persons designated by the custodian with authorized access.

2. Area Surrounding Cabinet. The cabinet will be positioned in a location that prevents unsupervised access to that location or allows timely detection of unsupervised access. Examples include locating the cabinet in locked room and in an isolated area apart from routine traffic patterns.

### V. DISPOSAL

A. A custodian seeking to dispose of any controlled substance will coordinate with the Director of Environmental Health and Safety to obtain authority to dispose and instructions through the submission of DEA Form 41.

B. In the event it is anticipated that regular and recurring acts of disposal will be required, prior coordination with the DEA may result in authorization to dispose without the need to obtain approval for each instance.

## **CONTROLLED SUBSTANCES MANUAL**

### **VI. LOSS AND INCIDENTS OF DIVERSION**

A. All instances of loss (i.e. unaccounted absence) and incidents of diversion (i.e. use for other than authorized purposes) of controlled substances or blank DEA Forms 222 must be immediately reported to the Director of Environmental Health and Safety, Director of Compliance, and Director of Campus Security upon discovery. The PI will follow up with a written loss or incident of diversion report.

B. On behalf of the University, the Director of Compliance will immediately notify the Field Division Office of the DEA by telephone of the loss or incident of diversion upon discovery (312-353-7889 or 312-353-8227). In addition, DEA Form 106 will be used to formally document the circumstances after they have been investigated and determined.

C. The Director of Campus Security will make notification to the North Chicago Police Department of incidents of diversion or loss.

D. Internal investigative efforts will be made in coordination with law enforcement agencies so as to not obstruct legitimate law enforcement activities.

### **VII. OVERSIGHT**

A. The custodian is responsible for day-to-day compliance with this manual and applicable law and for the supervision and oversight of the handling and storage of all controlled substances with that custodian's custody.

B. The Director of Environmental Health and Safety will conduct routine auditing and monitoring measures to assess the compliance with this manual and applicable law. These measures will include evaluating the current security measures in place and whether further measures would be appropriate. The following factors should be considered in this evaluation:

1. The type of activity conducted involving the controlled substances;
2. The type, form, and quantity of controlled substances handled and stored;
3. The building and location within the building of the controlled substances;
4. The type of storage device or container used;
5. The adequacy of key control systems and/or combination lock control systems;
6. The adequacy of detection, monitoring, and alarm systems, if any;
7. The adequacy of supervision over persons with authorized access to the location where controlled substances are handled or stored;
8. The escort or other procedures for handling persons without authorized access, such as business guests, visitors, and maintenance personnel;
9. The availability of local police or University security personnel; and
10. The adequacy of and compliance with the record-keeping responsibilities.

# CONTROLLED SUBSTANCES MANUAL

## VIII. INVENTORIES

A. The Director of Environmental Health and Safety shall inventory or cause an inventory to be conducted for all controlled substances.

B. Inventories for schedule II substances must be performed, documented, and maintained separately from all other inventories. Inventories of schedule III, IV, and V substances may be combined. Inventories will be maintained for five years.

C. Each inventory shall be within two years from the previous inventory and record the following data:

1. date and time of inventory (must be either at opening of business or close of business).
2. name of the substance.
3. unit description and strength (e.g. 10-milligram tablet or 10-milligram concentration per fluid milliliter).
4. number of units per container (e.g. 100 tablet bottles or 3-milliliter vial).
5. exact count of unopened containers and remaining units in opened containers.
6. typed name, title, and signature of person conducting inventory.