Controlled Substances
Management Program

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1.0 INTRODUCTION

1.1 The purpose of this program is to outline the roles, responsibilities, and procedures required to comply with the New York State Department of Health (NYSDOH) Public Health Law Part 80 and the Federal Controlled Substances Act Title 21 Part 1300. Work with controlled substances in the state of New York requires both a New York State Department of Health (NYSDOH) license and a federal Drug Enforcement Administration (DEA) registration.

There are two types of NY state licenses used for research (individual researcher and institutional). At Cornell University, those that work with controlled substances typically hold an individual researcher license. There are a few existing institutional (departmental) licenses with the department chair serving as the licensee. Any new institutional license must be approved by EHS based on need. Institutional licenses have additional requirements that are described within this document.

2.0 SCOPE

2.1 This program applies to the Ithaca Campus, Geneva Campus, and Cornell University remote facilities where Controlled Substances are used and stored. This program does not cover Weill Medical College and its subsidiary locations.

3.0 ROLES AND RESPONSIBILITIES

3.1 Environmental Health and Safety (EHS)

3.1.1 Act as the liaison to NYSDOH and DEA regulators
3.1.2 Develop and oversee the implementation and maintenance of the Controlled Substances Management Program
3.1.3 Keep current with changing regulations and communicate regulatory and policy requirements associated with the program
3.1.4 Assist researchers with NYSDOH license and federal DEA registration application processes
3.1.5 Provide support and resources to researchers to facilitate compliance with Controlled Substances laws and regulations
3.1.6 Facilitate reverse distribution of controlled substances used for research and orphaned substance resolution
3.1.7 Review Institutional Animal Care and Use Committee (IACUC) protocols involving controlled substances
3.1.8 Partner with procurement to implement controls to prevent unauthorized purchases of controlled substances

3.1.9 Conduct inspections of research areas where controlled substances are used or stored focusing on compliance with recordkeeping, storage, security, and work practices

3.1.10 Provide training on usage of controlled substances in research

3.1.11 Maintain records of all DEA research registrations

3.1.12 Approve new Institutional license/registration requests before applications are submitted to the state and DEA

3.1.13 Provide guidance for DEA-listed precursor chemicals

3.1.14 Provide support for NYS Certificate of Need (CON) for hypodermic needles and syringes

3.2 Licensee/Registrant (Individual)

3.2.1 Comply with all state and federal controlled substances laws and regulations and University requirements

3.2.2 Complete CU Learn course 5198 Research Use of Controlled Substances

3.2.3 Approve and oversee users working under the license/registration

3.2.4 Follow procedures set forth in Section 4.0

3.2.5 Report theft, suspected theft, and loss of all controlled substances managed under license/registration as described in sections 4.8 and 4.9

3.3 Licensee/Registrant (Institutional)

3.3.1 This role is held by the Department Chair or Unit Head

3.3.2 Serve as Signatory, Chair of Oversight Committee, and supervisor of all controlled substances activity under the license and registration

3.3.2.1 Sign all DEA documents and Form 222 for purchase of Schedule I and II controlled substances

3.3.3 Comply with all state and federal controlled substances laws and regulations and University requirements

3.3.4 Approve and oversee users working under the license/registration

3.3.5 Complete CU Learn course 5198 Research Use of Controlled Substances

3.3.6 Follow all procedures set forth in section 4.0

3.3.7 Report theft, suspected theft, and loss of all controlled substances managed under license/registration as described in sections 4.8 and 4.9

3.4 Institutional License/Registration Oversight Committee

3.4.1 Required for all Institutional licenses/registrations, established by the Department or Unit, and chaired by the Department or Unit Head

3.4.2 Prepare written policies and procedures for the management of controlled substances to be used by the Department or Unit

3.4.3 Evaluate and approve protocols under the institutional license/registration
3.4.4 Designate a Material Manager to assist with the management of Controlled Substances documentation, storage, and security

3.5 Material Manager

3.5.1 Coordinate day to day activities involving the research use of controlled substances under the license/registration (either individual or institutional), including maintaining the inventory (reconciliation, forms, receipts, and documentation), dispensing main stock, and ordering (Schedules III-V only)

3.5.2 Comply with all state and federal controlled substances laws and regulations and University requirements

3.5.3 Complete CU Learn course 5198 Research Use of Controlled Substances

3.5.4 Does not have Signatory Authority for license/registration applications, renewals, amendments, DEA Form 222, or approval of users

3.5.5 Report any issues, loss, theft, or suspicious activity involving controlled substances to registrant immediately

3.6 Senior Authorized User

3.6.1 Conduct research with controlled substances under a registrant’s license/registration in compliance with all state and federal controlled substances laws and regulations and University requirements

3.6.2 Complete CU Learn course 5198 Research Use of Controlled Substances

3.6.3 Report any issues, loss, theft, or suspicious activity involving controlled substances to registrant immediately

3.7 Authorized User

3.7.1 Conduct supervised research with controlled substances under a registrant’s license/registration in compliance with all state and federal laws controlled substance and regulations and University requirements

3.7.2 Complete CU Learn course 5198 Research Use of Controlled Substances

3.7.3 Does not have access to controlled substance storage

3.7.4 Report any issues, loss, theft, or suspicious activity involving controlled substances to registrant immediately

3.8 Procurement and Payment Services

3.8.1 Support procedures and policies put in place by EHS

3.8.2 Manage the approval and annual verification process for suppliers of controlled substances

3.8.3 Work with approved vendors to implement the controls outlined in 4.4 to prevent unauthorized purchases of controlled substances, and follow up with vendors and/or campus purchasers if controls are circumvented

3.8.4 Maintain Buying Manual procedures for controlled substances purchases
3.9 Cornell University Police Department (CUPD)
3.9.1 Conduct investigations into the theft or suspected theft of controlled substances
3.9.2 File reports on the significant loss of controlled substance(s)
3.9.3 Assist EHS as a witness to and/or with the destruction of orphaned controlled substances where needed

4.0 PROCEDURES

4.1 State and Federal Application Process
4.1.1 Contact EHS prior to starting application process with NYSDOH and DEA
4.1.2 Principal Investigators who wish to engage in research with Controlled Substances must apply for a NYSDOH license prior to applying for a Federal DEA registration. Applicants may not apply for a DEA registration until the state has issued a NYSDOH license number
4.1.2.1 New institutional licenses must be approved by Environmental Health and Safety prior to submitting the application
4.1.3 New York State Bureau of Narcotic Enforcement (NYSBNE), and in some instances the DEA, will inspect a lab as part of the application process. Applicants are responsible for ensuring all security measures, storage, paperwork, and protocols (including IACUC protocols and standard operating procedures) are complete and/or installed prior to inspections by the state and DEA

4.2 Storage of Controlled Substances
4.2.1 The storage of controlled substances must comply with Title 21, CFR.1301.72:
4.2.1.1 Schedule I-II: Securely locked, substantially constructed, Government Services Administration (GSA) certified safe, that is anchored to a wall/floor or in excess of 750lbs
4.2.1.1.1 Stocks of Schedule I-II controlled substances will be returned to the GSA approved safe at the end of each use
4.2.1.2 Schedule III-V: Securely double locked, substantially constructed safe or steel cabinet
4.2.1.2.1 Stocks of schedules III-V controlled substances will be returned to the dedicated lock box or safe at the end of each use
4.2.1.3 Schedule I-V can be stored together as long as security measures meet Schedule I-II requirements

4.3 Security

4.3.1 Access to controlled substances must comply with Title 21, CFR.1301.76:

4.3.1.1 Access to controlled substances will be limited to those authorized by the registrant

4.3.1.2 Access is to be denied to any individual with known or confirmed substance abuse, revoked or denied controlled substance license/registration, or a conviction of a crime involving controlled substances

4.3.1.3 Limit access to keys and combinations to the licensee/registrant, Material Manager, and Senior Authorized Users under the registration

4.4 Procurement of Controlled Substances

4.4.1 Controlled substances are restricted commodities and can only be purchased by those authorized under an active license/registration.

4.4.1.1 The purchase of controlled substances requires the DEA registration information, including registrant name, address of the registered location, and registration number

4.4.1.2 Ship to address for controlled substances must match the address on the registration. Vendors will verify the address in the DEA database prior to processing the order

4.4.1.3 Vendors will notify registrant of all purchases made with registration number

4.4.2 All purchasing of controlled substances used in research must be done through a Purchase Order (PO)

4.4.2.1 Use of Purchasing Card (P-Card), cash, check, or money order to purchase controlled substances is prohibited

4.4.2.1.1 Exemptions for purchasing through vendors that require alternative forms of payment must be approved by procurement and EHS

4.4.3 Controlled substances can only be purchased through the following vendors authorized by Cornell University’s Procurement and Payment Services: Krackeler, MWI, Midwest Vet, Coventrus (Shein), and VWR

4.4.3.1 Exemptions for purchasing from non-approved vendors must be approved by procurement, EHS, and the registrant

4.4.4 Purchases of Schedule I and II controlled substances require the DEA Form 222 in addition to other registrant information
4.4.4.1 Schedule I and II purchases must be completed by the registrant through a Purchase Order via the department’s business service center.

4.5 Documentation

4.5.1 All required documentation must be retained for a timeline set forth by regulations of the NYSDOH and DEA.

4.5.2 Schedule I and II records must be stored separately from Schedule III-V records.

4.5.3 Forms can be found online through Cornell EHS’s website.

4.5.4 Documentation must be readily available and stored at the registration address. The forms include, but are not limited to:

4.5.4.1 Initial Inventory

4.5.4.1.1 Records controlled substances at a new storage location (including change of address) immediately upon receipt of DEA registration number.

4.5.4.2 Receipt Record Log

4.5.4.2.1 Receipt records for purchases of controlled substances from DEA registered vendors.

4.5.4.3 Biennial Log

4.5.4.3.1 Performed every 2 years (or less) after initial inventory listing of controlled substances currently stored at the DEA registered location.

4.5.4.4 Usage Log

4.5.4.4.1 Summarizes the usage of a controlled substance from the time of acquisition to the end of use.

4.5.4.5 Dilution Log

4.5.4.5.1 Documents the usage details for a controlled substance that has been withdrawn from the original container and mixed with a solution to dilute the concentration.

4.5.4.6 Disposal Log

4.5.4.6.1 Record showing when a controlled substance has expired, is no longer usable, or no longer needed and transferred to a reverse distributor for destruction.

4.5.4.7 Authorized Personnel Log

4.5.4.7.1 List of each person allowed to handle controlled substances for research.
4.6 Reverse Distribution

4.6.1 Expired, unwanted, or unusable controlled substances must be transferred to a reverse distributor for destruction under an active NYSDOH license and DEA registration

4.6.1.1 The cost of reverse distribution for controlled substances used in research will be covered by Environmental Health and Safety and Risk Management

4.6.1.1.1 The licensee/registrant can still dispose of controlled substances through a reverse distributor or mail back program in compliance with DEA and NYSDOH guidelines at their own expense

4.6.2 Clearly label the controlled substances for disposal with “to be disposed” or “expired” and segregate these substances from the remaining controlled substance inventory within the secured storage location

4.6.3 Contact EHS Hazardous Materials and Waste group to arrange for reverse distribution of controlled substances

4.7 Orphaned Substances

4.7.1 The licensee/registrant must properly dispose of all controlled substances in their possession before the license/registration expires. Possessing a controlled substance without an active NYSDOH license and DEA registration is a violation of state and federal laws and regulations. In the event that controlled substances remain without an active license/registration, immediately contact EHS for assistance in disposing of the illegal substance(s)

4.7.1.1 EHS is required to contact the DEA for permission to destroy or reverse distribute orphaned substances, and the DEA has the authority to pursue legal action and/or fines

4.7.2 The department is responsible for contacting the licensee/registrant if they are no longer associated with the department or the university. Controlled substances left by a licensee/registrant are still legally their responsibility

4.7.2.1 EHS is required to contact the DEA which has the authority to pursue legal action and/or fines on the previous licensee/registrant
4.7.2.1.1 If the department cannot contact the licensee/registrant, the department will research any previous documentation associated with the substance(s) and the department may be responsible for any costs associated with disposal.

4.8 Theft or Suspected Theft of Controlled Substances

4.8.1 The licensee/registrant is responsible for notifying the Cornell University Police Department (CUPD) and EHS upon discovery of theft or suspected theft of controlled substances. CUPD will conduct an investigation into the incident.

4.8.2 The licensee/registrant is responsible for immediate reporting and submission of paperwork pertaining to controlled substance theft or suspected theft to both NYSDOH and the DEA.

4.8.2.1 EHS will assist throughout the reporting and investigation process.

4.8.2.2 Both the NYSDOH and DEA have different timeframes for reporting, but usually fall within 24 hours depending on the incident type.

4.9 Significant Loss of Controlled Substances

4.9.1 The licensee/registrant is responsible for notifying the Cornell University Police Department (CUPD) and EHS regarding the significant loss of controlled substance(s). CUPD will file a police report pertaining to the incident.

4.9.2 The licensee/registrant is responsible for immediate reporting and submission of all paperwork pertaining to the significant loss of controlled substances to both NYSDOH and the DEA.

4.9.2.1 Both the NYSDOH and DEA have different timeframes for reporting, but usually fall within 24 hours depending on the incident type.

4.9.3 NYSDOH requires notification of significant loss through form DOH-2094.

4.9.4 DEA requires notification of significant loss through online form DEA-106.

4.9.4.1 Significant loss must also be recorded in inventory records with an explanation of the event, two witness signatures, and the amount lost.

4.9.5 Recoverable substances must be disposed of via a DEA approved reverse distributor.
4.10 Signatory under Institutional License/Registration
   4.10.1 Signatory cannot be delegated
   4.10.2 DEA requires Signatory be assigned by a Power of Attorney
       4.10.2.1 Contact University Counsel’s Office

4.11 Training
   4.11.1 Training through CU Learn, course 5198, Research Use of Controlled
          Substances, is required for anyone using controlled substances for
          research at Cornell University

5.0 DEFINITIONS

5.1 Authorized Personnel Log – list of each person allowed to handle Controlled
   Substances for research at a given location
5.2 Authorized User (AU) – at Cornell, a graduate student, staff member, or student
    authorized by the Registrant to work with Controlled Substances under
    supervision of Registrant or SAU
5.3 Biennial Log – list of all Controlled Substances currently stored at the DEA
    registered location and is performed every two years following the initial
    inventory
5.4 Controlled Substance – a drug or other substance, or immediate precursor,
    included in Schedule I, II, III, IV, or V of CSA, Title 21, Section 802, (6)
5.5 Dilution Log – documents the usage details for a Controlled Substance that has
    been withdrawn from an original container and mixed with another solution
5.6 Disposal Log – documents the proper disposal of a Controlled Substance when it
    has expired, is no longer usable, or is no longer needed
5.7 Drug Enforcement Administration (DEA) – federal law enforcement agency under
    the United States Department of Justice tasked with combating drug smuggling
    and distribution within the United States
5.8 Drug Schedule – class assigned by regulatory body based on substance’s accepted
    medical use, abuse potential, and dependency potential
5.9 Initial Inventory – records Controlled Substances at a new storage location
    (including change of address) immediately upon receipt of a DEA registration
    number
5.10 Governmental Services Administration (GSA) – independent agency of the United
    States government established in 1949 to help manage and support the basic
    functioning of federal agencies
5.11 New York State Bureau of Narcotic Enforcement (NYSBNE) – state agency
    responsible for protecting the public health by combating the illegal use and
    trafficking of prescription and non-prescription Controlled Substances
New York State Department of Health (NYSDOH) – state agency tasked with ensuring high quality health services are available to all New York residents, including Controlled Substances

Orphaned Substance – Controlled Substances without an active DEA registration that were purchased under an active DEA registration

Oversight Committee – under institutional license/registration, a committee established for approving, supervising, and evaluating protocols and authorized users that meets regularly or as needed with the Department Chair or Unit Head serving as chair

Receipt Record Log – records purchases of Controlled Substances from DEA Registered distributors

Registrant/Licensee (Individual) – Individual that holds both a NYSDOH license and corresponding DEA registration to work with Controlled Substances

Registration/License (Institutional) – Department or Unit that holds a NYSDOH Institutional license and a DEA registration to work with Controlled Substances with responsibilities similar to that of an Individual license/registration except protocols are approved by an oversight committee and the department chair/unit head serves as the licensee/registrant, signatory, and chair of the oversight committee

Reverse Distributor – a person or company who receives Controlled Substances acquired from another DEA registrant for the purpose of returning unwanted, unusable, or outdated Controlled Substances to the manufacturer or the manufacturer’s agent or, where necessary, processing such substances or arranging for processing such substances for disposal by destruction

Senior Authorized User (SAU) – at Cornell, a faculty member, staff member, or Post Doc authorized by the Registrant to handle and work with Controlled Substances in defined project(s)

Signatory – under institutional license/registration, the Department Chair or Unit Head granted Power of Attorney to sign DEA documentations and Form 222

Transportation Log – optional record used when transporting Controlled Substances outside of the registration address for same day travel

Usage Log – summarizes the usage of a Controlled Substance from the time of acquisition to the end of use
6.0 REFERENCES

6.1 Office of Diversion Control (Page)
   6.1.1 http://www.deadiversion.usdoj.gov/

6.2 Title 21 CFR, Part 1300-1399 (Regulation)

6.3 Title 21 United States Code (USC) Controlled Substances Act (Law)
   6.3.1 https://www.deadiversion.usdoj.gov/21cfr/21usc/

6.4 Form DEA Form 225 (Research and Analytical), DEA Form 224 (Teaching) initial applications and renewal
   6.4.1 Application (Initial) - https://apps.deadiversion.usdoj.gov/webforms/
   6.4.2 Application (Renewal) – https://apps.deadiversion.usdoj.gov/webforms/jsp/regapps/common/renewalAppLogin.jsp

6.5 Categories and Fees:
   6.5.1 https://www.deadiversion.usdoj.gov/drugreg/categories.htm

6.6 State Bureau of Narcotic Enforcement (Page)
   6.6.1 http://www.health.state.ny.us/professionals/narcotic/

6.7 State Part 80 Rules and Regulations on Controlled Substances (Regulation)

6.8 State Article 33. Controlled Substances (Law)

6.9 State License Program website:
   6.9.1 http://www.health.state.ny.us/professionals/narcotic/forms.htm

6.10 Form DOH-4330 (License and Amendments)
   6.10.1 http://www.health.state.ny.us/forms/doh-4330.pdf

6.11 Application Instructions
   6.11.1 http://www.health.state.ny.us/forms/instructions/doh-4330_instructions.pdf