POLICY FOR THE ACQUISITION, USE AND DISPOSAL OF CONTROLLED SUBSTANCES IN RESEARCH

A. Purpose

The acquisition, use and disposal of controlled substances in New York State are strictly regulated by the New York State Department of Health (NYS DOH) Bureau of Narcotic Enforcement (BNE) and the United States Department of Justice Drug Enforcement Administration (US DEA). These regulations are intended to prevent diversion of controlled substances. The purpose of this policy is to ensure that researchers planning work with controlled substances are aware of and understand their responsibility for complying with the relevant state and federal statutes and regulations governing the use of these substances.

B. Applicability/scope

This Policy applies to the use of controlled substances in research conducted under the auspices of the Icahn School of Medicine at Mount Sinai (the "School"), including all *in vivo* research under IACUC-approved protocols and *in vitro* research.

Any individual who uses controlled substances for research under the auspices of the School must be: (a) licensed with the NYS DOH, and registered with the US DEA (a "Licensed individual/registrant") to conduct such research; or (b) authorized under the license of a Licensed individual/registrant with respect to such research.

The School does not hold an "institutional license" for use of controlled substances in research. Even if an individual already has a practitioner's (clinical) license and DEA registration for treatment of patients with controlled substances, if he or she will also be conducting laboratory or non-therapeutic research involving controlled substances, a separate research license from NYS DOH is required. In addition, for research with Schedule I drugs, a separate registration with the DEA is required.

C. Definitions

Controlled Substance - a drug or other substance, or immediate precursor, listed in any of Schedules I - V of the federal Controlled Substances Act (21 U.S.C. §§ 801-971: http://www.deadiversion.usdoj.gov/21cfr/21usc/index.html) or the New York State Controlled Substances Act (Article 33 of the NYS Public Health Law: https://www.health.ny.gov/professionals/narcotic/laws_and_regulations/). Controlled substances are divided into five categories, called Schedules, according to their potential for abuse, whether the substance has a currently accepted medical use in treatment in the United States, and their potential for physical and psychological dependence. Classification of a controlled substance in a particular Schedule affects the licensing, recordkeeping and security and storage requirements that are applicable, with drugs in Schedules I and II subject to the most stringent regulations: https://www.deadiversion.usdoj.gov/schedules/orangebook/c_cs_alpha.pdf

Licensed individual/registrant – The person who applied for and was issued a license by the NYS DOH and US DEA and is ultimately responsible for controlled substance research compliance. Typically, the Licensed individual/registrant is the Principal Investigator of a research protocol. See section **E. Responsibilities.**

Supervisor of Controlled Substance Activity – an individual who undertakes responsibilities including ordering, receiving, inventory, recordkeeping, and dispensing on behalf of the registrant. The role is officially designated by the registrant on form DOH-4330. Supervisors generally have access to the entire inventory of stored controlled substances.

Other Authorized Individual – A member of the Licensed individual/registrant's staff authorized to work with controlled substances under the Licensed individual/registrant's license/registration. See section **E. Responsibilities.**

D. Procedures

RESEARCHER LICENSING AND REGISTRATION

Authorization for acquisition of controlled substances for research is a two-step process: **(1)** licensing with the NYS DOH; and **(2)** registration with the US DEA.

1. **NYS DOH licensing**
   a. Use of substances in Schedules II-V requires a Class 4 license. Use of substances in Schedule I requires a Class 7 license. Use of substances in both Schedule I and Schedule II-V requires both licenses. In addition to form DOH-4330 (b), the license application must include the following within Appendix A1-Individual Research Protocol (see Appendix for example):
      - The curriculum vitae of the individual responsible for overseeing the controlled substance activity (typically, the PI).
      - the nature and objective of the project(s),
      - a listing of controlled substances to be utilized
      - the quantity of the substances,
      - the DEA registration number of both the researcher ordering and the distributor or manufacturer providing the substances
      - The animal species, number of animals, dose regimen and route of administration of controlled substances must be included.
      - A copy of the IACUC-approved protocol(s) in which controlled substances are used
      - A copy of the approval letter(s) for IACUC protocols in which controlled substances are used.
      -
   b. **The DOH-4330 license application and instructions are available at:** Instructions and additional information about licensing requirements are available at https://www.health.ny.gov/forms/doh-4330.pdf **.** Abridged instructions and additional information about licensing requirements are available at https://www.health.ny.gov/forms/instructions/doh-4330_instructions.pdf.

- **For floor plans of your research floor to be included in your application, please contact CCMS/IACUC at** dea-bne@mtsinai.onmicrosoft.com or 4-3008.

c. Special requirements for new applicants:
   - New applicants should obtain the New York State license BEFORE submitting a registration to the Drug Enforcement Agency. On the New York State license application, new applicants should indicate that they are new applicants and do not yet have a DEA registration number.
   - New applicants will be subject to an on-site facility inspection by the Bureau of Narcotic Enforcement, which may review information concerning the operation of the laboratory and inspect for compliance with security and storage requirements for controlled substances. Applicants may prepare for this inspection by referring to the pre-inspection checklist. (See appendix F).
   -

d. NYS DOH licenses must be renewed every two years. It is the responsibility of the Licensed individual/registrant to ensure that this license does not lapse.

2. US DEA registration

a. The US DEA registration requires inclusion of the licensee's state license number and identification of the controlled substances used.
b. **The registration application, DEA Form 225**, is available online at https://www.deadiversion.usdoj.gov/drugreg/registration.html
c. Registration procedures, including detailed instructions on form submission, are available here: https://www.deadiversion.usdoj.gov/drugreg/registration.html. Persons who are already registered with the DEA as a medical practitioner are not required to obtain an additional DEA registration for research involving any drug in Schedules II-V.
d. Upon receipt of a registration application, the DEA may schedule a telephone interview or an on-site inspection.
e. New registrants must complete their initial inventory of controlled substances immediately upon receipt of their DEA registration, on the first day of business after registration. This initial inventory should show zero quantities of substances that you will be acquiring under your individual license
f. DEA registration must be renewed annually. It is the responsibility of the Licensed individual/registrant to ensure that this registration does not lapse.

3. **Requirement to amend research license for new projects and/or additional substances:** If a Licensed individual/registrant wishes to use additional controlled substances not listed on the Individual Research Protocol (Appendix A1/NYSDOH) submitted with his or her most recent license application or renewal, or begins a new research project involving controlled substances that is not within the scope of the Individual Research Protocol (Appendix A1/NYSDOH), then the Licensed individual/registrant must submit an amendment to the license to NYS DOH that includes the additional controlled substances for the new project, as applicable.

- Amendments are submitted using the NYS DOH's initial license application form, which includes a place to indicate "amendment."

- After notification of the NYS DOH, the Licensed individual/registrant must also submit an amendment to their DEA registration.

- To submit a modification, visit the DEA Diversion Control Division registration page and select 'Make Changes to my DEA Registration.' Complete any changes as necessary. (*Contact the DEA NY regional office at 212-274-4537 to reach an agent managing your registration).

PROCUREMENT OF CONTROLLED SUBSTANCES

1. Before purchase, it is recommended to call a supplier to confirm that their licenses are in good standing with the NYS DOH and the DEA.
   a. CCMS established vendors
      i. **Patterson Veterinary Supply**
      Patterson Logistics Services Inc.
      925 Carolina Pines Blvd
      STE B
      Blythewood, SC 29016-7926
      DEA# **RP0349224**

      ii. **MWI Animal Health**
      1499 Zeager Road, Suite #2
      Elizabethtown, PA 17022
      DEA# RM0310540

2. DEA Registrants (permit holders) must obtain DEA Form 222 before purchasing schedule I and II materials. A copy of the DEA registration must accompany the supplier's requisition.

3. The controlled substances must be shipped to the registrant and address as indicated on the DEA registration. Upon completing Form 222, a copy must be emailed to the DEA at the close of the month the order was filled [21 CFR 1305.13(d)].

a. Schedule III – V materials do not require the requisition of Form 222.

4. General Provisions:
   a. All purchases of controlled substances must follow a strict chain of custody from the vendor's approved courier directly to the DEA Registrant or Supervisor of Controlled Substance Activity.
   b. Packages must be unpacked, inspected, labeled, and logged immediately upon receipt.
   c. Controlled substances must be placed in the lockbox or safe after processing.
      - Packages must never be left unattended or unsecured.

STORAGE AND SECURITY

Controlled substances shall at all times be properly safeguarded and securely kept at the address on file

with the NYSDOH/Drug Enforcement Administration (DEA) and which corresponds with the information indicated in the ordering of the controlled substances. Adequate security and storage must be provided and access to such storage must be limited to Licensed individual, Supervisor and/or Other Authorized Individuals (See schedule III-V working stock storage recommendation below). Security requirements vary depending on: (1) whether the storage is for working stocks or reserve or main stocks; and (2) the schedule of controlled substance. In general, 2 storage containers are required, one for working stocks and another for main stocks.

1. Working Stocks –
    a. Schedule I-IV controlled substances shall be kept in stationery (attached securely to a wall and anchored in a stud), locked double cabinets. Both cabinets must have key-locked doors with separate keys. Spring locks or combination locks are not acceptable.

    b. Key control and safe access to working stock is limited to registrant and authorized users for no more than 72 hours. When controlled substances remain in the working stock storage for more than 72 hours, it is still working stock storage and is in violation of NYS BNE approved storage and increases potential for diversion.

    c. Keys to storage areas must be accessible only to those authorized individuals. The key that locks the cabinet where Controlled Substances are stored must be locked up or kept in some other secure manner to ensure non-authorized users do not have access to the controlled substances.

    d. Non-controlled substances are not to be stored in the same safe as controlled substances.

    e. Schedule V controlled substances shall be stored in a stationary, securely locked cabinet of substantial construction.

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Lakeside® Double Door, Double Lock Narcotic Cabinet with Shelf

Availability: Usually ships in 14 to 17 days
Item #: WGB250390

List Price: ~~$422.00~~ Save up to **40%**
Price: $253.95

Product Information

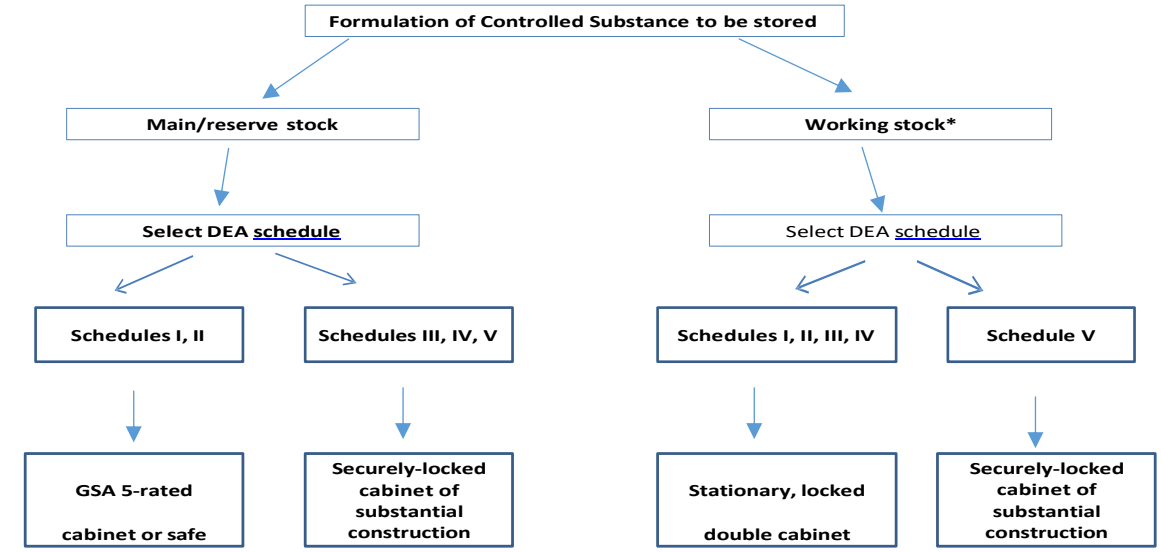
This Double Door, Double Lock Narcotic Cabinet with Shelf creates a controlled system for storing and dispensing adequate quantities of narcotics from the limited space at nurse's stations. Double door security and two key, two person safety system protects contents. One adjustable shelf to fit your needs. Two high-security cam locks provide extra protection against tampering. 20-gauge steel construction increases durability. Full-length piano hinges keep doors tightly aligned for added durability. Autumn White finish. 12"L x 8"W x 15"H overall.

**Recommended Working stock storage unit*

1. Reserve or main stocks –
   a. Schedule I and II controlled substances shall be stored in a GSA class 5 rated steel cabinet or equivalent safe approved by the Bureau of Narcotic Enforcement of the Department of Health. Any cabinet or safe weighing less than 750 pounds shall be bolted or cemented to the floor or wall in such a way that it cannot be removed. The door of the cabinet or safe shall contain a multiple position combination lock, a relocking device or the equivalent, and steel plate having a thickness of at least one-half inch.

   b. Schedule III, IV and V controlled substances shall be stored in a securely locked cabinet of substantial construction.

   c. Key control and safe access to main stock is limited to only registrant/licensed individual and designated supervisor.



*Please note – It is anticipated that most Investigators with greater than 2 lab members will be handling/storing Working Stocks of Controlled Substances .

REPORTING LOSS, THEFT OR UNAUTHORIZED USE

Each incident or suspected incident of possible theft, loss or diversion of a controlled substance must be immediately reported to the Licensed individual/registrant and campus security.
Thereafter, the Licensed individual/registrant must promptly report the incident to the NYS DOH.
Finally, the Licensed individual/registrant must report to DEA the theft or significant loss of any controlled substances within one business day of discovery.

Each agency has its own form that must be used for this reporting. Links to the forms are:
DEA
http://www.deadiversion.usdoj.gov/21cfr_reports/theft/index.html
NYS DOH
https://www.health.ny.gov/forms/doh-2094.pdf.

TRAINING

TBD

E. Responsibilities

1. **Licensed individual/registrant -** The responsibility for controlled substance research compliance rests with the Licensed individual/registrant. Typically, the Licensed individual/registrant is the Principal Investigator of a research protocol. The Licensed

individual/registrant is responsible for obtaining and renewing both the DEA registration and the New York State Department of Health license and for assuring that all acquisition, storage, security, inventory, disposal and record-keeping requirements are met.

a. **Supervisor of Controlled Substance Activity –** an individual who undertakes responsibilities including ordering, receiving, inventory, recordkeeping, and dispensing on behalf of the registrant. The role is officially designated by the registrant on form DOH-4330. Supervisors generally have access to the entire inventory of stored controlled substances.

2. **Other Authorized Individual** - The Licensed individual/registrant may authorize members of his or her staff to work with controlled substances under the Licensed individual/registrant's license/registration ("Other Authorized Individuals").

However, the Licensed individual/registrant retains overall responsibility for meeting all regulatory requirements. **Other Authorized Individuals must be listed on the Licensed individual/registrant's DOH-4330 license application, as set forth in section D(1)(b)(ii) above.**

Licensed individual/registrants may not name as Other Authorized Individuals any person who: (i) has been convicted of a felony offense relating to controlled substances; or (ii) at any time, has had an application for registration with the DEA denied, a DEA registration revoked or has surrendered a DEA registration for cause.

Other Authorized Individuals must follow all the rules and regulations outlined and referenced in this Policy, and are obligated to immediately report any suspected loss or diversion of controlled substances to their Licensed individual/registrant and to the ISMMS Campus Security (Campus Security).

F. Recordkeeping

The controlled substances regulations require significant record keeping at every point, including initial receipt, use, and disposal. See N.Y. Pub. Health L. §§ 3300-3397 and 10 N.Y.C.R.R. §§ 80.37, 80.112, and 21 CFR § 1304.03 and 04. These regulations specify the information required in each type of record, summarized below.

The Licensed individual/registrant is responsible for maintaining this documentation with respect to controlled substances used for his or her research. The records must be easily produced in the event of an inspection by NYS DOH or the DEA. Templates for recordkeeping are attached as Appendices C - E.

1. Initial receipt documentation (Appendix C)

Initial receipt documentation must include the date of receipt, name, address and registration number of vendor, type, and quantity of drug received. A duplicate invoice or separate itemized list furnished by the vendor will suffice if all the aforementioned information is contained on it and quantities have been verified. Quantities should be verified and documented as soon as possible after receipt to assure that they are as expected.

Receipt Log templates for Schedule I-II and Schedule III-V are attached as Appendix C Receipt Log templates (see appendices).

2. Use documentation (Appendix D)

Use documentation must include the name of the Licensed individual/registrant, the date, type and quantity of drug and signature of the Licensed individual/registrant or Other Authorized Individual using the controlled substance.

3. In addition, such records shall include the following information for each controlled substance:
    a. Name of substance.
    b. Each finished form (such as 10 mg. tablet, or 10 mg concentration per fluid ounce or milliliter) and the number of units or volume of finished form in each commercial container.
    c. The number of commercial containers of such finished form received from other persons, including the date of and number of containers in each receipt, and the name, address, and registration number of the person from whom the containers were received.
    d. The amount of such finished form dispensed, including the name and address of the person to whom it was dispensed, the date of dispensing, and the written or typewritten name or initials of the individual who dispensed or administered the substance.
    e. The number of units or volume of the finished form and/or commercial containers disposed of in any other manner by the researcher, including the date and manner of disposal.

4. Biennial Inventory Documentation (Appendix E)

An inventory of the stock of controlled substances at all locations where controlled substances are present must be recorded on the day after the DEA registration is received, when research with/possession of controlled substances begins and then every 2 years thereafter. The inventory must specify whether it was taken at the open or close of business on that day.

    a. A separate entry must be made with respect to each kind of substance or preparation, and each kind or size of package.
    b. Each entry shall show the name, quantity and content of controlled substance and the size of the individual package, the number of packages and the total content of all packages covered by the entry on hand as of the date of the inventory.
    c. This biennial inventory must be retained on file with other controlled substances records.

5. Intercampus transfers

TBD

6. Record Retention

All controlled substance records shall be readily available and maintained at the premises where the licensed activity is conducted.

Inventories and records of controlled substances listed in Schedules I and II, including DEA Form 222 (https://www.deadiversion.usdoj.gov/online_forms_apps.html), shall be maintained separately from other controlled substance records of the Licensed individual/registrant.

All records must be maintained by Licensed individual/registrant for a period of at least **five years** from the date of the last recorded purchase, transfer, use, or other transaction involving the controlled substance.

DISPOSAL

Licensed individual/registrants should make every effort to limit the amount of controlled substances requiring disposal by monitoring expiration dates and ensuring use of controlled substances within the appropriate timeframe, as well as limiting purchase/storage of controlled substances to appropriate quantities (e.g., sufficient to support the equivalent of 3-months of research). Disposal and/or surrender of controlled substances must be in accordance with applicable laws and regulations including, among others, 10 N.Y.C.R.R. § 80.51-52 and 21 C.F.R. § 1307.21.

1. If controlled substances expire or otherwise require disposal, the Licensed individual/registrant should contact a NYS DOH approved Reverse Distributor. (https://www.health.ny.gov/professionals/narcotic/licensing_and_certification/docs/reverse_distributor.pdf) and arrange for the documented return of the controlled substances through a reverse distribution process. EnvH&S is also available to provide guidance on this topic.
2. All controlled substances must remain securely stored in accordance with the "Storage" section of this Policy while awaiting NYS DOH and DEA approval for disposal.
3. Expired pharmaceuticals previously intended for use with animals must be clearly labeled to avoid accidental administration.
4. If controlled substances are discovered for which registration cannot be ascertained, please contact EnvH&S for guidance.
5. Any person disposing of a controlled substance must maintain written records containing:
    a. Date of return or destruction;
    b. Name, form, quantity of the substance returned or destroyed;
    c. Name, address, registry number of the person making the return;
    d. Name, address, registry number of the supplier or manufacturer to whom the substances are returned or the name and license number of the persons performing and witnessing the destruction.

G. Appendices

- The federal list of Schedule I-V controlled substances can be found at https://www.deadiversion.usdoj.gov/schedules/orangebook/c_cs_alpha.pdf.
- The state list of controlled substances in Schedules I - V is contained in §3306 of the New York State Controlled Substances Act, which can be found at

https://www.health.ny.gov/professionals/narcotic/laws_and_regulations/

H. Forms (available of CCMS/IACUC website)

Appendix. A1 NY DOH Class 4 & 7 Individual Researcher Protocol

Appendix A1

EXAMPLE

Class 4 & 7 Individual Researcher Protocol

In addition to the *License Application to Engage in a Controlled Substance Activity* (DOH-4330), complete and submit the following information for Class 4 & 7 Researcher (Individual) applications.

1. **Applicant/Researcher:**

(i) Qualifications & competence (Curriculum Vitae) of the applicant to engage in controlled substance research. (Attach CV)

A typical CV will include the following information:

- *Name & Contact Information*
- *Publications & Presentations*
- *Education*
- *Grants, Honors & Awards*
- *Employment & Experience*
- *Scholarly or Professional Memberships*

If applicant is a practitioner, provide his/her DEA Practitioner registration: FA123456 (if applicable)

2. **Research Project:** attached (See pages xx-xx) **Relevant Sections of Approved Animal Protocol:** attached (See pages xx-xx)

(i) Nature & objective of the project. (Attach additional sheets as necessary)

Title:

Role of stress in early adolescence and cognitive development

Nature & Objective (Concise Summary):

Stress at an early age is prominent in most youths growing up in America and the World. This study is designed to assess the impact of stress on cognitive development and support interventions to prevent long-term insult.

(ii) Name, schedule & quantity of the controlled substance(s) involved. (Attach additional sheets as necessary)

Name	Schedule	Quantity
Ketamine (100 mg/mL)	III-N	10 mL

(iii) Name, DEA registration & NYS controlled substance license of the provider(s) of controlled substance(s).

Name	DEA Registration	NYS Controlled Substance License
Patterson Veterinary Supply	RP123456	W123456789

If controlled substances are to be obtained by any means other than via a DEA registered distributor or manufacturer, explain: _____. Attach additional sheets as necessary

(iv) If animals are to be utilized in the research, provide: ☐ N/A

Species	Number of Animals	Dose Regimen (e.g., 10mg/kg, three times/week for five weeks)	Route of Administration
Mouse	50	90-120mg/kg	IP

(v) Will controlled substances be administered or dispensed to humans? ☐ Yes ☑ No

If administering or dispensing controlled substances to humans, attach the corresponding Institutional Review Board (IRB) approval & a detailed protocol setting forth:

- Provisions for the safe administration or dispensing of controlled substances to humans
- The proposed method of selecting humans.

- Insert CV

- Insert Project Description (from grant or funding source)

- Insert IACUC approval letter and relevant segments of the approved IACUC Animal Protocol (please ensure that requested controlled substances are captured/described in the document)

Appendix C: Receipt Log templates (Schedule I-II and Schedule III-V)

Icahn School of Medicine at Mount Sinai
CONTROLLED SUBSTANCES RECEIPT LOG SCHEDULE I-II

Licensed Individual: _____ **Laboratory/Storage Location:** _____

Date of Receipt	Name and address of vendor/distributor	Vendor's DEA #	Invoice or document reference #	Name of controlled substance	Quantity of controlled substance received	Number of units per container or package volume (e.g., 100 ml bottle or 20 capsule blister pack, etc.)	Total number of containers (e.g., 4 x 100-tablet bottles, 6 x 3 ml vials, 2 x 20 capsule blister packs, etc.)	Assigned internal container ID #s (shown as a range if more than 1 per line item)*

Notes:
*The PI/Licensed Individual must develop their own internal container ID inventory numbering system and assign numbers to each container (ex. J. Smith - 001)
File a copy of the purchase receipt with this receipt log and mark the date of receipt on the invoice
Do not use abbreviations, except for standard metric units
All records must be maintained for a period of at least 5 years from the date of the last recorded purchase, transfer, use or other transaction per NYS Title Section 80.112(b)

Icahn School of Medicine at Mount Sinai
CONTROLLED SUBSTANCES RECEIPT LOG SCHEDULE III-V

Licensed Individual: _____ **Laboratory/Storage Location:** _____

Date of Receipt	Name and address of vendor/distributor	Vendor's DEA #	Invoice or document reference #	Name of controlled substance	Quantity of controlled substance received	Number of units per container or package volume (e.g., 100 ml bottle or 20 capsule blister pack, etc.)	Total number of containers (e.g., 4 x 100-tablet bottles, 6 x 3 ml vials, 2 x 20 capsule blister packs, etc.)	Assigned internal container ID #s (shown as a range if more than 1 per line item)*

Notes:
*The PI/Licensed Individual must develop their own internal container ID inventory numbering system and assign numbers to each container (ex. J. Smith - 001)
File a copy of the purchase receipt with this receipt log and mark the date of receipt on the invoice
Do not use abbreviations, except for standard metric units
All records must be maintained for a period of at least 5 years from the date of the last recorded purchase, transfer, use or other transaction per NYS Title Section 80.112(b)

Appendix D: Use Log template

Icahn School of Medicine at Mount Sinai
CONTROLLED SUBSTANCE USE LOG*

PI/Licensed Individual: _____ **Assigned internal container ID #:** _____ **Starting amount (include units of measure):** _____

Laboratory/Storage Location: _____ **Name of controlled substance:** _____ **Concentration in finished form (e.g., ug/ml, mg/mL, mg/tablet):** _____

Schedule I or II (yes/no): _____

Date of Use	Previous Balance	Quantity Used	New Balance	Name of User (Print Full Name)	Use of Controlled Substance**

Notes:
*The PI/Licensed Individual must develop their own internal container ID inventory numbering system and assign numbers to each container (ex. J. Smith - 001)
**Protocol number may be used or example of application such as mouse anesthetic.
New Balance = previous/startng balance - quantity used. The previous balance is the amount on hand since the last use of the substance. All record entries must be in English.
Do not use abbreviations, except for standard metric units

Appendix E: Biennial Inventory template

Icahn School of Medicine at Mount Sinai
CONTROLLED SUBSTANCES BIENNIAL INVENTORY FORM*

DEA Registrant Name: _____ **DEA Registration #** _____ **NYSDOH License #** _____

Date of Inventory: _____ **Time of Inventory:** _____ (must be taken at start or end of business day)

	Name of Controlled Substance	**Form of Controlled Substance** *(e.g., tablet, capsule, solution, etc.)*	**Concentration per unit or container** *(e.g., 10mg/tablet, 10 mg/ml, etc.)*	**Number of units per container or package volume**** *(e.g., 100 ml bottle or 20 capsule blister pack, etc.)*	**Total number of containers** *(e.g., 4 x 100-tablet bottles, 6 x 3ml vials, 2 x 20 capsule blister packs, etc.)*	**Total content of all packages**	**Additional Information (NDC #, Lot #, Expiration Date, Internal reference #)**
1st substance inventoried **							
2nd substance inventoried							
3rd substance inventoried							
4th substance inventoried							
5th substance inventoried							

*Biennial inventory must be taken every 2 years from the initial receipt of controlled substances and subsequently within 2 years of the previous biennial inventory *(DEA Title 21 CFR, Section 1310.11 and NYCRR Title 10, Section 80.112).*

**All closed/intact containers or packages of the same controlled substance (i.e., form, concentration, etc) may be inventoried together as a single entry. Containers or packages that have had substances removed (i.e., for use, transfer or disposal), must be inventoried as a separate entry from closed/intact containers.

Notes:

Biennial Inventory Forms must be maintained for at least 5 years from the date of last purchase or transfer
All entries must be made in English
Do not use abbreviations, except for standard units of measure

Appendix F

Icahn School of Medicine at Mount Sinai

Pre - Inspection Checklist for NYSDOH Controlled Substance (CS) License Applicants

Upon receipt by NY State Department of Health (NYSDOH) of your controlled substances license application, an inspection will be scheduled with a representative from the Bureau of Narcotics Enforcement. Please use the checklist below to ensure that all facilities, necessary paperwork, and other relevant items are ready for inspection. Please return a signed, completed copy of this checklist to CCMS/IACUC, and please contact CCMS/IACUC with any questions or concerns.

Please note –

- License applicants – typically the PI of the lab – must be personally present at time of inspection
- Controlled substances storage unit (e.g., locker, cabinet, safe) must be installed prior to inspection
- A printed copy of the *Policy for the Acquisition, Use and Disposal of Controlled Substances in Research* should be available for your reference during the inspection.

YES	*NO*	*Checklist item*
		Applicant and all authorized individuals have reviewed the *Policy for the Acquisition, Use and Disposal of Controlled Substances in Research*
		No controlled substances are currently present in lab (Lockbox/Safe is currently empty)
		Knowledge of Authorized User(s) and their trustworthiness.
		Knowledge of how Controlled Substances will be obtained, stored, and used in the animal/ non-animal research program
		List of Authorized Users is current. Authorized Users are limited to the minimum number of personnel required for research.
		Appropriately rated lock box(es) and/or safe is properly secured and installed. It is in good working order and the keys are in a secure location.
		An appropriately rated floor safe is present if Schedule I or II CS will be used. It is bolted down if weighing less than 750lbs.
		CS record keeping documents are organized and ready for inspection. Receipt Logs, Use Logs, and Initial and Biennial Inventory Logs.
		CS Usage Logs and Inventory Logs for Schedule I and II substances are maintained separately from those for Schedule III-V.
		A copy of your New York State Education Department *Registration Certificate*, if licensed to practice as an MD, DO, RPA, DDS, DMD, RPh, DVM, etc.
		A copy of your US DEA registration, if currently licensed with the DEA to practice as an MD, DO, RPA, DDS, DMD, RPh, DVM, etc.
		Copies of the *Distributor Certificates* and DEA registrations numbers for any vendors from which you will be purchasing controlled substances
		A copy of the *Individual Research Protocol (Appendix A1)* is provided for the state license application

Created 1/24/2025_____

Printed Applicant Name and Signature Date