

CCMS Town Hall

November 6, 2025

Jonathan A. Cohen, DVM DACLAM
Associate Professor and Director
Center for Comparative Medicine and
Surgery



**Mount
Sinai**

New Clinical Veterinarian

- **Brenton G. Mays**
- Doctorate of Veterinary Medicine
 - Ohio State University 2022
- Laboratory Animal Residency Training
 - Columbia University Institute for Comparative Medicine 2025
 - ACLAM Board Eligible
- NHP experience- Transplant Medicine and Neurosurgery
- Swine Cardiovascular Models
- Rodent Surgery and Anesthesia
- Emergency Medicine



CCMS Operational Updates

CRL Offsite Housing Changes

- ▶ **August 2025-** Initiated the return of CRL Off-site Housing cages the main campus
 - Financial accountability to School Mandate to reduce spending
 - Available space options on the main campus due to government funding ordeal
- ▶ **November 2025-** approximately 2500 cages returned
 - Mid November Investigators choosing to remain at CRL will support unsubsidized per diem rate
- ▶ CRL will remain a partner for CCMS whole animal quarantine
 - Maintains institutional biosecurity goals to protect main campus colonies
- ▶ Dr. Kelly Yamada Head of Small Animal Medicine- point of contact for any questions

Mount Sinai Offsite Housing Pricing Structure for PIs

3,000 cage volume discount will be held for investigator pricing through 2026 regardless of actual cage usage

All-Inclusive Services at Charles River

- ✓ Husbandry (food/water/bedding)
- ✓ Veterinary Care
- ✓ Mating
- ✓ Euthanasia
- ✓ Cage moves/combinations
- ✓ Weaning/Identification
- ✓ Packing/Shipping of animals
- ✓ Biopsy Collection

Additional Support!

- ✓ Internet Colony Management
- ✓ Dedicated Project Manager Staff
- ✓ High level biosecurity technology track record

* Aging Cage does not include biopsy collection or breeding services

** Subsidized shipment fees will be adjusted by CCMS in November 2025



Weekly Isolator Per Cage Price

- Genetic Cage \$11.71 (1.67/day)
- *Aging Cage \$11.08 (1.58/day)

Cage Status (view cage availability)

1	2	3	4	5	16	17	18	19	20
6	7	8	9	10	21	22	23	24	25
11	12	13	14	15	26	27	28	29	30



Shipping Crate Costs Discounted 50%

- Crate cost \$28.90 (holds 2 cages)
- **Shipment fees T.B.D. for 2026



Weekly IVC Per Cage Price

- Genetic Cage \$11.13 (1.59/day)
- *Aging Cage \$10.53 (1.50/day)

Cage Status (view cage availability)

1	2	3	4	5	6	7	8
9	10	11	12	13	14	15	16
17	18	19	20	21	22	23	24
25	26	27	28	29	30	31	32
33	34	35	36	37	38	39	40
41	42	43	44	45	46	47	48
49	50	51	52	53	54	55	56
57	58	59	60	61	62	63	64
65	66	67	68	69	70	71	72
73	74	75	76	77	78	79	80
81	82	83	84	85	86	87	88
89	90	91	92	93	94	95	96



Charles River GEMS IVC Space



Infrastructure Expansion

- Charles River Wilmington has expanded our capacity to include IVC housing in our facility
- 96 cages/side
- Independent intake & exhaust for each unit from main source
- Bridge between isolator and full barrier room housing



IVC Biosecurity

- Non-CRL staff cannot enter the IVC room
- PAPRs and appropriate PPE for all employees in the room
- Change stations (ATS) for all husbandry and technical work
- Stations cleared between every line/project
- Quarterly PRIA screening of the rack (96 cages) using Pathogen Binder™ screening
 - <https://criver.widen.net/s/w9fqhks6p/rm-ts-pathogen-binder>



ICM Integration

- IVC Housing is fully integrated into ICM
 - Ensuring data and colony integrity
- PI/PM Communication – No Change
 - Customer portal view
 - Task requests/Task Approval
 - Shipment request
 - Biopsy Sample Collection



Cage Status (view cage availability)

1	2	3	4	5	6	7	8
9	10	11	12	13	14	15	16
17	18	19	20	21	22	23	24
25	26	27	28	29	30	31	32
33	34	35	36	37	38	39	40
41	42	43	44	45	46	47	48
49	50	51	52	53	54	55	56
57	58	59	60	61	62	63	64
65	66	67	68	69	70	71	72
73	74	75	76	77	78	79	80
81	82	83	84	85	86	87	88
89	90	91	92	93	94	95	96

CCMS Colony Management Program

Mismanaged rodent colonies equals wasted grant
money \$\$\$\$

\$1.30 2025 per diem (Includes)

- Setting breeders
- Checking for plugs
- Weaning
- Collecting tail or ear biopsy
for genetic analysis
- Packing animals for shipment
- Colony information is uploaded
to Softmouse database



CCMS Colony Management Program

Let us help you with your research goals



Jonathan A. Cohen, DVM

Scientific Director

Chineta Pullin

Research Program Director

212-241-3008

New CCMS Online Form Platform

- ▶ CCMS recently transitioned our online forms from the eRAP platform to RedCap
- ▶ Forms are identical in function with minor formatting changes due to RedCAP features
- ▶ Historical online form links housed in eRAP have been disabled
- ▶ ***Please refresh any bookmarked hyperlinks to ensure access and functionality**

Controlled Substance Update Refresher

What is a Controlled Substance?

- A controlled substance is a drug or chemical whose manufacture, possession, storage, use or disposal is regulated by the Drug Enforcement Administration (DEA)
- Included are all chemical substances in Schedules I-V of the Controlled Substances Act and any listed in the state laws of New York

Controlled Substances

- Placement of a controlled substance into one of the five Schedules is based on the following:
 - Medical use
 - Potential for abuse
 - Psychological or physiological dependence
- Since 1970, many substances have been added, removed, or transferred from one schedule to another.
- An updated list of the schedules is published annually in Title 21 Code of Federal Regulations (CFR) 1308.11-1308.15

Controlled Substances

Policy update



- Each Mount Sinai Principal Investigator must have a license/registration from:
 - Bureau of Narcotic Enforcement (BNE)
 - Drug Enforcement Administration (DEA)
- **NOTE:** The Drug Enforcement Administration is a law enforcement agency and can prosecute violators of the Controlled Substances Act
- The DEA will not provide a federal license until the PI obtains a state license.

CCMS Same Day Use Dispensing

- ▶ Supports compliance with the State and Federal controlled substance laws and continuity of approved IACUC research protocols using controlled substances
 - **Not intended to substitute the individual license mandate**
- ▶ Investigators submit completed controlled substance requisition 48 hours prior to an available drug pick up day (Monday, Wednesday, or Friday).
- ▶ A completed and accurate drug calculation sheet must accompany the requisition to support detail for the volume of agent(s) requested.
- ▶ Following veterinary approval of requisition/ calculation sheet, a CCMS Drug Pharmacy team member will follow up to confirm the next available pick up day and time.

CCMS Same Day Dispensing

- ▶ CCMS Personnel will be available 3 standing days a week (Monday, Wednesday or Friday) from 11-12pm to support pick up of agents associated with approved requisitions.

Req. Submission day*	Preferred pick up day
Friday	Monday
Monday	Wednesday
Wednesday	Friday

Requisition Submission by **12pm for preferred pick up day consideration*

- ▶ Once the experiments are completed that day with exhaustion of the controlled substance (per calculation), the empty syringe can be disposed of in an appropriate sharps container.
 - If there is any controlled substance remaining following procedures, it can be disposed of in the Cactus drug disposal unit located on the 26th floor
- ▶ Please contact **Dr. Hylton Gordon- Head of Comparative Surgery** or **Kamal Bartley-CCMS OR Supervisor** for any questions.

Application Process

- ▶ The Bureau of Narcotic Enforcement (BNE) is part of the New York State Department of Health.
- ▶ The Drug Enforcement Administration (DEA) requires you to have BOTH a BNE (state license) and a DEA license to purchase and use controlled substances in research settings
- ▶ The application for the BNE is located here (DOH-4330)
- ▶ <https://www.health.ny.gov/forms/doh-4330.pdf>
- ▶ DEA application
- ▶ <https://www.dea diversion.usdoj.gov/drugreg/registration.html>

NYSDOH Basic Application Details

NEW YORK STATE DEPARTMENT OF HEALTH
Bureau of Narcotic Enforcement

License Application to Engage in a Controlled Substance Activity

Refer to step-by-step Instructions for Applying to Engage in a Controlled Substance Activity

https://www.health.ny.gov/professionals/narcotic_licensing_and_certification/

PLEASE USE ADOBE TO FILL-IN

APPLICANT INFORMATION				MAILING ADDRESS	
Legal Name Mount Sinai School of Medicine				Use <u>ONLY</u> if U.S.P.S. Mail cannot be delivered to the location where the controlled substance activities will occur.	
d/b/a Department of Research				Street/PO Box	
Street 1488 Madison Avenue, Annenberg 26-100				Address Line	
City New York				City	
State NY	Zip 10029	County New York		State	Zip
BNE License # (if currently licensed) 04B-1234	NYS Department of State ID# 123456	NYS BOP Registration #	DEA Registration # MS123456	Licenses will be issued <u>only</u> for the physical address where the controlled substance activity will occur.	

REPRESENTATIVE CONTACT INFORMATION		
Name John Doe, MD PhD		Title Associate Professor
Telephone 212-241-6500	Fax	Email john.doe@mssm.edu

APPLICATION TYPE		
☒ NEW	Note: New applicants and those reporting a relocation or a change in ownership will be subject to an on-site facility inspection (excluding out-of-state applicants).	Date proposed for controlled substance activity to begin. ____/____/____
☐ CHANGE**	☐ Name Change Prior: New: ☐ Address Change Prior: New: ☐ Ownership/Operator Change Prior: New: ☐ Change in Storage Only Prior: New:	
☐ RENEWAL	☐ No Change since last application	
☐ AMENDMENT	Attach narrative outlining change(s) requested.	

LICENSE CLASSIFICATION (see instructions for multiple class requests)		New/Change/ Renewal Non- Refundable Fee	Amendment Non- Refundable Fee	Office Use Only
☐ Class 1 Manufacturer		\$1200	\$250	Cashline:
☐ Class 1a Manufacturer (Out-of-State)		\$1200	\$250	☐ Approved / /
☐ Class 2 Distributor		\$1200	\$250	☐ Initial Review / /
☐ Class 2a Distributor (Out-of-State)		\$1200	\$250	
☐ Class 2R Reverse Distributor		NO FEE	NO FEE	Comment(s)
☐ Class 3 Institutional Dispenser	Operating Certificate #	\$100	NO FEE	
☐ Class 3a Institutional Dispenser Limited	Operating Certificate #	\$100	NO FEE	
ADS Unit Currently On-Site ☐ New ADS Unit On-Site Since Last Application ☐				
☒ Class 4 Researcher (Schedules II-V)	☒ Individual ☐ Institutional	\$40	\$20	
☐ Class 5 Instructional Activities (Schedules II-V)		\$40	\$20	
☐ Class 7 Research/Instructional (Schedule I)	☐ Individual ☐ Institutional	\$40	\$20	
☐ Class 8 Analytical Laboratory		\$40	\$20	
☐ Class 9 Importer		\$1200	\$250	
☐ Class 9a Importer Broker		\$1200	\$250	
☐ Class 10 Exporter		\$1200	\$250	
☐ Class 10a Exporter Broker		\$1200	\$250	
☐ Class 11 Pharmacy - Registered Community Pharmacy for ADS Operations		NO FEE	NO FEE	Reviewer:

** Changes to current licenses may result in the issuance of a new BNE license number.

✓ New York State, county and other municipal agencies are **exempt** from licensing fees only if they are the applicant for licensure. Employees of an exempt entity are **NOT exempt** from licensing fees.

CONTROLLED SUBSTANCE SCHEDULE(S) TO BE UTILIZED (check all that apply)

☐ I ☐ II ☒ III ☒ IV ☒ V

STORAGE OF CONTROLLED SUBSTANCES (check all that apply)

☐ Vault	Storage must be installed and ready for inspection upon submission of this form. Describe storage and security used along with make and model numbers; photos must be submitted in a separate document.
☒ Safe	Storage is maintained in accordance with NYSDOH recommendations via a safe or a double-door, double-locked lock box that is mounted/secured to a permanent fixture.
☒ Cabinet	
☐ Cameras	
☐ Other	

SUPERVISOR OF CONTROLLED SUBSTANCE ACTIVITY

Name Registrant OR designated Supervisor	Title and Type of Professional License and Number Associate Professor, MD PhD 123456
Signature	Email Address john.doe2@mssm.edu

APPLICANT ACKNOWLEDGEMENTS

- The applicant fully understands that the license to be issued hereon shall be subject to the following stipulations and conditions:
- The applicant is knowledgeable concerning all laws and regulations, both State and Federal, regarding the licensed activity and shall comply with such requirements.
 - The licensee shall be under a continuing duty to inform the Department of Health of any changes, such as name, address or any substantial change to the physical security and means of record keeping regarding the controlled substance(s).
 - The license privilege herein applied for, if granted, shall not be transferred. Changes in name or ownership shall be immediately reported to the Department of Health.
 - Any license so issued as a result of the application for license shall be promptly returned to the Department of Health upon revocation or suspension of the license or the Federal license for the activity or activity for which the applicant was licensed has been discontinued.
 - Licensee shall promptly report to the Department of Health each incident or alleged incident of theft, loss or possible diversion of either controlled substances or Official New York State Prescriptions. Such notification shall be by contacting the Central Office of the Department of Health's Bureau of Narcotic Enforcement and then shall be reported on the applicable Department of Health forms. Reporting of such incident to other government agencies does not relieve the applicant of this responsibility.
 - Manufacturers and Distributors shall comply with NYS PBH Article 33, Title 2 §3322 and Title 6 §3374 to include a tested and authenticated process for suspicious ordering monitoring and reporting requirements pertaining to order size, unusual ordering frequency, and unusual ordering patterns at a minimum.
 - Applications are valid for 90 days from date of receipt. After 90 days, if application is not approved or denied for licensure, the application will be deemed insufficient. Applicants may reapply, if they so choose, by submitting a new application and fee.

Has the applicant or Supervisor of Controlled Substance Activity been convicted of an offense in any jurisdiction relating to any substance listed in PHL Article 33 as a controlled substance?	Has the applicant or Supervisor of Controlled Substance Activity ever had a State or Federal controlled substance license or registration or professional license or registration revoked, suspended, denied or restricted or been placed on probation?	If the applicant is a partnership, stockholder, proprietor or corporation (other than a corporation whose stock is owned and traded by the public): Has the business, any officer or the Supervisor of Controlled Substance Activity been convicted, fined, censured or had a license (State or Federal) suspended or revoked in any administrative or judicial proceeding relating to or arising out of the manufacture or distribution of drugs?
☐ YES * ☒ NO	☐ YES * ☒ NO	☐ YES * ☒ NO

* Applicants who answer "YES" to any of the above questions must submit a statement of explanation with documentation to support the explanation.

APPLICANT SIGNATURE

Under the penalties of perjury, I affirm that the statements herein are true, to the best of my knowledge, and that I am knowledgeable regarding the requirements of the licensed activity for which I am applying.

Name John Doe MD PhD	Title Associate Professor
Signature	Date ---/---/---

SUBMISSION REQUIREMENTS

Email the following to bneclensing@health.ny.gov ✓ Completed DOH-4330 application ✓ Photocopy or scan of your check or money order issued for application fee ✓ All supporting, required documentation, images of all storage, and forms for the class of license being applied for	Submit to mailing address: NYS DOH Bureau of Narcotic Enforcement Riverview Center Attn: Licensing Unit 150 Broadway Albany, NY 12204 ✓ Check or money order for licensing fee made out to: NYS DOH Bureau of Narcotic Enforcement ✓ Photocopy of DOH-4330 that was emailed – no additional documentation
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NYSDOH Basic Application Details

Appendix A1

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
- Grants, Honors & Awards
- Publications & Presentations
- Employment & Experience
- Education
- 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 xxx-xxx)

(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)

CCMS Vendor Recommendation

**Patterson Veterinary Supply
Patterson Logistics Services Inc.
925 Carolina Pines Blvd STE B
Blythewood, SC 29016-7926
DEA# RP0349224
BNE# 02A0659**

**MWI Animal Health
1499 Zeager Road, Suite #2
Elizabethtown, PA 17022
DEA# RM0310540
BNE# 02A0596**

As detailed in the Controlled Substance Institutional Policy available on CCMS website

NYSDOH Basic Application Details

- ▶ Checklist for NYS DOH License Application
- ▶ Completed DOH-4330 application with appropriate signatures
- ▶ Completed Appendix A1 (one appendix needed for each IACUC protocol) Application fee \$40: scan/photocopy of check/money order to NYS DOH Bureau of Narcotics Enforcement
- ▶ Curriculum Vitae of proposed licensee
- ▶ IACUC Approval letter
- ▶ Policies and procedures for safe storage of C.S. and methods used to reduce potential for diversion
- ▶ Copy of DEA registration (only applicable for clinicians with existing DEA registration)
- ▶ Digital photographs of all storage and security
 - Entrance and exits to the room where storage is installed
 - All areas of the room where storage is installed (to provide a 360-degree view)
 - All storage closed/locked and open to reveal all locking mechanisms and compartments
 - All security measures in place (key card access, alarm systems, locked doors, etc.)

NYSDOH BNE On-site Visit

- ▶ Once the application has been submitted
- ▶ Appropriate storage is installed,
- ▶ The NYS Bureau of Narcotics Enforcement will schedule an onsite visit
 - review the storage and documentation of the potential registrant.

Icahn School of Medicine at Mount Sinai

Pre - Inspection Checklist for NYSDOH Controlled Substance 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.

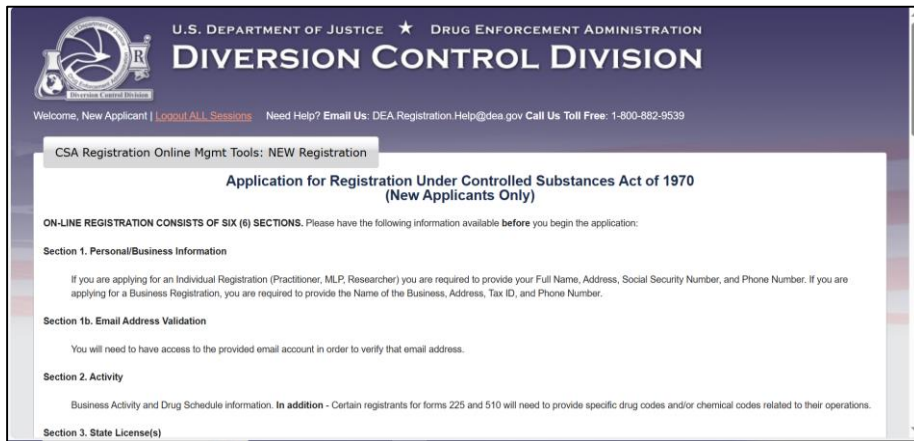
YES ☐	NO ☐	Applicant and all authorized individuals have reviewed the <i>Policy for the Acquisition, Use and Disposal of Controlled Substances in Research</i>
YES ☐	NO ☐	<u>No controlled substances are currently present in lab</u>
YES ☐	NO ☐	SDSs and other technical specifications for controlled substances you are ordering are printed and available for inspection
YES ☐	NO ☐	Specification sheets for controlled substances storage cabinet are printed and available for inspection
YES ☐	NO ☐	Controlled substances recordkeeping binder including <u>printed</u> , <u>blank</u> copies of all tracking forms/templates is ready for inspection. For blank templates refer to the <i>Appendices, Resources and Reference Documents</i> section of the <i>Policy</i> .
YES ☐	NO ☐	A copy of your New York State Education Department <i>Registration Certificate</i> , if licensed to practice as an MD, DO, RPA, DDS, DMD, RPh, DVM, etc.
YES ☐	NO ☐	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.
YES ☐	NO ☐	Copies of the <i>Distributor Certificates</i> and DEA registrations numbers for any vendors from which you will be purchasing controlled substances
YES ☐	NO ☐	A copy of the <i>Individual Research Protocol (Appendix A1)</i> is provided for the state license application

Created 1/24/2025

Printed Applicant Name and Signature

Date

Getting a DEA License



The screenshot shows the DEA Diversion Control Division's online registration application form. The header includes the U.S. Department of Justice and Drug Enforcement Administration logos, along with the text "DIVERSION CONTROL DIVISION". Below the header, there is a navigation bar with links for "Welcome, New Applicant", "Logout ALL Sessions", "Need Help?", "Email Us: DEA.Registration.Help@dea.gov", and "Call Us Toll Free: 1-800-882-9539". The main content area is titled "Application for Registration Under Controlled Substances Act of 1970 (New Applicants Only)". It states that the online registration consists of six sections and provides instructions for new applicants. The sections listed are: Section 1. Personal/Business Information, Section 1b. Email Address Validation, Section 2. Activity, and Section 3. State License(s).

- ▶ To obtain a DEA registration, a researcher must apply using a DEA Form 225. Applicants may submit the form by hard copy or online.
- ▶ <https://apps.dea.diversion.usdoj.gov/webforms2/spring/main?execution=e1s1> (DEA Diversion Internet Web Site)
- ▶ DEA Headquarters' Registration Section in Washington, D.C. at 1-800-882-9539 (Registration Call Center)

DEA Application process

Researchers must submit an application for a registration for either Schedule I or Schedule II-V:

Note: Similar to NYS DOH, if you seek to use both Schedule I and Schedule II – V, you will need to submit separate applications for each registration.

Schedule I applications require more detail

Must file and receive approval for a complete research protocol

- ☐ Supplemental protocol that includes detailed information C.S. use locations and procedures for storage, dispensing, and security to prevent diversion
- ☐ IACUC Approval Letter
- ☐ Curriculum Vitae of proposed registrant

Checklist for DEA Registration Application

- ☐ Completed DEA Form 225: Application for Registration under Controlled Substances Act
- ☐ \$296 application fee paid by credit card
- ☐ Copy of state license from NYS Dept. of Health
- ☐ Completed Power of Attorney (Schedule I & II only)

DEA Onsite visit

- Once applications have been submitted:
- The DEA will schedule an on-site inspection to review storage, material logging requirements, and researcher protocols similar to the NYS DOH.
- **Same Preparation Checklist expectations as the prior NYSDOH visit**
- This inspection is separate from the inspection by the NYS DOH
- You may commence work with scheduled materials **only after** you have received both a license from the NYS DOH and a registration from the DEA.

DEA Onsite Visit

Recent DEA site visit inquiries:

(contact CCMS/IACUC for assistance):

1. History of Mount Sinai as an institution (years established/ownership/parent companies/subsidiaries)
2. How controlled substances are shipped to Mount Sinai (common or contract carrier)
 - a. Is there an SOP as to what to do for suspicious orders
3. What facility is used for drug destruction (name, address, DEA #)
4. Information about the physical building including: physical construction, number of entrances, windows,
5. Who is the local PD, is there CCTV footage, how is it stored and where, are there outside guard stations,
6. Who has access to shipping/receiving, how are visits/deliveries handled re: access to the floor
7. information about the interior including: a copy of the floor plan, security contract,
8. Is there an alarm (what company, what system, how often is it tested), who is a contact for overall security in this building
9. HR: blank copy of employment application/how are employees screened

Investigator Responsibilities

- **DEA Registrants/NYS Licensed individual** are legally responsible for managing the controlled substances in accordance with the regulations, including inventory, recordkeeping, and security provisions.
- Specifically, they are responsible for:
 - Obtaining and maintaining appropriate licensure from the NYSDOH Bureau of Narcotics Enforcement- Form DOH 4330.
 - Obtaining and maintaining appropriate registration from the US DEA (Based on Category; Research – Form 225/225a).
 - Safeguarding controlled substances obtained through their license/registration from receipt until their destruction/disposal.
 - Establishing security measures for the purchase, acceptance, use, and ultimate disposal of the controlled substances used in their research.

Supervisor of Controlled Substance Activity

- **Supervisor of Controlled Substance Activity (Supervisor)** is 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 will generally have access to the entire inventory of stored controlled substances.
- To take on supervisory responsibilities with schedules I & II controlled substances, a Power of Attorney must be officially completed, signed, and kept on file by the registrant.

Authorized Users

- **Authorized Users** are trusted lab members who receive controlled substances under authorized supervision of the primary DEA registrant or supervisor.
- Authorized users of controlled substances are responsible for managing the controlled substances in accordance with regulations, including inventory, record keeping, and security provisions.
- They are responsible for following established security measures for the storage, use, and ultimate disposal of the controlled substances used in their research.
- They must be listed on the animal use or research protocol detailed on the registrant's NYS DOH License. Authorized Users only have access to materials dispensed to them by the registrant or supervisor, generally dilutions.

Security Requirements



<https://www.globalindustrial.com/>

- Ensure that controlled substances are stored in a manner that prevents their theft or misuse
- Store controlled substances at the location specified in the registration
 - Working Stock and Main Stock storage locations required
 - Schedule III-V working stock require a double-locked, substantially constructed cabinet that is fixed permanently in place
 - Schedule III-V Main stock stationary securely locked cabinet of substantial construction.
- Ensure that only authorized users have access to controlled substances
- Keep the storage unit locked when not in use
- Do not use bicycle locks, clasp locks or any other locking device that can be cut off the cabinet used for storing controlled substances

Security Requirements

New York State Department of Health Controlled Substance Minimum Storage Requirements - Class 4 and 7		
	Schedule I & II	Schedule III - V
Reserve and Main Stock	A Safe with a TL rating of 30 or higher <u>or</u> a vault with a GSA class 5 rating. Safes weighing <750lbs. Must be bolted to the floor.	A cabinet that is stationary, securely locked, and double- doored. Both cabinets must have key-locked doors with separate keys. Cabinets must be made of steel or other approved metal.
Working Solutions	A cabinet that is stationary, securely locked, and double- doored. Both cabinets must have key-locked doors with separate keys. Cabinets must be made of steel or other approved metal.	A cabinet that is stationary, securely locked, and double- doored. Both cabinets must have key-locked doors with separate keys. Cabinets must be made of steel or other approved metal. <i>* Schedule V does not require double door feature</i>

***Find recommended vendors on CCMS and/or IACUC website**

Questions

- ▶ IACUC/OACUW Office Hours every Monday 3:15-4:15
 - Contact Dr. Gates-Porter to register to attend
- ▶ All materials presented are housed on the CCMS website for further review
 - Controlled Substance SOP
 - Draft applications
 - FAQs
 - Record keeping templates

Email any urgent questions to:

- ▶ dea-bne@mtsinai.onmicrosoft.com