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 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)

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

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

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

PI/Licensed Individual: _____

Laboratory/Storage Location: _____

Assigned internal container ID #: _____

Name of controlled substance: _____

Schedule I or II (yes/no): _____

Starting amount (include units of measure): _____

Concentration in finished form (e.g., ug/ml, mg/mL, mg/tablet): _____

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

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

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)

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: John Doe MD PhD			**Use ONLY 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 *: 1468 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 only 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** ☐ Postal Only ☐ Physical Relocation	Prior:
		New:
	☐ **Ownership/Operator Change** ☐ **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
☐ Class 1 Manufacturer	$1200	$250
☐ Class 1a Manufacturer (Out-of-State)	$1200	$250
☐ Class 2 Distributor	$1200	$250
☐ Class 2a Distributor (Out-of-State)	$1200	$250
☐ Class 2R Reverse Distributor	NO FEE	NO FEE
☐ Class 3 Institutional Dispenser — Operating Certificate #	$100	NO FEE
☐ Class 3a Institutional Dispenser Limited — Operating Certificate # ADS Unit Currently On-Site ☐ New ADS Unit On-Site Since Last Application ☐	$100	NO FEE
☒ 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

Office Use Only

Cashline:

☐ Approved ____/____/____

☐ Initial Review ____/____/____

Comment(s)

_____

_____

_____

_____

_____

_____

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:** 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.
☒ Safe	
☒ 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.doe@mssm.edu

APPLICANT ACKNOWLEDGEMENTS

The applicant fully understands that the license to be issued hereon shall be subject to the following stipulations and conditions:

1. The applicant is knowledgeable concerning all laws and regulations, both State and Federal, regarding the licensed activity and shall comply with such requirements.
2. 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).
3. 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.
4. 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.
5. 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**.
6. 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.
7. 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, its employees, subsidiaries, managing officers, or directors failed to comply with the provisions of the Federal Controlled Substance Act or the laws of any State relating to controlled substances? ☐ YES * ☒ NO	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? ☐ YES * ☒ NO	**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

***** 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 of Applicant (Owner, Partner, COO, or Other Authorized Person):	Date: --/--/--

SUBMISSION REQUIREMENTS

Email the following to bnelicensing@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