

New York State Bureau of Narcotic Enforcement

Instructions for Investigators

August 20, 2024

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 and a DEA license to purchase and use controlled substances in research settings

This handbook will walk you through your BNE Application, which must be completed FIRST.

Even if you already have a DEA license you still need to obtain a second license to use controlled substances as a researcher.

The application for the BNE is located here (DOH-4330)
<https://www.health.ny.gov/forms/doh-4330.pdf>

Instructions for completing the form are located here:
https://www.health.ny.gov/forms/instructions/doh-4330_instructions.pdf

Information to include in your application

Application address = Where your lockbox is located

Applicant Information		
Legal Name:		
d/b/a: Stony Brook University		
Street*: (the physical address of your lock box)		
City: Stony Brook		
State: New York	Zip: 11794	County: Suffolk
Controlled Substance License#	*If using a PO Box, a street address must be included.	

Application type = New

☒ New	Note: New applications and those reporting a relocation or a change in ownership will be subject	Date proposed for controlled substance activity to begin 09/01/2024
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	to an on-site facility inspection	
	☐ Name Change	Prior Name: New Name:
	☐ Address Change ☐ Postal Only ☐ Relocation	Prior Address: New Address:
	☐ Ownership Change	Prior Owner: New Owner:
☐ Renewal	☐ No Change	
☐ Amendment	Attach narrative outlining change(s) requested	

License Class = Class 4 – Individual

License Classification (check only one box)			New License Renewal Fee	Amendment 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 3 Institutional Dispenser			\$100	N/A
☐ Class Institutional Dispenser Limited			\$100	N/A
☒ Class 4 Researcher (Schedules II-V)	☒ Individual	☐ Institutional	\$40 Do not send money. State employees are exempt from licensing fees.	\$20

Controlled Substances Schedule = III-V

Controlled Substance Schedule(s) to be Utilized (check all that apply)
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☐ I	☐ II	☒ III	☒ IV	☒ V
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If you have a safe (not just a lockbox): Select II-V

Controlled Substance Schedule(s) to be Utilized (check all that apply)				
☐ I	☒ II	☒ III	☒ IV	☒ V

Storage = Cabinet +/- Safe

☐ Vault	
☒ Safe	I applicable, "GSA grade 5 steel safe with Group 1R lock bolted to the floor"
☒ Cabinet	Small steel cabinet with double steel door and double cam lock mounted to the wall
☐ Other	
☒ Additional Security	If applicable, describe any badge access points and security cameras in use

Supervisor = Someone other than the Principal Investigator

Supervisor of Controlled Substance Activity	
Name: John Doe	Title: Lab Manager
Signature: <i>John Doe</i>	Type of Professional License and Number: NA

Other Requirements:

- Appendices A1 = Research protocol
https://www.health.ny.gov/forms/instructions/doh-4330_instructions_appendix_a1.pdf
- Curriculum Vitae – need to attach
- Describe your research project:
(ii) Name, schedule & quantity of the controlled substance(s) involved
(Attach additional sheets as necessary).

Name	Schedule	Quantity
Buprenorphine	III	5ml

(iii) Name, DEA registration & New York State controlled substance license for the manufacturer or distributor of controlled substance(s).

Name	DEA Registration	NYS controlled Substance License
Covetrus	RB0395219	02A1031
Covetrus	RB0395219	02A1031

(iv) If animals are to be utilized in the research provide:

Species	Number of Animals	Dose Regimen	Route of Administration
Mouse	100	0.1 mg/kg twice daily for 3 days	Subcutaneous

- Describe your storage = (Lockbox +/- Safe)

Describe in detail, all aspects of storage that will be utilized for this project. All storage must meet all requirements found in Article 33 and Part 80. A synopsis of these requirements can be found in the instructions for DOH-4330. Photographs of storage may also be submitted at the time of application. All storage must be installed and ready for inspection when submitting the application.

All controlled substances will be stored in a double-lock lockbox affixed to the wall with authorized badge access and security cameras in use.

OR

Working stock will be stored in a double-lock lockbox affixed to the wall while Main stock will be stored in a GSA Class 5 safe with authorized badge access and security cameras in use.

Policies and procedures must be submitted with the application. These must state all aspects of storage and access to controlled substances and

how prevention from diversion will be managed. If a controlled substance supervisor and/or other “authorized users” will have access to the controlled substances, the policies and procedures must reflect how security of the controlled substances will be maintained and how access will be controlled only to those people directly involved with the research project.

Standard Operating Procedure for controlled substance use is located on this page of the website. This includes procedures for purchasing, dispensing, documentation, and auditing of all controlled substances.

Repeat Appendix A1 for every protocol using controlled substances

Checklist for BNE license:

- ☒ New License Application DOH-4330
- ☒ Appendix A1
 - ☒ Curriculum Vitae of the Principal Investigator
 - ☒ Photo of storage
 - ☒ Standard operating procedure
- ☒ Repeat Appendix A1 for every protocol using controlled drugs

NOTE: Please send a copy of this of the License Application and the Class 4 & 7 Individual Researcher Protocol forms to the Office of Research Compliance.

Where to send the application:

New York State Department of Health Bureau of Narcotic Enforcement
Riverview Center
150 Broadway
Albany, NY 12204

bnelicensing@health.ny.gov