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 l	nformation		
Legal Name:				
d/b/a: Stony Brook Un	niversity			
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	Date proposed for controlled substance activity to begin
	change in owner ship will be subject	09/01/2024

	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 Classifica	ation (check	only one box)	New	Amendment
	·		License	Fee
			Renewal	
			Fee	
☐ Class 1 Manufa	acturer		\$1200	\$250
☐ Class 1a Manu	facturer (Ou	t-of State)	\$1200	\$250
☐ Class 2 Distribu	utor		\$1200	\$250
☐ Class 2a Distrib	outor (Out-o	f-State)	\$1200	\$250
☐ Class 3 Instituti	ional Dispen	ser	\$100	N/A
☐ Class Institution	nal Dispense	er Limited	\$100	N/A
	Individual	☐ Institutional	\$40	\$20
Researcher			Do not send	
(Schedules			money.	
II-V		J	State	
			employees	
			are exempt	
			from	
			licensing	
			fees.	

Controlled Substances Schedule = III-V

Controlled Substance Schedule(s) to be Utilized (check all that apply)

		× III	⊠IV	×V
If you have	o a cafa (not ivot	a laakhay): Salaat	F II A7	
ii you nave	a sale (not just	a lockbox): Select	l II-V	
Controlled	d Substance Sch	edule(s) to be Util	ized (check all tha	at apply)
	X II	× III	⊠IV	⊠V

Storage = Cabinet +/- Safe

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

Supervisor = Somone other than the Principal Investigator

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

Other Requirements:

- Appendices A1 = Research protocol <u>https://www.health.ny.gov/forms/instructions/doh-4330 instructions appendix a1.pdf</u>
- 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	Dose Regimen	Route of
	Animals		Administration
Mouse	100	0.1 mg/kg twice	Subcutaneous
		daily for 3 days	

Describe your storage = (Lockbox +/- Safe)

Describe in detail, all aspects of storage that will e 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:

- - □ Curriculum Vitae of the Principal Investigator
- ☑ 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