Controlled Substances
Standard Operating Procedures

Contents

1 Controlled Substances

1.1 Policy

Due to their abuse potential, drugs identified as controlled substances by the US Department of Justice, Drug Enforcement Administration (DEA), or New York State Controlled Substances Act; Article 33, and the Official Rules and Regulations of the New York State Department of Health are subject to extensive licensing, registration, storage, security, use, and disposal requirements. At Stony Brook University, the Office of Research Compliance (ORC) has the responsibility for assisting researchers in negotiating requirements, including obtaining appropriate regulatory documents. The Office of Research Compliance can be contacted at 631-632-9036 during regular business hours. Please note that this policy applies exclusively to the **research use** of controlled substances, **not including animal or human subject studies**.

1.2 Definitions

"Controlled Substance" - any "…drug, substance, or immediate precursor in schedules I to V, inclusive, of the New York controlled substance scheduling regulations adopted pursuant to New York State Controlled Substances Law Article 33."

"Schedules" - controlled substances are divided into five categories, known as Schedules. Schedules I and II are the most stringently regulated, and both have high potential for abuse. However, Schedule II drugs have a currently accepted medical use in treatment, while those in Schedule I do not. Schedule III drugs include many stimulants and depressants, pain-killers and cough suppressants, the veterinary anesthetic ketamine, and anabolic steroids. Schedule IV substances cover the balance of lower abuse potential stimulants and depressants, and Schedule V includes therapeutic drug mixtures containing very limited quantities of controlled substances.

"Principal Investigators" (PIs) using controlled substances in their research (including research involving animals and non-therapeutic research involving human subjects) are subject to extensive state and federal regulatory requirements. Note that these requirements (including licensing/registration with regulatory agencies) are separate from and in addition to requirements that apply to medical practice; therefore MDs conducting laboratory or non-therapeutic human subject research involving controlled substances must obtain licensure/registration for laboratory use of controlled substances.

1.3 Licensing and Registration

It is the responsibility of individual Principal Investigators (PI) to obtain appropriate licenses and registration, and to adhere to applicable state and federal regulatory requirements when

working with controlled substances. PIs must obtain research licensure from New York as well as registration from the federal DEA. Instructions for completing licensing/registration applications are summarized below:

State Licensing:

PIs must complete both the License Application to Engage in a Controlled Substance Activity (DOH-4330) and the Class 4 & 7 Individual Researcher Protocol forms and submit them to the Office of Research Compliance for processing. As part of the application process, the Office of Research Compliance will inspect the designated laboratory work area. Approved applicants will receive a 2-year state license to work with controlled substances in a manner consistent with the approved use(s) described in the application.

The BNE provides a renewal reminder notification via email at least 90 days prior to a license expiration. The licensee remains responsible for filing a complete and satisfactory renewal application prior to the expiration of the license. A digital photograph of storage is required to be submitted with the application package. Photographs of storage should depict all aspects of the storage and surrounding area, to include, but not limited to:

- Entrance and exits to the room where storage is installed
- All areas of the room (all walls to provide 360-degree view)
- All storage closed/locked and open to reveal all locking mechanisms in place and all doors and/or separated compartments.
- All security measures in-place (cameras, alarm system, biometric access, locked doors, etc.)
- All storage and security must be installed, operational, and ready to be inspected at the time the application is submitted to BNE. Failure to assure this may lead to denial of your application.

NOTE: The Office of Research Compliance also conducts periodic random inspections of licensees as well.

Federal Registration:

After receiving state licensing from New York, PIs will need a research laboratory registration form (Form DEA-225). This should be completed and returned to the Office of Research Compliance, where it will be processed for submission and payment to the DEA. Due to internal DEA protocols, PIs will receive their registration certificate (known as Form DEA-223) directly from the DEA. Upon receipt of certificates, PIs should make a copy and forward it to Stony Brook University Office of Research Compliance. DEA registration is valid for 12 months, at which time a renewal notice will be sent to the PI.

Note that a researcher may receive an initial registration period for a minimum of 9 months or a maximum of 15 months.
The DEA has also implemented an on-line registration system that can be directly accessed upon successful state licensing. Licensing information can be found here: https://www.deadiversion.usdoj.gov/online_forms_apps.html

Renewals, Modifications, Termination:
Registrants seeking to modify, transfer, or terminate their research laboratory use license and/or registration must submit a written request to the Office of Research Compliance.

New York State Department of Health - Bureau of Narcotic Enforcement

Renewal – Licenses require renewal every 2 years if there have been no changes to the licensee's controlled substance activity, name (legal, trade or d/b/a), ownership (operator), address, storage, and approved controlled substance schedules. Licensees whose license has been expired for more than 60 days are not eligible to renew their license, cannot conduct controlled substance activities, and must submit a "New" application. No extensions of expiration dates are allowed.

Modifications – Licensee changes including official name, address, or ownership must submit a new DOH-4330. Enter current and new information. Requires inspection. A new BNE license number may be issued. May require facility inspection by BNE (excluding out-of-state applicants).

Amendment – If you are submitting an application to amend your current license, attach to the application a narrative outlining the specific change(s) being requested.

Amendments are designated as 'Relocation' of storage, 'Add a Manufacturing or Distribution Activity', 'Add a Controlled Substance and/or Schedule' or 'Add a Further Activity'.

A licensee might not qualify to apply for an amendment and if so, will need to apply for a new license. An amendment may also be submitted for a change in or adding to the currently BNE approved storage for controlled substances.

Classes 4A, 4B, 5, 7A, and 7B are required to submit an application for amendment to their license for any change in research protocol that requires the addition or removal of a controlled substance or any other change in approve controlled substance activities.

Changes in licensed storage may be submitted as an amendment. Changes in storage may require an onsite inspection to be performed. This change may require facility inspection by BNE (excluding out-of-state applicants).

Drug Enforcement Administration

As of June 2020, Registrants will begin to receive renewal notifications approximately 60 days prior to the registration expiration date. 21 CFR 1301.13(e)(3). DEA no longer sends renewal notifications by U.S. Postal Service. Instead, an electronic reminder to renew will be sent at 60, 45, 30, 15, and 5 days prior to the expiration date of the registration to the associated email address. All registrants should ensure that the email address listed on their registration is correct and active. Registration is good for 1 year.

In addition, the Office of Research Compliance will dispatch frequent reminders to the DEA registrant as a courtesy to ensure continued compliance.

Renewal/reinstatement – Renewal of registration by the DEA is generally a 4-6-week process and is contingent upon the following criteria:

- *Renewal application submitted PRIOR to expiration date.* The registrant may continue operations, authorized by the registration, beyond the expiration date until final action is taken on the application. You can renew on-line or by completing a paper form.
- *Renewal application submitted AFTER expiration date.* The DEA will allow the reinstatement of an expired registration for one calendar month after the expiration date. If the registration is not renewed within that calendar month, an application for a new DEA registration will be required.

Note: Federal law prohibits the handling of controlled substances or List 1 chemicals for any period of time under an expired registration.

It is the responsibility of the DEA Registrant to renew his/her registration prior to its expiration and provide ORC with a copy of the renewed license.

DEA Registrants may call the DEA at **1-800-882-9539** to check on the status of their application, call their nearest DEA Field Office or email the DEA at: DEA.Registration.Help@dea.gov - Be sure to include your DEA Registration number in your email.

Copies of renewed DEA registrations must be submitted to the Office of Research Compliance.

If using a paper form the renewal application should be mailed to the following address:

Drug Enforcement Administration
Diversion Control Division
Attn: Registration & Program Support Section/DRR
P.O. Box 2639
Springfield, VA 22152-2639

Modification - A researcher may apply to modify a DEA registration at any time. Modifications can include change of business and/or mailing address, name change, addition of new drug codes, or change of drug schedules. There is no fee for a modification of registration. Modifications are handled in the same manner as applications and must be approved by DEA.

Every registrant under 21 U.S.C. 801-904 shall be required to report any change of professional or business address in accordance with DEA regulations. 21 U.S.C. 827(h). A researcher that moves to a new physical location must first request a modification of registration. The request must contain the registrant's name, address, and registration number as printed on the Certificate of Registration; the new name or address; and a signature in accordance with 21 CFR 1301.13(j). If the registrant's change of address involves changing the registrant's state, then the registrant must first provide the proper state-issued license in that new state and, if applicable, the proper state-issued controlled substances registration in that new state, prior to DEA's approval of any modification of the federal registration. 21 U.S.C. 823(f).

Termination - A researcher's registration shall terminate, without any further action by DEA, if and when a researcher dies, if a business ceases legal existence, if a researcher discontinues business or professional practice, or when a researcher surrenders a DEA registration. 21 CFR 1301.52(a).

If a researcher discontinues business activities either completely or only regarding controlled substances, the researcher must promptly notify the local Special Agent in Charge and seek authority and instructions to dispose of any controlled substances obtained under the authority of that registration. A researcher that discontinues business must return their DEA registration certificate to the local DEA Registration Program Specialist. 21 CFR 1301.52(c).

In the event a state board revokes a researcher's license or registration, DEA will request a voluntary surrender of that DEA registration. If a researcher surrenders their DEA registration for cause, it shall be terminated when a duly executed DEA Form 104, Voluntary Surrender of Controlled Substances Privileges, or any signed writing indicating a desire to surrender a registration is received by any DEA employee. 21 CFR 1301.52(a). If a researcher refuses to surrender their registration, DEA will pursue administrative action to revoke the DEA registration based on lack of state authorization. DEA may also pursue civil or criminal sanctions if there is sufficient evidence to justify a prosecution. All such actions are designed to protect the public health and safety.

Unwanted controlled substances in the researcher's possession must be disposed of in accordance with DEA regulations

Denial, Suspension, or Revocation of Registration - Under 21 U.S.C. 824(a), DEA has the authority to deny, suspend, or revoke a DEA registration upon a finding that a researcher has does any of the following:

1. Materially falsified the application.
2. Been convicted of a felony relating to a controlled substance or a List I chemical.
3. Had a state license or registration suspended, revoked, or denied by a competent state authority and is no longer authorized by state law to engage in the manufacturing, distribution,
   or dispensing of controlled substances or List I chemicals, or has had a suspension, revocation, or denial of a registration recommended by a competent state authority.
4. Committed an act which would render the DEA registration inconsistent with the public interest.
5. Been excluded (or directed to be excluded) from participation in a Medicare or state health care program.

1.4 Purchasing

Controlled substances are considered "restricted purchase items" at Stony Brook University and may only be ordered through procurement. Researchers are required to provide a copy of their current license to procurement at the time of each purchase. **Please note that Medical Practitioners may NOT use their prescription privileges to order controlled substances for in-vitro benchtop use.**

1.5 Scope of Use

Controlled substances may be used only for duly authorized, legitimate medical or scientific research purposes, to the extent permitted by a registrant's license and registration, and in conformity with state and federal statutes and regulations.

A PI may authorize members of their laboratory staff to work with controlled substances under their license/registration. Authorized staff must follow all of the rules and regulations outlined and referenced in this Policy, and are also obligated by law to immediately report any loss or diversion of controlled substances to their PI, Stony Brook Police Department, and Office of Research Compliance. Persons previously convicted of a felony offense relating to controlled substances or who, at any time, had an application for registration with the DEA denied, had a DEA registration revoked, or surrendered a DEA registration for "cause", may not be authorized for work with these materials. (In this instance, "cause" is the surrender of a license or registration resulting from a federal or state investigation into an individual's handling of controlled substances.)

1.6 Storage and Security Controls

Controlled substances must be maintained in a manner and location that complies with state and federal law. Any controlled substances not so maintained are subject to seizure and

forfeiture. Failure to comply with applicable requirements may also result in a suspension of the PI's purchasing privileges and disciplinary actions.

In order to guard against theft or diversion, all controlled substances - regardless of schedule - must be kept under lock and key, and accessible only to authorized personnel. The number of authorized staff must be kept to the minimum essential for efficient operation, and the stock of controlled substances must be limited to the smallest quantity needed.

Security requirements vary by drug schedule. Schedule I controlled substances are subject to the highest security requirements and must be stored separately from other drugs in an approved safe (as defined below). Schedule III through V substances must also be stored separately from other drugs in a secure locked location. Regardless of schedule, all controlled substances must be kept locked in their storage location except for the actual time required for authorized staff to remove, legitimately work with, and replace them.

Safes for Schedules I: An approved safe is one approved by the DEA prior to January 1, 1975, or any safe that minimally conforms to all of the following standards:

- Safe Manufacturer's National Association certified as being Class A, B or C.
- Underwriters Laboratories certified as being inspected for one or two hours.
- Underwriters Laboratories certified as being equipped with a relocking device.
- Weight of 750 pounds or more, **or** rendered immobile by being securely anchored to a permanent structure of the building.

The Office of Research Compliance can provide recommendations for safes that comply with these requirements.

1.7 Export

Federal law prohibits the export of controlled substances unless certain requirements are met, including, in most cases, export and import permits. Violators of the law risk arrest at U.S. Customs or on airplanes, imprisonment, and fines both in the United States and foreign countries. Licensed brokers are available for the transport of controlled substances.

1.8 Recordkeeping

PIs must maintain complete and accurate inventory records for all controlled substances. These records must be kept separately from all other records and documents, in or near the primary work area, and be readily available for inspection during regular work hours or at any other reasonable time. Records must be written, typewritten, or printed. The use of codes, symbols, or foreign languages in identifying a controlled substance or person in the record is prohibited. Records should be kept in such a manner as to facilitate quick and accurate assessment of quantity on hand and history of use to the individual container level. In the

event that any controlled substances are lost, destroyed, or stolen, the kind and quantity of the material and the date of discovery of such loss must be recorded in detail. All records must be maintained by PIs for a period of at **least three years** from the date of the last recorded purchase, transfer, use, or other transaction involving the controlled substance.

The recordkeeping system must include at least the following information maintained as prescribed in state and federal controlled substance laws and regulations:

- Receipt of Controlled Substance: A separate and current record of the receipt of controlled substances, indicating date received, name and address of supplier, and the type, strength or concentration, and amount of the controlled substances received. Each record must be signed by the person receiving the controlled substance. DEA Form 222 and invoices should be maintained separately as applicable.
  - Executed official order forms (DEA Form 222) or the electronic equivalent.
  - Unexecuted official order forms (DEA Form 222).
  - Power of Attorney authorization to sign order forms, if applicable.
  - Receipts and/or invoices for schedules III, IV, and V controlled substances.

- Use of Controlled Substances: A separate and current record for the storage and use of each controlled substance (use meaning to administer, dispense, professionally use, or otherwise dispose of), indicating the date, building and room, specific research experiment, controlled substance's application in the research, and type, strength and quantity of each controlled substance use. By noting starting volume or mass of substance in the container, each use is a subtraction from the starting quantity, and the running (decreasing) amount should equal the total amount remaining on-hand. Each record of use must be signed by the person working with the controlled substance. The inventory should also include a detailed list of any controlled substances lost, destroyed, or stolen, including the type, strength, and quantity of such substances, and the date of the discovery of such loss, destruction, or theft.
  - Records of controlled substances distributed (i.e., sales to other registrants, returns to vendors, distributions to reverse distributors).
  - Records of dispensing (dispensing log).
  - All inventory records of controlled substances, including the initial and biennial inventories, dated as of beginning or close of business.
  - Reports of Theft or Significant Loss (DEA Form 106), if applicable.
  - Inventory of Drugs Surrendered for Disposal (DEA Form 41), if applicable. 21 CFR 1304.22(c).

Biennial Inventory of Controlled Substances:

A complete and accurate inventory of the stock of controlled substances within each PI's laboratory must be recorded when he/she first engages in research with controlled substances and then biennially thereafter, **within four days of May 1** of each odd numbered year (2009, 2011, 2013, etc.). The inventory can be taken either as of the opening of business or the close of business on the inventory date and this should also be noted on the inventory. The type, strength, and quantity of all controlled substances must be recorded at this time in the manner prescribed in DEA regulations. The person conducting the inventory must also date and sign the record. Reminder notices and forms will be distributed by Stony Brook University Office of Research Compliance several weeks in advance. This biennial inventory must be retained on the laboratory premises for three years, separate from other business records and readily available for potential regulatory review as described above. Records must kept for a minimum of 2 years.

1.9 Disposal

Controlled substances from non-human research work may only be disposed under witness from the Federal DEA, through a reverse distributor by documented return to the supplier or manufacturer, or as otherwise authorized or directed by regulatory agency personnel. Expired material, unused or unwanted product, or neat waste must be accumulated and stored under lock and key until ready for disposal. The Office of Research Compliance should be contacted to arrange for a disposal visit or permission to otherwise dispose of controlled substances. Controlled substances consumed in a reaction, or converted into a non-recoverable hazardous waste mixture may be disposed of through routine waste disposal procedures.

All controlled substances to be destroyed by a registrant, or caused to be destroyed by a registrant pursuant to 21 CFR 1317.95(c), must be destroyed in compliance with applicable federal, state, tribal, and local laws and regulations and must be rendered non-retrievable. 21 CFR 1317.90(a). A researcher may dispose of its controlled substances inventory in the following manner:

1. Promptly destroy that controlled substance in accordance with 21 CFR 1317.90 using an onsite method of destruction. 21 CFR 1317.05(a)(1).
2. Send controlled substances to an entity registered with DEA to handle returns/disposals (known as a reverse distributor). 21 CFR 1317.05(a)(2).
3. Contact the local DEA Diversion Field Office to request assistance to dispose of the controlled substances pursuant to 21 CFR 1317.05(a)(4).
4. For the purpose of return or recall, promptly deliver the controlled substance by common or contract carrier pick-up or pick-up by other registrants at the registrant's registered location to:
   The registered person from whom it was obtained, the registered manufacturer of the

substance, or another registrant authorized by the manufacturer to accept returns or recalls on
the manufacturer's behalf. 21 CFR 1317.05(3).

A record of the destruction should be kept pursuant to 21 CFR 1304.21(e).

1.10 Reporting of Loss, Destruction, Theft, or Unauthorized Use

Any losses of any controlled substance, including thefts, unauthorized uses, or unauthorized destruction must be reported to the Stony Brook University Police Department and Stony Brook University Office of Research Compliance immediately upon discovery. Registrants must also document the incident in writing for submittal to the Federal DEA (within one business day). The BNE requires the use of form DOH-2094 for reporting the loss of controlled substances, submitted within 1 business day of the incident.

The written statement must describe the kinds and quantities of controlled substances in question, and the specific circumstances involved. If the circumstances are unknown, immediate notice should still be given to regulators and a complete statement provided thereafter if the loss is substantiated. Regulators should be kept apprised of any ongoing investigation and notified if the loss is not subsequently substantiated. In addition, where a controlled substance is stolen, lost, or destroyed in transit, the consignee (and consignor if within this state) is also required to prepare a loss report that includes documentary evidence that local authorities were notified. The registrant should retain a copy of the statement for at least three years.

1.11 Resources and References

Stony Brook University Purchasing Department - Research and Development Campus, Building 17, Stony Brook University, New York 11795-6000 (631) 632-6010

Office of Research Compliance - W5530 Frank Melville Jr. Memorial Library (631) 632-9036

Stony Brook University Police Department - Dutchess Hall on South Campus. Dial 333 from campus phones or (631) 632-3333/(631) 632-6350 from non-campus phones.

State of New York Department of Health – 433 River Street, Suite 303 Troy, New York 12180-2299 (518) 402-0707

New York Bureau of Narcotic Enforcement (866) 811-7957

New York licensing bnelicensing@health.ny.gov.

US Dept. of Justice, Drug Enforcement Division (DEA) (www.dea.gov) (212) 337-3900 (New York Area Office) 10th Avenue New York, NY 10011