# STATE OF NEW YORK
# DEPARTMENT OF HEALTH

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Dear Class 4 and/or Class 7 Researcher Licensee:

The Department of Health's Bureau of Narcotic Enforcement recently redesigned several aspects of the process to obtain a controlled substance license. This redesign will affect researchers holding Class 4 and/or Class 7 controlled substance licenses as detailed below.

**Redesigned Application Process**

Consistent with past practice, the renewal of a controlled substance license will still require the submission of a *License Application to Engage in a Controlled Substance Activity* (DOH-4330) to the Bureau of Narcotic Enforcement. However, in the fall of 2008, use of a revised application will be implemented. The revised application will more comprehensively document that applicants have satisfied the licensing requirements as outlined in Article 33 of the Public Health Law (PHL) and the Part 80 Rules and Regulations on Controlled Substance in New York State. The Bureau of Narcotic Enforcement will provide applicants with the materials necessary for renewal at least 90 days prior to the expiration date of their license.

**Submission Requirements**

Applicants for Class 4 and/or Class 7 **(individual)** researcher licenses will be required to submit the following information as part of their initial and renewal applications:

- ✓ The curriculum vitae of the individual responsible for overseeing the controlled substance activity.
- ✓ A controlled substance protocol, which includes the nature and objective of the project(s), a listing of controlled substances to be utilized, the quantity of the substances and the Drug Enforcement Administration registration number of both the researcher ordering and the distributor or manufacturer providing the substances.
- ✓ If animals are used in the research, the species, number of animals, dose regimen and route of administration of controlled substances must be included.
- ✓ If the research involves the dispensing, administration or prescribing of controlled substances to human subjects, the corresponding Institutional Review Board approval must be submitted.

Applicants for Class 4 and/or Class 7 **(institutional)** researcher licenses will be required to submit the following information as part of their application:

- ✓ A description of the system within the institution (e.g., committee) for approving, supervising and evaluating projects.
- ✓ The name of each committee member that will approve specific projects and his/her qualifications to serve on the committee.
- ✓ A listing of each currently approved and active project involving controlled substances, including the name of the project, names and qualifications of the individuals working on and supervising the project, the controlled substances being utilized, the quantity of the substances and the Drug Enforcement Administration registration number of both the researcher ordering and the distributor or manufacturer providing the substances.
- ✓ If the research involves the dispensing and administering of controlled substances to human subjects, the corresponding Institutional Review Board approval must be submitted.

Of particular note to institutional researchers is Section 3326 of the Public Health Law, which requires that **upon approval of each project**, the institution shall provide specific information related to the project to the Department of Health. A system to allow for the electronic reporting of this information is currently being developed and is expected to be in place by 2009. As planned, each institutional researcher licensee will be required to apply to establish an account through the Department of Health's Health Commerce System for the purpose of electronically reporting specific project information upon approval of each project.

In late 2008, follow-up will be conducted with all Class 4 and Class 7 institutional researcher licensees in an effort to ensure that the project information currently on file with the Bureau of Narcotic Enforcement is complete and up-to-date. At that time, the following information relative to each of the institution's approved and active projects will be requested.

| | | |
|---|---|---|
| Licensee: | | |
| Controlled Substance License # | DEA Registration # | |
| Project Name: | | |
| Project Duration: | | |
| Principal Investigator: | | |
| Degree/Professional License (if any) | | |
| Project Supervisor: | | |
| Degree/Professional License (if any) | | |
| IRB # (if applicable): | | |
| *Controlled Substances Utilized (list each)* | *Quantity* | *DEA Registration # of distributor or manufacturer providing controlled substances* |
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**Record Keeping and Inventory**

Class 4 and Class 7 researchers should be aware of their record keeping and inventory responsibilities. Researchers are required to keep records showing receipt, administration, dispensing or destruction of all controlled substances and maintain the records, as noted below.

Records relating to the receipt of controlled substances must include the date of receipt, name and address of vendor and type and quantity of the drug received. Records of controlled substances used must include the name of the person authorized to control and use the substances, the date, type and quantity of the substances and signature of the user.

In addition to the above, every two years, researchers must prepare an inventory of all controlled substances. This inventory must be retained on file with other controlled substances records and be kept available for inspection for at least five years.

In addition to the project information that will be requested at the end of 2008, Class 4 and Class 7 researchers will also be asked to provide a current inventory of their controlled substances.

*The record keeping and inventory requirements noted above are outlined in PHL Section 3329 and Section 80.37 and 80.112.*

**Reporting of Dispensing Information**

In addition to the above, practitioners who dispense controlled substances are required to file with the Department of Health information regarding such dispensing. "Dispense" means to deliver a controlled substance to an ultimate user or research subject by lawful means and includes the packaging, labeling or compounding necessary to prepare the substance for such delivery.

Researchers holding Class 4 and/or Class 7 controlled substance licenses are deemed to be practitioners under Article 33. Researchers who dispense controlled substances to research subjects as part of their protocols (as authorized by their controlled substance license) are required to report such dispensing to the Department. Researchers are not required to report the prescribing or administration of a controlled substance to a research subject.

Through the Department of Health's Health Commerce System, practitioners must also report specific controlled substance dispensing information electronically by the 15th of the month following the month in which the controlled substance was dispensed.

Researchers who dispense controlled substances as part of their research protocols must apply on line at https://commerce.health.state.ny.us/pub/ to establish a Health Commerce System account.

*The dispensing information requirements noted above are outlined in PHL Section 3331(6) and 80.71(e).*

**Drug Destruction**

Researchers in possession of controlled substances which are undesired, deteriorated, obsolete or for any reason no longer needed must request from the Bureau of Narcotic Enforcement approval for the on-site destruction of the controlled substances. This process requires the submission of a *Request for Approval of On-Site Destruction of Controlled Substances* (DOH-2340) and *Controlled Substance Inventory Form* (DOH-166). These forms can be downloaded from the Department of Health Web site at http://www.nyhealth.gov/professionals/narcotic/forms.htm.

Please note that any person holding a Federal registration number who is in possession of a controlled substance listed in any schedule may return that substance to either the distributor from whom he/she obtained it or to the manufacturer of the substance, provided that the appropriate forms are utilized and/or applicable records are kept. A distributor or manufacturer must accept full packages of controlled substances still in their sealed containers, but may choose to accept partial containers, as well.

*The drug disposal requirements noted above are outlined in 80.51 and 80.52.*

**Theft or Loss**

Researchers are also under a continuing duty to promptly notify the Bureau of Narcotic Enforcement of any theft, loss or possible diversion of controlled substances using the *Loss of Controlled Substances Report* (DOH-2094). This form can be downloaded from the Department of Health Web site at http://www.nyhealth.gov/professionals/narcotic/forms.htm.

*The theft or loss requirements noted above are outlined in PHL Section 3374 and Part 80.20.*

All of the above requirements, as outlined in Article 33 and Part 80, can be viewed on the Department of Health Web site at www.health.state.ny.us/professionals/narcotic/.

The Bureau of Narcotic Enforcement is committed to ensuring a smooth transition to this process. In this regard, you are encouraged to contact the Bureau with any questions at 1-866-811-7957 (Option #3).

Sincerely,

Paula Johnston
Health Program Administrator