

Title: Use of Controlled Substances in Research and Instructional Activities Policy	Policy Category: Research
Issuing Authority: Office of the Vice President for Research	Responsibility: Office of Research Compliance
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Printed copies are for reference only. Please refer to the electronic copy for the latest version.

Policy Statement/Background:

None

Policy:

Certain research and instructional activities conducted under the auspices of this University require the use of controlled substances. Controlled substances, which are drugs with high potential for abuse, are identified in the schedules contained within the Controlled Substance Inventory List, published by the Drug Enforcement Administration (DEA) of the U.S. Department of Justice. Faculty, staff and students of the University must comply with all applicable state and federal laws and regulations that govern the procurement, use and documentation of controlled substances. The University reserves the right to conduct audits and inspections to assess such compliance.

Use of Controlled Substances Within the DLAR

The Division of Laboratory Animal Resources (DLAR) is licensed to conduct research with controlled substances (specifically those substances listed in schedules II-V). DLAR purchases analgesics and anesthetics commonly used in animal care, some of which are controlled substances. Investigators having need for these substances for routine veterinary use within DLAR facilities may obtain them from DLAR staff. Anyone using controlled substances for any other purpose within DLAR must first obtain an individual license from the State and a registration from the DEA.

Use of Controlled Substances in Patient Care Activities

The University Hospital, Dental Care Center and the University Health Service each holds institutional dispensing licenses that allow for controlled substance use in patient care activities conducted within those sites only. The activities of these facilities are governed by internal policies and procedures, and specific state and federal laws and regulations. Controlled substances for patient use may only be prescribed by faculty holding appropriate DEA and state registration. University Hospital house staff may prescribe controlled substances under the institutional registration after obtaining appropriate authorization.

Individual Licensure for Research and Instructional Activities:

Faculty members must obtain an individual license and registration for the use of controlled substances in research and instructional activities not covered under preceding sections unless they are members of a department that obtains a departmental license (see below). Faculty members who serve as either principal investigators or supervisors of the research or instructional activity in which controlled substances are used are personally responsible for:

- Obtaining and maintaining appropriate licensure from the NYS Department of Health.
- Obtaining and maintaining appropriate registration with the Drug Enforcement Administration.
- Submitting copies of the license and registration to the Office of Research Compliance each time they are issued or renewed.
- Complying with all state and federal laws and regulations pertaining to such use of controlled substances, including license/registration restrictions, and requirements regarding physical and other security, disposal of outdated stock, and inventory and record-keeping procedures.

Departmental Licensure

Departments with a number of faculty working with controlled substances may find it efficient to obtain licensure at the departmental level. The department chair then assumes the responsibilities listed above.

Additional Requirements

Investigators are responsible for obtaining all applicable institutional approvals (e.g., Institutional Animal Care and Use Committee, Committees on Research Involving Human Subjects, etc). Applicants who are submitting research proposals to a sponsor for funding are required to report their intention to use controlled substances to the Office of Sponsored Programs.

Definitions:

None

Contact:

Additional information about this policy is available here:

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<https://www.stonybrook.edu/commcms/research-compliance/index.php>

Relevant Standards, Codes, Rules, Regulations, Statutes and Policies:

- [The Controlled Substances Act](#)
- [Code of Federal Regulations, Title 21, Chapter II \(Parts 1300-1308\)](#)
- [NYCRR Title 10, Chapter II, Subchapter K - Controlled Substances \(Part 80\)](#)
- [Stony Brook Office of Research Compliance Website, Controlled Substances](#)