

# NYU CONTROLLED SUBSTANCES USE AND DISPOSAL POLICY

## PRINCIPAL INVESTIGATOR RESPONSIBILITIES SUMMARY

### 1.0 General responsibilities for Principal Investigator (PI) or their designee:

- 1.1 Familiarizing themselves with the hazards and effects of the controlled substances they use through attendance at training sessions conducted by the NYU Operational Risk Management Department;
- 1.2 Receiving, storing, and dispensing controlled substances in approved locations in accordance with the Policy;
- 1.3 Maintaining a controlled substances inventory, as per the policy;
- 1.4 Notifying their supervisors of exposures, spills or any other pertinent problems.

### 2.0 Specific Responsibilities for Principal Investigator or their designee

- 2.1 In order to use controlled substances for research purposes, PI work under the license of the Unit Registrant (holds DEA and Bureau of Narcotic Enforcement registrations for their department).
- 2.2 PI shall keep a record of all such substances received and used by them. Forms can be found in Appendix B of the policy.
- 2.3 A receipt record of all controlled substances received shall include date of receipt, name and address of vendor, type and quantity of drug received. A duplicate invoice or separate itemized list furnished by the vendor will be sufficient to meet this record requirement providing it contains all the information required (See Form 2 in Appendix B of the policy).
- 2.4 Use records of all controlled substances used shall include: the name of the person authorized to control and use such drugs, the date, name, schedule, quantity of drug, and initials or signature of the user (See Form 3 in Appendix B of the policy).
- 2.5 In addition, such records shall contain the following information for each controlled substance:
  - Name of substance;
  - Each finished form (such as 10 mg. tablet or 10 mg. concentration per fluid ounce or milliliter) and the number of units or volume of finished form in each commercial container;
  - The number of commercial containers of such finished form received from other persons, including the date of and number of containers in each receipt, and the name, address, and registration number of the person from whom the containers were received;
  - The amount of such finished form dispensed, including the name and address of the person to whom it was dispensed, the date of dispensing, and the written or

typewritten name or initials of the individual who dispensed or administered the substance.

- 2.6 A Record of Utilization of Controlled Substances form can be used to monitor the use of these controlled substances. These forms could also be used to record the results of physical inventories required by New York State Bureau of Narcotic Enforcement.
- 2.7 The NYSDOH Bureau of Narcotic Enforcement requires records to be kept for 5 years. The Drug Enforcement Administration (DEA) requires records to be kept for at least two years, for inspection and copying by officers or employees of the United States authorized by the Attorney General.
- 2.8 As new containers of controlled substances are received, each container must either maintain its original label, or have a new label with the appropriate information affixed to the container (see 2.11 for appropriate information needed).
- 2.9 For each container a receipt record must be created; it must be recorded as inventory and stored appropriately.
- 2.10 The label of a drug listed in schedule II, III, or IV must contain a clear, concise warning that it is a crime to transfer the drug to any person other than the intended recipient.
- 2.11 The label must include chemical name. No abbreviations, structures or formulae should be used. If the container has the original label, the information on the label will be sufficient to meet this requirement.
- 2.12 Controlled substances (including expired controlled substances) must be properly safeguarded and securely stored. At a minimum, a solid metal cabinet or safe is compliant with the NYSDOH code with separate outer and inner, key-locked doors is required for drugs in Schedules III, IV and V. A safe is required for Schedules I and II drugs. See policy for access log.
- 2.13 A documented, physical inventory of controlled substances (See Form 4 in Appendix B of the policy) must be taken biennially.
- 2.14 All orders for controlled drugs must be on approved NYU requisition order forms, be approved by the Office of Veterinary Resources Business Manager or designee and follow University procedure for ordering supplies
- 2.15 A DEA triplicate order form must be used for ordering Schedule I and II Controlled Substances, along with the NYU requisition order form.
- 2.16 Orders for Schedules III through V controlled drugs do not require a special

the government order form, but the licensee's typed DEA research number must be on the NYU purchase requisition form.

2.17 There are three disposal options for expired or unwanted controlled substances recommended. Expired controlled substances can be accumulated for disposal, but must be secured. The methods are return to supplier, sink disposal or reverse distribution. DEA and NY State DOH forms need to be completed and approved prior to disposal. Review the policy for details

2.18 Spills - Breakage, spills, or other witnessed controlled substance losses must be documented by the researcher and witnessed on the inventory record.

2.19 Loss or theft - Any loss or theft of controlled substances must be reported to NYU Operational Risk Management Department for investigation to determine if further action is required.