

Policy #0101

Ordering, Storage and Use of Controlled Substances In Experimental Animals

DRUGS COVERED

The policy shall cover all drugs classified as controlled substances by the Federal Government and the State of New York, including drugs in classes I - V. Class I controlled substances, such as “ecstasy” have no medicinal value but may be used in studies in experimental animals, while drugs in classes II - V are used in animals as anesthetics and analgesics.

RESPONSIBLE STAFF

The Principal Investigator (PI), as named on the animal use protocol form, will be responsible for controlled substances used in animals listed under their approved protocols. The PI is responsible for oversight of purchasing, storage, use and disposal of controlled substances for his/her laboratory. The PI is responsible for training new employees, although he/she may gain assistance and advice from members of the Institutional Animal Care and Use Committee (IACUC) or the Institute for Animal Studies (IAS). The New User’s Orientation to Animal Use Face to Face training includes discussion of the purchase, use, storage and disposal of controlled substances.

REGISTRATION

Each PI must obtain and maintain appropriate registration to purchase and use controlled substances. Each PI with a M.D. degree or with an M.D. degree plus a Ph.D. must be registered with the Federal D.E.A. Each PI with a Ph.D. degree or a D.V.M./V.M.D. degree without a M.D. degree must be registered with the Federal D.E.A and the N.Y. State DOH. Forms and information are available at:

- <https://www.deadiversion.usdoj.gov/drugreg/index.html#regapps>
- www.health.ny.gov/professionals/narcotic/forms.htm

PURCHASE

Controlled substances for use in animal research using University funds or grant funds must be purchased through the Purchasing Department (Purchasing) of Albert Einstein College of Medicine (Einstein). Purchasing will track all purchases of controlled substances for use in animals and will provide a report, upon request, to Dr. Lawrence Herbst, Director of the IAS, or Dr. Linda Jelicks, the Animal Program Compliance Coordinator, so that they can confirm that all purchases were in accordance with an approved protocol and can include those laboratories ordering controlled substances in semiannual IACUC inspections.

STORAGE

Regulations require that controlled substances must be stored under double locks at all times except when drugs are being withdrawn from containers. The preferred location for storage is a double-lock drug box or a locked safe in a locked room. Locations for storage of controlled substances will be inspected twice yearly by members of the IACUC as they inspect laboratories utilizing animals

RECORDS

Each PI is responsible for maintaining appropriate records of acquisition, use and disposal of controlled substances, as required by Federal and New York laws and regulations. These records will be inspected twice yearly by members of the IACUC as they inspect laboratories utilizing animals.

SHARING AND BORROWING

Sharing and borrowing of controlled substances between staff or between laboratories must be in compliance with requirements of individual licenses. The license holder must be listed as approved personnel on the animal use protocol under which the controlled substances will be used in animals.

PURCHASE FROM THE IAS

Purchasing controlled substances from the IAS is not allowed at Einstein as per Drug Enforcement Agency Rules and Regulations.

DISPOSAL OF CONTROLLED SUBSTANCES

Expired or unneeded controlled substances must be discarded or returned as dictated by federal and state laws and regulations. For New York State Drug Enforcement Agency's

instructions and forms regarding the destruction of controlled substances, please visit the following website: <http://www.health.ny.gov/professionals/narcotic/forms.htm>.

REPORTING OF MISHAPS

The PI must promptly report any mishaps with controlled substances to the Director of Security of the Resnick Campus, to the Chairman of the IACUC, and to the respective agencies (DEA and NYS-DOH) according to their controlled substance licensing requirements. Reportable mishaps will include, but are not limited to: losses, discrepancies in written records, disappearances of written records, or suspected dilution.

REVIEW OF THIS POLICY

This policy, once enacted, will be reviewed twice yearly by the IACUC as part of semi-annual program and facility evaluations.