

RESOLUTION-POLICY

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| X | Action Item |
| | For Information Only |

From: Dr. William Freind, Rowan University Senate President

To: Dr. James Newell, Provost

Date: 3/20/14

RE: Senate Resolution *140307-1*

Use of Controlled Substances in Laboratory Animals Policy PROPOSAL

Whereas, the University must maintain compliance with regulations and guidelines governing the use of controlled substances in research using living animals, specified in the Controlled Substance Act (CSA), which is enforced through the Drug Enforcement Agency (DEA) and Food and Drug Administration (FDA), as well as the Animal Welfare Act and United States Department of Agriculture Animal Care Policy;

Whereas, the university does not currently have such a policy in place;

THEREFORE LET IT BE RESOLVED, that the current Use of Controlled Substances in Laboratory Animals Policy be approved.

USE OF CONTROLLED SUBSTANCES IN LABORATORY ANIMALS POLICY

ROWAN UNIVERSITY

I. Introduction

Live animals used in research need to be cared for in a manner that is consistent with acceptable and adequate veterinary care guidelines and recommendations as put forth in the Animal Welfare Act and as stated in the United States Department of Agriculture Animal Care Policy.

In order to meet the guidelines and regulations so that adequate and acceptable veterinary care is provided to all laboratory animals, researchers may require the mechanisms and ability to procure, store, administer and dispose of controlled substances, which are regulated through the Controlled Substance Act.

The policy set forth below provides guidelines to acquire and retain controlled substances and provide proper and humane care to laboratory animals.

II. Definition of Controlled Substances

Controlled substances are drugs or other substances regulated under the Controlled Substance Act (CSA) and enforced through the Drug Enforcement Agency (DEA) and Food and Drug Administration (FDA). Controlled substances are listed on a schedule, which bases the classification of the controlled substances on the following factors based on medical use, potential for abuse, and safety. Schedules range from I to V. To review the Schedule of Controlled Substances, please visit the U.S. Department of Justice Drug Enforcement Administration, Office of Diversion Control webpage at

<http://www.deadiversion.usdoj.gov/21cfr/cfr/2108cfrt.htm>.

Schedule I Drug

- The drug or other substance has a high potential for abuse.

- The drug or other substance has no currently accepted medical use in treatment in the United States.
- There is a lack of accepted safety for use of the drug or other substance under medical supervision.

Schedule II Drug

- The drug or other substance has a high potential for abuse.
- The drug or other substance has a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions.
- Abuse of the drug or other substances may lead to severe psychological or physical dependence.

Schedule III Drug

- The drug or other substance has a potential for abuse less than the drugs or other substances in schedules I and II.
- The drug or other substance has a currently accepted medical use in treatment in the United States.
- Abuse of the drug or other substance may lead to moderate or low physical dependence or high psychological dependence.

Schedule IV Drug

- The drug or other substance has a low potential for abuse relative to the drugs or other substances in schedule III.
- The drug or other substance has a currently accepted medical use in treatment in the United States.
- Abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule III.

Schedule V Drug

- The drug or other substance has a low potential for abuse relative to the drugs or other substances in schedule IV.
- The drug or other substance has a currently accepted medical use in treatment in the United States.
- Abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule IV.

III. Definitions of Terms

Expiration – The month *after* the date indicated on the container or manufacturer's packaging/label

Non-drug Medical Materials – Includes things like sutures, wound clips, catheters, needles, syringes, and any other medical device or non-drug material used during the course of veterinary care on laboratory animals

Non-survival procedure (acute/terminal) – A procedure in which the animal is euthanized before anesthetic recovery

Survival procedure – A procedure from which the animal recovers from anesthesia

Registrant – Individual, who either is in the process of or has in their possession a registration from the federal government or state government, that grants the individual authority to dispense or administer a controlled substance as defined and set forth in the Controlled Substance Act

Administer – Direct application of a controlled substance to the body of a patient or research subject by a practitioner (or, in his presence, by his authorized agent), or the patient or research subject at the direction and in the presence of the practitioner, whether such application be by injection, inhalation, ingestion, or any other means

Agent – Authorized person who acts on behalf of or at the direction of a manufacturer, distributor, or dispenser; except that such term does not include a common or contract carrier, public warehouseman, or employee of the carrier or warehouseman, when acting in the usual and lawful course of the carrier's or warehouseman's business

Dispense – Deliver a controlled substance to an ultimate user or research subject by, or pursuant to the lawful order of, a practitioner, including the prescribing and administering of a controlled substance and the packaging, labeling or compounding necessary to prepare the substance for such delivery. The term "dispenser" means a practitioner who so delivers a controlled substance to an ultimate user or research subject.

IV. Policy

Scope

This policy applies to all Rowan University faculty and investigators proposing to conduct or conducting research that may or does require the use of Controlled Substances.

When registering with federal and state agencies and departments, an approved Institutional Animal Care and Use Committee (IACUC) protocol must be associated and done prior to the registration process so that adequate support and verification of the allowable use of the controlled substance can be validated with government departments

and agencies as well as with the Rowan University Research Office.

Registration

All Rowan University faculty and investigators having a legitimate need and use to order, store, handle, use, and dispose of controlled substances for the purpose of conducting research must notify the Research Office and all of the appropriate government agencies and departments prior to any such activities being undertaken.

A registrant must notify the Research Office using the Controlled Substance Notification Form. Federal and state registrations must be renewed annually, and it is the responsibility of the registrant holder to complete the annual renewal form and submit to the appropriate governmental agencies. As the registrant of the controlled substances, the registrant is responsible for all controlled substances under their responsibility being administered, dispensed, and used in course of conducting research using laboratory animals. Registrants are also required to submit the Controlled Substance Notification Form when they are obtaining a registration for a controlled substance where a registration has not previously been obtained.

Federal, Initial and Renewal Registration Process -

<http://www.deadiversion.usdoj.gov/drugreg/index.html#1>

In order to obtain a DEA registration, registrants must go to the Department of Justice (DoJ), Drug Enforcement Administration (DEA), Office of Diversion Control (ODC) website to obtain DEA Form 225 – New Application for Manufacturer, Distributor, Researcher, Analytical Laboratory, Importer, Exporter. The form is electronic and can be submitted electronically via online. On an annual basis, the registrant is required to renew the registration.

State, Initial and Renewal Registration Process -

<http://www.niconsumeraffairs.gov/drug/> In order to obtain a Controlled Dangerous Substance registration for the State of New Jersey, registrants must contact the State of New Jersey Drug Control Unit (DCU). The DCU is a unit located within the Division of Consumer Affairs of the State of New Jersey Department of Law & Public Safety. On an annual basis, the registrant is required to renew the registration.

Departmental Administration

Not all researchers need to obtain and receive a registration from the federal and state government entities to use Controlled Substances in the course of conducting research. The following paragraph is to assist Departments and Colleges in the acquisition and administration of controlled substances.

Departments or animal facilities, where laboratory animals are used in research, must identify an employee who is qualified to obtain and hold a registration with the federal and state government entities to manage and administer controlled substances as is regulated and defined in the Controlled Substance Act, as well as the New Jersey State Administrative Code Title 13:

Chapter 45:1.1 to 1.6. The employee identified to hold a registration must adhere to this policy.

Ordering, Handling, and Disposing of Controlled Substances

When ordering, receiving, storing, and disposing of any controlled substances, all Rowan University personnel or affiliates of Rowan University using Rowan University owned facilities must contact the Environment, Health, and Safety Office within the Rowan University Facilities and Operations Department - <http://www.rowan.edu/adminfinance/facilities/ehs/> - **prior to**

any such activities being undertaken. Additionally, on an annual basis and at the time of the initial order of any controlled substances, Rowan University personnel or affiliates of Rowan University using Rowan University owned facilities must notify the Research Office of the plan to order, store and use controlled substances. If the controlled substance is identified and adequately discussed and documented in an IACUC Protocol that is reviewed by the IACUC Committee, then that constitutes notification to the Research Office. The notification, if not done through the IACUC protocol review process, should be directed to the Research Office and adequately address what the controlled substance is, what schedule is the controlled substance, the location where the controlled substance is used and stored, how the controlled substance will be used, and to what extent training will be provided to ensure safety.

The use of controlled drugs must be recorded every time the drug is administered to an animal. The recording of the use of controlled drugs must be documented by the use of a log. Additionally, for any researchers who are acting as agents of a registrant in the performance of their research must use a log to record and document the acquisition, use, and return of the controlled substance to the registrant.

Controlled Substances/Drugs Logs must include at a minimum the following:

- Drug Name and Concentration
- Initial Drug Weight/Volume (Total quantity supplied)
- Date Drug was Issued/Available for Use
- Expiration Date
- Registrant/License Holder Name
- Date to Record Dispensing/Use of Drug
- IACUC Protocol Number of Study/Research
- Name of Principal Investigator
- Species/Animal
- Amount Used
- Amount Remaining/Amount not Used
- Purpose
- Printed Name(s) and Signatures of Researchers Administering Drugs in the Research

Controlled drugs that are incorporated into a mixture must be recorded. When recording the mixture, the following information must be documented:

- Initial amount
- Schedule of controlled substance mixed
- Log for the newly created mixture

The vial or container housing the mixture must include at a minimum the following information:

- Creation date
- Expiration date
- Concentration of each component
- Dosing information
- Other pertinent information as applicable

Storing of Controlled Substances

Storage of controlled drugs must adhere to the Controlled Substances Act, as well as the New Jersey State Administrative Code Title 13: Chapter 45. Small quantities of controlled substances must be stored in a safe or steel cabinet. If the safe or steel cabinet is less than 750

pounds, then the safe or steel cabinet must be secured, either bolted or cemented, to the floor or wall in a manner that it cannot be readily removed.

IMPORTANT: If the controlled substances to be purchased, stored, and dispensed on campus are either Schedule I or II controlled substances/drugs, then a proper safe, as indicated in the Controlled Substance Act and New Jersey State Administrative Code Title 13: Chapter 45, must be procured and in place prior to any Schedule I and/or II controlled substances coming onto

and being retained on Rowan University's campus and/or owned facilities.

General Guidelines for the Administration and Management of Controlled Drugs/Substances

- Store all controlled substances/drugs in a secure, dedicated location.
- Labeling should not be defaced, altered, or changed in any manner where the lettering and name of the controlled substance is hidden or unclear.
 - o Registrants responsible for the controlled substance should label the controlled substance with a standard format so that it is easily and quickly known and understood.
 - o Scheduling Label standard formatting:
 - CS-I (for controlled substances listed on schedule 1)
 - CS-II (for controlled substances listed on schedule 2)
 - CS-III (for controlled substances listed on schedule 3)
 - CS-IV (for controlled substances listed on schedule 4)
 - CS-V (for controlled substances listed on schedule 5)
- Responsibilities should be assigned to one (1) specific individual, with another individual as a back-up.
- A log must be created to properly record and track the use of the controlled substance, and the log must be stored in a locked drawer or cabinet that is only

accessible to the person who is responsible for and in control of storing and dispensing the Controlled Substance/Drug.

- Establish an inventory system to reduce and minimize the amount of controlled substances on-hand.
- Conduct monthly inventory count of controlled substances, drugs, and non-drug materials.
- Expired and Non-expired drugs or medical materials should be separated in a manner that minimizes, and preferably eliminates, risk of error or using expired drugs and materials in an inappropriate manner .
- Discard all expired drugs or medical materials following federal and state guidelines and regulations. Contact the Environment, Health, and Safety Office within Rowan University's Department of Facilities and Operations to coordinate disposal.

Expired Drugs

Expired drugs are prohibited for use involving any live animals. For drugs that are aliquoted from stock solutions, drug containers housing the new solution must include at a minimum the following on the container:

- Name
- Concentration
- Expiration date

All dilutions and mixtures of drugs are to be discarded after one (1) month from the date of preparation, unless a longer or shorter shelf life is specified by the manufacturer.

All expired drugs should be discarded as soon as possible through the appropriate channels and procedures.

Non-pharmaceutical Grade Compounds

Non-pharmaceutical grade compounds are drugs, biologics, reagents, etc. which **were not** approved by the Food & Drug Administration (FDA) or for which a chemical purity standard

has not been written/established by the United States Pharmacopeia/National Formulary and other institutions of authority, such as but not limited to British Pharmacopeia.

Non-pharmaceutical grade compounds at a minimum must meet the following standards:

- Lack of acceptable/available veterinary or human pharmaceutical-grade compounds
- Investigation of novel therapeutic drugs
- Specific and cited review and approval by the IACUC
- The following specific information for each compound must be documented:
 - o Grade
 - o Purity
 - o Sterility
 - o pH
 - o Pyrogenicity
 - o Osmolality
 - o Stability

Cost savings cannot be the sole justification for using non-pharmaceutical-grade compounds in animals.

V. References

United States Department of Agriculture; Animal and Plant Health Inspection Service; Animal Care Policy; Policy #3 – Veterinary Care;

http://www.aphis.usda.gov/animal_welfare/policy.php

7 U.S.C. 2131-2159; 7 CFR 2.22, 2.80, and 371.7.; Title 9 - Animals and Animal Products.

Chapter 1 – Animal and Plant Health Inspection Service, Department of Agriculture; Subchapter A – Animal Welfare;

<http://www.gpo.gov/fdsys/pkg/CFR-2009-title9->

[vol1/xml/CFR-2009-title9-vol1-chap1-subchapA.xml](http://www.gpo.gov/fdsys/pkg/CFR-2009-title9-vol1-chap1-subchapA.xml)

National Institutes of Health; Office of Extramural Research; Office of Laboratory Animal

Welfare; Public Health Services Policy on Humane Care and Use of Laboratory Animals

Policy; <http://grants.nih.gov/grants/olaw/references/phspol.htm>

United States Department of Justice; Drug Enforcement Agency; Office of Diversion Control; Title 21 (United States Code – USC) Controlled Substance Act; Subchapter 1 – Control

and Environment; <http://www.deadiversion.usdoj.gov/21cfr/21usc/index.html>

New Jersey Office of the Attorney General; Division of Consumer Affairs; Drug Control Unit; N.J.S.A. 24:21-1 to 24:21-53; N.J.A.C. 13:45C-1.1 to 13:45C-1.6;

http://www.state.nj.us/lps/ca/drug/cds_statregs.pdf

Department of Law & Public Safety; Division of Consumer Affairs; New Jersey Drug Control

Unit; <http://www.niconsumeraffairs.gov/drug/>

Acceptance:

_____ I give my approval. I have forwarded this item to _____ for implementation.

_____ No approval is actually needed. I have forwarded this item to the following individual or office for informational purposes only:

ADDITIONAL REVIEW NEEDED:

_____ I am willing to give approval if the following modification(s) are made:

_____ Before I can approve or reject this item, I need clarification on the following:

_____ I have forwarded this item to the following individual or office for further consideration and consultation.

Rejection:

_____ I decline acceptance of this item for the following reason:

Please Return this Copy to the University Senate President ~ Retain a Copy for Your Records