RUTGERS
THE STATE UNIVERSITY OF NEW JERSEY

UNIVERSITY POLICY

Policy Name:	Policy for Controlled Substances					
Section #:	90.2.3	**Section Title:**	Compliance		**Formerly Book:**	N/A
Approval Authority:	President		**Adopted:**	07/01/2013	**Reviewed:**	01/16/2019
Responsible Executive:	Senior Vice President, Research and Economic Development		**Revised:**	01/16/2019 (reinstated and rewritten)		
Responsible Office:	Office of Research and Economic Development		**Contact:**	Assistant Vice President for Research, Office of Research and Economic Development research@ored.rutgers.edu		

1. **Policy Statement**

This Policy addresses the proper use of Controlled Substances (CS) by University Personnel in research, teaching, and clinical veterinary care of research animals. This Policy does not apply to University health care professionals using CS in humans for clinical or research purposes. It is intended to guide University Personnel in the performance of activities involving CS and to facilitate compliance with state and federal laws. Failure to comply with this Policy may lead to the imposition of University, state, and/or federal sanctions against non-compliant individuals.

2. **Reason for Policy**

A controlled substance (CS) is a substance where the manufacture, possession, distribution, dispensing, or use is regulated under the Federal Controlled Substances Act (CSA) (Title 21 C.F.R., Part 1300-End) or the New Jersey Controlled Dangerous Substances (CDS) Act (Schedules I through V of article 2 of P.L.1970, c.226 (C.24:21-1 *et seq*.)), respectively.

In NJ, Listed Chemicals and Controlled Substances fall under the single definition of "Controlled Dangerous Substances" (CDS), which is a drug, substance, or an immediate precursor in Schedules I through V of article 2 of P.L.1970, c.226 (C.24:21-1 *et seq*.).

Listed chemicals (LC) are categorized into two groups. List I chemicals become part of the molecular structure of illicit drugs. List II chemicals are catalysts or reagents and do not become part of the molecular structure of illicit drugs. List II chemicals facilitate chemical reactions. List I and List II chemicals have legitimate uses but can also be used to illegally manufacture CS. List I and List II chemicals are not considered Controlled Substances by the United States Drug Enforcement Administration (DEA) but are a concern. As an end user of Listed Chemicals, Rutgers is not required to acquire a DEA registration for Listed Chemical receipt or use. However, certain controls must be placed on List I chemicals to prevent theft or loss. LC are beyond the current scope of this policy. Contact Rutgers Environmental Health and Safety (REHS) for List I and II chemicals storage requirements.

University Personnel who are authorized to handle CS during the course of their activities are responsible for the security of CS while in their possession. This responsibility includes the prevention of diversion and the reporting to a University official any knowledge of a diversion of

CS. When conducting research with animals that involves the use of CS, University Personnel are required to comply with this Policy and all applicable state and federal regulations regarding the use, storage, required inventories, inventory control, disposal, and required records and reports for CS.

3. **Who Should Read This Policy**

All members of the Rutgers University community including faculty, staff, students, guests, visiting researchers, and contract employees handling or using CS for animal research in University facilities or in conjunction with any University-related activity.

This Policy does not apply to University health care professionals using CS in humans for clinical or research purposes.

4. **Resources**

New Jersey Administrative Code Title 13, Law and Public Safety, Chapter 45H, Controlled Dangerous Substances

Drug Enforcement Administration (DEA) Diversion Control Division

Drug Enforcement Administration (DEA) Diversion Control Division: List of all Controlled Substances (CS) and their schedules

Drug Enforcement Administration (DEA) Diversion Control Division: List I and List II Chemicals

Registrant Record of Controlled Substances Destroyed: DEA Form 41

Theft or Loss of Controlled Substances: DEA Form 106

Report Of Theft Or Loss Of Controlled Substances: NJ Form DDC-52

5. **Definitions**

Approved Storage Safe or Cabinet	A securely locked, substantially constructed safe or cabinet approved by the Registrant Designee in accordance with generally accepted security protocols where a Principal Investigator (PI) stores CS when they are not in use.
Authorized Personnel	Authorized Personnel are the Registrant Designee, Registration Coordinators (RC), and Unit Coordinators (UC) and designees.
Authorized CS Users	There are two types of Authorized CS users. The first is a Principal Investigator (PI) or person identified by the PI who requires access to an Approved Storage Safe or Cabinet and/or obtains or uses CS in the absence of others. For purposes of animal research, an Authorized CS User is a PI holding an Institutional Animal Care and Use Committee (IACUC)-approved animal use protocol, which includes the use of specific CS. The second group of Authorized CS users is Comparative Medicine Resources (CMR) staff involved in clinical veterinary care.
Authorized Storage Location	A room or other CS storage location under a DEA registration approved by the Registrant Designee. There may be more than one Authorized Storage Location for a Registered Location.
Comparative Medicine Resources (CMR)	CMR provides support to Rutgers University faculty and staff who use animals in their research and teaching. CMR promotes humane care and treatment of all Rutgers animals and holds services and facilities to the highest standards.
Controlled Substance/ Controlled Dangerous Substance	Substances where the manufacture, possession, distribution, dispensing, or use for conducting research or analysis is regulated under the Federal Controlled Substances Act (FCSA) and/or the New Jersey Controlled Dangerous Substances Act.

Federal Controlled Substances Act	The CSA is the Federal United States Drug Policy where the manufacture, importation, possession, use, and distribution of certain substances is regulated (Title 21 C.F.R., Part 1300-End.). CS fall under one of five schedules (Schedules I, II, III, IV, or V).
Institutional Animal Care and Use Committee (IACUC)	Institutional Animal Care and Use Committee at the University.
Listed Chemicals (LC)	List I and List II chemicals (LC) are not CS as defined by the DEA. LC have legitimate uses but can also be used to illegally manufacture CS. In New Jersey, LC and CS fall under one definition "Controlled Dangerous Substances," which is a drug, substance, or an immediate precursor in Schedules I through V.
New Jersey Controlled Dangerous Substances Act	An Act concerning controlled dangerous substances related to persons who distribute, dispense, or conduct research or analysis using CDS. Related information can be found under New Jersey Legislature: *New Jersey Controlled Dangerous Substances Act*. N.J.S.A. 24:21-1 *et seq*.
Principal Investigator (PI)	A PI is a faculty or staff member responsible for the valid use of CS. The PI must have an IACUC-approved animal use protocol, which includes the use of specific CS.
Registered Location	A building or group of buildings, which are in close proximity and preferably are physically connected via tunnel, closed corridor, or bridge that are covered by a single registration. Any location where CS are received, stored, or used must be registered with the DEA.
Registrant Designee	The person authorized by the University President to oversee the use of CS at the University. An employee knowledgeable in all aspects of the CS regulations as it relates to the University's activities with the authority to set and enforce controlled substance policy and standards. An alternate will be appointed to serve in the Registrant Designee's absence.
Registrations	**Researcher Registration**. An institutional DEA CS registration in the researcher category or a New Jersey Drug Control Unit Controlled Dangerous Substances (NJ DCU CDS) registration in the researcher-facility category held in the name of the Registrant, Rutgers, The State University of New Jersey, for the purpose of this policy will be referred to as a Researcher Registration. The Registrant Designee must approve all registrations used for animal research. An individual may be given written power of attorney to manage a registration. A registration is issued for a specific location. **Individual Researcher Registration**. A DEA CS registration in the researcher category or a NJ DCU CDS registration in the researcher-facility category used by an individual researcher. Individual Researcher Registrations for research, teaching, and clinical veterinary care of research animals are no longer permitted for use or storage of Controlled Substances in University facilities. **Practitioner Registration**. A DEA CS registration or a NJ CDU CDS registration used by a practitioner such as a dentist, physician, veterinarian, or other person licensed to dispense, or administer, a controlled substance in the course of professional practice. A licensed CMR veterinarian may utilize a Practitioner Registration and serve as a Registrant for providing clinical veterinary care under this Policy.

Registration Coordinator (RC)	The person responsible for a Registered Location. An alternate will be appointed for each RC to serve in their absence. A person may serve as RC for more than one Registered Location. The RC and alternate are granted written Power of Attorney to sign DEA-222 forms for ordering Schedule I and II CS and purchase orders for Schedule I-V CS. The RC transfers CS to either the UC or the Authorized CS User following the requirements described in this Policy. Depending upon the size of a Registered Location and the volume of CS at the location, the RC may also act as the UC. The RC is responsible for maintaining all CS required records, reports, and inventories.
Unit Coordinator (UC)	A person responsible for the management of CS in an Authorized Storage Location. An alternate will be appointed for each UC to serve in their absence. The UC or designee works with the RC to ensure CS are ordered, received, stored, and distributed to the PI's.
University Personnel	University faculty, staff, students, guests, visiting researchers, and contract employees.

6. **The Policy**

Rutgers, The State University of New Jersey

Policy for Controlled Substances

I. Purpose

The DEA and New Jersey Drug Control Unit (DCU) require all legitimate handlers of CS to provide effective controls to guard against theft and diversion. Rutgers, The State University of New Jersey, (University) organizes and maintains an internal regulatory compliance program to monitor adherence to and compliance with all laws and regulations enforced by the New Jersey DCU and the DEA pertaining to the receipt, storage, recordkeeping, dispensing, use, inventory, security and disposal of CS which are used in animal research to meet the requirements set forth in 21 CFR 1300 -1399 and the NJ CDS Act and Regulations as set forth in the New Jersey Administrative Code Title 13, Law and Public Safety, Chapter 45H, Controlled Dangerous Substances.

II. Applicability

The University commits itself to promoting compliance with both the spirit and letter of state and federal regulations concerning the use of CS. This University Policy for Controlled Substances (Policy) applies to all University faculty, staff, students, guests, visiting researchers, and contract employees (University Personnel) handling or conducting animal research with CS in University facilities or in conjunction with any University-related activity.

This Policy does not apply to University health care professionals using CS in humans for clinical or research purposes.

The Registrant Designee, who shall be designated by the University President or his or her designee (President), has the responsibility to assure compliance with this Policy. The President will delegate to the Registrant Designee the authority to establish procedures to administer the CS management program in compliance with federal and state regulations and this Policy. Any deviation from this Policy must be authorized by the Registrant Designee.

University Personnel, who are authorized to handle CS during the course of research, are responsible for their security while in their possession. This responsibility includes the prevention of diversion and the reporting of any knowledge of a diversion of CS by anyone to a University official.

III. Objectives

The objectives of this Policy are to:

A. Assist University Personnel in the interpretation and proper application of the pertinent regulations.

B. Set and enforce internal standards for handling and use of CS.

C. Define the University CS management process.

D. Assign responsibility to appropriate University Personnel for CS compliance.

E. Provide training on CS regulatory requirements and this University Policy and corresponding procedures.

F. Monitor compliance with regulatory requirements and this Policy, conduct internal audits and accountabilities of CS, and document audit findings, recommendations and resolutions.

G. Respond appropriately to failures to comply with regulatory requirements and this Policy and take steps to prevent similar failures.

H. Monitor regulatory developments for potential impact on the University Institutional Registrations.

IV. Licensure/Registration

Researcher Registrations Required.

A. The University will maintain Researcher Registrations (state and federal) for all locations where Schedule II-V CS use is required in animal research.

B. Schedule I CS require a separate Researcher Registration, in addition to those registrations obtained for Schedule II through V CS.

C. CS that are stored or used in University facilities can only be obtained by the Registrant Designee for Rutgers, The State University of New Jersey. Individual Researcher Registrations for research, teaching, and clinical veterinary care of research animals are not permitted for use or storage of CS in any University facilities. Only the Registrant Designee can procure CS directly through University Procurement Services.

D. For PIs with existing Individual Researcher Registrations used for animal research, CS inventories must be surrendered, or if approved transferred to the University Researcher Registrations at such time as established by the Registrant Designee.

E. A Registered Location may cover a single building or it may cover a group of buildings close to one another, as approved by the local field office of the DEA.

F. A Registered Location may utilize one or more Authorized Storage Locations.

G. The licensed CMR veterinarians on each campus may require one or more registrations, Registered Locations, and/or Authorized Storage Locations as a Practitioner Registration.

V. Registered Locations

PIs that need to use CS in animal research or teaching will do so under the authority of a Researcher Registration approved by the Registrant Designee. If work must be performed in locations not currently served by an existing Researcher Registration, security and validation of use will be evaluated before a new Registered Location will be created and the appropriate state and federal licensing and registrations acquired.

Approved Storage Safes or Cabinets will be provided in animal facilities as need is determined.

VI. Training

The University, at the direction of the Registrant Designee will provide training as appropriate for University Personnel who work with CS and those who create and retain CS required records, reports, and inventories. Training will be required as set forth in this Policy for all University Personnel working with CS.

A. Mandatory Initial Training

Training will be provided in the form of live seminars or online courses. University Personnel who work with CS must demonstrate knowledge of relevant federal and state regulations, and University policy and procedures.

Training programs will include information on the following:

- Federal and state regulations
- Disposal and destruction
- University policy
- Reporting spills, loss, or theft
- Registration requirements
- Compounding, mixing, manufacturing
- Schedules of CS
- Non-pharmaceutical grade CS in animals
- Ordering and receiving CS at the University
- Drug diversion
- Record keeping, record retention
- Expired CS
- Storage and security
- Leaving the program (ceasing use of CS)
- Inventory, reconciliation, accountability
- Terminating University employment

B. Recurrent Training

Refresher training is required every year following initial training. Additional training occurs as needed based upon regulation and programmatic updates, and internal audit findings.

C. Tracking Training

Documentation of training will be maintained by the Registrant Designee.

VII. Authorized Personnel/Background Checks

Persons who have been convicted of a drug-related felony are not permitted to work with CS.

Authorized Personnel must undergo criminal background checks as needed.

Authorized CS Users must be approved by the Registrant Designee before work with CS in animal research can begin. Authorized CS Users are required to sign a statement that he or she has not been convicted of a drug-related felony. PIs wishing to use CS must designate in writing those individuals authorized to work with CS in each Authorized Location under the PI's supervision. This would include anyone who (a) uses a CS, (b) has access to a safe combination or key where CS is stored, or (c) has unsupervised access to areas where CS are used or stored. A list of Authorized CS Users must be kept up-to-date by the PI and provided to the Registrant Designee promptly as changes occur.

VIII. Ordering, Receiving and Requesting CS

A. Ordering CS for animal research.

CS shall be ordered only by RCs or designees through the Researcher or Practitioner Registrations. RCs or designees periodically order CS anticipating need (based on number of approved protocols with CS use) and demand to ensure that CS are readily available when needed.

1. Individual Researcher Registrations cannot be used to order CS for animal research. University Procurement will only approve CS orders from the RC or designee.

2. The RC or designee checks the request and verifies that (a) the PI has an approved protocol authorizing the use of the CS or has been approved by the Registrant Designee, (b) all necessary forms and other paper work and empty or expired CS have been returned and (c) if the CS is available or needs to be ordered.

B. Receiving CS.

The RC or designee receives all CS from vendors, checks the order for accuracy, assigns tracking numbers to each unit of CS for inventory, and places it in an Approved Storage Safe or Cabinet at the address listed on the registration.

C. CS Request by Authorized CS User.

1. The PI or designee requests CS through the UC or designee. If the Authorized CS User has no outstanding paper work or CS, the UC or designee fills the order.
2. The order is entered into the Controlled Substance Log (CSL).
3. The PI is informed when the order has been filled. Filled orders are placed in approved secured storage at the registration location until pick up during normal working hours.
4. A Controlled Substance Usage Form (CSUF) is issued along with the CS to the Authorized CS User.
5. CS usage must be documented on the CSUF at the time that a CS is used and must be secured in an Approved Storage Safe or Cabinet when not in use.
6. When a CS container is empty or expired, the empty or expired vial must be returned to the RC or designee along with the completed CSUF.

IX. Storage

A. Approved Storage Safe or Cabinet. Safes that weigh less than 750 pounds must be permanently secured to the floor or wall. A safe is strongly recommended for storage of Schedules I and II.

B. Approval of storage location. All Authorized Storage Locations must be approved by the Registrant Designee.

C. When not in use CS must be stored in an Approved Storage Safe or Cabinet in an Authorized Storage Location at the appropriate registration site per manufacturer's instructions.

D. Federal and state registration certificates must be maintained at the Authorized Storage Location or must be readily available for inspection during normal office hours.

E. Registrant prescription pads and DEA order forms must be securely stored in a locked Authorized Storage Location.

F. Access

The DEA or NJ DCU, and Office of Research and Economic Development (ORED) Authorized Personnel must have access to all storage units during business hours.

DEA or NJ DCU may conduct a site visit for new registration applications and approval of storage cabinets or safes.

G. Storage in Secondary Vessels

CS transferred from the manufacturer's packaging to a secondary storage vessel in its original form or mixed as a cocktail must be legibly labeled as specified in the Controlled Substance Procedures.

X. Disposal, Destruction, Loss, or Theft

A. Unwanted and Expired CS

Unwanted and expired CS must be returned to the UC or RC or designee where CS was obtained. CS must remain secured in an Authorized Storage Location and clearly labeled as "Expired". CS must be discarded with strict adherence to procedures described in the Controlled Substance Procedures. Expired CS shall be destroyed on a periodic basis.

B. Orphaned CS

Orphaned CS (i.e., CS that are not associated with an existing DEA registration and are discovered) will be considered "found" material and should be reported immediately to the Registrant Designee and the campus RC. The campus RC will contact REHS to coordinate its collection, storage, disposal, and documentation through the Rutgers University Police Department (RUPD).

C. Reporting Lost or Stolen CS

Any person who believes that CS is misplaced or stolen must report the loss or theft to the Registrant Designee and the RC as soon as possible, but no later than 24 hours from such discovery. The RC first contacts RUPD and REHS to commence an investigation and then submits a completed DEA Form 106 to the New Jersey DEA Diversion Control Office and Public Safety and a Form DDC-52 to the New Jersey Department of Law and Public Safety Enforcement Bureau Drug Control Unit.

D. Spillage of CS

Any spillage or other loss of CS is reported within 24 hours to the RC. If the campus RC is not available, the loss is reported to the Registrant Designee or the UC.

Loss of CS resulting from inadvertent CS release from broken manufacturer's vials or bottles, a secondary vessel or syringe, that can be recovered must be documented, however, law enforcement and New Jersey DEA Diversion Control Office need not be notified. If CS loss is significant and cannot be recovered or theft cannot be ruled out, the loss must be reported to RUPD and New Jersey DEA Diversion Control Office and New Jersey Drug Control Unit.

XI. Recordkeeping

A. Registrants are required to maintain all records of purchase, use, and disposal of CS for a 2 year period after their final disposition.

B. Authorized CS Users must document use on required forms and recordkeeping systems as provided by the RC or UC on the same calendar day of CS use or administration.

C. Authorized CS Users must keep required forms in a location such that they are readily available for review.

XII. Initial and Biennial Inventories – Inventory Control

A. Initial Inventory. An Initial Inventory is conducted when a Registered Location commences use of CS (this will be required when the University transitions to Institutional Registrations).

B. Biennial Inventory. The Biennial Inventory report is a snapshot of the entire CS inventory under a single registration on one calendar date. It is not to be updated as CS are used.

1. Within 24 months of the Initial Inventory, a Biennial Inventory must be conducted. A Biennial Inventory is required to be conducted every 24 months thereafter.

2. Each Authorized Storage Location must conduct a Biennial Inventory of CS on hand within two years of the previous biennial inventory date. A DEA required

inventory is a complete count, measure or weight of all CS, in any form, on hand on the date of the inventory.

3. The required inventories will be conducted by, witnessed by, and signed by two individuals.

4. The Biennial Inventory must include:

   a. Date of Inventory.
   b. Designation of whether it was conducted as of the open or close of business.
   c. The inventory document must include in its title the word “Biennial”.
   d. The name of the CS.
   e. The concentration of the CS.
   f. The number of commercial containers and the size of the containers.
   g. Waste material must be designated as such.

C. Inventory Control - CS usage logs

1. Authorized CS Users must maintain a record of all CS usage on the CSUF.

2. A separate CSUF must be kept for each separate container of CS.

3. When a CS container is empty, the corresponding CSUF must be returned to the UC or designee accompanied by the empty container.

4. The CSUF must be returned to the UC or designee with unused or expired CS.

5. Authorized CS Users will be permitted a limited number of containers of any CS. Empty containers must be returned to obtain new containers

XIII. Monitoring and Auditing

A. Only Researcher and Practitioner Registrations are permitted. Practitioner Registrations must be authorized by the Registrant Designee.

B. Audits of Authorized Personnel and Authorized CS User records will be performed periodically. Comprehensive audits of each Authorized Storage Location occur at least every two years. A comprehensive audit is a periodic inspection of a Rutgers Researcher Registration. Self-audits and random audits are conducted on a routine basis to ensure compliance with the internal standards as outlined in the Policy. Self-audits are performed periodically to reduce or eliminate the risk of violations. Random audits are unannounced and include a high-level review of CS activities and Rutgers-required policy and procedures. CS activities will be subject to comprehensive and random audits performed by the University.