RUTGERS
THE STATE UNIVERSITY OF NEW JERSEY

**CONTROLLED SUBSTANCE**
**STANDARD OPERATING PROCEDURES**

**TITLE: Overview of Controlled Substance Procedures**

**SOP Category: All Personnel Handling CS**

**Revision Date: August 3, 2020**

**Contents**



## I. Policy

University guidelines are established for the procurement, transfer, use, security, disposal, recordkeeping, training and auditing of Controlled Substances (CS) used in animal research, testing and teaching in accordance with the Code of Federal Regulations as described in 21 CFR 1300-1308 and/or the New Jersey Controlled Dangerous Substances (NJ CDS) Act (Schedules I through V of article 2 of P.L.1970, c.226 (C.24:21-1 et seq.)). The Registration Coordinator (RC) or designee procures all CS for Authorized CS Users.

## II. Definitions

**Approved Storage Safe or Cabinet**
A securely locked, substantially constructed safe or cabinet approved by the controlled substances Registrant Designee where a Principal Investigator (PI) stores CS when they are not in use.

**Authorized Personnel**
Authorized Personnel are the Registrant Designee, RC, Unit Coordinators (UC) and designees.

**Authorized CS Users**
There are two types of Authorized CS users. The first is a PI or person identified by the PI who requires access to a safe or storage 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 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 Drug Enforcement Administration (DEA) registration approved by the Registrant Designee. There may be more than one Authorized Storage Location for a Registered Location.

**Comparative Medicine Resources**
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 NJ CDS 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**
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 NJ, LC and CS fall under one definition (Controlled Dangerous Substances, which is a drug, substance, or an immediate precursor in Schedules I through V).

See http://www.deadiversion.usdoj.gov/chem_prog/34chems.htm.

**New Jersey Controlled Dangerous Substances Act**
An Act concerning CDS related to persons who distribute, dispense, or conduct research or analysis using CDS. Related information can be found under New Jersey Legislature http://www.njleg.state.nj.us/. *New Jersey Controlled Dangerous Substances Act*. N.J.S.A. 24:21-1 et seq.

**Principal Investigator**
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 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 CS registration in the researcher activity held in the name of the Registrant, Rutgers, The State University of New Jersey. The Registrant Designee must approve all registrations. An individual may be given written power of attorney to manage a registration. A registration is issued by the DEA for a specific location.

**Individual Researcher Registration.** A CS registration 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 CS 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.

**Registration Coordinator (RC)**
The person responsible for a Registered Location. An alternate will be appointed 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 SOP. 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 to serve in their absence. The UC works with the RC to ensure CS are ordered, received, stored and distributed to the PI's. The UC or designee interfaces directly with the PI and is available for CS deliveries.

**University Personnel**
University faculty, staff, students, guests, visiting researchers and contract employees.

## III. Forms

**Controlled Substance Authorization Release (CSAR)**
The CSAR is an attestation that must be completed by all personnel conducting animal research before being authorized to handle CS.

**Controlled Substance Request Form (CSRF)**
The CSRF is used by Authorized CS Users to request that CS be ordered by the RC. PI's conducting animal research may not place orders directly with vendors.

**Controlled Substance Log (CSL)**
A CSL is the master inventory of CS maintained by the RC.

**Controlled Substance Usage Form (CSUF)**
The CSUF is used by Authorized CS Users to document each use of a CS. A separate CSUF is issued with each container of CS and must be returned to the Registration Coordinator, directly or via the Unit Coordinator, with the empty, unneeded or expired CS container.

**DEA Form 222**
DEA Form 222 is used by a RC to order Schedule I and II CS.

**DEA Form 41**
DEA Form 41 is used by a RC to record destruction of CS and receive DEA approval for disposal.

**DEA Form 106**
DEA Form 106 is used to notify the New Jersey DEA Field Division Office of the theft or significant loss of any controlled substance upon discovery within one business day.

**DDC-52**
NJ DDC-52 Form must be submitted to the NJ DCU of the theft or significant loss of any controlled substance upon discovery within one business day.

## IV. CS Procedures

### A. Mandatory Training

1. 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 DEA required records, reports and inventories. Training is required as set forth in the University Policy for all University Personnel working with CS.
2. Mandatory Initial Training is provided through live seminars or online courses. Additional training on the federal and state regulations will be required for Rutgers CS program auditors.
3. Training programs will include information on the following:
    - Federal and state regulations
    - University policy
    - Reporting spills, loss or theft
    - Registration requirements
    - Schedules of CS
    - Ordering and receiving CS at the University
    - Disposal and destruction
    - Drug diversion
    - Record keeping, record retention
    - Expired CS
    - Storage and security
    - Leaving the program (ceasing use of CS)
    - Inventory, reconciliation, accountability
4. Refresher training is required every year following initial training. Additional training occurs as needed based upon regulation and programmatic updates, and internal audit findings.
5. Documentation of training will be maintained by the Registrant Designee.

### B. Authorized Personnel/Background Checks

1. Persons who have been convicted of a drug-related felony are not permitted to work with CS.
2. Authorized Personnel must undergo criminal background checks as needed.
3. Authorized CS Users must be approved by the Registrant Designee /RC before work with CS can begin.
4. Authorized CS Users are required to sign a statement that he or she has not been convicted of a drug-related felony.
5. 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. A list of Authorized Personnel must be kept up-to-date by the PI and provided to the Registrant Designee/RC promptly as changes occur. The list must include anyone who:
    a. uses a CS
    b. has access to a safe combination or key where CS is stored
    c. has unsupervised access to areas where CS are used or stored

## C. Ordering CS

1. The campus RC, UC or their designee orders and procures all CS for Authorized CS Users. For commonly used drugs, the RC or designee periodically orders enough CS, anticipating need and demand, to ensure that they are readily available. Other CS will be ordered on request.
2. The RC or designee orders Schedule III, IV and V CS through approved vendors using normal procurement procedures.
3. The RC, UC or their designee uses DEA Form 222 (in triplicate) to order Schedule I and II CS. A hard copy (Copy 1 and 2) is sent by mail to the vendor, and the RC or designee retains Copy 3 (purchaser copy). Unused DEA Order Forms are kept in a secure location. Instructions for ordering DEA form 222 are located at: http://www.deadiversion.usdoj.gov/faq/dea222.htm).

## D. Receiving CS

1. Only Authorized Personnel receive and open boxes or packages of CS.
2. Authorized Personnel verify the accuracy of the order and number each individual unit of CS (bottles / vials/ or packages) sequentially to track inventory.
3. Authorized Personnel store the CS in an Approved Storage Safe or Cabinet in an Authorized Storage Location until transferred to an Authorized CS User. The Office of Research and Regulatory Affairs (ORRA), New Jersey Drug Control Unit (DCU) or DEA, and Authorized Personnel must have access to all storage units during business hours i.e. weekdays 8:30 a.m. to 5 p.m. All records and inventories of Schedules I and II CS must be kept separately from records and inventories of schedule III, IV and V CS. CS. Schedules I and II should be stored separately from Schedules III, IV and V. Schedules III, IV and V may be stored with Schedule I and II provided the security measures for Schedule I and II are followed.
4. Authorized Personnel document each CS order received. Recording each CS name, sequential number range, date received, source of CS, quantity received, lot number(s), expiration date(s) and identity of the data entry person in the **Controlled Substance Log (CSL).**
5. For Schedule I or II drugs, when the CS is received, Copy 3 of DEA form 222 (purchaser's copy) is filled by entering the number of packages received and the date received.
6. All CS invoices are kept at the registered location. Copy 3 of DEA form 222, for all Schedule I or II, are kept in a separate file at the registered location.

## E. CS Request by Authorized CS User

1. Authorized CS Users request CS by submitting a completed **Controlled Substance Request Form** (CSRF) to Authorized Personnel based on the physical location where the CS is to be stored. These forms are available online or at registered locations.
2. The Authorized CS User and Authorized Personnel, both sign the (CSRF). A copy of the completed CSRF is given to the Authorized CS User together with the CS and the **Controlled Substance Usage Form** (CSUF). A copy of the CSRF is kept in a file at the campus RC's registered location. Another copy is sent to the Office of Research Advancement, Department of Financial Operations for billing purposes.
3. Authorized CS Users must request CS at least 3 days in advance. Additional time should be allotted for any unique substances that need to be ordered or for the request of Schedule I and II CS not currently described on the University's registration as the registration must be amended prior to the order being placed.

4. Authorized Personnel check the CSRF and verify the following:
    a. The PI has an approved protocol authorizing the use of the CS or has been approved by the Registrant Designee.
    b. The completed CSUF and corresponding empty or expired CS have been returned.
    c. The CS is in inventory (if not, it is ordered).
5. If the Authorized CS User has no outstanding CSUF or CS of the same type, the campus RC or designee fills the order.
6. Authorized Personnel enter the order in the CSL to track CS inventory, usage and expiration dates. The CSL will be backed up on a regular basis to prevent alterations.
7. All CS orders are delivered to the registered location and placed in an Approved Storage Safe or Cabinet at the Authorized Storage location. The PI is informed when the request is available for pick up during normal working hours. Upon request CS orders may be taken to the PI (a nominal fee may apply).
8. The Authorized CS User submits the completed CSUF with the expired or unused CS to Authorized Personnel. The return of expired or unused CS along with the completed CSUF is required before the Authorized CS User submits a new request for the same CS. Authorized Personnel complete the header section of the CSUF.
9. Authorized Personnel issue the CSUF together with the CS to the Authorized CS User, with explicit instructions that (a) all usage must be documented on the CSUF at the time that the CS is used and (b) that CS must be placed in an Approved Storage Safe or Cabinet when not in use. ORRA, DCU or DEA, and Authorized Personnel must have access to all storage units during business hours i.e. weekdays 8:30 a.m. to 5 p.m.
10. If transferring CS from one building to another at the same registered location, utilizing two Authorized Personnel is always advised and mandatory for transfer of Schedule I CS. The Authorized CS User stores CS in an Approved Storage Safe or Cabinet at an Authorized Storage Location.
11. When the CS is finished or expired, it must be returned to the campus RC or designee along with the completed CSUF. Any unused amount of a CS must be entered on the CSUF and the reason for the unused must be noted on the form (i.e.: expired). Both the Authorized CS User and Authorized Personnel must initial this documentation of the unused amount. The CSUF is filed at the registered location where it was ordered and documented in the CSL.

**F. Storing CS**

1. When not in use CS must be stored in an Approved Storage Safe or Cabinet in an Authorized Storage Location according to manufacturer's instructions. Safes that weigh less than 750 pounds should be permanently secured to the floor or wall. A safe is strongly recommended for storage of Schedules I and II.
2. All CS Storage Locations must be approved by the Registrant Designee.
3. Federal and state registration certificates must be must be readily available at the Authorized Storage Location for inspection during normal office hours.
4. Registrant prescription pads and DEA order forms must be securely stored in a locked Authorized Storage Location.
5. All storage units must be accessible to the NJ DCU or DEA, and CS Authorized Personnel during business hours. DEA or NJ DCU may conduct a site visit for new registration applications and approval of storage cabinets or safes.

6. 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 with its own unique identifier and preparation expiration date. Additional information that does not fit on the vial must be provided on a corresponding usage form and stored with the container.

   The vessel label must include:

   a. Unique identifier from the original vial plus a distinguishing number or letter for each dilution.
   b. Name of CS and other active ingredients if a drug cocktail.
   c. Date of expiration of preparation.
   d. Volume or weight in grams transferred.

   The usage form must include:

   a. Name and concentration of CS and other active ingredients if a drug cocktail.
   b. Date of transfer or preparation.
   c. Date of expiration from manufacturer.
   d. Volume or weight in grams transferred.
   e. Unique identifier from the original vial plus a distinguishing number or letter for each dilution.

7. Unwanted and expired CS must be returned to the RC or designee where CS was obtained. Expired CS must be placed in a sealed tamper proof container in a separate approved storage area in an Authorized Storage Location and clearly labeled as "Expired". Expired CS shall be destroyed on a periodic basis.

**G. CS Disposal, Destruction, Loss or Theft**

1. A database is used to track expiration dates and send notices and reminders to Authorized Personnel.
2. Only Authorized Personnel as directed by the NJ CDS Act may dispose of unused or expired CS. All CS must be kept in an Approved Storage Safe or Cabinet until they are disposed.
3. CS is destroyed using a method approved by the DEA and in consultation with the Rutgers University Police Department (RUPD) and Rutgers Environmental Health & Safety (REHS). The recommended method of destruction is to use a reverse distributor or request approval from the DEA. If written approval is received from the DEA alternate methods that render the CS irretrievable may be allowed as approved by the Registrant Designee if witnessed and documented by Authorized Personnel.
4. To dispose of CS, a Authorized Personnel complete a DEA Form 41. Authorized Personnel schedule an date to witness drug destruction following receipt of written authorization from the DEA. Two department-authorized personnel destroy CS in accordance with a method and by the date approved and authorized by the DEA.
5. Non-recoverable waste or residual amounts of CS that remain in a vial/container but cannot be withdrawn from the container may be discarded in a biohazard sharps container. Residual amounts must be properly recorded on the usage log but the destruction need not be recorded on a DEA form 41.
6. Recoverable waste remaining in a vial or syringe that cannot be further utilized must be secured, recorded on the corresponding usage log, and returned to the RC/UC. Recoverable unused waste will be recorded, destroyed and witnessed by Authorized Personnel in accordance with DEA regulations and recorded on the corresponding usage log.
7. There are three DEA CS cited below, which are also EPA listed hazardous wastes and must be managed through a reverse distributor that is permitted to accept hazardous

waste. The DEA CS listed as hazardous waste must also be stored and disposed of in accordance with the Resource Conservation and Recovery Act (RCRA) regulations for hazardous waste generators found in 40CFR Part 262. Contact REHS Environmental Services Group for specific disposal guidance on these materials via email at hazwaste@aps.rutgers.edu. The CS also listed as hazardous waste are as follows:

a. Chloral and Chloral Hydrate (U034) (AKA - Noctec)
b. Paraldehyde (U182) (AKA - Paral)
c. Phentermine (P046) (AKA - Ethanamine, Fastin, Ionamin, or Phentride)

8. All expired or unused drug related substances not controlled or restricted by the DEA or NJ DCU shall be promptly discarded in accordance with REHS Hazardous Waste Disposal Policy/Procedures (rehs.rutgers.edu).
9. Any orphaned CS, which 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 and RUPD to coordinate its collection, storage, disposal and documentation.
10. Any person who believes that CS has been misplaced or stolen must report the loss or theft to the Registrant Designee and the campus RC as soon as possible, and no later than 24 hours from such discovery. The campus RC first contacts RUPD and REHS, to commence an investigation, notifies the DEA field division office and the NJ DCU within one business day of discovery. A completed DEA Form 106 must be submitted to the New Jersey DEA Diversion Control office and Public Safety within 15 days and a Form DDC-52 must be submitted to the NJ DCU office.
11. Any spillage or other loss of CS is reported within 24 hours to the campus RC. If the campus RC is not available, the loss is reported to the Registrant Designee or UC.
12. 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 the NJ DEA Diversion Control Office and the NJ DCU.
13. All empty containers from used CS should be returned to the UC for verification and promptly discarded. Labels should be removed or defaced before empty containers are placed in a sharps container. All empty containers from expired or used CS are referred to as "Over Classified RMW" and should be discarded in accordance with the REHS Biological and Medical Waste Disposal Policy https://ipo.rutgers.edu/sites/default/files/RutgersBiowastePolicy.pdf.

## H. CS Recordkeeping

1. Registrants are required to maintain all records of purchase, use and disposal of CS for a 2 year period after their final disposition.
2. Authorized Personnel and authorized CS Users must keep required forms in a location such that they are readily available for review.
3. 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.
4. Authorized Personnel must record CS inventory, usage and expiration dates on the CSL. The CSL will be backed up on a regular basis to prevent alterations.
5. Authorized CS Users must maintain a record of all CS usage on the CSUF. A separate CSUF must be kept for each separate container of CS.
6. A list of Authorized CS Users must be kept up-to-date by the PI and provided to the Registrant Designee/RC or designee promptly as changes occur.

## I. Audit by The Rutgers Animal Care Unit

1. Comprehensive Registration Audits of each Rutgers research registration will be performed every two years. The Rutgers Animal Care Unit has the authority to perform an unannounced review of operations for each Rutgers research registration at their discretion.
2. The Rutgers Animal Care Unit may perform announced or unannounced PI laboratory visits to determine whether CS activities are in compliance with the applicable CSA and NJ CS Act implementing regulations and internal Rutgers CS policies and procedures. Laboratory audits may include a review of CS storage, record keeping and for the presence of expired CS.

**J. Laboratory Audit by the Registrant Designee/RC/UC**

1. Scheduled and unannounced Laboratory audits are conducted by the RC/UC to ensure PI compliance with the applicable CSA and NJ CDS Act implementing regulations and internal standards as outlined in the CS policy. The RC has the authority to perform a scheduled or unannounced review of lab policy and procedures versus Rutgers required policy and procedures.
    a. The RC in coordination with the UC schedules laboratory audits of each PI on a routine basis. The UC will contact the PI to schedule an audit.
    b. The PI will provide the RC/UC with the most recent CSUF. The CSUF is used to determine the audit period and what CS is reconciled. The RC will determine the audit period to include at least six months of activity and records.
    c. All expired CS in animal study areas, including research laboratories will be confiscated at the time of discovery without remuneration including expired CS stored in animal study areas that may be intended for tissue culture use.
    d. Scheduled Laboratory audits conducted by the RC include:
        - Review of any coincident activities being conducted in the PI laboratory to verify that they are authorized activities for that PI.
        - Verification that the research being conducted coincides with the protocols on file.
        - Audit of records and reports for proper completion and retention in accordance with the applicable sections of 21CFR1300.
        - Review of the following Policy requirements:
            Requesting and receiving CS
            Storage
            Disposal
            Inventories
            Controlled substance records

2. Unannounced PI Laboratory Audits by the RC/UC may include any CS activities described in a scheduled audit.
3. On completion of the PI laboratory audit the RC/UC reviews internal standards and observations with the PI and approved lab personnel.
4. A report capturing the audit purpose, duration, findings and recommendations that mitigate non-compliance situations and minimize regulatory risk is provided to the PI within 60 days of audit completion. Reports will be kept on file with the RC/UC and distributed to the Registrant Designee, ORRA and the Senior VP for Research and Economic Development as needed.
5. Written responses to the recommendations provided in the Audit Report, with a corrective action plan will be provided to the Registrant Designee/RC.