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THE STATE UNIVERSITY
OF NEW JERSEY

Rutgers

Controlled Substance Program

Legal Authority

Federal Regulation of CS

THE COMPREHENSIVE DRUG ABUSE PREVENTION AND CONTROL ACT OF 1971

Referred to as the Controlled Substances Act or the CSA

- The Drug Enforcement Administration (DEA) is assigned the lead responsibility for enforcing the CSA.
- DEA is primarily **a law enforcement agency** but is also a **regulatory agency** which regulates the legitimate use of controlled substances by health care professionals and others.
- The Office of Diversion Control, with oversight of 1.6 million registrants, is the regulatory branch within DEA that carries out this function.

NJ Drug Control Unit (DCU)

New Jersey Administrative Code

Title 13
Law and Public Safety
Chapter 45
Controlled Dangerous Substances

- The State of NJ has established a Drug Control Unit within the Department of Law and Public Safety.
- The NJ DCU is assigned the lead responsibility for enforcing the NJ controlled Dangerous Substance (CDS) Act.
- The Unit requires all CDS registrants renew their registration annually.

CS Schedules

A controlled substance is a drug with abuse potential

	Catagory	Characterization	Examples
C I	Schedule I	No medical use No medical value High abuse potential	GHB Heroin Marijuana MDMA (Ecstasy)
C II	Schedule II	Some medical value Highly addictive Strong abuse potential	Cocaine Morphine Amphetamine Pentobarbital Fentanyl
C III	Schedule III	Acceptable medical value Moderate to low addiction potential Moderate abuse potential	Ketamine Buprenorphine Telazol (Tiletamine & Zolazepham) Anabolic Steroids
C IV	Schedule IV	Acceptable medical value Low addiction potential Low abuse potential	Diazepam Phenobarbital Midazolam Tramadol
C V	Schedule V	Lower addiction potential than C-IV Contain limited quantities of CS	Cough syrup with codeine

https://www.deadiversion.usdoj.gov/schedules/index.html

DEA Regulations

Registration

A Registration is required to legally possess a controlled substance

- Limited exceptions such as law enforcement officers, agents and – importantly – patients with legal prescription – known as the ultimate user.
- A State Registration is required before a Federal DEA number will be issued.
- Separate Registrations are required for each place where controlled substances are stored.
  - Limited exceptions, including a “Campus Registration”.

Recordkeeping and Reporting

Security

Recordkeeping Requirements

Retention	Minimum of two year retention period
Location	Generally must be kept at registered address (may request authority to store at a central location)
Accessibility	Schedule II Records Must be separate from others Schedule III – V May be “readily retrievable”

DEA Security Requirements

Security Considerations

- Access Controls
  - Key control
  - Chain of Custody
- Facility Access
  - Open campus
  - Card access readers

Access

- Must be limited to absolute minimum number of individuals required to accomplish work mission.
- A person who has previously lost a DEA registration in an administrative action and/or who has been convicted of a drug related felony may not have access to controlled substances without a special waiver from DEA headquarters.

Storage

- Securely locked – substantially constructed affixed safe or cabinet.

Theft and Significant Loss

The Registration Designee (CSRD) or Registration Coordinator (RC) **must** contact RUPD and **report all thefts and significant losses** to the NJ DEA Diversion Control Office and the NJ DCU.

The DCU and DEA must be notified in writing **within 24 hours of initial discovery.**

A DEA form 106 must also be submitted.

Report to the Registrant Designee and the campus RC, immediately upon discovery.

Any suspicion that a CS has been **misplaced or stolen.**

If CS loss **cannot be recovered or thoroughly justified** as a minor inventory discrepancy.

<u>It is imperative that you report suspected diversion or loss to CS program staff immediately.</u>

Report to campus RC within 24hrs. If the RC is not available, report to the Registrant Designee or UC.

Any spillage or other type of **loss** of CS.

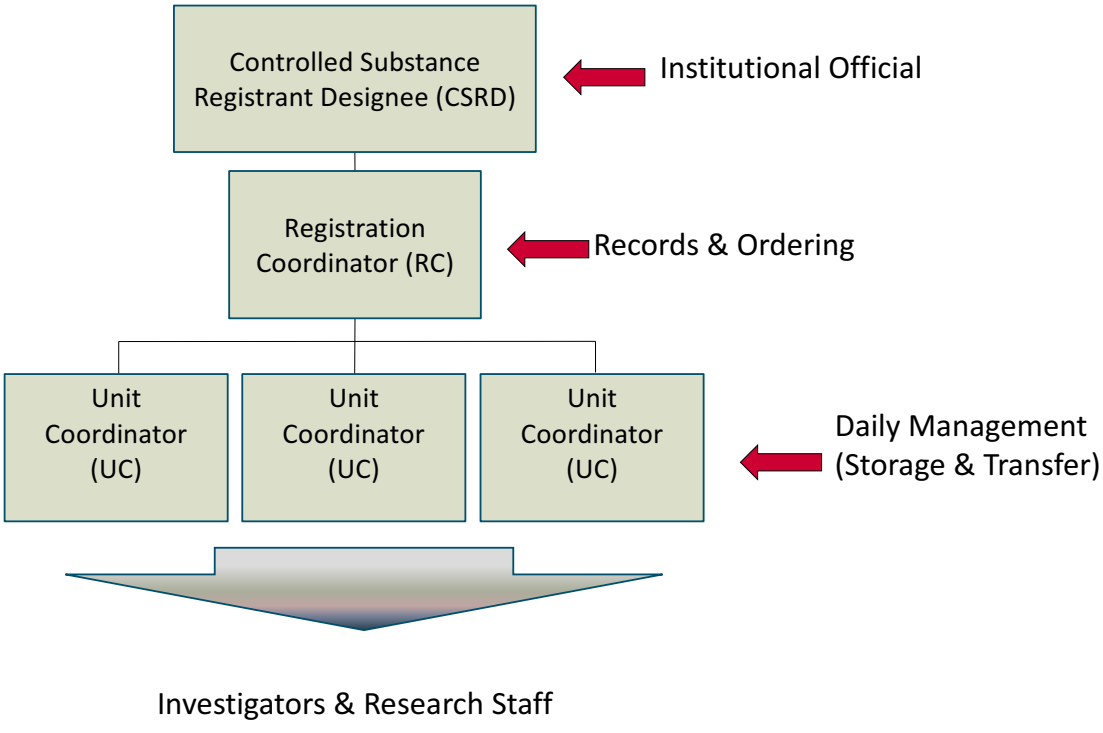
Any loss of CS resulting from inadvertent release from a broken manufacturer's container, a secondary vessel or syringe **that can be recovered** (RUPD, the DEA and NJ DCU will not be notified).

Rutgers Controlled Substance Program

The Policy

The 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.

https://policies.rutgers.edu/view-policies/research-section-90



Mandatory Training

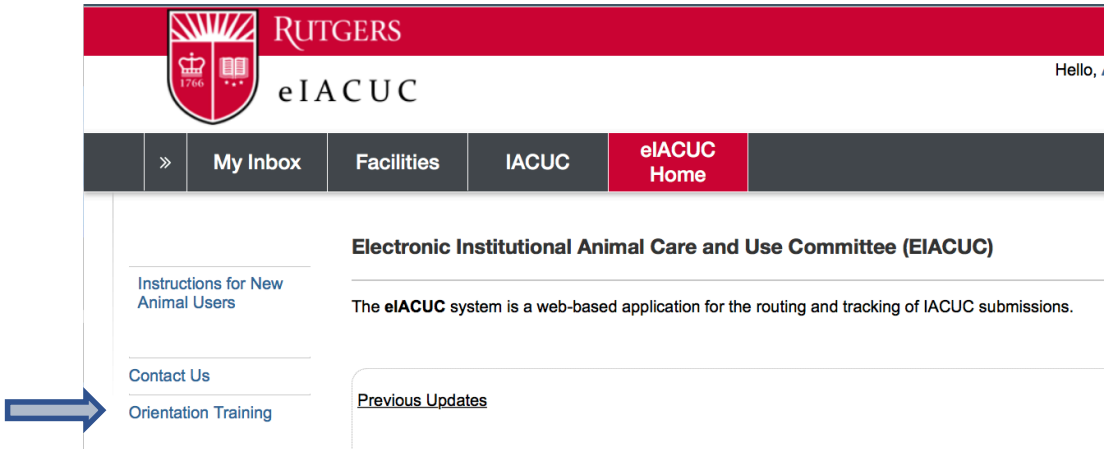
- **Initial Training**
  - Classroom session
  - Laboratory hands-on

    *Record Keeping *Storage *Disposal

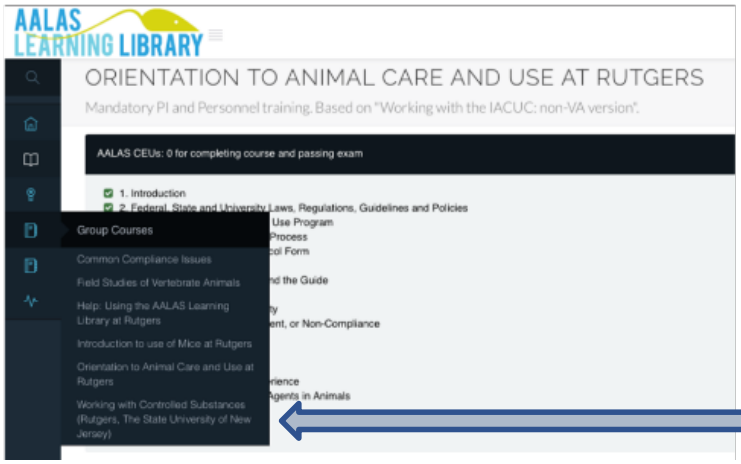
- **Annual Online Refresher Course**

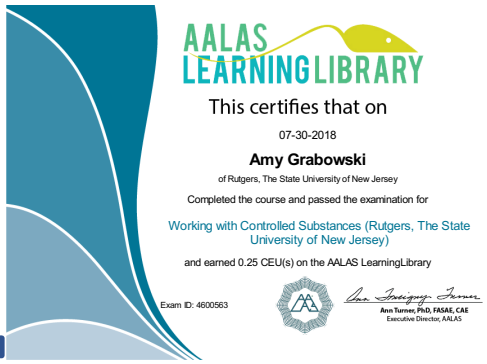
  AALAS Learning Library

  Access through eIACUC.rutgers.edu



Print out your CEU certificate





- **Training Documentation will be added to eIACUC.**

Personnel Forms

Personnel forms must be approved **before** CS requests are accepted
Any changes in personnel must be reported to the UC

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COMPARATIVE MEDICINE RESOURCES
CONTROLLED SUBSTANCE PERSONNEL

Building #:
Approved Location:

A controlled substance (CS) registrant's log book must be maintained for each registration location.
A controlled substance site log book must be maintained for each authorized site where controlled substances are stored.
For Schedule 1 drugs, there must be a separate DEA and NJ CDS registration for each registration site.

REGISTRATION UNIT SITE INFORMATION

RC/UC Information

Unit Name	
Unit Address	
Responsible Individual (RC or UC)	
Authorized Site Contact Person	

AUTHORIZED STORAGE SITES & PERSONNEL
All authorized sites must be approved by the Controlled Substance Coordinator or his designee.

AUTHORIZED USER SITE INFORMATION

PI & Lab Contact
(RU email address only)

Responsible Individual (PI or RC)		Email	
Authorized Site Contact Person		Email	
Authorized Site Location (Bldg/Room/Phone):			

AUTHORIZATION: *I hereby certify that I have designated the personnel listed below as Authorized Users for this Authorized site under the registration listed above.*

PI Signs

Signature	Date

AUTHORIZED USERS

Lab Personnel with access & unsupervised use

	Full Name (print)	Initials (print)	Signature	Initials	Date of Authorization	Date of Departure*
1.						
	Location (Bldg/Room/Ph):					
2.						
	Location (Bldg/Room/Ph):					
3.						
	Location (Bldg/Room/Ph):					
4.						
	Location (Bldg/Room/Ph):					

* The person is no longer an Authorized User as of "Date of Departure" if completed.

Personnel Forms

Personnel forms must be completed **before** CS requests are accepted

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COMPARATIVE MEDICINE RESOURCES
CONTROLLED SUBSTANCE RELEASE

All personnel conducting research at Rutgers, The State University of New Jersey must complete this release form before being authorized to handle Controlled Substances.

Controlled Substance (CS): Substances where the manufacture, possession, distribution, dispensing or use for conducting research or analysis is regulated under the Federal Controlled Substances Act ("CSA") and/or the NJ CDS Act.

I, the undersigned, accept responsibility for the purpose of the handling of CS under a university registration and acknowledge that: (I) all CS must be stored in a securely locked, substantially constructed cabinet; (2) detailed records of drug use must be maintained; (3) the storage, handling and/or use of the substances and/or vials are to be used only by approved personnel in strict accordance with the principal investigator's Rutgers University Animal Care and Use Committee protocol; (4) all missing or lost CS must be reported to CMR within 24 hours; (5) expired CS must never be used and must be returned to CMR along with the usage log (6) all drugs must be returned to CMR upon separation of the CS user from the institution; and (7) changes in the key laboratory personnel must be reported to CMR within ten days.

Have you ever been charged in a court of law, hearing, or other administrative procedure with any violation of the laws of the United States or of any individual state relating to Controlled Dangerous Substances or any felony offense? ____Yes ____ No

Have you ever had any disciplinary action taken against you or been convicted of the laws of the United States or of any individual state, relating to the manufacture, distribution, or dispensing of CS? ____Yes ____ No

PI & Lab Personnel with access & unsupervised use →

Print full legal name (First, Middle, Last)	Email	Phone

Address of residence (Street, City, State)	Employee ID # (Not Net ID)

Signature	Date

☐ Principal Investigator	☐ Key Personnel	☐ CMR Staff

Select one above

Supervisor Signs →

Supervisor Name	Supervisor Signature	Date

Department Chair	Email	Phone

CMR reserves the right to limit the availability of certain CS. Proof of identification may be requested upon submission of this form. Noncompliance with university policy may result in the loss of the privilege to receive or continue the use of CS.

CMR Office Use	☐ *Release Approved*	☐ *Release Requires further attention*
	Received by	*Building/School/Campus*

PI Requests

PI completes CS request form (CSRF)

PI gives form to the local Unit Coordinator

Local Unit Coordinator (UC) reviews PI request

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COMPARATIVE MEDICINE RESOURCES

CONTROLLED SUBSTANCE REQUEST FORM (CSRF)

Principal Investigator: _____Department: _____Today's Date: _____

Lab Contact Person: _____Phone #: _____Email:_____

Lab Person Placing Order: _____Phone #:_____E-mail: _____

Fund Source/Index No.:_____Protocol No.:_____ Species: _____

Approved Storage Location: _____

			Official Use only		
	Controlled substance needed	Amount /Quantity	Drug Schedule	Unique ID	Unit Cost
1					
2					
3					
4					
5					
6					
7					

Please attach any special instructions to this requisition.

For items typically stocked please provide 72 hours advanced notice. Contact the Unit Coordinator for availability. Special order items may take longer, and an Expedited Request Fee may be charged. If you need to change or cancel the order, please contact Authorized Personnel in advance.

Controlled Substance received by lab. Name: _____Date: _____ Initials: _____

CS is issued if there an approved animal protocol and the CS is in stock

If the request is not in stock CS is ordered

Transfer to PI

UC Completes

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COMPARATIVE MEDICINE RESOURCES

CONTROLLED SUBSTANCE USAGE FORM (CSUF)

Return of this form together with any empty or expired controlled substance container is mandatory before new requests are filled.

Registration Site:_____Container Lot #_____
Principal Investigator_____Authorized User: _____
Drug Name: _____ Schedule (I II III IV V)_____ Unique ID: _____
Concentration: _____mg/ml Volume issued: _____ml
Date Issued/Prepared: _____ Expiration Date:_____ Weight In: _____w/cap
PI Secured Location of storage: _____

Please note: Controlled substances must be stored in an approved, securely locked, substantially constructed safe or cabinet with restricted access.

Date	Amount [ ]ml [ ]mg Withdrawn	Balance	[1] Animal ID	Protocol	[2] Procedure	Initials	Wgt no cap

INVENTORY RECONCILIATION				
Date	On Hand (Log)	On Hand (Actual)	Initial	Comment(s)

*Use one form for each vial or container.
*Label each new bottle individually and in consecutive order. Use oldest bottle first.
[1]Enter USDA number for USDA covered species, enter number of animals for non-USDA covered species.
[2] Enter any wasted amount under "procedure". This documentation of waste must have two signatures.

CMR CSUF Page ____of_____ April 2, 2019

CS is transferred to the PI

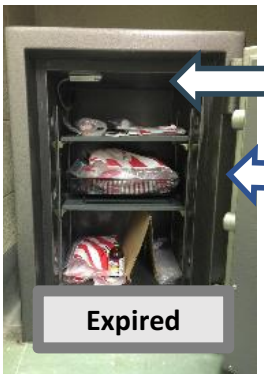
Copy of CSRF & usage form (CSUF) issued to PI with CS

A copy of the CSRF & CSUF remains in UC file

Laboratory Storage

PI stores CS in approved secured location

Securely locked, substantially constructed, affixed safe or affixed cabinet with lockbox.



Clearly label and separate expired CS

CI & CII Separated from schedules III-V
CIII-CV with CI & CII provided:

1. CI & CII security measures followed
2. Kept separated from CI & CII
3. Zero increase in accessibility

YES

NO

Laboratory Recordkeeping

All CS usage must be documented on the CSUF

PI stores CS usage logs in a secure location

One form for each vial or container (this includes dilutions)

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COMPARATIVE MEDICINE RESOURCES

CONTROLLED SUBSTANCE USAGE FORM (CSUF)

Return of this form together with any empty or expired controlled substance container is mandatory before new requests are filled.

Registration Site: RT Container Lot # HS2525

Principal Investigator Sherman Klump Authorized User: Henry Jones Jr

Drug Name: Ketamine Schedule (I II III IV V) Unique ID: RT-19-123

Concentration: 100 mg/ml mg/ml Volume issued: 10ml ml

Date Issued/Prepared: 1/1/19 Expiration Date: 6/1/19 Weight In: 34.5g w/cap

PI Secured Location of storage: Education Bldg Room 123

Please note: Controlled substances must be stored in an approved, securely locked, substantially constructed safe or cabinet with restricted access.

Date	Amount [ ]ml [ ]mg Withdrawn	Balance	[1] Animal ID	Protocol	[2] Procedure	Initials	Wgt no cap
1/1/19	0	10 ml	----------		----------	JH	34.3g
1/2/19	1.2ml	8.8 ml	Rat 1	RU12345	Sub Q implant	H/J	

INVENTORY RECONCILIATION				
Date	On Hand (Log)	On Hand (Actual)	Initial	Comment(s)

UC Site information

PI information

Document any dilutions

PI storage information

Record All Usage Daily

Reconcile

- Any wasted CS requires documentation and two signatures
- All corrections require a single line out & initials (no scribbling over)

Return & Disposal

PI returns unused or expired CS & CSUF to local UC

UC reviews CSUF & CS container before issuing additional CS

UC logs in CS usage

UC arranges for CS disposal using approved methods

Inventory Requirements

Each Registration Location must conduct a Biennial Inventory of CS on hand

- Within two years of the previous biennial inventory date
- Must be a physical count, including everything “on hand”
- Witnessed and signed by two individuals

RUTGERS THE STATE UNIVERSITY OF NEW JERSEY	Office of Research Advancement BIENNIAL INVENTORY OF DRUGS ON HAND[1]	Inventory Date _____ [ ] start of business [ ] end of business DEA Registration number:_____

Drug Name & Lot Number	Container ID	Concentration/Form	Container Size	Quantity on Hand	User/Site	Comment

Signatures of the TWO individuals taking the inventory: 1)_____ 2) _____
Print the **full names** of the TWO individuals taking the inventory: 1)_____ 2) _____
Date: _____ **Date**:_____

[1] An inventory of drugs on hand should be performed by the registrant (registration holder) periodically. DEA requires an inventory at least every two years. It may be done more frequently but should be titled “Biennial Inventory”. This is not to be a running total but a one-point-in-time snapshot of all drugs held by the registrant in all locations. A signed hard copy should be available for inspection by DEA. The Newark DEA office recommends “Biennial” be in the title of the form and that two people sign the inventory.

Laboratory Audit Checklist

Controlled Substances Laboratory Audit Checklist

Registration Activities			
	Yes	No	Comments
Are the activities within the parameters of the registration? (e.g., substance, schedule, analytical research, etc.)			
Are protocols kept updated and approved?			
Is there a laboratory SOP?			
Personnel			
Is the laboratory Authorized User Form up to date?			
Have all authorized users signed the Authorization Release Form?			
Is there a CS Request Form on file?			
Have authorized users had CS training?			
Are all approved users aware of proper theft or loss procedures?			
Usage Logs			
Are overall inventory records maintained?			
Are overall inventories for Schedule I & II kept separate from III-V?			
Are usage records for the last 2 years maintained readily available?			
Are usage records for Schedule I & II kept separate from III-V?			
Have the usage records recently been reconciled for accuracy?			
Is CS documented at the time of receipt and containers weighed with/without cap?			
Are containers labeled with unique identifiers?			
Do diluted solutions have separate usage logs?			
Are diluted solutions labeled with the drug name, weight, date, concentration, caution statement or appropriate reference code?			
Are exact quantities of usage recorded?			
Is the usage log initialed by an Authorized User?			
Is expired or unwanted CS documented and returned to the Unit Coordinator?			
Is the final net weight recorded at the time of usage?			

Laboratory Audit Checklist

Laboratory Audit Checklist Continued			
	YES	No	
Disposal			
Are expired/unwanted CS kept secured until returned to the Unit Coordinator?			
Are expired substances labeled as expired?			
Are containers with non-recoverable substance returned to the Unit Coordinator?			
Are non-recoverable substance properly accounted for in the usage forms?			
Are empty containers confirmed empty, rinsed with rinsate and disposed of in the proper receptacle?			
Security/Storage			
Is CS stored in a securely locked, substantially constructed, anchored cabinet, refrigerator or safe?			
Is the storage located at a location approved by the Registration Coordinator?			
Is the storage location kept secured with a two-lock system?			
Is access to the storage area kept to a minimum number of authorized users?			
Are keys kept secured in a separate location?			
Have cases of theft or loss been reported to the Authorities and on DEA form 106?			
Are non-recoverable losses documented and signed by an authorized person and witness?			

Laboratory Audit: Scheduled and unannounced audits of PI laboratories are conducted by the RC/UC to ensure compliance.

- Regulatory findings and internal standards observations are reviewed.
- Recommendations and best practices for corrective actions are presented.