

Controlled Substances
Program (CSP)
Guidelines

Issued: 10/31/2023

Controlled substances (CS) are drugs or chemicals whose manufacture, possession, and use are regulated by the government. UC Irvine currently maintains federal Drug Enforcement Administration (DEA) departmental registrations governing the use of CS for research, veterinary, and teaching purposes.

UC Irvine's <u>CSP policy</u> and <u>Procedure (PDF)</u> describes authorization to conduct work with CS, employee and institutional responsibilities, and operational requirements. The CSP is managed by the CS Program Coordinator in Environmental Health & Safety (EH&S).

Principal Investigators (PIs) are required to apply for a Controlled Substance Use Authorization (CSUA) with EH&S to possess, use and store controlled substances/ precursor chemicals for research.

Determine if the drug is a controlled substance

- 1. To determine if the **drug** is a controlled substance, please visit the following link: https://www.deadiversion.usdoj.gov/schedules/orangebook/c_cs_alpha.pdf. This link will provide you with the name of the substance, the DEA number, the schedule number, and other common names for the substance. This information will be useful when completing your CSUA application.
- 2. To determine if the **chemical** requires a CSUA, please visit the following websites:
 - Drugs and Chemicals of Concern
 - List I chemicals
 - California Department of Justice Precursor Chemicals- Only pages 1 and 2 are applicable.
- 3. Still not sure, please send an e-mail to the CS Program Coordinator at occhlth@uci.edu and provide the names of the controlled substance/precursor chemicals to be used for research.
- 4. The following common anesthesia or analgesia drugs such as xylazine, isofluorane, halothane or propofol are not controlled substances. Consider storing these agents in such a way that the drugs are not visible or accessible but they should **not be** stored with the controlled substances.

Once determined a CSUA is required, please download the latest application listed under Forms (Controlled Substance Use Authorization) on our website.

Personnel CSUA Requirements

For PI's

<u>CSUA Application</u>: PI's must list all of the controlled substances (CS) or precursor chemicals they plan to use in the course of their research during the next year. <u>Per DEA requirements, the CSUA application is required to be renewed annually</u>

- **Completion of online training**. Please log on to the <u>UC Learning Center</u>, type "Controlled Substances", in the search box. Select "register" to complete the course. EH&S will receive the training completion. Training renewal is required every 3 years.
- Completion of PI Screening Data Sheet Form 1A
- *An approved IACUC/IRB protocol: Depending on the purpose and controlled substance schedule number, additional authorization or registrations maybe required. Any work involving a Schedule I or II controlled substance will require Research Advisory Panel authorization and additional months for processing and approval.
- Expect an audit of your lab twice per year to evaluate compliance with UCI's DEA registration requirements. Unannounced spot inspections by EH&S will be performed to ensure preparation for the true unannounced inspections by the DEA.
- Per registration, the Federal Drug Enforcement Administration (DEA) and UCI require a controlled substance biennial inventory to be performed and documented on a specific day once every two years. The CS Program Coordinator will assist the PI in preparing the inventory status for unannounced DEA inspections. The <u>Biennial Inventory</u> is a snapshot of the department's on-hand CS Inventory at the "close of business for that day."

All research staff that handle controlled substances or precursor chemicals must complete the following:

- **Completion of online training**. Please log on to the <u>UC Learning Center</u>, type "Controlled Substances", in the search box. Select "register" to complete the course. EH&S will receive the training completion. Training renewal is required every 3 years.
- Complete Personnel Screening Data Sheet Form 2A Authorized personnel are individuals
 designated by the PI to access and work with controlled substances/precursor chemicals under a
 particular CSUA. Final approval of authorized personnel rests with the Controlled Substance
 Program Coordinator following the verification of DEA required information that applicants
 provide on the Personnel Screening Data Sheet.

Authorized personnel applicants must answer questions concerning:

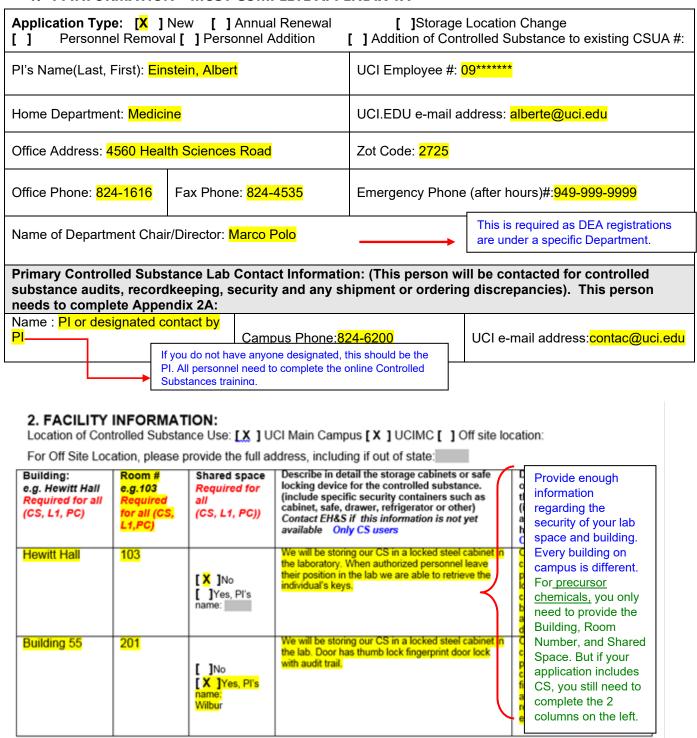
- Felony convictions in connection with controlled substances
- Surrender of previous registrations or having a registration revoked, suspended, or denied
- Any use of narcotics, amphetamines, or barbiturates other than those prescribed to the applicant by a physician

How to complete the CSUA Application

There should be one CSUA form for every PI that is using controlled substances/precursor chemicals; if you use both, you may list all of them in one application.

Example of an approved CSUA form:

1. PI INFORMATION - MUST COMPLETE APPENDIX 1A



[]No [X]Yes Is the use location different from the storage location (Con	trolled substances must be returned to
approved storage location after procedure)	
List procedure location(s):	
Building: We take our CS to Hewitt Hall Vivarium-only when needed to	Room: 456
work on the animals after each use we inventory the use and bring back all	
drugs to the locked cabinet.	
Building:	Room:

CS STORAGE LOCATION: Controlled substance storage locations are strictly regulated. Contact the Controlled Substance Program Coordinator at (949) 824-1616 or occhlth@uci.edu for more details before investing in storage facilities. All facilities must be approved by the Controlled Substances Program Coordinator prior to use.

3. AUTHORIZED PERSONNEL required for all (CS, L1, PC)

All Personnel listed must complete the Screening Data Sheet: See Appendix 2A. Addi are available at https://ehs.uci.edu/programs/occhlth/cs/Appendix_2A_PSDS_applican

Name: Last, First	UCI E-Mail e.g. <u>anteater@uci.edu</u>	Controlled Substance Screening Data Sheet submitted? Yes/No	Controlled Substance training completed? Yes/No	Authorized to Pickup Controlled Substances at EH&S Yes/No	Di
Newton, Isaac	newtonex@uci.edu	Yes	Yes	Yes	To
Curie, Marie	cmarieex@uci.edu	Yes	Yes	Yes	To
Mendel, <u>Gregor</u>	mendgex@uci.edu	Yes	Yes	Yes	To

Identify everyone involved in the use of Controlled Substances/ Precursor Chemicals.

Everyone listed in this section should have completed the CS training and Appendix 2A. If there is any one individual missing any of the forms or training, the CSUA is put on HOLD – (no orders can be approved until everyone has completed all the training and paperwork).

If you need additional rows, hit the Tab button.

How to complete Personnel Screening Forms

Principal Investigator Personnel Screening Data Sheet (Appendix 1A) Controlled Substances Program - Environmental Health & Safety -UCI	
All Principal Investigators (PI) filing for a Controlled Substance Use Authorization (CSUA) are required to submit a Personal Screening Data Sheet to EH&S, per UCI policies and procedures Sec. 903-15, Section 707-10 and 21CFR1301.90. CS training is required prior to personnel approval per UCOP BUS50.	List completion date of UC
PI: Complete CS Training and submit this form to EH&S by: Fax (949-824-4535) E-mail (occhith@uci.edu) or Mail (Attn: EH&S CSUA-EOT 2725) 01/25/2017	Learning Center online "Controlled Substances" training.
CS Training required through JCLearning Center, beyword search "controlled substances". Training completed off	daning.
PI Name (First Middle Last): Albert Einstein Date of Birth: 01/25/19**	
Driver's LicenseID # or Passport#: U22***** State/Country CA	PI's must complete with
UCIAffiliate ID#: 09************************************	accurate information.
Home Address: 88 Two Stars Lane Example, Nowhere, CA 85832	
Phone Number: 949 824 1616 E-Mail Address: contac@uci.edu	
Within the past five years, have you been convicted of a felony, or within the past two years of any misdemeanor, or are you presently formally charged with committing a criminal offense? (Do not include any traffic violations, juvenile offenses or military convictions, except by general court-martial.) If the answer is Yes, furnish details of conviction, offense, location, date, and sentence on additional page. Yes,	
In the past three years, have you ever knowingly used any narcotics, amphetamines, or barbiturates, other than those prescribed to you by a physician? If the answer is Yes, furnish details on additional page.	PI's must complete with
☐ Yes ■ No	accurate information.
Have you ever surrendered a controlled substance registration or had a controlled substance registration revoked, suspended or denied?	
Yes No	
By signing below, I agree to comply with UCI's Controlled Substances Program Policies and Procedures and I authorize inquiries of courts and law enforcement agencies for possible pending charges or convictions. I understand that any talse information, omission of information, or misuse of controlled substances will jeopardize my position with the University. Information included herein will not preclude me from utilizing of controlled substances in non-human research at UCI, but will be considered as part of the overall evaluation of qualifications in the application.	
The DEA requires that an employee who has knowledge of drug diversion from his/her employer by a fellow employee is obligated to report such information to a responsible security official of the employer. At UCI all such reports can be made confidentially to the Controlled Substances Program Coordinator who will inform the appropriate officials and initiate an investigation of the allegations. The protection of an individual's right to privacy will be upheld in all confidential inquiries.	PI signature required for
Principal Investigator Signature: Albert Einstein Date: 01/25/2017	final approval by CS
Controlled Substance Program, EH88 - Phone: 949-824-8280 - Fax: 949-824-4595 - 20T CODE 2725	Program Coordinator.

Personnel Screening Data Sheet (Appendix 2A) Controlled Substances Program - Environmental Health & Safety - UCI proposed handlers of controlled substances (CS) must submit a Personal Screening Data Sheet to EH&S, per UCI licies and procedures Sec. 903-15, Section 707-10 and 21CFR1301.90, CS training is required prior to personnel proval per UCOP BUSSO.	Learning Center online "Controlled Substances" training.
plicant: Complete CS Training and submit this form to your PI for signature. Return form to EH&S by either: Fax (949-824-4535) E-mail (occhith@uci.edu), or Mail (Athr: EH&S CSUA, 2OT 2725)	_ /
01/25/2017)
Training required through <u>UC Learning Center</u> , keyword search "controlled substances Training completed on UT2-3/2017	1
SIGN APPLICANT PRIVILEGES: Designate as CS Lab Contact (Circle one: Primary / Secondage Authorized Recipient (OK to Pickup Controlled Substance Shipments)	PI to assign applicant privileges.
Applicant Name (First Middle Last): Isaac Newton Date of Birth: 03/21/19**) L
Oniver's LicenseilD # or Passport#: N22***** State/Country CA	All and for the second second
Employee or Student ID#: 091******	All applicants are required complete and provide
tome Address: 1616 Express Way, Nowhere, CA 96772	accurate information to be
Total Carlos	authorized users.
ab/Office Location: HH 103 Phone Number: 824-**** E-Mail Address: newtonex@usi.edu)
Tate, and sentence on additional page. Yes The past three years, have you ever knowingly used any narcotics, amphetamines, or barbiturates, other than those prescribed to you by a physician? If the answer is Yes, furnish details on additional page.	All applicants are required to complete and provide accurate information to be
lave you ever surrendered a controlled substance registration or had a controlled substance registration revoked, sussended or denied?	II.
fave you ever surrendered a controlled substance registration or had a controlled substance registration revoked,	authorized users.
lave you ever surrendered a controlled substance registration or had a controlled substance registration revoked, suspended or denied?	II.
President of the desired and the controlled substance registration or had a controlled substance registration revoked, suspended or denired? Yes No Typic	II.
Have you ever surrendered a controlled substance registration or had a controlled substance registration revoked, suspended or denied? Yes No By signing below, I agree to comply with UCI's Controlled Substances Program Policies and Procedures and I substances program Policies and Procedures and I substances in policies and procedures and I substances or convictions. I understand that any false information, ornission of information, or misuse of controlled substances will jeopardize my position with the University, Information included herein will not preclude me from utilizing controlled substances in non-human research at UCI, but will be considered as part of the overall evaluation of qualifications in the application. The DEA requires that an employee who has knowledge of drug diversion from hisher employer by a fellow employee is sbligated to report such information to a responsible security official of the employer. At UCI all such reports can be made confidentially to the Controlled Substance Program Coordinator who will inform the appropriate officials and inflate an	authorized users.
Have you ever sumendered a controlled substance registration or had a controlled substance registration revoked, suspended or denied? Yes No By signing below, I agree to comply with UCPs Controlled Substances Program Policies and Procedures and I surforize inquiries of courts and law enforcement agencies for possible pending charges or conscitions. I understand that any false information, omission of information, or misuse of controlled substances will jeopardize my position with the Iniversity, information included herein will not preclude me from utilizing controlled substances in non-human research at JCI, but will be considered as part of the overall evaluation of qualifications in the application. The DEA requires that an employee who has knowledge of drug diversion from his/her employer by a fellow employee is obligated to report such information to a responsible security official of the employer. At UCI all such reports can be made confidentially to the Controlled Substance Program Coordinator who will inform the appropriate officials and initiate an investigation of the allegations. The protection of an individual's right to privacy will be upheld in all confidential inquiries applicant signature: Saac Newton	II.
Place you ever sumendered a controlled substance registration or had a controlled substance registration revoked, suspended or denied? Yes No By signing below, I agree to comply with UCPs Controlled Substances Program Policies and Procedures and I surforize inquiries of courts and law enforcement agencies for possible pending charges or convictions. I understand that any false information, omission of information, or misuse of controlled substances will jeopardize my position with the Iniversity, information included herein will not preclude me from utilizing controlled substances in non-human research at JCI, but will be considered as part of the overall evaluation of qualifications in the application. The DEA requires that an employee who has knowledge of drug diversion from his/her employer by a fellow employee is shighested to report such information to a responsible security efficial of the employer. At UCI all such reports can be made confiderately to the Controlled Substance Program Coordinator who will inform the appropriate officials and initiate an investigation of the allegations. The protection of an individual's right to privacy will be upheld in all confideratial inquiries applicant signature: Saac Newton	Applicant and PI signatur

4. Controlled Substance Information required from Title 21 PART 1301.18-Research Protocols

Name(s) of controlled substance(s) to be used: (DEA drug codes can be found at: http://www.deadiversion.usdoj.gov/schedules/orangebook/c_cs_alpha.pdf

[X] Animal Protocols: All CS used in animals:

Controlled Substance	DEA Number/	Annual CS estimate for this project	Title of Research Project:	Purpose: Analgesia, Euthanasia,	Approved Animal Protocol # & Expiration date	Durati on of Project	Number and Species of Research Subjects	Dosage to be Administered	Route and Method of Administration
Pentobarbital Nembutal	2270	1 bottle	Studies Retinal Wound Evaluation with rats	Euthanasia mice with spinal injury will be grafted with human spinal stem cells.	2017-1060 exp 8/2018	3 years	20 rats	75-100 mg/kg for 60 minutes	intraperitoneal (IP) injection
Pentobarbital Euthasoi	2270	1 bottle	Studies Retinal Wound Evaluation with rats	Euthanasia mice with spinal injury will be grafted with human spinal stem cells.	2017-1060 exp 8/2018	3 years	20 rats	75-100 mg/kg for 60 minutes	intraperitoneal (IP) injection
Ketamine	7285	10 bottles	Studies Retinal Wound Evaluation with rats	Analgesia, - mice with spinal injury will be grafted with human spinal stem cells. The recovery of motor functions will be then tollowed for 6 months	2017-1060 exp 8/2018	3 years	20 rats	75-100 mg/kg for 60 minutes	intraperitoneal (IP) injection
Morphine	9300	2 bottles	Studies Retinal Wound Evaluation with rats	Analgesia, - mice with spinal injury will be grafted with numan spinal stem cells. The recovery of motor functions will be then tollowed for 6 months	2017-1060 exp 8/2018	3 years	20 rats	75-100 mg/kg for 60 minutes	intraperitoneal (IP) injection

List all the controlled substances approved on IACUC

Concerta: nethylphenid		DEA # 1724	Schedule II	Estimated Average Amount on Hand at any Given Time/ 56 pkg at 160ML	estimate d quantity to be used per year: 6 weeks			if an optimal dose of **** is D in **** patients **** years	IRB Protocol Number 2009-####	Protocol Expiration Date MM/DD/YY	Duration of Project Ongoing, months, etc.
	-	Controlled	d Substan e visit our	t of DEA # and S ces and Precurs website under R ns/occhith/contro	or Chemicals esources						
	4		†								
		informa	tion: (L1	and CP only;							
				nical # L1 stimulant, chemical standa ridine 2704 Agent will be used as rea the deprotection of *** in phase organic synthesis							
[] In-\ Precursor Chemical Piperidine	DEA #	Schedu	lle Purp stim Age the pha	ulant, chemic ent will be us deprotection se organic s	al standar ed as reag of *** in s ynthesis t	d) gent for solid-	Duration of Project Ongoing, 6 months, etc.	Will the CP or L1 chresearch be used to controlled substance	synthesize a		
Precursor Chemical	DEA #	Schedu	lle Purp stim Age the pha	ulant, chemic ent will be us deprotection	al standar ed as reag of *** in s ynthesis t	d) gent for solid-	Project Ongoing, 6 months,	research be used to controlled substance	synthesize a		

Submit the CSUA application and signed personnel screening forms to EHS at occhlth@uci.edu

The approval is contingent upon the storage meeting DEA requirements by the CS Program Coordinator. When the storage has been approved, a CSUA # will be generated. A non-transferable approval decal will be placed by the CS Program Coordinator on the identified storage and photo taken for the DEA.