

**Environmental Health and Safety** 

# CHAPMAN UNIVERSITY Controlled Substances Program



# **CHAPMAN UNIVERSITY Controlled Substances Program**

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#### INTRODUCTION

Research use of selected drugs are regulated by the Federal Drug Enforcement Administration (DEA) and California Department of Justice (CA-DOJ). To assist Chapman University personnel in compliance with these regulations and Chapman University policy, specific institutional requirements have been established for the management of controlled substances.

**Scope of Program & Institutional Registration:** This document applies to all Chapman University personnel working with controlled substances, and pharmaceutical substances. This Program and any future Chapman University Institutional Registration with the DEA covers Schedule III-V controlled substances regulated by the DEA (see Appendix A) used in research at all Chapman University campus locations.

#### **DEFINITIONS:**

<u>Authorized Researcher</u> - A Principal Investigator or laboratory member (e.g., staff, graduate students, undergraduate students, post-docs, visiting scholars and co-faculty) who are assigned by the Participating Faculty/Senior Research Staff to work with controlled substances within their laboratory.

<u>Controlled Substances Act (CSA)</u> - Title 21 United States Code (USC) Controlled Substances Act (<u>21</u> <u>U.S.C. §801</u> et seq.)

<u>Drug Enforcement Administration (DEA)</u> – the agency responsible for enforcing the controlled substances laws and regulations of the United States.

<u>Environment, Health and Safety (EH&S)</u> – the administrative unit that manages the location's Environment, Health and Safety programs.

<u>Program Administrator</u> – person from Environment, Health and Safety charged with implementing and managing the Controlled Substances Program on a day-to-day basis. This person is also called Controlled Substance Officer.

<u>Responsible Official</u> – personnel with responsibility for oversight of the Controlled Substance Program. This is the EH&S Manager/Director.

<u>Controlled Substances</u> – Narcotic and non-narcotic drugs under the jurisdiction of the Federal Controlled Substances Act and the California Uniform Controlled Substances Act, including but not limited to those substances listed in 21 CFR §1308.11-1308.15

#### REGULATIONS

Compliance with federal and state laws and university procedures governing controlled substances and precursor chemicals is required by all individuals and groups associated with Chapman University. These regulations include the following:

1. Code of Federal Regulations: Title 21, Chapter II (Parts 1300 to end) – These regulations

implement the Controlled Substances Act of 1970, the Diversion Control Amendments of 1984, 1985, 1986, 2011 and subsequent amendments https://www.deadiversion.usdoj.gov/21cfr/cfr/1300/1300 05.htm

2. Health and Safety Code Division 10: California Uniform Controlled Substances Act. (http://leginfo.legislature.ca.gov/faces/codes.xhtml).

#### CONTROLLED SUBSTANCES

#### Responsibilities

### 1.0 Environmental Health & Safety

Chapman University's Department of Environmental Health & Safety (EH&S) in the Office of Risk Management providers oversight, including policy development for any use of controlled substances for research purposes within the University. This includes:

- Identifies need for new registrations, assesses current registration limitations, applies for, maintains and renews DEA institutional registrations. Liaison with DEA on registration issues.
- 2. With regard to any University institutional DEA registration, oversees initiation and maintenance of the institutional research registration for DEA Schedule III V controlled substances.
- 3. With regard to any need by research personnel for the use of controlled substances not covered by the University Institutional Registration, collaborates with the researcher in a way to support the procurement and use of controlled substances by way of individual researcher-held DEA licensure. Activity under any individual license held by any University researcher will be coordinated with EH&S, including approval for the purchase and use of controlled substances.
- 4. Coordinates research authorizations for use and transfer of controlled substances involving the University's DEA Registration.
- 5. Procures and dispenses orders for controlled substances used in research.
- 6. Performs periodic compliance inspections.
- 8. Develops and promulgate compliance tools.
- 9. Authorizes Purchase requisitions for acquisition of controlled substances from outside vendors
- 10. Communicates with agencies on all compliance issues, including report lost or stolen controlled substances to the Department of Public Safety and the DEA within 24 hours.
- 11. Provides for appropriate disposal of controlled substances (Schedule III-V) obtained under CU's institutional DEA registration or researcher individual license.

#### 2.0 Participating Faculty/Senior Research Staff

For the purpose of internal control, faculty and researchers whose work involves the use of Schedule III – V controlled substances shall enroll such work and secure EH&S's approval, which includes submittal of *Chapman University's Controlled Substance Authorized Researcher Application (Form 2)*. The responsibilities of the participating faculty and Authorized Users are:

- 1. Comply with university, federal and state regulations pertaining to the possession of controlled substances via adherence to *Chapman University's Controlled Substances Program*.
- 2. Maintain strict control over inventory and security for controlled substances.
- 3. Ensure that controlled substances are NOT intermingled in any manner (usage, storage, etc.) with those controlled substances owned by other individual(s) or other sources. Any controlled substances held by research personnel under an individual DEA license must be maintained in separate storage and not intermingled with controlled substances held under institutional registration.
- 4. Ensure necessary researcher authorization for individuals in the laboratory who are assigned to work with controlled substances (e.g., staff, graduate students, post-docs, visiting scholars or co-faculty) and maintain documentation to verify currently authorized researchers.
- 5. Take the *on-line Controlled Substances Training* available from the EH&S Office. Also ensure that all Authorized Researchers complete this training.
- 6. Provide training to Authorized Researchers on laboratory-specific operations involving controlled substances. Provide information on the health hazards of the substances, including local and systemic toxicity, and the conditions and situations that could result in exposure. Retain training records for at least one year.
- 7. Ensure Authorized Researchers receive, store, use, dispose of, and continually maintain usage log sheets and on-line chemical inventory management system for controlled substances per the University's Program. Maintain usage logs for 2 years after complete use or disposal of controlled substance, or for longer periods of time as may be required by EH&S, the DEA or other regulatory agency.
- 8. Ensure that periodic self-inspections are conducted minimally on a annual basis, using *Controlled Substance Periodic Inspection Checklist (Form 7)*. Retain inspection records for at least one year. Submit a copy to EH&S.
- 9. Biennially, complete the physical inventory, as required by regulations and directed by the institutional program.
- 10. Prior to moving, contact CU Controlled Substances Program Office to seek approval for moving storage location of Controlled Substances.
- 11. Immediately report missing controlled substances to Environmental Health & Safety by calling (714) 532-7794 and emailing <a href="EHS@chapman.edu">EHS@chapman.edu</a>. EH&S will forward cases of suspected theft or diversion to Chapman's Department of Public Safety. Any imminent safety threats are to be reported to Public Safety by calling 911 from any campus phone or local law authority if off-campus.
- 12. Ensure any delegated duties associated with this program are conducted in a timely manner.

#### 3.0 Authorized Researcher

An Authorized Researcher is responsible for:

- Submitting CU Controlled Substance Authorized Researcher Application (Form 2) to EH&S.
- 2. Take the on-line Controlled Substances Training available via EH&S.
- Complying with university, federal and state regulations pertaining to the possession of controlled substances via adherence to *Chapman University's Controlled Substances Program regarding*:
  - Authorization
  - Ordering
  - Training
  - Security, receiving, storing, using, maintenance of usage log sheets, disposing of controlled substances
  - Reporting theft or loss of controlled substances.
- 4. If delegated by Participating Faculty/Senior Research Staff, participating in or conducting program activities such as maintaining on-line inventory, periodic inspections, biennial campus-wide inventory, etc.

#### 4.0 Controlled Substances Distribution Office (EH&S or its authorized agent)

- 1. Review relevant terms and conditions when drug order is delivered to Distribution Office from an outside vendor.
- 2. Receives and stores controlled substances in a secure cabinet or safe, including refrigeration if needed.
- 3. Maintains log book that contains the following information: PI, controlled substance, strength, form, and date received from the carrier.
- 4. Maintains records of all controlled substance transactions.
- 5. Notifies laboratory by phone or email when their orders are ready use. Releases orders to researchers who are listed as Authorized Recipients in the CSA and have signature cards on file.

#### Use Authorization

Any university faculty or senior research staff member planning to use Schedule III – V controlled substances for research must first gain EH&S approval. This is done by submitting the <u>CU Controlled</u> <u>Substance Authorized Researcher Application (Form 2)</u>. This form fulfills the regulatory requirement to fairly assess the likelihood of personnel to commit a drug security breach. Authorization to access controlled substances will be denied to any personnel who has been convicted of a felony offense relating to controlled substances or who, at any time had an application for DEA registration denied or registration revoked—in accordance with Section 21 CFR 1301.90. Requestors agree to consent to a University requirement for a current background check. Names of all new Authorized Researchers are

made available to the U.S. Drug Enforcement Administration (for screening of criminal history).

The form also communicates the Requestor's responsibility to:

- Take the on-line Controlled Substances Training
- Obtain the requisite health and safety training on the hazards of working with the controlled substance from his/her supervisor.
- Follow listed work practices as further detailed in the Controlled Substances & Precursor Chemicals Program.

#### **Purchasing of Controlled Substances**

Any University faculty or senior research staff member needing to purchase Schedule III – V controlled substances for research must gain EH&S use/ purchasing approval.

**Step 1:** For use/ purchasing approval, prior to any initial request to purchase Controlled Substances under the Chapman University DEA registration, submit the following Form 1 to EH&S:

- CU Controlled Substance Purchase Request Application (Form 1) \* Identifies the
  controlled substances requested, names of the authorized researchers, and provides
  proof of legitimate research use including approval from one of the following:
  - Institutional Animal Care and Use Committee (IACUC) for animal research.
  - Institutional Review Board (IRB) for human subjects related research, or the applicant's department chairperson (if the applicant is the department chairperson or higher, approval must be obtained by the applicant's supervisor).
  - **Department Chair** for research that does not involve animals or humans.

**NOTE:** This process does not cover authorization requirements of the Institutional Animal Care and Use Committee (IACUC) or the Institutional Review Board (IRB) which must be separately secured through the Office of Research and Sponsored Program Administration (ORSPA), nor does it cover authorizations required to use Controlled Substances at a location not covered by the Chapman University DEA registration permit.

**Step 2:** The authorized researcher will create a Purchase Requisition via University-standard PeopleSoft processes. The researcher will use a Vendor on this list of EH&S Authorized Vendors. The researcher will attach a completed Form 1 to the online Purchase Requisition, which will be electronically routed to EH&S for review and approval. The purchase of controlled substances under the Chapman University Institutional License cannot be advanced without EH&S approval. For more information on Purchasing procedures, please see the related information in this document found at this <u>link</u>, and/or contact <a href="http://www.chapman.edu/faculty-staff/purchasing.aspx">http://www.chapman.edu/faculty-staff/purchasing.aspx</a>

IMPORTANT: Under no circumstances can controlled substances be purchased using a P-Card, other credit card, or by any means other than through the University's established Purchasing System via PeopleSoft. The management of controlled substances under the Chapman University DEA Registration creates a significant obligation to researchers to follow all elements of this Controlled Substances and Precursor Chemical Program Manual. A failure to follow established policies and procedures can result in a discontinuance of researcher authority to purchase controlled substances and may jeopardize the Institutional Registration that is held in the name of the University. This could

result in a loss of the authority granted by the DEA to purchase controlled substances, impacting the entire Chapman University science research community. This same notice applies to any controlled substances purchase under any EH&S-approved individual license that may be held by a researcher.

#### Central Receiving & Dispensing Process

All authorized controlled substance purchases are delivered to the Authorized Purchaser at the address shown on the DEA Institutional License and will be received in accordance with guidelines provided in this manual and with Chapman University EH&S Policies and Procedures.

#### Inventory & Recordkeeping

Per the Code of Federal Regulations- Title 21, Section 1304, complete and accurate records shall be kept of all controlled substances purchased, manufactured, transferred, or wasted.

#### FOR AUTHORIZED RESEARCHERS: Controlled Substance Logbooks

Each authorized Faculty or Senior Research Staff Member in possession of controlled substances must maintain an up-to-date legible usage log of each controlled substance in possession using the *CU Controlled Substances Usage Log (Form 3*). Records must be kept locally for a minimum of two years from final disposition of the controlled substance. Logbooks shall be kept available for periodic audit by EH&S and the DEA. DEA inspections are unannounced.

#### FOR AUTHORIZED RESEARCHERS: Biennial Inventory Submission

On a periodic two-year institutional cycle, beginning January 18, 2017, each Faculty or Senior Research Staff Member must submit a controlled substance inventory on the 3<sup>rd</sup> Wednesday of January every other year to EH&S using the *Substances Biennial Inventory Form (Form 4)*. Researchers will be provided notice 30 days in advance of the date.

#### Storage & Security

The University's overall security system involves a coordinated system of physical and administrative controls.

**Public Safety:** Chapman University's Department of Public Safety has officers who continuously patrol the University and enforce public safety and security.

**Building Systems:** Chapman University's buildings have card key or key systems to lock building after hours, with some facilities also having video cameras stationed at the entrances to buildings.

**Access:** Access within the laboratory must be limited to the smallest number of CU Controlled Substance Authorized Researchers necessary to perform related research activities to help assure complete accountability and reconciliation of any discrepancy that may result.

Screening of Authorized Researchers: All researchers intending to handle controlled

substances, including faculty and senior research staff, are required to undergo background screening via submission of the *CU Controlled Substance Authorized Researcher Application* (Form 2).

**Work Practices:** Controlled substances must never be left unattended at any time. Discovery of an unattended controlled substance, or an unsecured storage area, exposes the institution to losing its registration.

**Containers/ Labeling**: Controlled substances must not be transferred from the original containers for inventory purposes. Identifying labels must not be removed from the original containers. If the substance is converted or diluted, the new container must be labeled properly. Dilutions and working solutions usage must be recorded on the *CU – Controlled Substance Dilution Usage* Log (form 10).

**Storage:** Controlled substances shall be stored in a securely locked, substantially constructed cabinet, located where access is limited. When not in use all controlled substances must be stored there. The lockers in the vivarium 190T is the only approved location. There is a wall mounted locker with individual lockboxes for controlled substances that can be stored at room temperature. For those needing cooler storage there is a lock box in the 4°C refrigerator.

- i. Do not store the keys near the lockbox; and
- ii. Do not store the keys together.

#### **Records and Disposing:**

**Loss or Theft:** Any detected loss or theft of controlled substances must be reported immediately to Chapman University's Public Safety Office at 714-997-6763 and the Risk Management / EH&S Office at 714-532-7794.

#### Transfers

#### **Intra-Campus Transfers:**

Ownership of controlled substances may only be transferred to an individual covered under the University's Program, and such transfer may only occur upon specific written approval granted by EH&S.

An intra-campus transfer of a controlled substance will be approved only if the following criteria are met:

- 1. The original inventory must have been acquired under the Chapman DEA registration.
- 2. The Faculty or Senior Research Staff Member receiving the substance(s) must submit a *Controlled Substance Purchase Request Application (Form 1)* to EH&S and receive approval from EH&S for such transfer.
- 3. Both parties maintain documentation of any approved transfer.

#### **Prohibition of Inter-Campus Transfers:**

Under no circumstances can controlled substances falling under the Institutional Registration be transferred into or out of the location as identified on the DEA Registration. Faculty/Researchers with dual appointments at Chapman University and other universities and/or labs are prohibited from taking

or transferring controlled substances into or out of those other laboratories. Also, faculty with on - and off - campus laboratories is prohibited from taking or transferring controlled substances into or out of on - campus laboratories.

#### **Disposal**

Controlled substances to be disposed must be properly accounted for, and are not allowed to be disintegrated, crushed into powder and dissolved in water for disposal. A request for waste pick up must be made to EH&S's Hazardous Waste Program by submitting the *Request Form (Form 6)* via email to EHS@chapman.edu.

#### **Categories of Waste:**

- 1. **Wasted Controlled Substances** These include items such as unused tablets, injections, oral liquid or preparations compounded in error, which contain controlled substances.
- Expired Controlled Substances These include controlled substances, which have exceeded their shelf life, unwanted Controlled Substances classified as non-formulary drugs or a drug that has fallen into disuse.

Destruction of properly submitted controlled substances is managed by EH&S per the DEA's requirements: http://www.deadiversion.usdoj.gov/21cfr reports/surrend/index.html

NOTE: EH&S only manages the disposal of DEA controlled substances (Schedule III-V) obtained under CU's institutional DEA registration; individual registrants are responsible for managing the disposal of their controlled substances per DEA requirements. Any such disposal must be done under the direction and supervision of EH&S.

#### APPENDIX A: SCHEDULES OF CONTROLLED SUBSTANCES

The Federal <u>Drug Enforcement Administration (DEA)</u> lists controlled substances into 5 schedules. These drugs are listed in the Controlled Substance Act (CSA) of 1970. Examples of drugs in each schedule are listed below – this is not a complete listing, for drugs not listed please use the hyperlinks included.

Section 812 of the Controlled Substances Act (21 U.S.C. §801 et seq.) (CSA) lists substances that were controlled in 1970 when the law was enacted. Since then, approximately 160 substances have been added, removed, or transferred from one schedule to another. The current official list of controlled substances can be found in section 1308 of the most recent issue of Title 21 Code of Federal Regulations (CFR) Part 1300 to end (21 CFR §1308) and the final rules which were published in the Federal Register subsequent to the issuance of the CFR.

This list describes the basic or parent chemical and do not describe the salts, isomers and salts of isomers, esters, ethers and derivatives which may be controlled substances. These lists are intended as general references and are not comprehensive listings of all controlled substances. Please note that a substance need not be listed as a controlled substance to be treated as a Schedule I substance for criminal prosecution. A controlled substance analogue is a substance that is intended for human consumption and is structurally or pharmacologically substantially similar to or is represented as being similar to a Schedule I or Schedule II substance and is not an approved medication in the United States. (See 21 U.S.C. §802(32)(A) for the definition of a controlled substance analogue and 21U.S.C. §813 for the schedule.)

#### **Lists of Controlled Substances**

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

#### APPENDIX B: CHAPMAN UNIVERSITY LIST OF FORMS

- Form 1 CU Controlled Substance Purchase Request Application
- Form 2 CU Controlled Substances Authorized Researcher Application
- Form 3 Chapman University Controlled Substance Usage Log
- Form 4 Biennial Controlled Substance Inventory Form
- Form 6 Controlled Substance Disposal Request Form
- Form 7 CU Controlled Substance Periodic Inspection Checklist
- Form 8 CU Signature Sheet for Controlled Substances
- Form 9 Transfer of Controlled Substances to Chapman University
- Form 10 Chapman University Controlled Substance Dilution Usage Log

**CU Controlled Substance Purchase Request Application**\*\*\*Submit to EH&S to EHS@chapman.edu or via fax at (714-464-4522) – Attention Controlled Substances Program Office\*\*\*

1) Applicant (Faculty/ Proto	col Dir	ector or	Co-director):		
Name:Last, First, M					
Title:					
Dept: Ph	one:				
E-mail Address:					
Account to bill:					
2) Controlled Substance(s)	Reque	sted:	New purchase ; OR, □ Transf	er (from another ow	ner)
Substance			dering requirements, specify:	Quantity:	
	(III-V)	(manufact	turer, product #, etc.)	Unit size	# of units
Shipping preference/ urgency: _					
3) Use/ Storage Locations:					
Building	Room		Security Measures (See I	Nritten Program for	req'ts.)
			☐ Safe* ☐ Securely locked, substantiall ☐ Other:	y constructed cab	inet
			<ul><li>□ Safe*</li><li>□ Securely locked, substantiall</li><li>□ Other:</li></ul>	y constructed cab	inet

4) Research Users of Listed Substance(s):
NOTE: Each Research User (including the Faculty/Protocol Director or Co-director Applicant)

must initially submit an A	uthorized Researcher Application	on (CSP Form 2) to	EH&S_
Name (Last, First, MI)	Title	Phone #	SU ID#
5) Controlled Substances Us  Research Protocol (Title):	• •		
Applicant to maintain copy of rese	earch protocol/Standard Operating Proc	edure on file for revie	w by EH&S and
Approval by either:  □IACAUC and/or IRB Protocol  OR	col Approval (Protocol ID#: )		
Senior Research Staff N	the research being conducte Member, I certify that his/ her ate and necessary for their r	requested use	of DEA Controlled
Dept. Chair Signature	Print Name		Date
6) Certification - for the responsible.  I, certify that the information abide by the use requirement Program.	provided above is accurate	, and that I unde	erstand and will
Print name	Tit	le	
Signature		Date	

### CU Controlled Substances- Authorized Researcher Application This is to

be completed by each researcher seeking use authorization

*	**Submit to EH&S (ehs@chapmar	n.edu) or via fax at (714-46 Program Office***	64-4522) – Attention Controlled Substances
Re	searcher:	Title:	Date of Birth
	Last, First, M.I. st 4 Digits of Social Security #		Date of Birth
Ph	one: Responsible Fa	aculty/Protocol Director or	Co-director:
<b>Ba</b> 1.	or are you presently formally charged	d with committing a criminal ons, except by general court-	or within the past two years, of any misdemeanor offense? (Do not include any traffic violations, martial). If the answer is yes, furnish details of
	Yes - Provide details as attachme	ent 🛮 No	
2.	In the past three years, have you even those prescribed to you by a physician		tics, amphetamines or barbiturates, other than ish details.
	☐ <b>Yes -</b> Provide details as attachmen	nt 🗆 <b>No</b>	
Au	thorized Researcher Responsibilitie	<u>es:</u>	
1.	Take Chapman University's on-line C	Controlled Substances Traini	ng - Contact EH&S for information.
	Receive laboratory-specific training - general chemical safety, condition - health hazards of controlled sub Follow the appropriate work practice	ons and situations that could estance, including local and s	systemic toxicity.

- Chemical Precursor Program, which include:
- Properly store/ secure controlled substances to prevent unauthorized access. Accurately record your controlled substance usage, transfer, disposal, and any other inventory fluctuations via updating the Controlled Substance Usage Logbook (Form 3).
  - Properly dispose of controlled substances via EH&S' Hazardous Waste Program.
  - Report any lost/ stolen controlled substances to Chapman University EH&S @ 714-532-7794. imminent safety threat exists, contact Chapman University's Department of Public Safety Department at 714-997-6763.

#### **Reporting Diversion of Controlled Substances**

The DEA requires (per 21 CFR, Part 1301.91) that an employee who has knowledge of drug diversion from their employer by a fellow employee has an obligation to report such information to a responsible security official of the employer. A failure to report information of drug diversion will be considered in determining the feasibility of continuing to allow an employee to work in a drug security area.

- Chapman University shall treat such information as confidential and shall take reasonable steps to protect the confidentiality of the information and the identity of the employee furnishing the information. All such reports can be made confidentially to the Chapman University EH&S @ 714-532-7794. EH&S will then forward the information to Public Safety.
- If an imminent safety threat exists, contact Chapman University's Department of Public Safety.

#### Disciplinary Action for Employees who Engage in Illicit Activities (21 CFR, Part 1301.92)

It is the position of the DEA that employees who possess, sell, use or divert Controlled Substances will subject themselves not only to State or Federal prosecution for any illicit activity, but shall also immediately become subject of independent action regarding their continued employment. Chapman University will assess the seriousness of the employee's violation, the position of responsibility held by the employee, past record of employment, etc., in determining whether to suspend, transfer, terminate or take other action against the employee.

I certify the accuracy of the above information and that I have above statements; and authorize CU to make any necessar	y background checks including inquiries with
the Federal Drug Enforcement Agency's local field office for	possible pending charges or convictions I
may have.	
Researcher Signature:	Date:

## **Chapman University - CONTROLLED SUBSTANCE USAGE LOG**

- 1. One log sheet must be completed for each container of Controlled Substance. If the material is converted or diluted, start a new log form to track that usage; reference the original container's lot or serial # and original bottle # assigned by lab.
- 2. Controlled Substance usage must be tracked on a per dose (use) basis and only by an Authorized Researcher. Record total quantity of the substance to the nearest metric unit weight/volume or the total number of units finished form.

Fill out grey boxes upon receipt:

Participating Faculty/ Senior Research Staff:	Building:	Room:
, ,		
Drug Name:	Lot or Serial #:	Container Amount:
Expiration Date:	Strength:	Form:
	, and the second	
Date Received or Generated	Unique Bottle Number Assigned by Lab:	Date Disposed – Indicate EH&S pickup time:
	,	_ ' '

	Date	Protocol #	Amount Removed (in mls, tablets, etc.)	Amount Remaining (in mls, tablets, etc.)	Activity Type (e.g., prepare solution; administer to animal)	Species ID or No. of animals	Name of Authorized Researcher (print)	Initial
1								
2								
3								
4								
5								
6								
7								
8								
9								
10								
11								
12								
13								
14								
15								
16								
. •								

	Date	Protocol #	Amount Removed (in mls, tablets, etc.)	Amount Remaining (in mls, tablets, etc.)	Activity Type (e.g., prepare solution; administer to animal)	Species & ID #	Name of Authorized Researcher (Print)	Initial
17								
18								
19								
20								
21								
22								
23								
24								
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#### BIENNIAL CONTROLLED SUBSTANCE INVENTORY FORM

Chapman University Environmental Health & Safety-OH&S Program

#### **INSTRUCTIONS:**

EH&S's records indicate that you have procured the following controlled substances via EH&S.

- 1. Starting January 18, 2017, indicate the total quantity of the substance to the nearest metric unit weight/volume of the total number of units (for Schedule II, perform an exact count or measure of quantity). If applicable, provide the concentration and volume for solutions made from original container.
  - Only inventory controlled substances acquired from EH&S. (Do not include inventory acquired from other sources.)
  - Include any expired or waste controlled substances that are still in your possession.
  - Indicate zero quantities also.
- 2. The authorized researcher who performs the inventory must print and sign this form.
- 3. Submit to EH&S's Controlled Substances Program Office via email @ehs@chapman.edu fax at 714-464-4522 no later than 2:00 pm on the 3rd Wednesday in January each subject year.

Questions? Call EH&S - 714-516-5660

#### LABORATORY INFORMATION:

Name of Faculty/ Senior Staff:		Department/Building/Room Number:
Phone:	E-mail	Reasons for being Maintained:  Research
Inventory Date: January,	20	Inventory recorded by (Print/Signature):

INVENTORY INFORMATION: EH&S records show that the Controlled Substances noted below were acquired under the University's registration.

Controlled Substance	Schedule Number	Total Inventory Quantity	on January , 20
		Concentration	Volume or Weight
		In the Original Containers:	
		Solution from the original #1:	
		Solution from the original #2:	
		Concentration	Volume or Weight
		In the Original Containers:	
		Solution from the original #1:	
		Concentration	Volume or Weight
		In the Original Containers:	
		Solution from the original #1:	
		Concentration	Volume or Weight
		In the Original Containers:	
		Solution from the original #1:	

#### **CHAPMAN UNIVERSITY**

#### CONTROLLED SUBSTANCES DISPOSAL REQUEST FORM

EH&S (ehs@chapman.edu - FAX 714-464-4522

CSA Expiration Date:	Phone #	:
Campus Location:		
Building:	Room:	
	Campus Location:	Campus Location:

- 1. List the controlled substance name and strength (e.g. 100 mg/ml) in column 1, amount of controlled substance in column 2 (e.g. 3 packages of 100 tablets, 1 package with 33 tablets out of 100). Note: The exact amount of the controlled substance must be specified.
- 2. Completed form must be signed and dated by principal investigator or authorized user.
- 3. Send original copy of form to EH&S MS RISK or faxed or emailed. The PI must also keep a copy.
- 4. Upon receipt of complete form, EH&S will schedule the pickup of controlled substances. Legacy Materials

Chapman Program

(1) Controlled Substance		(2) AMOUNT				(3) Controlled	
Name and Strength		QTY	FULL PACKAGE SIZE	QTY	PARTIAL COUNT	AL PACKAGE SIZE	Substance Schedule
			OIZL		COON	OIZL	

DL or Authorized Hear Brint Name, Sign and Date	Received By:		
PI or Authorized User Print Name, Sign and Date Relinquished by:	EH&S signature and pick-up Date		
Print, Signature, Date	Printed Name		

# **CU Controlled Substance Periodic Inspection Checklist**

This checklist is to be completed on an annual basis by the Participating Faculty/Senior Research Staff or his/her designated Authorized Researcher to ensure that the laboratory is meeting all regulatory and institutional requirements for research use of Controlled Substances. **Submit a copy to EH&S at ehs@chapman.edu.** Retain this inspection checklist, including findings *and* corrective actions, for a minimum of 1 year. Contact EH&S-Controlled Substances Program at 714-516-5660 for questions or additional information.

Pa	rticipa	ting F	Caculty/Protocol Director: Inspection Date:
In	specteo	d By:_	
Bu	ilding	•	Room Numbers (Storage/Use Areas):
>	If No i	is chec	eked for any item, complete "Follow-up Actions" on back of checklist.
,	N	N/A	
			1. List of Authorized Researchers is current?

Y	N	N/A	
			1. List of Authorized Researchers is current?
			2. Have all authorized researchers completed the Controlled Substances Program Training?
			3. Is the specific training provided by the supervisor documented?
			On-line Inventory Verification
			4. Is the controlled substances inventory included in CHIMERA?
			Physical Security Measures/Storage/Use
			5. CU Controlled Substance are stored in a securely locked, substantially constructed cabinet?
			6. Key to the cabinet is maintained under the control of the Participating Faculty/Senior Research Staff and/or other designated Authorized Researcher?
			7. Are any of the Controlled Substances past their expiration dates?
			8. All Controlled Substances stock and dilution containers are labeled properly
			Maintenance of CU Controlled Substance Usage Logs
			9. One log sheet is completed for each container including each dilution.
			10. All fields completed correctly.
			11. Physical Inventory matches Controlled Substance Usage Logs (Form 3) for each container?
			If there is a discrepancy between the physical inventory and the usage log inform participating faculty/senior research staff and call EH&S 714-516-7199 immediately.

**Follow-up actions:** 

Item #	Description of Problem	Corrective Actions (include date corrected)

**Additional Comments:** 

CU Signature Sheet for Controlled Substances

This is to be completed by each researcher who will pick up or order Controlled Substances.

Name:
Background check date:
Date of training:
Storage box #
Key #
Signature:
Date:



## Environmental Health and Safety

## **Transfer of Controlled Substances to Chapman University**

Only for use with Schedule III-V Controlled Substances

Name:
Title:
DEA #:
Authorizes the transfer to Chapman University (DEA License # RU0507446) of:
Substance:
Schedule:
Unit Size/Concentration:
Quantity
Lot:
Expiration:
Transferring personnel
Printed Name
Signature
Date
Receiving personnel
Printed name ————
Signature
Date

# **Chapman University - CONTROLLED SUBSTANCE DILUTION USAGE LOG**

- 1. One log sheet must be completed for each dilution vial of Controlled Substance.
- 2. Controlled Substance usage must be tracked on a per dose (use) basis and only by an Authorized Researcher. Record total quantity of the substance to the nearest metric unit weight/volume.
- 3. The unique dilution vial number is assigned by the lab and must be written on the dilution vial.

Participating Faculty/ Senior Research Staff:	Building:	Room:
- and parting a country account of the country and the country are considered as the country and the country are considered as the country and the country are considered as the cou		
Drug Name:	Lot or Serial #:	Dilution Volume:
Expiration Date:	Strength:	
Expiration Date.	Suerigui.	
Date Generated	Unique Dilution Vial Number Assigned by Lab:	Date Disposed – Indicate EH&S pickup date:
	, , ,	

	Date	Protocol #	Amount Removed (mls)	Amount Remaining (mls)	Activity Type	No. of animals	Name of Authorized Researcher	Initials
1								
2								
3								
4								
5								
6								
7								
8								
9								
10								
11								
12								
13								
14								
15								
16								

	Date	Protocol #	Amount Removed (mls)	Amount Remaining (mls)	Activity Type	No. of animals	Name of Authorized Researcher	Initials
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