

**OKLAHOMA CHRISTIAN UNIVERSITY  
INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC)  
POLICIES AND PROCEDURES FOR USING CONTROLLED SUBSTANCES IN  
RESEARCH**

**MARCH 13, 2017**

**I. STATE REGISTRATION**

Researchers who maintain or intend to maintain a supply of Schedule II through Schedule VI controlled substances must comply with the provisions of the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control Administrative Rules, which are Title 475 of the Oklahoma Administrative Code and Title 63 of the Oklahoma State Statutes. They are to apply for controlled substances registration on forms approved by the Oklahoma Bureau of Narcotics and Dangerous Drugs Control (OBNDCC).

**II. FEDERAL LICENSE**

Researchers must also register with the U.S. Department of Justice Drug Enforcement Agency (DEA). Contact the DEA's Diversion Control Program for registration information and applications. Researchers must comply with Title 21 CFR.

**III. POLICIES AND PROCEDURES**

The Oklahoma Christian University Policies and Procedures for Using Controlled Substances in Research focuses on safe storage and disposal, and good record keeping. Researchers planning to use controlled substances as part of their research must complete the Controlled Substance Protocol Review Form.

For more information, please contact Dr. Bill Luttrell, Chair, Institutional Animal Care and Use Committee (IACUC), at bill.luttrell@oc.edu or (405)-425-5421.

**IV. ADMINISTRATIVE POLICY STATEMENT**

In conducting research and teaching activities with controlled substances, University employees and any other individuals using University resources or facilities, or receiving funds administered by the University, and volunteers and representatives who may speak or act as agents for the University must comply with this policy and federal and state regulations relating to controlled substances.

Failure to comply with this policy may be grounds for discipline by the University, referral for research misconduct proceedings, and/or reporting to external licensing authorities by the University. Any disciplinary action imposed will follow the applicable administrative policies and procedures for the individual's employment.

## V. RESPONSIBILITIES

Drug Enforcement Administration (DEA) Registrants (Licensed Researchers) must:

- Maintain a current DEA registration whenever controlled substances are being used
- Require any person that handles controlled substances to complete a DEA-based questionnaire
- Keep a record of the questionnaire until that person no longer handles controlled substances
- Authorize the purchase, use, and disposal of controlled substances
- Maintain an accurate list of authorized users of controlled substances
- Supervise the use of controlled substances
- Conduct a physical inventory of controlled substances at least every two years
- Maintain all records for at least three years
- Report any significant volume discrepancies to the OC IACUC, OC Campus Police Department and DEA

Authorized Users (Authorized Agents) must:

- Complete and submit the Questionnaire for Access to Controlled Substances for Research Purposes by Non-DEA License Holders (Form 1) to the DEA Registrant for themselves and subordinates, such as students and staff members
- Complete the Controlled Substances Protocol Review Form (Form 2) and submit with the IACUC proposal to the Chair of the IACUC
- Comply with the directions for using controlled substances given by the Registrant
- Maintain accurate records of the acquisition, use, and disposition of controlled substances
- Use proper personal protective equipment and adhere to safe practices while using controlled substances
- Report any significant volume discrepancies to the DEA Registrant

Exclusions: This policy does not apply to controlled substances dispensed by a clinical practitioner to a patient in the course of professional practice as authorized by his/her license. This policy does not cover teaching activity performed within a clinical environment. However, clinical teaching activities must comply with DEA and OBNDD.

State and federal governments have numerous regulations pertaining to the legal purchase and use of controlled substances. University employees and other individuals covered by this policy must comply with this policy in order to ensure that they follow all applicable regulations and safely handle and prevent diversion of controlled substances.

## VI. DEFINITIONS

Authorized Agent or Authorized User

- A University employee authorized to use controlled substances by a DEA Registrant
- Controlled Substance**  
Any substance listed in the Controlled Substances Act, Code of Federal Regulations (21 CFR, part 1300 to end)
- DEA Registrant or Licensed Researcher**  
A University employee delegated by his/her department head to hold DEA registration and is responsible for ordering, storing, using and disposing of controlled substances in his/her Unit.
- Disposal**  
Disposal of expired, excess and unwanted controlled substances. Disposal also refers to controlled substances that are residual (often referred to as waste) or have been contaminated through use.
- Disposition Records**  
An accurate, continuous and current record used to track the acquisition, use and disposal of controlled substances. These are not the same as lab books a researcher uses to record scientific findings.
- Drug Enforcement Administration (DEA)**  
The agency within the United States Department of Justice that enforces the controlled substances laws and regulations.
- Licensed Practitioner**  
A physician, dentist, veterinarian, or other individual licensed, registered or otherwise permitted by the United States or the jurisdiction in which they practice, to dispense a controlled substance in the course of professional practice.
- Location**  
A room or designated area where controlled substances are stored or used. A location is managed by a single University employee and has a single address.
- Registration**  
Formal grant of specific authority by the DEA
- Research**  
Systematic investigation, including development, testing and evaluation designed to develop or contribute to generalizable knowledge.
- Unit**  
Any organizational entity within the University that has budgetary authority. Includes, but is not limited to, colleges, departments, centers, offices and programs.

## **VII. STANDARD OPERATING PROCEDURES**

All faculty, staff, and students who work with controlled substances for research must review this document and associated forms very closely. Students are required to successfully complete required training modules. If controlled substances are to be administered to animals, training is to be documented on IACUC Appendix 6—Qualifications for Working with Animals.

DEA-Based Questionnaire: All individuals conducting research and/or teaching activities, with the exception of Drug Enforcement Administration (DEA) Registrants, must complete the DEA-based questionnaire for employee screening procedures. The form is attached to this document as the Questionnaire for Access to Controlled Substances for Research Purposes by Non-DEA License Holders (Form 1). Once completed, submit the questionnaire to the DEA registrant in your unit. The DEA registrant will maintain a file of the completed questionnaires.

Authorized Users Signature Log: Before a person is allowed to sign the Authorized Users Signature Log (Form 3) and use controlled substances in the lab, the required training must be completed to the satisfaction of the DEA Registrant or the Authorized Agent.

Using and Recording the Disposition of Controlled Substances: All individuals conducting research and/or teaching activities with controlled substances must document all actions taken with the controlled substances using Forms 4, 5, and 6. This includes receiving, using, diluting/combining, transferring and disposing of expired, excess, or unwanted controlled substances. Unit registrant will have a log to record controlled substances. Record the use of controlled substances on disposition records. Disposition records must be page numbered and filed in a binder for three years.

Taking Inventory: DEA Registrants must complete an inventory to compare the actual count of controlled substances in the safe to the amount in the written disposition records at least once every two years. More frequent inventories are recommended if using Schedule I or Schedule II drugs, high volumes, multiple controlled substances, or having more than one Authorized User.

Maintaining Registrations: DEA registrations must remain current. OBNDD and DEA must be notified when a registration address changes or becomes inactive.

Disposal of Controlled Substances: Controlled substances that are expired, excess, and unwanted must be disposed of according to DEA regulations and guidelines which are as follows: Researchers who have excess controlled substances in syringes after a research procedure are required to collect the excess in a slurry bottle and document the contents of the slurry bottle on a Controlled Substances Disposal Form. Schedule I and II controlled substances should be placed in a separate slurry bottle from those in Schedules III-V. Controlled substances in their original container which need to be disposed of should remain in the original container with the volume recorded on the Controlled Substances Disposal Form (Form 6).

Reporting a Theft: If a theft is suspected, immediately notify the DEA Registrant who will notify OC Campus Police Department, the DEA, and OBNDD. The Unit Registrant must then complete DEA Form 106, Report of Theft or Loss of Controlled Substances, and submit it electronically to the DEA with a copy to the OBNDD. Reporting a Loss: If a container of a controlled substance is broken, the Unit Registrant will document the loss in the disposition record, to include the date of the incident and the signature of a witness,

if available. The Unit Registrant must complete DEA Form 41 for the amount of the substance lost and write "unintentional destruction" on the form. The Unit Registrant must then obtain the signatures of the person who broke the bottle and the witness (if possible) and sign the Form 41 as required. The original form 41 is sent to the OBNDD and a copy of it is retained in the disposition binder in the Unit.

DEA Contact Information:

DEA

100 Washington Avenue South, Suite 800

Minneapolis, MN 55401

Phone: 612-344-4128

Retaining Records: Controlled substances records must be maintained for at least three years. Other contracts or regulations may require longer retention periods.

Oversight: The IACUC or IRB will review controlled substances records and security measures periodically as well as security measures and compliance procedures for controlled substance storage facilities as needed.

## VIII. PURCHASING, RECEIVING AND STORING CONTROLLED SUBSTANCES

Registration Structure: The department or Unit head must appoint a DEA Registrant for each Department, College, or Unit. The Unit Registrant must obtain a Drug Enforcement Administration (DEA) registration for each University building address where controlled substances will be stored. DEA prefers that each Unit obtain only one registration for each building where controlled substances are stored.

DEA Registration for the Unit Registrant: For use of controlled substances in research, complete DEA Form 225. For use of controlled substances in teaching, complete DEA Form 224.

Purchasing: OC encourages the purchase of controlled substances from Spectrum Chemical Corporation. DEA Form 222 is required to purchase Schedule I and Schedule II drugs. If using these scheduled drugs request Form 222 when applying for a DEA registration. When the DEA Registrant is unavailable, a Power of Attorney may be used to order controlled substances and execute DEA order forms. Power of Attorney may be granted by DEA Registrants to the department head or senior administrator using a copy of the DEA form. The Power of Attorney form must be attached to each order form and is only assigned for a specific period of time.

Receiving: When picking up controlled substances from the on-campus mailroom or when receiving by UPS, Fedex, the DEA Registrant or Authorized User must verify the contents and rectify any discrepancies. Sign and date the purchase receipt and file it with the controlled substances records. Provide a copy of the receipt to the DEA Registrant.

Labeling: If controlled substances are removed from their original packaging and compounded, diluted or combined, each new container must be labeled and tracked. The

label must include: the name of the controlled substances, the schedule of the drug, the lot number, the final concentration, the amount per container and the expiration date (not more than 30 days after dilution date).

Storing and Securing: Controlled substances must be stored in a safe separate from other drugs or materials. The safe must be bolted to an immovable object. Safe access is limited to those people who will be using controlled substances for teaching or research—that is, only the DEA Registrant (Licensed Researcher) or the Authorized User (Authorized Agent) can have the key or combination to the safe where bulk storage is located. Undergraduate students cannot be Licensed Researchers or Authorized Agents, and therefore, cannot handle bulk storage. However, after successful completion of required training in handling of controlled substances, dilute solutions of Schedule IV drugs can be handled and used by undergraduate students in the lab.

The following forms are to be used in keeping controlled substances records:

- Form 1: Questionnaire for Access to Controlled Substances for Research Purposes by Non-DEA License Holders
- Form 2: Controlled Substance Protocol Review Form
- Form 3: Authorized Users Signature Log
- Form 4: Controlled Substances Disposition Record (Bulk Drug)
- Form 5: Controlled Substances Single Drug Disposition Record (Diluted Drug)
- Form 6: Controlled Substances Disposal Form

Information for drafting this document and the attached forms came from assessing documents from websites of the following institutions: DEA, Old Dominion University, University of Minnesota, and the University of Oklahoma Health Sciences Center.

**FORM 1**  
**Questionnaire for Access to Controlled Substances for Research**  
**Purposes by Non-DEA License Holders**

You must complete this questionnaire if you are an OC employee, student, volunteer or other individual acting on behalf of the University and your duties require access to controlled substances for University research purposes. **There is one exception: this form is not required for employees who already hold a license/registration with the federal Drug Enforcement Administration (DEA) and serve as a Unit Registrant under the University's *Policies and Procedures for Using Controlled Substances in Research*.**

The purpose of the questionnaire is to determine if you are disqualified under DEA regulations from having access to controlled substances for University research purposes while working under the DEA registration of another University employee ("Unit Registrant"). You are legally required to answer these questions. If the answer to either question is "Yes," you will not be eligible for a University job or research responsibility requiring access to controlled substances unless the University finds sufficient extenuating circumstances.

Some of the information requested on this form may be considered private data under federal and state guidelines. Private data will be shared internally only with your supervisor, your Unit Registrant under the controlled substances policy, and other University officials who have a need to know the information to do their jobs. Outside the University private data will be disclosed only as authorized by law.

**Note:** You are required to provide updated information to your supervisor and Unit Registrant if any of the answers below change from a "No" to a "Yes" while you have a University job or research responsibility with access to controlled substances.

1. Have you ever been convicted of a felony drug offense? (A conviction includes a guilty plea.)

Yes    No

If yes, please describe the type of offense, the state and court where you were convicted and the date of conviction. If applicable, include extenuating circumstances you believe existed.

2. Have you ever been denied a DEA registration, had a DEA registration revoked or surrendered a DEA registration for cause?

Yes No

If yes, please describe the basis for the DEA's action and the date this action occurred. If applicable, include extenuating circumstances you believe existed.

I certify that the above information is accurate and complete to the best of my knowledge. I understand that I may be subject to disciplinary action, including possible termination, for failure to provide accurate and complete information at the time I sign this form, or failure to provide updated information to my supervisor and Unit Registrant if my answer to either of the above questions becomes "Yes" while I have a University job or research responsibility with access to controlled substances.

Name: (print/type) \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

Please provide your date of birth or OC employee ID# or student ID# to verify records:

\_\_\_\_\_

Supervisor's Name: (print/type)

\_\_\_\_\_



## *FAQs*

### **How should a Unit Registrant interpret the answers to the questionnaire?**

If the answer to any of the questions is “yes,” the person should not be allowed to sign the Authorized Users Signature Log and will not be allowed access to controlled substances.

### **What if someone answered “yes” in the questionnaire and filled in extenuating circumstances?**

Please forward these situations to the Chair of the IACUC or IRB, who will consult with OC Human Resources or the OC General Counsel for advice. In the rare situation where this might occur, there would only be very specific circumstances where someone might still be allowed access to controlled substances for research. One example might be where there was a felony drug offense, but because of certain situations that person was allowed to erase that felony from their files or was able to reduce it to lesser offense.

**Can an individual refuse to complete the questionnaire to avoid reporting a “yes” answer?** Yes, an individual can refuse to complete the questionnaire but this means the person will not become an Authorized User and will not be allowed to use controlled substances for research in the lab. Individuals who choose not to fill out the form must tell their supervisor of their decision. The individual’s job will not be lost automatically because of this situation and the supervisor should consider modified job duties and assignments. If this situation poses concerns for the unit, the supervisor may contact the HR representative for assistance. If this individual’s job is significantly impacted by this change, then appropriate consideration should be given to re-assignment to another position, based upon that individual’s and department’s circumstances.

**FORM 2****CONTROLLED SUBSTANCE PROTOCOL REVIEW FORM**

Directions: Researchers planning to use controlled substances as part of their research with animals or humans must complete this form. Researchers must have a current DEA license and OBNDD Registration. This form must be submitted with the IACUC or IRB Proposal. The Chair of the IACUC or IRB will review the application and contact the applicant if there are any questions or concerns. The applicant will receive confirmation to proceed with the project from the Chair of the IACUC or IRB.

<b>Administrative Information</b>	
Name of Researcher	
Type of Application <input type="checkbox"/> Initial Application <input type="checkbox"/> Renewal Application <input type="checkbox"/> Amendment	
Department	
Campus Address	
Office Phone	Emergency/After Hours Phone
Fax	Email
Title of Research or Teaching Project	
Please list all personnel authorized to work with controlled substances under your supervision.	
Proposed Starting Date	
Grant Number (if applicable)	
Does the research involve the administration of drugs to live animals? <input type="checkbox"/> Yes <input type="checkbox"/> No  If yes, has the project been reviewed by the IACUC? <input type="checkbox"/> Yes (indicate the protocol number) <input type="checkbox"/> No	
Does the research involve the administration of drugs to human subjects? <input type="checkbox"/> Yes <input type="checkbox"/> No  If yes, has the project been reviewed by the IRB? <input type="checkbox"/> Yes (indicate the protocol number) <input type="checkbox"/> No	
<b>Controlled Substances</b>	
Current DEA license expiration date	Current OBNDD registration expiration date

List the name(s) and amount(s) of controlled substance(s) to be used in the research project.

Which controlled substance schedule(s) are you planning to use? (Please check all that apply)

I    II    III    IV    V    VI

Where will the controlled substances be stored? (Please include building name(s) and room number(s)).

Describe security measures to prevent theft or loss of controlled substances.

Is a securely locked, substantially constructed cabinet or safe used for storage of controlled substances?

Yes  
 No

Where will the controlled substances be used? (Please include building name(s) and room number(s)).

Describe security measures to prevent theft or loss of controlled substances during use.

Describe the proposed use(s) of the controlled substance in research. Please include the number and species of research subjects, dose to be administered, the route and method of administration, and duration of the project. (Attach an extra sheet if necessary.)

### Certification

The signature below affirms that the researcher will comply with all of the rules and regulations outlined in the Oklahoma Christian University Policies and Procedures for Research Using Controlled Substances.

Signature

Date

Authorization by Department Chair	
<b>I authorize the use of controlled substances as outlined in this protocol submission and certify that the researcher possesses appropriate licensure through DEA and OBNDD.</b>	
<b>Signature</b>	<b>Date</b>
Authorization by Chair of IACUC or IRB	
Signature	Date

## FORM 3

Last updated: October 12, 2012

### *Authorized Users Signature Log*

Signatures of all persons designated by the Unit Registrant as Authorized Users for this Location are required according to OC Controlled Substances policy.

**Lab Location Address:** (building and room #) \_\_\_\_\_

**Unit Registrant Name:** (print) \_\_\_\_\_

Date Signed	Name Please print	Job Title	Signature	Initials As used in CS records	Date Departed

I hereby certify that I have designated the persons listed above as Authorized Users for this location. Person is no longer an Authorized User when a "Date Departed" is entered.

**Unit Registrant's Signature:** \_\_\_\_\_ **Date:** \_\_\_\_\_

# FORM 4 (Bulk Drug)

## *Controlled Substances Disposition Record*

Drug Name: \_\_\_\_\_ Concentration/Strength: \_\_\_\_\_

Form (liquid, tablets, patch, etc): \_\_\_\_\_ Amount/Container (# tablets or mls/bottle): \_\_\_\_\_

Date	Quantity Received	Received From	*Lab Ref #	Quantity Used	Calculated Quantity in Open Bottle	Unopened Containers	Use Information or Comments	Initials

\*Lab Ref # is a unique number added to the controlled substance bottle in some labs. This is not required.

Unit Registrant Name: (print) \_\_\_\_\_

Location of Lab: \_\_\_\_\_

Location of Safe: \_\_\_\_\_

## FORM 5 (Diluted Drug)

### *Controlled Substances Disposition Record*

Drug Name: \_\_\_\_\_ Concentration/Strength: \_\_\_\_\_

Form (liquid, tablets, patch, etc): \_\_\_\_\_ Amount/Container (# tablets or mls/bottle): \_\_\_\_\_

Date	Quantity Received	Received From	*Lab Ref #	Quantity Used	Calculated Quantity in Open Bottle	Unopened Containers	Use Information or Comments	Initials

\*Lab Ref # is a unique number added to the controlled substance bottle in some labs. This is not required.

Unit Registrant Name: (print) \_\_\_\_\_

Location of Lab: \_\_\_\_\_

Location of Safe: \_\_\_\_\_

## FORM 6

### Controlled Substances Disposal Form

**DEA Address:**  
(as it appears on certificate)

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

**Signatures:**

DEA Registrant: \_\_\_\_\_

\*Staff Surrendering: \_\_\_\_\_

\*DEHS Custody: \_\_\_\_\_

**Date:**

DEA #: \_\_\_\_\_

\*Sign when controlled substances are picked up

Record controlled substances placed into slurry bottle, and expired and excess controlled substances in original container.

	C-II (Check)	Name of Controlled Substance	Concentration	Volume,ml	Quantity,mg
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					
14					
15					
16					
17					
18					
19					
20					