



ENVIRONMENTAL HEALTH AND SAFETY
STANDARD OPERATING PROCEDURES

SOP No. 24.01.99.W1.46AR WTAMU Controlled Substances Procedure

Approved: January 6, 2014

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Environmental Health and Safety at WTAMU is composed of two distinct but integrated environmental safety departments that report to the Vice President of Research and Compliance. Academic and Research Environmental Health and Safety (AR-EHS) is responsible for research and academic related compliance, which includes laboratory and academic research and the associated compliance committees. Fire and Life Safety (FLS-EHS) is responsible for fire related compliance and conducts fire and life safety inspections of campus buildings and assists with the testing all fire detection and suppression systems.

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## Purpose:

The purpose of West Texas A & M University's standard operating procedure establishes processes and controls for the purchase, storage, use, and disposal of controlled substances.

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## Definitions

- Controlled Substance Standard Operating Procedure: A procedure manual that provides a laboratory and its Principal Investigator (PI) with information needed to comply with applicable laws and regulations associated with the use of controlled substances in their research, instruction, service, and testing.
  
- Practitioner's Manual: A Drug Enforcement Administration (DEA) document that summarizes and explains the basic requirements for prescribing, administering, and dispensing controlled substances under the Controlled Substances Act (CSA), 21 USC 801-890, and the DEA regulations, Title 21, Code of Federal Regulations (CFR), Parts 1300 to 1316. Pertinent citations to the law and regulations are included in this manual.
  
- Controlled Substances Registration Program: A Texas Department of Public Safety (DPS) program, The Controlled Substances Registration Program was established as a result of the passage of the Texas Controlled Substances Act in 1973. This program involves the registration of all persons or institutions that manufacture, distribute, analyze, or dispense controlled substances in Texas. Registrants include practitioners (medical doctors, dentists, veterinarians, podiatrists, and therapeutic optometrists), mid-level practitioners (advanced practice nurses and physicians' assistants), pharmacies, hospitals, manufacturers, researchers, teaching institutions, distributors, and analysts. There are approximately 75,000 registrants currently registered. The purpose of registering these individuals and institutions is to attempt to more effectively control the diversion of controlled substances from legitimate channels and to promote public health and welfare by controlling illegal drug trafficking.
  
- Controlled Substance: is defined as a substance, including a drug and immediate precursors and controlled glassware, listed in Schedules I through V or Penalty Group 1 through 4 of the Health and Safety Code, Chapter 481, the Texas Controlled Substance Act.
  
- Practitioners: Physicians, dentists, veterinarians, and other registrants authorized to prescribe, dispense, and administer controlled substances
  
- Memorandum of Understanding (MOU): is describing a bilateral or multilateral agreement between two or more parties. It expresses a convergence of will between the parties, indicating an intended common line of action.
  
- Principal Investigator (or Researcher): The Principal Investigator (PI) is charged to conduct objective research that generates independent, high quality, and reproducible results. The Principal Investigator is responsible for the management and integrity of the

design, conduct, and reporting of the research project and for managing, monitoring, and ensuring the integrity of any collaborative relationships. Additionally, the Principal Investigator is responsible for the direction and oversight of compliance, financial, personnel, and other related aspects of the research project and for coordination with school, department, and central administration personnel to assure research is conducted in accordance with Federal regulations and University and sponsoring agency policies and procedures.

The Principal Investigator reports to a designated official such as a dean, department head, or division chief.

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## **Official Rule/Responsibilities/Process**

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### **1. GENERAL**

- 1.1. WTAMU will comply with state and federal law, including the Memorandum of Understanding (MOU) and DEA regulations governing the purchase, storage, use, and disposal of controlled substances.
- 1.2. AR-EHS is responsible for WTAMU's Controlled Substance Program. The purpose of this program is to ensure compliance with state and federal law and DEA regulations by individuals holding a DEA/DPS registration due to the nature of their work at WTAMU.
- 1.3. All WTAMU employees and students are responsible for full compliance with state and federal law, DEA/DPS regulations, and WTAMU requirements governing the purchase, storage, use, and disposal of controlled substances.
- 1.4. The WTAMU Police Department (UPD) is responsible for providing PIs, Practitioners, and the Office of Research Compliance assistance and recommendations regarding storage and site security. Unauthorized use, theft, or loss of controlled substances shall be reported to the UPD.
- 1.5. Storage must meet requirements of the DEA and the DPS, and compliance must be demonstrated to AR-EHS personnel prior to ordering controlled substances.

### **2. APPLICABILITY**

2.1 This procedure applies to anyone purchasing, receiving, storing, using or disposing DEA-controlled substances in the course of WTAMU-approved research or testing, instruction or service on the WTAMU campus.

### **3. THE CONTROLLED SUBSTANCE STANDARD OPERATING PROCEDURE:**

3.1 AR-EHS, in coordination with other appropriate university offices will develop, maintain and update periodically a Controlled Substances Standard Operating Procedure for the university to serve as a guide to PIs and Practitioners to comply with applicable laws and regulations associated with the use of controlled substances in research, instruction, service, and testing; and will contain WTAMU forms used in the Controlled Substance Program and articulate specific details of and methods to comply with requirements stated in this SOP.

### **4. FAILURE TO COMPLY**

4.1 Failure to comply with this procedure may be grounds for suspension or termination of research by the Vice President of Research and Compliance, or other disciplinary action, and/or reporting to external licensing authorities.

### **5. PROCEDURES**

#### **5.1. DEA and DPS Registration- Request for WTAMU Approval**

Once a PI or practitioner has determined that his or her research, instruction service, or testing will involve the purchase, storage, use, or disposal of a controlled substance, approval must be obtained from his/her department/unit head, dean/vice president, as appropriate, and AR-EHS prior to submission of an application for a DEA/DPS registration.

5.1.1 A criminal background check on the PI and authorized personnel must also be conducted before approval may be granted for submission of an application for a DEA/DPS registration. The procedure regarding the criminal background check must comply with Texas A&M University System (TAMUS) policies and regulations and WTAMU rules and procedures. Once approval for the application for registration has been granted, the PI must apply for and obtain DEA/DPS registration.

5.1.2 Following approval from the dean or vice president, PIs or Practitioners must register with and be approved by AR-EHS. These requirements will include, at a minimum, the following:

- Request for use of Controlled Substance (Appendix A);
- Signed Investigator, Practitioner, or Authorized User Assurance Statement (Appendix B);
- Verification that a completed criminal background check has been done per TAMUS policies and regulations and WTAMU rules and procedures;
- Controlled Substance SOP customized to address the use of controlled substances under the specific DEA registration and approved by AR-EHS. This SOP documents:
  - Schedule of controlled substances;
  - Description of the mechanism utilized to secure the controlled substance (e.g., double-locking mechanism, a safe, etc.). If a locking device is used which requires a key, access to the key must be limited and defined;

- Location(s) where controlled substances will be stored; security recommendations from the UPD and security requirements as implemented;
- Location(s) where controlled substances will be used;
- Details regarding mechanism of transportation;
- Procedures and templates for recordkeeping of controlled substances including receipt and usage logs (Appendix C & D);
- Disposal method(s) for controlled substances;
- Procedures for reporting theft or significant loss of controlled substances or alteration of records indicating drug loss.

## 5.2 Obtaining DEA/DPS Registration

Once WTAMU approval to apply for a DEA/DPS registration has been obtained, PIs or Practitioners are responsible for obtaining their registration directly from the DEA/DPS.

PIs or Practitioners must notify AR-EHS and provide a copy of their registration application and any other correspondence in support of the application. Copies of all subsequent correspondence to and from the DEA/DPS regarding the application, including approval or denial, and a copy of the registration certificate, must be sent to the AR-EHS in a timely manner.

5.2.1 DPS registration occurs simultaneously with the application for DEA registration. The DEA number should be marked as “Pending” on the DPS application.

## 5.3 Prior to obtaining controlled substances:

5.3.1 Once a DEA certificate and DPS approval have been obtained and AR-EHS has been notified of such approvals, prior to obtaining controlled substances, PIs or Practitioners must:

5.3.1.1 Successfully complete a location and document audit by AR-EHS;

5.3.1.2 Obtain signed approval from department head, dean, and AR-EHS to purchase, store, use, and dispose of controlled substances. (Appendix A)

## 5.4 Purchase, Storage, Use, and Disposal of Controlled Substances:

5.4.1 Controlled substances allowed by the DEA certification may be ordered and stored in accordance with DEA regulations, the approved specific Controlled Substance SOP;

- 5.4.2 Only authorized individuals, approved by AR-EHS and listed in the registration application and the attachment to the Controlled Substance SOP, may access or handle controlled substances. To add or remove names of authorized individuals contact AR-EHS;
- 5.4.3 No employee may sell, furnish, or transfer controlled substances covered by the MOU to any person or entity not holding a DPS permit, unless the recipient is specifically exempted by law. Every sale, furnishing, or transfer of a controlled item leaving the campus shall be reported to the UPD and the DPS as appropriate.
- 5.4.4 Security: Controlled substances must be securely stored at all times. Access to controlled substances must be restricted to authorized individuals. Instances of non-compliance or possible non-compliance must be reported immediately to AR-EHS.
- 5.4.5 Recordkeeping: Complete and accurate controlled substance records, including date and quantity of usage and inventory logs, must be kept at all times. Records must provide a complete audit trail, from the receipt/acquisition to the disposal of drugs, including chain of custody. Records should include invoices from suppliers, date of receipt, name and address of supplier, name of the authorized individual who received/used the substance, formulation (liquid/tablet), quantity and dose of drug received, and expiration date. Instances of non-compliance with recordkeeping must be reported to AR-EHS; (Appendix C & D)
- 5.4.6 The PI or Practitioner and/or authorized user must promptly report any theft, loss, or unauthorized use of controlled substances to the UPD and AR-EHS within one business day of notice of such theft, loss, or unauthorized use;
- 5.4.7 Suspected criminal activity should be reported to the UPD and AR-EHS.
- 5.4.8 On or before the AR-EHS approval anniversary date, an annual renewal checklist must be submitted to AR-EHS. Reminder notice shall be sent by AR-EHS; (Appendix E)
- 5.4.9 Audits of controlled substance records including usage and inventory logs should be performed once a year by AR-EHS.
- 5.4.10 AR-EHS shall conduct periodic inspections and compliance review of the authorized individuals and the site(s) or location(s) where the controlled substances are stored and used.

5.4.11 All instances of non-compliance or possible non-compliance must be reported immediately to AR-EHS .

## 6. CONTACT PERSON

6.1 The DEA/DPS license holder is directly responsible for implementing security measures established by WTAMU, and serves as the, primary WTAMU contact with DPS. AR-EHS serves as the secondary WTAMU contact. UPD is available to provide assistance as appropriate upon request.

## 7. TRAINING

West Texas A & M University Environmental Health and Safety will follow the Texas A & M University System Policy [33.05.02 Required Employee Training](#). Staff and faculty whose required training is delinquent more than 90 days will have their internet access terminated until all trainings are completed. Only Blackboard and Single Sign-on will be accessible. Internet access will be restored once training has been completed. Student workers whose required training is delinquent more than 90 days will need to be terminated by their manager through Student Employment.

## 8. RECORD RETENTION

No official state records may be destroyed without permission from the Texas State Library as outlined in [Texas Government Code, Section 441.187](#) and [13 Texas Administrative Code, Title 13, Part 1, Chapter 6, Subchapter A, Rule 6.7](#). The Texas State Library certifies Agency retention schedules as a means of granting permission to destroy official state records.

West Texas A & M University Records Retention Schedule is certified by the Texas State Library and Archives Commission. West Texas A & M University Environmental Health and Safety will follow [Texas A & M University Records Retention Schedule](#) as stated in the Standard Operating Procedure [61.99.01.W0.01 Records Management](#). All official state records (paper, microform, electronic, or any other media) must be retained for the minimum period designated.

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### Related Statutes, Policies, or Requirements (If applicable)

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- Texas Health and Safety Code Chapter 481
- A full text version of the Select Agent Rule (42 CFR 73) is accessible at
- <http://www.cdc.gov/od/sap/>
- Title 21 CFR, Part 1300-1399 (Federal Regulation)
- Title 21 United States Code (USC) Controlled Substances Act 801, et seq. (Federal Law)
- Part 80 Rules and Regulations on Controlled Substances (State Regulation)
- Article 33. Controlled Substances (State Law)

- List of Controlled substances - <http://www.dea.gov/diversion/schedules/index.html>

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## **Contact Office**

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WTAMU Environmental Health and Safety and Office of Research Compliance

806-651-2270



# West Texas A&M University

## Office of Research

WTAMU Box 60217 Canyon, Tx 79016  
806.651.2270

### Request for Use of Controlled Substance

The purpose of West Texas A & M University’s procedure on the transfer, receipt, and storage of controlled substances is to ensure that “controlled substances” on West Texas A & M University campus are handled safely, secured properly, and properly registered with the State of Texas (Department of Public Safety Regulatory Services Division), U.S. Department of Justice Drug Enforcement Agency (DEA), and/or the United States Department of Agriculture, Animal Plant Health Inspection Service (APHIS). For additional information please read Standard Operating Procedure 24.01.99.W1.46AR WTAMU Controlled Substances Procedure.

**\*\*\*Please note: Prior to registering for a controlled substance, approval must be obtained from Department Head, Dean, EHS, and VP of Research and Compliance – as well as applicable WTAMU research compliance committees, including IRB, IACUC, or IBC. Please review: SOP No. 24.01.99.W1.46AR WTAMU**

### Controlled Substances Procedure

***All controlled substances must be ordered and obtained through AR-EHS. Laboratories receiving, shipping, or possessing controlled substances must be registered with the State of Texas and DEA. Contact AR-EHS for help with this registration.***

I \_\_\_\_\_ (PI, Faculty, or Instructor) am requesting WTAMU Environmental Health and Safety to authorize the purchase, transfer, and/or storage of a controlled substance. The controlled substance will be used/stored in \_\_\_\_\_ Building \_\_\_\_\_ Room #.

Controlled Substance	Type of Scheduled substance (I, II, IIN, III, IIIN, IV, V) Definitions are located on Appendix B	# of items	Cost

Description of research being conducted with the controlled substance:

Provide justification on why the controlled substance is needed:

I attest this controlled substance will be used in research work at WTAMU, in the specified laboratory identified above, and will be maintained and utilized according to all associated TAMUS, WTAMU, EHS or industry standard environmental health and safety operating procedures including federal and state regulations. I will follow the records and reporting requirements and the controlled substance will also be stored and secured to prevent damage, theft, or misuse according to [Title 21 Code of Federal Regulations \(CFR\) Part 1300](#) to end [\(21 CFR §1308\)](#).

By signing below, you are agreeing to all statements and information listed above:

\_\_\_\_\_  
PI/Faculty/Instructor Signature

\_\_\_\_\_  
Date

**Supervisory approval required:**

\_\_\_\_\_  
Department Head Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Dean Signature

\_\_\_\_\_  
Date

**Compliance Approval required:**

\_\_\_\_\_  
EHS Approval

\_\_\_\_\_  
Date

\_\_\_\_\_  
Vice President of Research and Compliance Approval

\_\_\_\_\_  
Date

Deliver to:

WTAMU  
AR-EHS  
Killgore Research Center  
806.651.2270

Email: [ar-ehs@mail.wtamu.edu](mailto:ar-ehs@mail.wtamu.edu) or deliver to office KRC 184

# West Texas A&M University

## Office of Research

WTAMU Box 60217 Canyon, Tx 79016  
806.651.2270

### INVESTIGATOR, PRACTITIONER, AUTHORIZED USER ASSURANCE STATEMENT

Questionnaire for West Texas A & M University Personnel Who Will Have Access to Substances Regulated by the U.S. Drug Enforcement Agency or Texas Department of Public Safety.

To comply with federal Drug Enforcement Agency guidance, West Texas A & M University requires that all persons who will have access to controlled substances during work or research activities answer the following questions. By signing below, you authorize inquiries of courts and law enforcement agencies for possible pending charges or convictions. Any false information, omission of information, or misuse of controlled substances will jeopardize your position with the University. Information included herein will not preclude employment, but will be considered as part of the overall evaluation of qualifications in the application. The protection of an individual's right to privacy will be upheld in all confidential inquiries.

Name: \_\_\_\_\_.

Authorization (circle one):      Investigator                  Practitioner                  Authorized User

Circle one:    Faculty                  Staff                  Student                  Other

Lab/Office location: \_\_\_\_\_.

Phone: \_\_\_\_\_.

E-mail address: \_\_\_\_\_.

Buff ID: \_\_\_\_\_.

1) 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 an additional page.

Yes                   No

2) 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 an additional page.

Yes                   No

Applicant signature: \_\_\_\_\_.

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

DEA registration #: \_\_\_\_\_                  TXDPS License #: \_\_\_\_\_.

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

# West Texas A&M University

## Office of Research

WTAMU Box 60217 Canyon, Tx 79016  
806.651.2270

### Record of Receipt Log for an Individual Licensee

#### Receipt Log

(Individual Licensee, Multiple Drugs, Single Storage Location)

VENDOR invoices and DEA Form 222 (schedule I & II only) should be kept along with this record.

Individual License Holder: \_\_\_\_\_.

DEA registration #: \_\_\_\_\_.

TXDPS License #: \_\_\_\_\_.

Storage Cabinet (room/building): \_\_\_\_\_.

Schedule (I-V): \_\_\_\_\_.

Received Date	Received By (print)	Received by (sign)	Source (Vendor)	Drug & Concentration	Amount per unit	Order number	Number of units	Tracking number	*Accounted for (date)

Receipt: Logs for schedules I & II must be maintained separately from schedules III-V. Invoices and copies of DEA Form 222 should be retained with receipt records.

\*Accounted for date: when drug accounting is complete (Use Log complete and substance used up or any unused portions disposed of).

# West Texas A&M University

## Office of Research

WTAMU Box 60217 Canyon, Tx 79016  
806.651.2270

### Record of Use Log for an Individual Licensee

(Individual Licensee, Multiple Drugs, Single Storage Location)

**Individual License Holder:** \_\_\_\_\_ . **Storage Cabinet (room/building):** \_\_\_\_\_ .  
**DEA registration #:** \_\_\_\_\_ . **TXDPS License #:** \_\_\_\_\_ .

**Authorized User: Name:** \_\_\_\_\_ . **Protocol #** \_\_\_\_\_ .  
**Name:** \_\_\_\_\_ . **Protocol #** \_\_\_\_\_ .

**Item:** \_\_\_\_\_ . **\*Tracking #:** \_\_\_\_\_ . **Amount/unit:** \_\_\_\_\_ .  
**Strength:** \_\_\_\_\_ . **# Units:** \_\_\_\_\_ . **Total Amount:** \_\_\_\_\_ .

Unit # (if applicable)	Date Dispensed	Protocol #	Species & ID# (or purpose, if non-animal)	Start amount & Unit # (if more than 1 unit)	Amount Dispensed	**Balance	Dispensed by (print)	Dispensed by (signature)

\*A separate log sheet must be completed for each Tracking # (except multiple units of a single order may be on the same log sheer). If the material is converted or diluted, start a new log form to track that usage; reference the original tracking #.

\*\*If balanced amount is "0" because of disposal, indicate date disposed, route of disposal (reverse distributor name or other route), and record disposal details in disposal log.

# West Texas A&M University

## Office of Research

WTAMU Box 60217 Canyon, Tx 79016  
806.651.2270

### Controlled Substance Renewal Checklist

Individual License Holder: \_\_\_\_\_ . Location (room/building): \_\_\_\_ .  
 DEA registration #: \_\_\_\_\_ . TXDPS License #: \_\_\_\_\_ . Schedule  
 (I-V): \_\_\_\_\_ .  
 Authorized User: Name: \_\_\_\_\_ . Protocol # \_\_\_\_\_ . Name: \_\_\_\_\_  
 \_\_\_\_\_ . Protocol # \_\_\_\_\_ .

#### SECTION 1:

Select the correct response for each statement.	Yes, No, or N/A
Is the registrant listed in the approved protocol(s) (IRB, IBC, IACUC) where controlled substances are approved? And when listed, does the registrant have as a role of 'Providing anesthesia, analgesia, sedation, tranquilization, or euthanasia'?	
Are the state and federal registrations current?	
Does the IACUC-approved protocol contain the current DEA and TXDPS registration numbers?	
Are the <i>current</i> DEA and TXDPS registrations maintained with the C.S. records?	

#### SECTION 2: Authorized Users

Select the correct response for each statement.	Yes, No, or N/A
Have 'Authorized Users' (other than the registrant) been identified? <i>If the response is 'No' or 'Not Applicable,' then proceed to Section 3.</i>	
Is an Authorized Users list being maintained inside the controlled substance file?	
Have the Authorized Users signed and initialed the Authorized Users list? <i>Note: Initials are used for log-outs of C.S., purchases, receipts, transfers, administration, and audits.</i>	
Has the registrant signed/dated the Authorized Users list?	
Are all Authorized Users listed as approved personnel on the IACUC-approved protocol(s)?	
Is access to controlled substances limited to only those persons on the 'Authorized Users List'?	
Has the registrant signed/dated the Authorized Users list?	
Has the registrant signed/dated the Authorized Users list?	

#### SECTION 3: Form 222 (only applies to Schedule 1 and Schedule II)

Select the correct response for each statement.	Yes, No, or N/A
Does this registration include Schedule I, Schedule II, or Schedule IIN substances? <i>If the response is 'No,' then proceed to Section 4.</i>	
Are all Form 222s secured by the registrant? <i>Note: Form 222s are federal accountable forms, failure to secure the forms is a potential citation.</i>	
Are all completed Form 222s signed by the registrant? <i>Note: Under federal regulation, ONLY the registrant may sign Form 222s.</i>	



Are copies of all signed Form 222s maintained by the registrant? <i>Note: Any secure storage is acceptable, but every copy &lt;even voided copies&gt; are accountable. Do not destroy!</i>	
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#### SECTION 4: Receiving Controlled Substances (C.S.)

Select the correct response for each statement.	Yes, No, or N/A
Have C.S. been ordered and/or received during this period? If the response is 'No,' then proceed to Section 5.	
Are C.S. counted and quantities verified upon receipt?	
For Schedule I substances (if applicable): Are the receiving documents signed and dated by the	
For Schedules III, IV, & V (if applicable): Are receiving documents signed and dated by an Authorized User or Registrant?	
Are receiving forms maintained as either a hard copy or a retrievable scanned copy?	
Have discrepancies been identified during the receipt review?	
Have discrepancies been documented on the receiving form and reported to the vendor/pharmacy providing the C.S.?	
Are receipt documents being maintained for 3 years from the date of receipt? <i>Note: All receipt, discrepancies, or other documents must be maintained, but not necessarily in the same log book as other C.S. documentation.</i>	

#### SECTION 5: Transfers of Controlled Substances (C.S.)

Select the correct response for each statement.	Yes, No, or N/A
Have transfers of C.S. between registrant occurred during this period? If the response is 'No,' then proceed to Section 6.	
Was the transfer between two controlled substance registrants?	
Are there appropriate transfer documents showing who received the C.S., volume received, bottle or container unique identifiers, and signatures from both receiver and provider? <i>Note: 222 forms must be used for Schedule I/II;</i>	

#### SECTION 6: Dispensing Recordkeeping Controlled Substances (C.S.)

Select the correct response for each statement.	Yes, No, or N/A
Are the templates being used? <i>Note: If templates are not used, then confirm all necessary information is captured</i>	
Are the dispensing records complete? <i>Note: Complete C.S. records will show the agent(s) used, beginning volume or weight, the amount left after each withdrawal, having no empty lines, and signed or initialed where appropriate.</i>	
Are the records stored in a secure manner? <i>Note: Primary security may be a folder, binder, or heavy clip holding all records. Secondary security is the C.S. cabinet, locked file drawer, locked room, etc.</i>	
Do the records indicate any usage by individuals not on the 'Authorized User's list'?	
Are Schedule I records maintained in a bound notebook? <i>Note: If you do not have any Schedule I agents, then select 'Not Applicable'.</i>	
Are records completed in pen and contain no 'white out'. <i>Note: Errors should be single-lined through, with an initial and date of the person making the correction.</i>	
Are prior internal audits maintained? Were prior discrepancies or deficiencies corrected? <i>Note: The Procedures Plan recommends a QUARTERLY internal audit.</i>	
Are mixtures created? If so, are expiration dates, volumes, dispensing recorded? <i>If the response is 'No,' then proceed to Section 7.</i>	
If mixtures are created, then is a separate Mixture Log and Source Log maintained and tracked?	
If mixtures are created, are expiration dates based on the most limited date used, volumes & dispensing	

#### SECTION 7: Labeling of Controlled Substances

Select the correct response for each statement.	Yes, No, or N/A
Is each bottle (or other primary container) individually identified by a unique (not re-used) number? <i>Note: The unique identifier may be assigned by the vendor or the registrant.</i>	
Is the original packaging being used showing the product information? <i>Note: If not specified information must be transferred to the new container.</i>	
If syringes are filled and stored, is each syringe labeled and tracked on the log sheet? <i>Note: If syringes are used, then syringe labels should include: Name, Lot Number, Date combined/mixed, final concentration, expiration/discard date, and initials of who created the syringe mixture.</i>	

## SECTION 8: Storage

Select the correct response for each statement.	Yes, No, or N/A
Have C.S. been stored during this period? If the response is 'NO,' then proceed to Section 10.	
Are C.S. behind two (2) locks? <i>Note: Individuals who are not on the 'Authorized User' list and the C.S. should be separated by a minimum of two locks.</i>	
Are keys (if used) kept on separate rings, secured, and out of plain in sight?	
Does anyone other than the 'Authorized Users' have access to the keys or access codes?	
Are the C.S. stored at the address on the registration?	
Are there primary and secondary storage or use locations? <i>Note: A secondary location is a location geographically distant from the storage (primary) location.</i>	
Are any C.S. removed from the C.S. cabinet returned to the C.S. cabinet within 24 hours (or the end of the work day – whichever is first)?	

## SECTION 9: Disposal

Select the correct response for each statement.	Yes, No, or N/A
Have any products required disposal during this period? <i>If the response is 'No,' then proceed to Section 10.</i>	
Did you use a 'Reverse Distributor' vendor for disposal?	
Are records maintained (either as scanned document or signed hard copy) for three (3) years after disposal?	

## SECTION 10: Losses

Select the correct response for each statement.	Yes, No, or N/A
Have there been any losses of C.S. during this period? <i>If the response is 'No,' then proceed to Section 11.</i>	
Were the losses documented?	
Were the losses reported to Office of Research and Compliance and the DEA? <i>Note: Losses should be reported to ORC at <a href="mailto:ar-ehs@wtamu.edu">ar-ehs@wtamu.edu</a>. Losses of a significant nature must also be reported to the federal agents by the on-line reporting system within 24 hours of documenting the loss.</i>	

## SECTION 11: Terminating a Registration:

<p><i>Note: If the registrant no longer needs the controlled substances registration, they should communicate a 'termination request' to the following agencies/activities and document the request with their other records:</i></p> <ul style="list-style-type: none"> <li>* Texas DPS.</li> <li>*The federal DEA.</li> <li>*The IACUC (to modify the protocol's association with the controlled substances registration).</li> </ul>
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# West Texas A&M University

## Office of Research

WTAMU Box 60217 Canyon, Tx 79016  
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### Definition of Controlled Substance Schedules

Drugs and other substances that are considered controlled substances under the Controlled Substances Act (CSA) are divided into five schedules. An updated and complete list of the schedules is published annually in [Title 21 Code of Federal Regulations \(C.F.R.\) §§ 1308.11 through 1308.15](#). Substances are placed in their respective schedules based on whether they have a currently accepted medical use in treatment in the United States, their relative abuse potential, and likelihood of causing dependence when abused. Some examples of the drugs in each schedule are listed below.

**Schedule I Controlled Substances:** Substances in this schedule have no currently accepted medical use in the United States, a lack of accepted safety for use under medical supervision, and a high potential for abuse.

Some examples of substances listed in Schedule I are: heroin, lysergic acid diethylamide (LSD), marijuana (cannabis), peyote, methaqualone, and 3,4-methylenedioxymethamphetamine ("Ecstasy").

**Schedule II/IIN Controlled Substances (2/2N):** Substances in this schedule have a high potential for abuse which may lead to severe psychological or physical dependence.

Examples of Schedule II narcotics include: hydromorphone (Dilaudid®), methadone (Dolophine®), meperidine (Demerol®), oxycodone (OxyContin®, Percocet®), and fentanyl (Sublimaze®, Duragesic®). Other Schedule II narcotics include: morphine, opium, and codeine.

Examples of Schedule IIN stimulants include: amphetamine (Dexedrine®, Adderall®), methamphetamine (Desoxyn®), and methylphenidate (Ritalin®).

Other Schedule II substances include: amobarbital, glutethimide, and pentobarbital.

**Schedule III/IIIN Controlled Substances (3/3N):** Substances in this schedule have a potential for abuse less than substances in Schedules I or II and abuse may lead to moderate or low physical dependence or high psychological dependence.

Examples of Schedule III narcotics include: combination products containing less than 15 milligrams of hydrocodone per dosage unit (Vicodin®), products containing not more than 90 milligrams of codeine per dosage unit (Tylenol with Codeine®), and buprenorphine (Suboxone®).

Examples of Schedule IIIN non-narcotics include: benzphetamine (Didrex®), phendimetrazine, ketamine, and anabolic steroids such as Depo®-Testosterone.

**Schedule IV Controlled Substances:** Substances in this schedule have a low potential for abuse relative to substances in Schedule III.

Examples of Schedule IV substances include: alprazolam (Xanax®), carisoprodol (Soma®), clonazepam (Klonopin®), clorazepate (Tranxene®), diazepam (Valium®), lorazepam (Ativan®), midazolam (Versed®), temazepam (Restoril®), and triazolam (Halcion®).

**Schedule V Controlled Substances:** Substances in this schedule have a low potential for abuse relative to substances listed in Schedule IV and consist primarily of preparations containing limited quantities of certain narcotics.

Examples of Schedule V substances include: cough preparations containing not more than 200 milligrams of codeine per 100 milliliters or per 100 grams (Robitussin AC®, Phenergan with Codeine®), and ezogabine.