

**The University of Texas at San Antonio
Office of Environmental Health, Safety and Risk Management**

Policy on Controlled Substance Use in Research

Review and Signature Page

This policy has been reviewed for regulatory compliance and best management practices by the undersigned individuals and is hereby adopted for use and compliance by all employees at the University of Texas at San Antonio.

Printed Name	Signature	Title	Date
James Weaver	Signature on file	Director, Institutional Compliance and Risk	1/30/09
J. Brian Moroney	Signature on file	Director, EHSRM	1/30/09
Wendy McCoy	Signature on file	Laboratory Safety Manger	1/30/09

Review Date	Signature of Director of EHSRM
May 20, 2011	Signature on file

This plan was reviewed/revised on 5/20/2011 and replaces the 5/28/2008 version. Changes to this plan have been highlighted in "gray" and are summarized below:

Throughout: Laboratory Safety Officer (LSO) has been updated to Laboratory Safety Manager (LSM). (not highlighted)

VIII: Intra-facility Tranfers has been revised.

IX: More information on the Form 41 has been provided.

XI: The website has been updated.

Appendix B: The inventory form has been updated.

Appendix C: A new question has been added to the checklist.

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I. Purpose and Scope

Through a Memorandum of Understanding (MOU) between the Texas Higher Education Coordinating Board and the Texas Department of Public Safety (TDPS), UTSA researchers are allowed to use controlled substances in their research on campus under the conditions listed in this policy. A controlled substance is defined in 21 U.S.C. 802, section 102 as, "a drug or other substance, or immediate precursor, included in Schedules I, II, III, IV, or V of part B of this subchapter. The term does not include distilled spirits, wine, malt beverages, or tobacco, as those terms are defined or used in subtitle E of the Internal Revenue Code of 1986." The regulations for controlled substances may be found in Title 21 of the Code of Federal Regulations – Food and Drug Administration, Chapter 2 – Drug Enforcement Administration (DEA), Department of Justice, Parts 1300-1316 (21 CFR §1300-1316).

No Principle Investigator (PI or Licensee) may use controlled substances on campus for research purposes until they have obtained licenses from the DEA and TDPS and these licenses have been registered with the UTSA Office of Environmental Health, Safety and Risk Management (EHSRM) and the Laboratory Safety Manger (LSM).

II. Application and Licensing

The PI must first obtain federal licensure from the DEA. The application can be obtained from the DEA website. Prior to applying, certain documentation is needed for an interview with DEA. This documentation may need to be submitted to the local DEA office and should be on hand prior to an interview. Information packets on this documentation and the application process are available in EHSRM from the LSM. First time applications and reapplication after a period of non-licensure will most likely require a phone interview by the local DEA office and possibly an inspection.

Licenses must be renewed on a yearly basis. DEA will send out renewal documentation/notices a few months prior to the expiration of the license. If no changes are necessary, including controlled substance listings, then the renewal can be done online. A copy of the completed online renewal form should be printed out and kept with the PI's controlled substance records. A copy of this renewal form must be sent to EHSRM immediately.

Initial and paper renewal applications for the DEA license must be routed through the office of the Vice President for Business Affairs (VPBA) via the Senior Administrative Assistant. The application will be sent to the UTSA Police Department (UTSA-PD) and to EHSRM for their approval. After approval and signature by the VPBA or AVPBA as the certifying official, the application is returned to the PI to be forwarded to DEA.

Once the DEA license is obtained, the PI must apply to the Texas Department of Public Safety (TDPS) for state licensure. This application will then be routed for processing and approval in the same manner as the DEA application. TDPS sends
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out renewal forms a few months prior to the renewal deadline. As with the DEA license, the TDPS license must be renewed on a yearly basis. Once the application is approved by the TDPS and both licenses are in place in the laboratory and a readable copy of each has been provided to EHSRM, the PI may order controlled substances as allowed by the licenses. Licenses are issued for specific schedules of controlled substances and only the specified items on the specific schedules may be ordered. If an item not specified on the license is needed, the PI must contact the local DEA office to add this item to the license and get approval before an order can be placed.

Compliance with all federal regulations is solely the responsibility of the licensee. Failure to comply can result in fines of up to \$10,000 per item. Failure to comply can also result in loss of license or imprisonment.

III. Committee Approval

All research involving controlled substances must be approved by the appropriate committee prior to the start of any project. The PI must obtain appropriate committee approval prior to the start of any project.

- The Institutional Animal Use and Care Committee (IACUC) must approve research projects involving animals and controlled substances.
- The Institutional Review Board (IRB) must approve research projects involving humans and controlled substances.

According to the scope of these projects, approval of the Institutional Biosafety Committee (IBC) and/or the Chemical Safety Committee (CSC) may be required as well. The institutional Laboratory Safety Committee (LSC) has oversight for compliance with federal, state, local and UTSA regulations and policies pertaining to laboratories including work with controlled substances.

IV. Ordering Controlled Substances

Prior to placing a first order for controlled substances, the licensee should contact EHSRM to set up an appointment with the LSM to review UTSA procedures and some of the federal regulations pertinent to inventory and storage. The LSM strives to stay updated on pertinent federal regulations, but in no way should be the only source of information utilized by a licensee. The licensee has the sole responsibility for compliance with federal regulations and is subject to penalties and fines if not in compliance.

All purchase orders (PBOs, PB4s) for controlled substances must utilize the commodity code 190-36. Use of this commodity code will route the order to EHSRM for approval. Failure to use this code may result in disciplinary action. The individual placing the order will require the vendor to label the package directly to the PI and to ensure the packing slip is secured to the outside of the package. A Form 222 must be sent to the vendor when placing orders for Schedule I or II controlled substances. Form 222 must be obtained from DEA in advance.

EHSRM will verify that the PI has a current license, and provide to the PI and any other appropriate University offices any additional direction regarding the order that may be required. The requestor must be the person who holds the licenses for use of controlled substances. A designee is not allowed to place controlled substance orders for approval. Proper labeling on the box will indicate that only the addressee (licensed PI) should open the box.

No purchases of controlled substances may be made using a Procard or personal credit card. Such use can result in revocation of Procard privileges or other actions.

V. Delivery and Receiving

All controlled substance orders will be delivered to Central Receiving Warehouse (CRW). EHSRM will inform CRW personnel when the order is placed as well as anticipated delivery date and any information necessary to identify the package, including PO number, PI, and vendor. Proper labeling on the box will indicate that only the addressee should open the box. CRW personnel will lock the package in a secure location and contact the PI. The PI or approved designee must go to CRW in person to pick up the package and be prepared to present a valid UTSA ID or Texas driver's license picture identification card. A designee as described in section VII may pick up the package if proper documentation has been provided to CRW and EHSRM in advance of ordering. A designee must be approved in advance by EHSRM.

Upon receipt of the package the addressee must provide the necessary receipt documentation to the CRW personnel including a signature. The PI or designee will open the package and confirm the amount received in the presence of CRW personnel. CRW personnel will serve as a witness and will document and verify shipment content by providing a signature on the packing slip. The PI or designee must also sign the packing slip. Any discrepancy must be annotated on the packing slip.

VI. Storage and Security

Once the controlled substance is released to the PI or designee, it must be taken directly to the laboratory and secured in accordance with DEA regulations. Exact inventories with annotations of amounts received and amounts used along with the dates used must be kept in the laboratory. Biennial Inventories must be done at least every two years. It is strongly recommended that these "biennial" inventories be done more frequently such as quarterly. Audits of the inventories will be conducted periodically by the university Compliance Office, IACUC, and/or EHSRM. The use of the UTSA Controlled Substance Inventory form is mandatory (Appendix B).

The controlled substance must be secured at all times when not in use in the laboratory. The University Compliance Office, IACUC and/or EHSRM personnel will review the storage location and security precautions during their periodic audits – any suspected security issues noted will be reported to UTSA-PD for advice and consultation with the license holder as well as the Laboratory Safety Committee.

The laboratory itself must be secured at all times when unoccupied. Only the licensed PI, or designee as appointed in section VII, should have access to the storage area.

No extra keys or lock combinations can be given out other than to the designee. Any known or suspected theft should be reported immediately to the UTSA-PD. The LSM should also be contacted immediately. At no time should students be given unsupervised access to controlled substances.

VII. Appointing a Designee

At their discretion, the licensee can designate one other person to have access to the storage area and carry out other functions except ordering of controlled substances. This person must be a staff member. To designate this individual, the licensee must fill out a "Power of Attorney" letter. An example letter is given in Appendix A of this document. This letter must be stored with the controlled substances and provided to DEA at their request. Copies must be provided to the LSM, Central Receiving Warehouse (CRW), and UTSA-PD. If a person is being removed as a designee, for whatever reason, the LSM, CRW, and UTSA-PD must be notified immediately (within 24 hours) by email or phone.

VIII. Intra-facility Transfers

The DEA has recommended against intra-facility transfers. The Laboratory Safety Manager (LSM) can provide alternatives according to the situation. Prior to undertaking any transfer, please contact the LSM.

IX. Disposal

UTSA has been granted permission by DEA to dispose of controlled substances through a registered chemical waste stream. The approved procedure involves the PI, the local DEA office, UTSA-PD and EHSRM. Appropriate notice must be given to the LSM whenever disposal using this procedure is needed. The LSM will coordinate the arrangements for disposal and acquire the necessary DEA documentation. EHSRM will submit a form 41 request for disposal to the DEA on behalf of the PI. In order to submit this form, EHSRM will need the name of the drug, number of containers, concentration and amount of each drug requested for disposal. Upon pick up for disposal, the PI will sign the form 41. After disposal has occurred, the person carrying out the disposal and the witnessing police officer will sign the form 41. Copies of the signed form will be provided to DEA, the PI, UTSA-PD and to EHSRM. A copy of each form 41 shall be added to a PI's controlled substance inventory logbook as proof of such disposal.

The other approved option for disposal is utilizing a reverse distributor. In no case may controlled substances be disposed of by any other methods.

X. Abandoned Controlled Substances

A PI cannot abandon a controlled substance. Such abandonment is subject to DEA fines and penalties. Any controlled substances found abandoned in research laboratories will be turned over to UTSA-PD for storage. The licensed PI will be contacted to arrange proper disposal. If UTSA is unable to contact the PI or if the PI does not arrange for proper disposal within seven (7) days of being contacted by UTSA, UTSA will contact the DEA. The DEA may take criminal and other action against the licensee.

XI. Schedules of Controlled Substances

Schedules I-V for controlled substances (The term "listed chemical" means any list I chemical or any list II chemical) may be obtained at the following link:

<http://www.deadiversion.usdoj.gov/schedules/#list>

Appendix A
Designee Letter

Controlled Substance Designee Letter

As a controlled substance licensee, I designate _____ to carry out all needed actions in regard to the use of controlled substances in my laboratory **with the exception of ordering**. This person is allowed to have access to the storage location, provide dilutions to other lab personnel for immediate use in their work, properly administer the substances to animals, update inventory records, pick-up orders of controlled substances from Central Receiving Warehouse and any other actions as needed except as noted above.

DEA License # _____ TDPS License# _____

Licensee's Name (Print) _____

Licensee's Signature _____

Date _____

As a designee, I understand the federal, state, local and UTSA regulations, policies, and procedures in regards to the use of controlled substances in research on campus. I am aware that failure to comply with these regulations, policies, and procedures could result in disciplinary actions up to and including termination, fines, criminal penalties and other actions. I understand that I **cannot order** controlled substances.

Designee's Job Title _____

Designee's Name (Print) _____

Designee's Signature _____

Date _____

This designation of authority ends with separation of the designee from UTSA or upon leaving employment with the licensee.

Original must be stored with controlled substance inventory.

Copies must be provided to LSM, Designee, UTSA Police Department, and Warehouse Manager.

Appendix B

Inventory Form

Appendix C: Inspection Checklist Items

<u>Security & Access</u>	1.	Is access to Lab area secured?
	2.	Are the controlled substance(s) properly secured?
	3.	Is access to controlled substance(s) limited to the licensee and designee (if applicable)?
<u>License & Inventory</u>	4.	Are DEA and TDPS licenses current?
	5.	Is storage limited to the controlled substance(s), their records, and inventories?
	6.	Is documentation of orders available, including Form 222 if pertinent?
	7.	Is an initial inventory available?
	8.	Is a biennial inventory available?
	9.	When was the biennial inventory conducted?
	10.	Is the biennial inventory properly annotated?
	11.	Is the inventory updated on a daily basis or as the controlled substance is used?
	12.	Does the physical inventory match the written inventory?
	13.	Is a designee letter available?
<u>Theft & Disposal</u>	14.	Has there been a loss or theft of a controlled substance on site?
	15.	If a theft or loss has occurred is the appropriate documentation available?
	16.	Is a Form 41 available for disposal of controlled substances?
<u>Transfer</u>	17.	Have any intra-facility transfers occurred?
	18.	Is the appropriate documentation available for any transfers?
<u>Other</u>	19.	Any additional concerns or observations?