
BYU

BRIGHAM YOUNG
UNIVERSITY

Provo, Utah

Controlled Substances Program

For Academic Units

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1.0 DEFINITION AND OVERVIEW

The term Controlled Substance means a drug or other substance, or immediate precursor, included in schedule I, II, III, IV, or V of Title 21 Chapter 13, subchapter I Part B Section 812 United States Code. A listing, by schedule, of Controlled Substances may be found at:

[http:// deادiversion.usdoj.gov/21cfr/21usc/812.htm](http://deادiversion.usdoj.gov/21cfr/21usc/812.htm)

The Controlled Substances Program involves the following six main elements.

- **Licenses:** Brigham Young University will establish Drug Enforcement Agency (DEA) licenses in the name of each respective University faculty investigators and/or staff who wish to carry a license. Each individual using controlled substances for research purposes will obtain a professional license from the State of Utah and a license through BYU from the DEA permitting the possession and use of those controlled substances.
- **Security:** Each individual possessing controlled substances will institute security measures including secure storage locations, checks of people allowed access to the drugs, and restricted access to laboratories housing the controlled substances.
- **Records:** Records of controlled substance purchases, use, and inventories will be maintained by the respective individual with a license.
- **Training:** Training on pertinent regulations, laws, and this program will be given to all individuals given access to controlled substances.
- **University Oversight:** Once every two years the University Research Safety/Controlled Substance Officer in the Risk Management Office will complete a controlled substance program review. This will include physical inventories, a records review as well as security assessments.

2.0 POLICY

Brigham Young University certifies that the program for use of Controlled Substances is in accordance with applicable federal and state statutes. BYU students and employees with access to controlled substances will handle those materials in compliance with University Policy and Procedures, Federal and State laws and in such a way as to minimize the potential for inappropriate use of the substances. This Policy is for Academic Units – Faculty Members, Staff and Students. This Policy does not cover Athletics or the Student Health Center.

3.0 REQUIREMENTS

Controlled Substances Act (21 USC Chapter 13)
Title 21 of the Code of Federal Regulations parts 1300-1321
Utah Controlled Substances Act (Utah Code Title 58 Chapter 37)

Utah Administrative Rules R-156-37

4.0 PURPOSE

The possession and use of controlled substances is a necessary element in certain academic and research activities carried out at Brigham Young University. Diversion of controlled substances for illicit use can cause significant harm, including life altering personal damage, loss of professional standing, and institutional liability. The purpose of this program is to require and ensure proper use of Controlled Substances, to minimize the risk of drug diversion or theft and to protect University employees from injury and potential criminal charges.

5.0 SCOPE

This program applies to all Brigham Young University faculty, administrators, staff and students who use controlled substances for academic and/or research purposes, with the exception of Athletics and the Student Health Center. This includes, but is not limited to the use of controlled substances in animal research. This program does not apply to the medical use of controlled substances prescribed by a physician.

6.0 PROCEDURES.**6.1 Licensing**

Each BYU faculty member who uses or possesses controlled substances for academic or research purposes will:

- Take and pass the State of Utah Controlled Substances exam (fee paid by faculty),
- Obtain a State of Utah professional license (fee paid by faculty),
- Obtain a Drug Enforcement Agency (DEA) license (fee paid by faculty).
- Upon termination from BYU, (or earlier at the discretion of the license holder) return the DEA license to the University. If the license held is a personal license, the license will accompany the holder upon termination.

6.2 Security

The following security measures will be implemented for all controlled substances:

- Controlled substances will be stored in a substantial, non-portable, lockable cabinet, safe, or other device that is kept locked whenever it is not under the direct physical observation of an approved person.
- Only approved users will be allowed access to controlled substances.
- Proposed controlled substance storage locations will be reviewed by University Police.

6.3 Authorization

All persons holding current Utah State Professional and DEA licenses are authorized to possess controlled substances at Brigham Young University consistent with the licenses.

Others may be authorized access to controlled substances if they are approved in writing by a PI who has a valid controlled substance license. Before authorizing access to controlled substances, the PI will review candidate criminal history over the previous five years as well as any history of drug abuse within the past three years using the Controlled Substance User Authorization Form (see Appendix A). University Police may perform a background check at the University's expense. The license holder will maintain a list of authorized people and will retain a copy of the Controlled Substance User Authorization Form for all people authorized access to controlled substances in his/her laboratory.

6.4 Inventory Records

Inventory records will include the following information for each controlled substance in a running log:

- Name of the controlled substance,
- The physical form of the drug (examples: 10 mg tablet, 10 mg/ml liquid etc.),
- The quantity in each container,
- The number of containers,
- The date and quantity used.
- The name of the individual using the material

6.5 Acquisition

Controlled Substances shall be obtained in the following manner:

- The license holder shall create a BYU purchase requisition that shall be routed to Purchasing
- Purchasing shall have a single Purchasing Agent that will handle all Controlled Substance purchases. This purchasing agent shall have a list of all license holders and license numbers. The Agent shall contact the vendor and make the purchase with the license number of the faculty member desiring the substance.
- Controlled Substances shall not be obtained using P-Cards.
- Controlled Substances shall be transported to the BYU Campus by special courier requiring a signature for delivery.
- Only the license holder may receive controlled drugs that he/she has purchased.
- Once acquired, the controlled drugs shall be logged in the individual's inventory record.

6.6 Disposal

Controlled substances may be discarded in one of the following ways:

- Controlled substances may be destroyed on site according to 21 CFR 1317 parts .05 and .95.

- As a secondary option, controlled substances may be delivered to a licensed controlled substance disposal or recycling company. The PI will maintain records showing the proper disposal of the substances. This is the preferred disposal option for controlled substances at Brigham Young University. See Appendix B for details.

7.0 RESPONSIBILITIES

7.1 Principal Investigator:

- Obtains appropriate licenses
- Provides secure storage
- Approves other users via the Controlled Substance User Authorization Form
- Trains other authorized users
- Maintains inventory records
- Completes the annual physical inventory.
- Reports any suspected misuse of controlled substances to University Police
- Responsible for disposal of out-of-date, unused, or unneeded drugs

7.2 Authorized Users (other than licensed PI's)

- Understand policies, programs, laws and regulations covering controlled substances
- Maintains security.
- Reports inventory discrepancies to the PI
- Reports suspected misuse of controlled substances to University Police

7.3 Research Safety/Controlled Substance Officer (with the Risk Management Office)

- Completes Biennial review/audit of Controlled Substance Program
- Assists PI's with training and licensing

7.4 University Police

- Review controlled substance security
- Keep a file of biennial review reports
- Investigate suspected misuse of controlled substances

8.0 TRAINING

All faculty, administrators, students and employees falling within the scope of this program are to be trained in the University Controlled Substance Program before being allowed access to controlled substances. In addition, the PI will train authorized users on the relevant regulations and laws pertaining to the use and storage of controlled substances.

8.1 Training must include at least the following elements:

- Appropriate security
- Proper storage
- Required inventory records

- Reporting suspected misuse
- Reporting inventory discrepancies
- Potential for abuse of the agents in the laboratory

9.0 MONITORING

9.1 Annual Inventory

Once each year the licensed individual will measure or count all Schedule II drugs stored in the laboratory. In addition he/she will visually check and estimate the inventory of all other controlled substances. The PI will report inventory discrepancies to University Police.

9.2 Biennial Review

The University Research Safety/Controlled Substance Officer will complete a physical inventory of all controlled substances once every two years. The review will include:

- All required records will be checked.
- Security of controlled substances will be assessed (University Police will assist)
- The status of controlled substance use by each PI will be evaluated. If a PI no longer needs to use controlled substances, suggested disposition of current controlled substance inventories for that PI will be included in the report.
- The biennial review report will be submitted to University Police.

10.0 APPENDIX

APPENDIX A

Controlled Substance User Authorization

Applicant Name (printed)

Yes or No 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.

Yes or No 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.

Signature of Applicant

Date

The above named person has demonstrated an adequate understanding of the University Controlled Substance Program, as well as state and federal controlled substance laws. After careful evaluation, I authorize _____ access to controlled substances in my laboratory.

PI Name: _____

Date: _____

PI Signature: _____

APPENDIX B
Disposal of Controlled Substances

This procedure is to be used by University Personnel that have a DEA license who have controlled substances that were originally purchased on their license, of which they wish to dispose.

The process is called Reverse Distribution. Anyone with a controlled substance that wishes to surrender the item for disposal may contact the following company that has authorization from the DEA to act as a disposal agent:

National Products, Inc.
Pharmaceutical Division
1600 South Empire Road
Salt Lake City, UT 84104

Attention: Michael Winn
Office: (801) 328-3986 ext. 290
Cell: (801) 750-0726

- All drugs must be listed on DEA Form 41 (copy attached). ORCA has an electronic, fillable PDF version of the form on file. The form may also be found on the Internet.
- Multiple containers of the same drug may be listed on the same line (ex. 4 containers of Ketamine of varying quantities or age).
- All schedule 2 drugs must be listed on separate forms.
- Each DEA registrant/license holder is considered a separate account.
- The drugs are to be packaged and shipped to National Products Inc. via either FedEx or UPS (as there must be a tracking number for the shipment) along with the completed enclosed DEA Form 41.
- National Products will incinerate the drugs and send the registrant an invoice for the service. The charge is \$15.00 per line item.
- Once the bill is paid National Products will send a confirmation, DEA notice to the registrant that will list the drugs destroyed for the faculty member's record.

It is suggested that the person wishing to dispose of controlled substances call Michael Winn and let him know that he/she is sending a package.