

3341-7-09 Use of Controlled Substances in Research.

Applicability	Faculty and staff who hold federal Drug Enforcement Administration (DEA) licenses to use controlled substances for research purposes.
Responsible Office	Office of Research Compliance
Responsible Administrator	Vice President of Research

(A) Policy Statement and Purpose

Controlled substances are drugs which are regulated by the DEA and the Ohio State Board of Pharmacy because of potential for abuse. This Policy describes the responsibilities of the investigators who use controlled substances in research and the investigators' responsibilities to comply with State of Ohio and DEA requirements concerning the administration, handling, storage, destruction and/or transfer of controlled substances.

(B) Policy**(1) Policy Scope**

While controlled substances are infrequently purchased by BGSU for research purposes, there are several units on the BGSU campus that hold DEA licenses. This policy has been created to ensure that BGSU and its Investigators are in compliance with the federal and state laws governing controlled substances, thus minimizing risk to the university.

Controlled substances are designated by the DEA as Schedule I - V according to their medical use, potential for abuse, and safety or dependence liability. Each controlled substance, or basic class thereof, has been assigned an "Administration Controlled Substances Code Number" for purposes of identification of the substances or class on certain Certificates of Registration issued by the Administration pursuant to 21 CFR 1301.35 and on certain

order forms issued by the Administration pursuant to 21 CFR 1305.05.

(a) Schedule of Controlled Substances (21 CFR 1308)

Schedule I Substances have a high potential for abuse and no accepted medical use in treatment in the United States. Examples of Schedule I Substances include heroin, lysergic acid diethylamide (LSD), and methaqualone.

Schedule II Substances have currently accepted medical use in treatment in the United States; however, they have severe restrictions, due to their high potential for abuse, which may lead to severe psychological or physical dependence. Examples of Schedule II Substances include pentobarbital, morphine, cocaine, and methadone.

Schedule III Substances have currently accepted medical use in treatment in the United States and less potential for abuse than the substances listed in schedule I and II. Abuse may lead to moderate or low physical dependence or high psychological dependence. Ketamine, codeine and hydrocodone are examples of Schedule III Substances.

Schedule IV Substances have accepted medical use in clinical treatment and a lower potential for abuse relative to substances in schedule III. Abuse of Schedule IV Substance, however, may lead to limited physical dependence or psychological dependence. Examples of drugs included in schedule IV are midazolam, lorazepam, and phenobarbital.

Schedule V Substances have currently accepted medical uses with low potential for abuse. Cough medicines with codeine are examples of Schedule V drugs.

(b) Corrective Measures

Failure of Investigators and Authorized Individuals to follow the requirements of this Policy may result in personal civil and criminal liability under state and federal

law and termination of university employment. In addition, failure may result in university disciplinary action under applicable faculty and staff policies.

(2) Policy Procedures

(a) University Registration Requirements

Investigators wishing to apply for DEA licenses for research purposes must obtain approval from their Department Chair, Dean, and the Vice President for Research using the “Request to Apply for DEA Controlled Substance License” Form found on the Office of Research Compliance webpage.

The Office of Research Compliance shall serve as the primary point of contact for Investigators under this Policy and will notify Investigators when their request has been approved or denied.

(b) Recordkeeping Requirements

Every BGSU Investigator holding a DEA license is responsible for maintaining appropriate records and inventories of all controlled substances used in their research at the university.

Federal law requires that all controlled substance records shall be maintained for a minimum of two years from the date of such inventory or records, for inspection and copying by authorized employees of the DEA. If the Investigator is required to follow a BGSU archival plan which requires a longer retention period, that policy will also be followed.

BGSU controlled substance records must conform to the record keeping and inventory requirements of federal law and the procedures described below. Controlled substance records include all purchasing records, all administration, use and destruction records, all controlled substance ordering forms (DEA Form 222), and all inventory records.

Investigators who purchase controlled substances are responsible for maintaining the DEA Form 222s and individual purchase invoices associated with such purchases. All Investigators are responsible for maintaining the use, administration, transfer and waste/destruction records required by the processes described in this Policy below.

Records pertaining to controlled substances in Schedules I and II must be maintained separately from all other records of the investigator registrant/licensee. Records for Schedule III, IV, and V controlled substances must be maintained separately from all other records of the registrant/licensee.

Federal and state law and this Policy require that controlled substance records must be made available immediately upon request by the U.S. Department of Justice Drug Enforcement Administration, the State Medical Board of Ohio, and the Office of Research Compliance.

(c) Investigator Procedures

Investigators are responsible for managing the use of controlled substances in their laboratories. In the event that Investigators are on leave or are absent, they may designate an Authorized Individual to carry out the duties on their behalf.

(i) Purchasing Records

Investigators are responsible for obtaining and maintaining the following information for all controlled substance purchased:

- (a) A copy of the invoice
- (b) A copy of the purchase order
- (c) A copy of the shipping document

- (d) A copy of the packing slip
- (e) The name, address, and DEA number of the company from which the controlled substance was purchased
- (f) The name of the controlled substance purchased
- (g) The size and strength of the controlled substance purchased
- (h) The amount purchased (which should match the amount received)

All purchases must be made through FMS. The purchasing record (invoice, purchase order, shipping document, or packing slip) must be annotated with the handwritten date of receipt. Investigators purchasing Schedule I or II controlled substances are required to maintain a copy of the invoice and individual DEA Form 222 for each purchase. Investigators purchasing Schedule I or II Controlled substances must also complete a Record of DEA Form 222 Use to maintain accountability for all DEA Form 222's used.

(ii) Inventory Records

Maintaining an accurate inventory for controlled substances is essential and mandatory, as this is a key to detecting loss and theft. In following best research practice, Investigator controlled substance inventories should only include the minimum amount necessary for research use.

Complete DEA inventory requirements can be found at the following site: http://www.deadiversion.usdoj.gov/21cfr/cfr/1304/1304_11.htm .

(iii) Administration/Use/Waste Records

Investigators must maintain administration/use records containing the following information:

- (a) How the investigator administered/used the controlled substance
- (b) The date administered/dispensed
- (c) If not administered/used personally by the registered investigator, the initials of person who administered/used under the direction of the investigator
- (d) The name of the controlled substance
- (e) The strength and size of the controlled substance
- (f) The amount administered/used/wasted (number of units or volume)

(iv) Storage and Security Processes

Security depends greatly on the type, quantity, and form of controlled substances being used in a research project. Schedule I, II, III, IV, and V controlled substances must be stored in a locked steel cabinet or a locked substantially constructed cabinet. Controlled substances should not be located near a glass panel where they can be visible from the outside.

Researchers must provide effective controls to guard against theft of controlled substances, such as limiting the number of keys and the number of employees who will have access to these keys, securing keys when not in use, and developing a key accountability standard operating procedure.

(v) Disposal

To minimize waste, Investigators with research registrations/licenses should only purchase and store those quantities of controlled substances that they reasonably intend to use. Damaged, expired, unwanted, unusable, or non-returnable controlled substances must be accounted for, retained, and disposed of in accordance with applicable State and Federal regulations.

A Registrant's Inventory of Drugs Surrendered (DEA Form 41) must be completed prior to disposing of any DEA controlled substance. Two copies of the form must be sent to the local Ohio DEA branch and one copy must be retained by the investigator for at least five years.

Investigators must maintain disposal records with the following information:

- (a) The Investigator's DEA number, name, and address
- (b) If a reverse distribution (see below) is done, the reverse distributor's DEA number, name, and address
- (c) The number of units (in finished forms and/or commercial containers) disposed of in any manner, including the manner of disposal

The disposal record must be dated to reflect when the products were sent for destruction and left the Investigator's inventory.

(vi) Disposal Options

There are two disposal options for expired or unwanted controlled substances:

(a) Contact the Supplier:

Some suppliers will take back pharmaceuticals for credit. If possible, this is the best means of controlled substance disposal.

(b) Reverse Distribution:

For large quantities (greater than one (1) pound), contact a Reverse Distributor. This option transfers ownership of the controlled substance to a DEA-approved Pharmaceutical Returns Processor for re-use, re-sale or destruction at a hazardous waste incinerator. This process may involve the completion of DEA Form 222 or DEA Form 41.

(c) Surrender to DEA:

This is a service that the DEA provides to registrants enabling them to clear their stocks of unwanted items. Follow the instructions for completing DEA Form 41.

(vii) Transfer of Investigators from the Institution

Controlled substances purchased by Investigators conducting research are the property of Bowling Green State University. Investigators who plan to leave the university (e.g. accept a position at another university, retire, etc.) must contact the Office of Research prior to their departure to arrange appropriate transfer or disposal of the controlled substances.

(viii) Spills

Breakage, spills, or other witnessed controlled substance losses do not need to be reported. This type of loss, however, must be documented by the registrant and witness on the inventory record. Controlled substances that can be recovered after a spill, but cannot be used because of contamination (e.g., tablets), must be placed in the disposal/destruction waste stream as described in Section 5 above. If the spilled controlled substance is not recoverable (e.g., liquids), the registrant must document the circumstances in their inventory records and the witnesses must sign.

(ix) Theft of or Missing Controlled Substances Reporting

Investigators must maintain complete accountability of all controlled substances stored or used in their laboratory. This makes keeping good records essential so that any shortages or missing controlled substances will not go unnoticed. Theft or misuse of a controlled substance is a criminal act that must be reported to the following agencies and offices:

Ohio State Board of Pharmacy	(614) 446-4143 (phone)
DEA Columbus Resident Office	(614) 255-4200 (phone)
Bowling Green State University Police	(419) 372- 2346 (phone)
Office of Research Compliance	(419) 372-7716 (phone)

In addition to the immediate phone reporting, a Report of Theft or Loss of Controlled Substances form (DEA Form 106) must be completed and submitted to the Ohio DEA office. Investigators must keep one copy of any DEA Form 106 submitted to the DEA for at least five years.

Online reporting to the DEA is also necessary if small quantities of controlled substances become

unaccounted for on a re-occurring basis. The online reporting process can be accessed at http://www.deadiversion.usdoj.gov/21cfr_reports/theft/index.html. Investigators should print and keep one copy of any online DEA Form 106 submitted in their controlled substance inventory records.

(x) Other Pertinent Record Information

- (a) Maintain current, complete and accurate records to reflect controlled substances (1) received (purchased), (2) sold (administered and dispensed), (3) otherwise disposed of, (4) theft or loss
- (b) Separate records are required for each research location
- (c) Separate records are required for each independent activity for which an investigator is registered.

When recording dates of receipt, importation, distribution, exportation, or other transfers, the date on which the controlled substances are actually received, imported, distributed, exported, or otherwise transferred shall be used as the date of receipt or distribution on any documents of transfer (e.g. invoices or packing slips).

(d) Resources for Investigators

(i) BGSU Forms

This form is used to request Institutional permission to apply for a DEA controlled substance license:

- (a) Request to Apply for DEA Controlled Substance License

(ii) DEA Forms

These forms will be used to log the purchasing, administering, dispensing, and inventory of controlled substances possessed by BGSU Investigators holding DEA Research Registrations:

- (a) Registrants Inventory of Drugs Surrendered (DEA Form 41)
- (b) Report of Theft or Loss of Controlled Substances (DEA Form 106)
- (c) DEA Order Forms Request (for DEA Form 222)

(iii) Manuals

- (a) DEA Practitioner's Manual

(iv) Controlled Substance Links

- (a) Code of Federal Regulations Schedule of Controlled Substances
- (b) U.S. Department of Justice Drug Enforcement Administration Office of Diversion Control
- (c) DEA Security Regulation (21 CFR 1301.71 thru 21 CFR 1301.76)

(e) Policy Definitions

Controlled substances: Drugs that are regulated by the federal Drug Enforcement Administration and the Ohio State Board of Pharmacy because of potential for abuse.

DEA: The federal Drug Enforcement Administration.

Investigator: A Bowling Green State University faculty or staff member using controlled substances for research purposes. This person is the lead scientist for a particular project.

Authorized Individuals: Bowling Green State University lab personnel who handle or manage controlled substances on behalf an Investigator. Authorized Individuals are trained in shipping, receiving, security, inventory, and record keeping by the Investigator.

(f) Implementation of Policy

WHO	TASK
Vice President for Research	<ul style="list-style-type: none"> • Oversight and enforcement of this Policy.
Research Compliance Officer	<ul style="list-style-type: none"> • Maintaining records (e.g., copies of controlled substance licenses, the purpose of the license, and individuals working under the license). • Monitoring by conducting annual reviews to assure compliance with this Policy. • Makes all records available to the Vice President for Research. • Annually providing a report to the Vice President for Research which contains the information found during annual inspection. • Serves as “Approver” for all controlled substances in FMS.
Investigators	<ul style="list-style-type: none"> • Ensuring the appropriate purchase, use/administration, storage, destruction, and transfer for controlled substances. • Maintaining all required controlled substance recordkeeping. • Providing controlled substance documentation to the state, federal and university oversight entities listed in this Policy. • Notifying the Department Chair/School Director and Office of Research Compliance of all controlled substance licenses, the purpose for holding the

	license, and the individuals working under the license. <ul style="list-style-type: none">• Ensure that all requests to purchase controlled substances are made through FMS.
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Registered Date: May 6, 2015