Ohio Administrative Code

Rule 3341-7-09 Use of Controlled Substances for Non-Therapeutic Purposes.

Effective: January 30, 2026

(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 Registrant who uses controlled substances for non-therapeutic purposes and the Registrant's responsibilities to comply with State of Ohio and DEA requirements concerning the purchase, administration, handling, storage, destruction and/or transfer of controlled substances. This policy has been created to ensure that BGSU and its Registrants are in compliance with the federal and state laws governing controlled substances, thus minimizing risk to the university.

(B) 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.

Registrant: A Bowling Green State University faculty or staff member using controlled substances for non-therapeutic purposes. The Registrant is the lead scientist or principal investigator for projects that use controlled substances. Registrants must complete University training in shipping, receiving, security, inventory, and recordkeeping for controlled substances. A Registrant may designate an Authorized Agent to handle or manage a controlled substance: no other authorization for use by another person is permitted.

Authorized Agent: BGSU lab personnel designated by a Registrant to handle or manage controlled substances under the Registrant's supervision. Agents must be trained by the Registrant in shipping, receiving, security, inventory, and recordkeeping. They may perform approved activities without the Registrant physically present only if authorized in writing, documented under the research protocol,

and all actions are recorded in compliance with DEA and university requirements. The Registrant remains fully responsible for all Agent activities.

(C) Examples of controlled substances

Controlled substances are designated by the DEA (in 21 CFR Part 1308) 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.

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 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.

(D) Policy

(1) University registration requirements

Investigators wishing to apply for DEA licenses for research purposes must obtain approvals from the Division of Research by completing the form(s) located on BGSU's Research Integrity webpage.

BGSU's Research Integrity shall serve as the primary point of contact for all Registrants under this Policy and will notify applicants when their request has been approved or denied.

(2) Recordkeeping requirements

Every BGSU Registrant 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 Registrant 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.

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

Records pertaining to controlled substances in Schedules I and II must be maintained separately from all other records of the 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 Division of Research.

(3) Registrant procedures

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

Registrants are responsible for obtaining and maintaining the following information for all controlled substances 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; and

(h) The amount purchased (which should match the amount received).

All purchases must be made through approved university systems. The purchasing record (invoice,

purchase order, shipping document, or packing slip) must be annotated with the handwritten date of receipt. Registrants purchasing Schedule I or II controlled substances are required to maintain a copy of the invoice and individual DEA Form 222 for each purchase. Registrants 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.

(4) 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, Registrant controlled-substance inventories should only include the minimum amount necessary for research use.

Complete DEA inventory requirements can be found in the DEA Researcher's Manual.

(5) Administration/use/waste records

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

(a) How the Registrant administered/used the controlled substance;

(b) The date administered/dispensed;

(c) Initials of Authorized Agent(s) if administered/used under the Registrant's direction;

(d) The name of the controlled substance;

(e) The strength and size of the controlled substance; and

(f) Theamount administered/used/wasted (number of units or volume)

(6) 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 substantially constructed locked cabinet. Controlled substances should not be located near a transparent panel or window where they can be visible from the outside.

Registrants 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.

(7) Disposal costs and records

To minimize waste, Registrants should only purchase and store 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. Registrants are responsible for all costs associated with the disposal of controlled substances. Prior to initiating disposal, the Registrant must obtain permission for their disposal plan from Research Integrity in coordination with Environmental Health and Safety.

Registrants must maintain disposal records with the following information:

(a) The Registrant's DEA number, name, and address;

(b) If a reverse distribution (see below) is done, the reverse distributor's DEA number, name, and address; and

(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 Registrant's inventory.

(8) Disposal options

There are three 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: A reverse distributor 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) Destruction: The University may destroy the controlled substances on-site only if the method renders the substance completely non-retrievable. Destruction must comply with DEA requirements and applicable DOT/EPA regulations. The Registrant must complete DEA Form 41 for each destruction event. Two authorized witnesses must be physically present during the destruction process and must sign DEA Form 41 to attest to the destruction. Acceptable destruction methods include the use of commercially-available products that meet non-retrievable standards. All records of destruction, including DEA Form 41 with witness signatures, must be retained for at least two years in accordance with DEA regulations.

(9) Transfer of registrants from the institution

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

(10) Spills

Non-recoverable or non-significant breakages, spills, and 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.

(11) Reporting of missing or stolen controlled substances

Registrants 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)
Research Integrity	(419) 372-2484 (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. Registrants must keep one copy of any DEA Form 106 submitted to the DEA for at least two 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 https://apps.deadiversion.usdoj.gov/TLR/.

Registrants should print and keep one copy of any online DEA Form 106 submitted in their controlled substance inventory records.

(12) Other pertinent record information

In addition to the other requirements of this Policy, Registrants must:

(a) Maintain current, complete and accurate records to reflect controlled substances received (purchased); sold (administered and dispensed); otherwise disposed of; and any theft or loss.

(b) Separate records are required for each research location.

(c) Separate records are required for each independent activity for which a Registrant 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).

(13) Resources for registrants

(a) BGSU forms

This form is used to initiate the request for Institutional permission to apply for a DEA controlled substance license: Request to Use Controlled Substance (Non-Therapeutic).

(b) 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:

(i) Registrants Inventory of Drugs Surrendered (DEA Form 41)

(ii) Report of Theft or Loss of Controlled Substances (DEA Form 106)

(iii) DEA Order Forms Request (for DEA Form 222)

(c) Manuals

DEA Practitioner's Manual

(d) Controlled substance links

(i) Code of Federal Regulations Schedule of Controlled Substances

(ii) U.S. Department of Justice Drug Enforcement Administration Office of Diversion Control

(iii) DEA Security Regulation (21 CFR 1301.71 thru 21 CFR 1301.76)

(E) Implementation of policy

Who	Task
Vice President for Research	• Oversight and enforcement of this policy.
Research Compliance Officer / Research Integrity	•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 university systems or processes.
Registrants	•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 Research Integrity of all controlled substance licenses, the purpose for holding the license, and the individuals Authorized Agents working under the license. • Ensure that all requests to purchase controlled substances are made using the appropriate university systems or processes.

(F) Corrective measures

Failure of any Registrant or Authorized Agent 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.