

## University Policy

**Applies to:** Faculty and research staff who hold individual, or work under a college-based program using, federal Drug Enforcement Administration research or instructing registrations and State of Ohio Board of Pharmacy Terminal Distributor Licenses to specifically use controlled substances in animal or laboratory research. The policy also applies to faculty, staff, and students acting as an authorized agent under such registrations.

**Responsible Office**

**Office of Research**

## POLICY

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Controlled substances are drugs that are regulated by the Drug Enforcement Administration (DEA) and the State of Ohio Board of Pharmacy because of potential for abuse. DEA regulations and Board of Pharmacy rules allow faculty and staff researchers (investigators) to obtain and use controlled substances in Institutional Animal Care and Use Committee (IACUC)-approved animal research or Institutional Biosafety Committee (IBC)-approved research with cell culture systems; or other in vitro analyses (“laboratory research”). To do so, investigators must either: 1) hold a current individual DEA research or instructing registration and a Board of Pharmacy Terminal Distributor (TDDD) License or 2) conduct their research as an authorized agent of a university official or investigator who holds a current DEA registration and Board of Pharmacy TDDD License.

This policy does not apply to controlled substances used in Institutional Review Board (IRB)-approved research involving the use of human subjects by faculty and staff who are licensed healthcare practitioners in the State of Ohio and hold current DEA registrations. Further, this policy does not apply to controlled substances used in IACUC-approved veterinary clinical trials by faculty and staff who are licensed veterinarians in the State of Ohio and hold current DEA registrations for veterinary use.

### **Purpose of the Policy**

This policy describes the responsibilities of the university, registrants, and authorized agents who use controlled substances in animal, cell culture, or in-vitro analytical laboratory research, and specifically, their responsibilities to comply with Board of Pharmacy and DEA requirements concerning the administration, handling, storage, destruction, and/or transfer of controlled substances used in such research.

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# Individual Investigator Use of Controlled Substances in Non-Therapeutic Research

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### Definitions

Term	Definition
Authorized agent	Investigators or lab staff acting directly on behalf of a registration holder (registrant). The faculty, staff, and student laboratory members of such investigators in turn become authorized agents themselves. Students under the age of 18 and volunteers are not permitted to serve as authorized agents under this policy.
Controlled substances	Drugs that are regulated by the DEA and the Board of Pharmacy because of potential for abuse. See Policy Details section and DEA Controlled Substance Schedules in Resources section below for a description of the different categories and examples of controlled substances.
DEA research or instructing registration	A special DEA license that allows practitioner and non-practitioner investigators to obtain and use controlled substances in animal or laboratory research.
Investigator	A faculty or staff researcher; most often a principal investigator of a research study.
Practitioner	A physician, dentist, veterinarian, pharmacist, nurse practitioner, or other licensed medical professional, possessing a DEA registration to prescribe, dispense, or administer a controlled substance in the course of her/his professional practice.
Non-practitioner	An investigator who conducts animal or laboratory research at the university and does not have a practitioner's license.
Registration holder ("registrant")	A university official or investigator who holds an individual federal DEA research or instructing registration specifically for the use of controlled substances in animal or laboratory research.

### Policy Details

#### I. Permitted Users of **Controlled Substances** in Research

##### A. **Practitioners**

1. A licensed healthcare or veterinary medicine practitioner is permitted to dispense or administer a controlled substance in the course of her/his professional practice at the university, or as an **investigator** conducting therapeutic human subject or veterinary clinical trials at the university. To use controlled substances in non-therapeutic animal or laboratory research, investigators who are licensed practitioners must also hold a current **DEA research or instructing registration** or be an **authorized agent** as defined above. Clinical practitioners must not issue a prescription to themselves to obtain controlled substances to be stored or dispensed for research purposes.



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### B. Investigators

1. Practitioner and **non-practitioner** investigators may be registered as “researchers” under DEA regulations. To obtain a DEA research or instructing registration, an investigator must first obtain a separate Board of Pharmacy TDDD License.
2. With a current DEA research or instructing registration, investigators may purchase and use/administer controlled substances in research on animals or in laboratory research.
3. Investigators with DEA research or instructing registrations may not use controlled substances in research involving the use of human subjects, or dispense or write prescriptions.
4. When using controlled substances in research on animals, investigators with a DEA research or instructing registration may do so only pursuant to an IACUC-approved protocol, which defines the specific agent(s), dosage(s), and method(s) of administration of controlled substances used in the research protocol.
5. Without a DEA registration, investigators may lawfully purchase, use in research, and store only those controlled substances in the forms described on the DEA exempt chemical preparation list pursuant to [21 CFR §1308.24](#). Such distribution, possession, or use must be intended for laboratory, industrial, or educational purposes and not for immediate or subsequent administration to a human being or other animal. See [deadiversion.usdoj.gov/schedules/exempt/exempt\\_chemlist.pdf](http://deadiversion.usdoj.gov/schedules/exempt/exempt_chemlist.pdf) and Procedures Section X – Exempt Chemical Preparations.

### C. Authorized Agents

1. Authorized agents may also use controlled substances in animal or laboratory research under an investigator’s research or instructing registration if they are specifically listed on an Ohio State University Controlled Substances Authorized Agent List (OSU Controlled Substance Form 3). See Procedures Section II – Agent Authorization and Training. Authorized agents using controlled substances are also required to comply with the terms of this policy and the procedures within. Before receiving approval to use controlled substances as an authorized agent under this policy, authorized agents must attend a training session provided by the college and/or department of their primary **registration holder**.

## II. Schedules of DEA Controlled Substances

- A. 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 controlled 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. Refer to [21 CFR §1308](#) for the schedules of controlled substances (see also [deadiversion.usdoj.gov/schedules/index.html](http://deadiversion.usdoj.gov/schedules/index.html)).

Controlled Substances Schedules	Definition	Examples
Schedule I	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.	Heroin, lysergic acid diethylamide (LSD), marijuana, peyote, methaqualone, ecstasy
Schedule II	Substances in this schedule have currently accepted medical use; however, they have severe restrictions due to their high potential for abuse, which may lead to severe psychological or physical dependence.	Morphine, oxycodone, phencyclidine (PCP), cocaine, methadone, pentobarbital, fentanyl, methamphetamine
Schedule III	Substances in this schedule have currently accepted medical use and less potential for abuse relative to the controlled substances listed in Schedules I/II. Abuse may lead to	Ketamine, anabolic steroids, codeine and hydrocodone with



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Controlled Substances Schedules	Definition	Examples
	moderate or low physical dependence or high psychological dependence.	aspirin or Tylenol®, some barbiturates
Schedule IV	Substances in this schedule have accepted medical use and a lower potential for abuse relative to Schedule III controlled substances. Abuse may lead to limited physical dependence or psychological dependence.	Alprazolam (Xanax®), clonazepam (Klonopin®), diazepam (Valium®), lorazepam (Ativan®)
Schedule V	Substances in this schedule have accepted medical use with low potential for abuse and consist primarily of preparations containing limited quantities of certain narcotics.	Cough medicines with less than 200mg of codeine, pregabalin (Lyrica®)

### III. Recordkeeping Requirements

- A. Every investigator holding a DEA research or instructing registration and a Board of Pharmacy TDDD License is responsible for maintaining appropriate records and inventories of all controlled substances used in her/his research or instruction at the university. Hereafter, these investigators will be referred to as “registrants.”
- B. Authorized agents are also responsible for maintaining appropriate records and inventories of controlled substances used in their research or instruction at the university.
- C. While federal and state laws have shorter records retention requirements, this policy requires registered/licensed investigators to retain controlled substance records for five years. Refer to the data retention requirements of the Research Data Policy.
- D. Controlled substance records must otherwise conform to the record keeping and inventory requirements of federal law and the procedures described below. Controlled substance records include all purchasing records (from university and external sources); all inventory, administration, use, transfer, and waste/destruction records; all controlled substance ordering forms, including DEA Form 222 for Schedule I/II controlled substances; and all authorized agent records.
  1. Separate records are recorded for each research location and for each independent activity for which an investigator is registered (e.g. dispensing or instructing, research, manufacturing, etc. [See 21 CFR §1301.13\(e\) for a complete listing of independent activities.](#)
  2. Separate records are required for each controlled substance product or formulation.
  3. When recording dates of receipt, distribution, or other transfers, the date on which the controlled substances are actually received, distributed, or otherwise transferred must be used as the date of receipt or distribution on any documents of transfer (e.g., invoices or packing slips).
  4. Approved university controlled substance record templates include:
    - a. OSU Controlled Substance Form 1.1: Controlled Substance Usage Log
    - b. OSU Controlled Substance Forms 1.2A and 1.2B: Controlled Substance Dilution and Administration Logs (to be used together)
    - c. OSU Controlled Substance Form 2: Individual Drug Log
    - d. OSU Controlled Substance Form 3: Controlled Substances Authorized Agent List
    - e. OSU Controlled Substance Form 4: Controlled Substance Program Security Release
    - f. OSU Controlled Substance Form 5: Purchasing/Receiving Log
    - g. OSU Controlled Substance Form 6: Record of DEA Form 222 Use (for Schedule I/II controlled substances). Use is optional and intended as an additional deterrent to diversion activity.



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- E. Federal regulations require that records pertaining to controlled substances in Schedules I/II must be maintained separately from all other records of the registrant and authorized agent. Records for Schedule III, IV, and V controlled substances must be maintained either separately from all other records or in such form that the information required is readily retrievable from the ordinary business records of the registrant and authorized agent. "Readily retrievable" means that Schedule III, IV, and V records can be separated out from other records in a reasonable time.
- F. Controlled substance records must be made available immediately upon request by the U.S. Department of Justice Drug Enforcement Administration, the State of Ohio Board of Pharmacy, the State Medical Board of Ohio, the Ohio State University Office of Research, and the college and/or department under which the registration was obtained.

#### IV. Monitoring and Auditing Requirements

- A. The college and/or department of the registrant is responsible for monitoring the registration, recordkeeping, inventory, security, and disposal of controlled substances used in research by their investigators.
- B. All registrants and their authorized agents must be audited by the college and/or department on an annual basis to assure compliance with DEA and Board of Pharmacy regulations and this policy.
- C. Audits must be performed by impartial individuals who are free of conflicts of interest and who are not involved in the day-to-day maintenance of the controlled substance inventory or conduct of the research using controlled substances.
- D. Requirements for annual audit include:
  - 1. Audits must be performed at times when no controlled substances are being used in the inspected laboratory.
  - 2. Minimum requirements
    - a. Inventory: per the DEA, "the registrant shall take a new inventory of all stocks of controlled substances on hand." This includes:
      - i. The name of each substance.
      - ii. Each finished form of the substance (e.g., 10mg tablet or 10mg/ml concentration).
      - iii. The number of units (or volume, weight, etc.) of each substance: for Schedules I and II make an exact count or measure of the contents for Schedules I and II; for Schedules III, IV, and V make an estimated count or measure of the contents unless the container holds more than 1,000 tablets or capsules in which case make an exact count of the contents.
      - iv. The number of commercial containers of each finished form (e.g., four 100-tablet bottles).
      - v. For any damaged, defective, or impure substance awaiting disposal, also record the total quantity of the substance to the nearest metric unit weight or total number of units of finished form, the reason for the substance being maintained, and whether the substance is capable of use in the manufacture of another controlled substance in finished form.
  - 3. Suggested additional information to review and record
    - a. Storage:
      - i. Are controlled substances being stored in a locked and secure location with access limited to those authorized to use the controlled substances?
    - b. Forms and recordkeeping:
      - i. Are ordering, inventory, and destruction records being maintained on the proper forms (e.g., DEA Form 222, DEA Form 41, OSU Controlled Substance Form 2, OSU Controlled Substance Form 5)?



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- ii. Are use/administration/waste records being maintained on the proper forms (e.g., OSU Controlled Substance Form 1.1 or Forms 1.2A and 1.2B)?
- iii. Are all personnel involved in the use of controlled substances on the authorized agent list (i.e., OSU Controlled Substance Form 3) and do training records exist for them?
- iv. Are records pertaining to Schedules I/II controlled substances being maintained separately from all other records?
- c. Drug accountability
  - i. Can amounts of controlled substances purchased be reconciled against inventory, use, administration, and waste records?
  - ii. Is any inventory past the expiration date?
- E. Off-cycle audits: As a best practice, new registrants or newly authorized agents and their laboratories should be audited within the first 30 days of their participation in controlled substances research.
- F. Should deficiencies be noted on any audit or annual review, additional audits must take place to determine whether corrective action has been taken or if deficiencies still exist.
- G. Should any reports of violations of this policy be received, an investigation and/or audit led by the college and/or department of the registrant must take place.
- V. Corrective Measures
  - A. Failure of registrants and authorized agents to follow the requirements of this policy may result in personal civil and criminal liability under state and federal law. Failure may also result in university disciplinary action under applicable university policies and/or rules, including loss or limitation of privileges to conduct animal or laboratory research at the university, or termination of employment.
  - B. When issues of non-compliance are identified, the college and/or department of the registrant, in consultation with applicable university units, will be responsible for determining the corrective action plan and/or disciplinary actions to be taken. Corrective action plans may include, but are not limited to, re-training of faculty, staff, and students; purchasing ability limitations; and laboratory shutdown.
  - C. The college and/or department of the registrant must notify the Office of Research Compliance in the event of any serious violations and/or any level/type of recurring violation.

## PROCEDURE

Issued: 09/20/2010

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### I. Registration

#### A. University

1. Investigators who seek to obtain a research or instructing registration for use of controlled substances in animal or laboratory research must first notify their college and/or department (e.g., Associate Dean for Research, College Research Officer) prior to registering with the Board of Pharmacy and/or the DEA.
2. The investigator must complete a Controlled Substance Program Security Release (OSU Controlled Substance Form 4) and submit to a criminal background check if one has not been performed within the past 12 months. For additional information on conducting background checks, contact the responsible program administrator or college research officer, or see the Office of Research Compliance website [FAQ page](#).



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3. Once Board of Pharmacy licenses and DEA registrations and/or renewals have been obtained (see below), registrants must provide copies to their college and/or department (e.g., associate dean for research, college research officer).

**B. State of Ohio Board of Pharmacy**

1. Investigators who are not pharmacists independently licensed by the State of Ohio Board of Pharmacy must obtain a TDDD License by applying to the State of Ohio Board of Pharmacy, [pharmacy.ohio.gov/Documents/Licensing/TDDD/Apps/Limited%20License%20Application.pdf](http://pharmacy.ohio.gov/Documents/Licensing/TDDD/Apps/Limited%20License%20Application.pdf)
2. If not a licensed pharmacist, investigators should request a Category III license, which would allow the licensee to possess, have custody or control of, and distribute any controlled substances contained in Schedules II-V and/or possess and have custody or control of Schedule I controlled substances contained in certain locations (e.g., research facilities, laboratories).
  - a. In addition to the application, the following three documents must also be submitted to the Board of Pharmacy when requesting a Category III license:
    - i. List of personnel having access to and/or administering drug,
    - ii. Protocol, and
    - iii. Drug list.

**C. Drug Enforcement Administration (DEA)**

1. The DEA generally requires that an investigator first obtain a TDDD License from the Board of Pharmacy before the DEA will issue a registration for researchers or teaching institutions.
2. Investigators need to determine which activities will be performed to determine which type of registration to request.

<b>Business Activity</b>	<b>Controlled Substances</b>	<b>DEA Application Forms</b>	<b>Registration Period</b>	<b>Coincident Activities Allowed</b>
<b>Dispensing or Instructing</b> Includes practitioner, hospital/clinic, retail pharmacy, central fill pharmacy, teaching institution	Schedules II through V	New – 224 Renewal – 224a	3 years	May conduct research and instructional activities with those controlled substances for which registration was granted, except that a mid-level practitioner may conduct such research only to the extent expressly authorized under state statute. A pharmacist may manufacture an aqueous or oleaginous solution or solid dosage form containing a narcotic controlled substance in Schedule II–V in a proportion not exceeding 20% of the complete solution, compound or mixture. A retail pharmacy may perform central fill pharmacy activities.
<b>Research</b>	Schedule I	New – 225 Renewal – 225a	1 year	A researcher may manufacture or import the basic class of controlled substance or substances for which registration was issued, provided that such manufacture or import is set forth in the protocol required in <a href="#">§1301.18</a> and to distribute such class to persons registered or authorized to conduct research with such class of substance or registered or authorized to conduct chemical analysis with controlled substances.
<b>Research</b>	Schedules II through V	New – 225 Renewal – 225a	1 year	May conduct chemical analysis with controlled substances in those schedules for which registration was issued; manufacture such controlled substances if and to the extent that such manufacture is set forth in a statement filed with the application for registration or reregistration and provided that the manufacture is not for the purposes of dosage form development; import such controlled substances for research purposes; distribute such controlled substances to persons



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Business Activity	Controlled Substances	DEA Application Forms	Registration Period	Coincident Activities Allowed
				registered or authorized to conduct chemical analysis, instructional activities or research with such controlled substances, and to persons exempted from registration pursuant to <a href="#">§ 1301.24</a> ; and conduct instructional activities with controlled substances

3. Investigators may apply for a [DEA registration online](#) (DEA’s preferred method of application).
4. Investigators wishing to use Schedule I compounds must submit the paper version of DEA Form 225 and cannot apply online for their initial application. The paper version of DEA Form 225 can be obtained via [deadiversion.usdoj.gov/drugreg/reg\\_apps/225/225\\_form.pdf](http://deadiversion.usdoj.gov/drugreg/reg_apps/225/225_form.pdf)
  - a. In addition to the application, a protocol to conduct research with controlled substances listed in Schedule I must be submitted. Refer to [21 CFR §1301.18](#) for specific requirements.

**D. Renewal Applications for Board of Pharmacy and DEA**

1. Each registrant is responsible for ensuring her/his registrations remain valid.
2. License and registration renewal must take place through the Board of Pharmacy and the DEA processes, respectively.
3. Schedules for renewal vary based on the type of license/registration.

**E. Registration Changes**

1. Registrants with name, address, schedule, and/or drug code changes should first make those change requests with the Board of Pharmacy. Once approved by the state, the registrant must submit a change request to the DEA via the DEA website: [deadiversion.usdoj.gov/webforms/jsp/regapps/common/updateLogin.jsp](http://deadiversion.usdoj.gov/webforms/jsp/regapps/common/updateLogin.jsp). Changes will become effective immediately upon DEA approval.
2. Registrants seeking to terminate their DEA registration because they discontinue research requiring a registration or plan to leave the university must notify in writing their college and/or department (e.g., Associate Dean for Research, College Research Officer), the [State of Ohio Board of Pharmacy](#), and the [DEA](#) at [DEA.Registration.Help@usdoj.gov](mailto:DEA.Registration.Help@usdoj.gov).
3. Registrants who seek to terminate their DEA registration by transferring such research activities to another person must submit in person or by registered or certified mail, return receipt requested, to the DEA Special Agent in Charge, at least 14 calendar days in advance of the date of the proposed transfer the following information:
  - a. The name, address, registration number, and authorized business activity of the registrant discontinuing the business (registrant-transferor);
  - b. The name, address, registration number, and authorized business activity of the person acquiring the business (registrant-transferee);
  - c. Whether the business activities will be continued at the location registered by the person discontinuing business, or moved to another location (if the latter, the address of the new location should be listed);
  - d. Whether the registrant-transferor has a quota to manufacture or procure any controlled substance listed in Schedule I or II (if so, the basic class or class of the substance should be indicated); and
  - e. The date on which the transfer of controlled substances will occur.
4. Should transfer of controlled substances inventory also need to accompany the transfer of registration, refer to [21 CFR §1301.52](#) for specific requirements.
5. Registrants are required to notify their college and/or department of any changes to the registration.



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### II. Agent Authorization and Training

#### A. Agent Authorization

1. Investigators wanting to conduct animal or laboratory research with controlled substances as an authorized agent should contact the registrant for their college and/or department (or their responsible program administrator). For a list of contacts, see the Office of Research Compliance [Controlled Substances Web Page](#). A Controlled Substance Program Security Release (OSU Controlled Substance Form 4) must be completed and a criminal background check performed if one has not been performed within the past 12 months.
2. The laboratory members of such investigators in turn become authorized agents themselves and must complete a [Controlled Substance Program Security Release](#) (OSU Controlled Substance Form 4), submit to a criminal background check if one has not been performed within the past 12 months, and be documented on the college and/or department [Controlled Substances Authorized Agent List](#) (OSU Controlled Substance Form 3). Copies of OSU Controlled Substance Forms [3](#) and [4](#) must be forwarded to the college and/or department registration holder (or their responsible program administrator).
3. Students under the age of 18 and volunteers are not permitted to serve as authorized agents under this policy.

#### B. Training

1. All registrants and authorized agents must undergo appropriate training on the use of controlled substances in research to meet the regulatory requirements.
2. The college and/or department of the registrant under whom the research is being conducted must provide the training required by this policy whenever possible. Alternatively, training can be provided by another college/department, with its permission.
3. In-person training is required for all registrants, authorized agents, and/or students before they may be involved in controlled substance use in research.
4. The registrant or her/his responsible program administrator must maintain all training records associated with her/his registration.
5. A required, but not exhaustive, list of training elements includes: regulatory overview, controlled substance schedules, recordkeeping requirements and form use, storage, disposal, personnel changes, best practices.
6. Continuing education and/or re-training may take place as necessary (e.g., as new regulatory requirements are published, as part of a corrective action plan, etc.).

### III. Purchasing/Ordering

- A. As a general rule, only the minimum amount of controlled substances needed for current research projects should be obtained.
- B. Controlled Substances Purchased from University-Based Pharmacies
  1. Controlled substances may be purchased and/or acquired through university-based pharmacies (e.g., Colleges of Medicine or Veterinary Medicine). See the Office of Research Compliance [Controlled Substances Web Page](#) for additional information.
  2. Registrants are responsible for maintaining the DEA Form 222s for Schedule I or II controlled substances (and recording the use thereof on OSU Controlled Substance Form 6 should they choose).
  3. Registrants and authorized agents may obtain controlled substances by providing the following to a university-based pharmacy:
    - a. An approved university eRequest form, which includes the following information:



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- i. Name of individual picking up (this person must be on the Ohio State University Controlled Substances Authorized Agent List (OSU Controlled Substance Form 3)).
      - ii. Location (must match location on the list of approved sites).
      - iii. Item number, quantity, name and estimated price of the controlled substance(s) being purchased.
    - b. A DEA Form 222 (only required by individual DEA registrants submitting a request for Schedule I/II controlled substances).
    - c. A copy of the investigator's current DEA research or instructing registration, if applicable.
    - d. A current university ID.
    - e. A copy of the Ohio State University Controlled Substances Authorized Agent List (OSU Controlled Substance Form 3). Only those listed on the form or the registrant will be permitted to receive controlled substances.
  4. Registrants and authorized agents are responsible for maintaining copies of the university eRequest forms or other purchasing records (e.g., 100Ws) used for each controlled substance purchase.
- C. Controlled Substances Purchased from Non-University Pharmacies or Distributors
1. Registrants and authorized agents are responsible for obtaining and maintaining the following information for all controlled substances purchased from non-university pharmacies or distributors:
    - a. A copy of the invoice, purchase order, or eRequest form.
    - b. A copy of the shipping document, packing slip, or receipt.
    - c. The name, address, and DEA number of the company from which the controlled substance was purchased.
    - d. The name of the controlled substance purchased.
    - e. The size and strength of the controlled substance purchased.
    - f. The amount purchased (which should match the amount received).
    - g. For Schedule I/II controlled substances, a copy of the invoice and individual DEA Form 222.
    - h. Optional for Schedule I/II controlled substances, a Record of DEA Form 222 Use (OSU Controlled Substance Form 6) to maintain accountability for all DEA Form 222s used. If used, the dates and amounts received entries on this form must match the corresponding entries on the Controlled Substances Record (OSU Controlled Substance Form 1) for each controlled substance purchased.
- D. DEA Ordering Forms
1. The Controlled Substance Ordering Form (DEA Form 222) is a paper-based form used to order Schedule I/II controlled substances. This form is requisitioned directly from the DEA and is required to be filled out in triplicate. The DEA Form 222 also allows the exchange of Schedule I/II controlled substances from the registrant to another party registered with the DEA (typically used when a controlled substance is sent to a reverse distributor for credit or disposal).
  2. Requests for DEA Form 222 can be made on-line at this DEA site: [deadiversion.usdoj.gov/online\\_forms\\_apps.html](http://deadiversion.usdoj.gov/online_forms_apps.html). Alternatively, a registrant may obtain a Controlled Substance Ordering System (CSOS) digital certificate from the DEA Certification Authority to sign electronic orders for controlled substances. See [21 CFR §1311 subpart B](#).
  3. Registrants will receive the maximum number of order form books allowed for their business activity.
  4. Schedule III, IV, and V controlled substance orders do not require a DEA Form 222. These controlled substances can be ordered directly from the manufacturer or university-based pharmacy.



# Individual Investigator Use of Controlled Substances in Non-Therapeutic Research

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5. All unused DEA Form 222s must be submitted to the nearest DEA office if a registrant's DEA research or instructing registration or Board of Pharmacy TDDD License terminates because she/he dies, discontinues her/his research, changes the name or address as shown on her/his registration, or is suspended.

#### IV. Storage and Security

- A. Registrants and authorized agents may only receive and store the minimum amount of controlled substances needed for current research. All 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.
- B. Registrants and authorized agents using and storing controlled substances must provide effective controls to guard against theft. This includes, but is not limited to, restricting the number of keys that access the controlled substances and limiting the number of employees who will have access to these keys. Keys for locked cabinets must be kept in secure locations when not in use. If controlled substances are locked using a combination or numerical coded lock, combinations/codes must be changed upon turnover of an employee who has knowledge of the combination/code. In addition to locked access control, only authorized personnel should be permitted to access a university laboratory where controlled substances are used or stored.
- C. Non-laboratory personnel/visitors entering areas where controlled substances are used or stored must always provide identification and a rationale for access. Controlled substances must never remain unlocked or unattended during laboratory maintenance work or other required access by individuals who are not the registrant or authorized agent.
- D. The Office of Environmental Health and Safety will perform annual inspections of laboratory safety and security.

#### V. Inventory

- A. This section delineates the responsibilities of registrants and authorized agents in maintaining an up-to-date physical inventory of all controlled substances in their laboratories. Monitoring and auditing of inventories is a college/department function as prescribed in Policy Section IV.
- B. Each inventory must contain a complete and accurate record of all controlled substances on hand on the date the inventory is taken. The inventory may be taken at either the opening of business or at the close of business on the inventory date, and this must be indicated on the inventory.
- C. Inventory must be maintained on an Ohio State University Controlled Substance Record (OSU Controlled Substance Form 1.1 or Forms 1.2A and 1.2B, depending upon the needs and preferences of the laboratory) for each controlled substance used in their laboratories. OSU Controlled Substance Form 1.1 or Forms 1.2A and 1.2B meet DEA requirements for controlled substance inventory, administration, and use documentation requirements. Complete DEA inventory requirements can be found at this site: [deadiversion.usdoj.gov/21cfr/cfr/1304/1304\\_11.htm](http://deadiversion.usdoj.gov/21cfr/cfr/1304/1304_11.htm)
- D. Minimum inventory requirements include:
  1. Initial inventory date.
  2. Annual inventory date (while the DEA requires bi-annual inventory, the Board of Pharmacy requires an annual inventory).
  3. Inventory date for substances that are newly listed on Controlled Substance Schedules I-V.
  4. For each controlled substance in finished form the inventory must include:
    - a. The name of the substance;
    - b. Each finished form of the substance (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter);



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- c. The number of units or volume of each finished form in each commercial container (e.g., 100-tablet bottle or 3-milliliter vial);
    - i. If the substance is listed in Schedules I or II, make an exact count or measure of the contents; or
    - ii. If the substance is listed in Schedule III, IV, or V, make an estimated count or measure of the contents, unless the container holds more than 1,000 tablets or capsules in which case there must be an exact count of the contents.
  - d. The number of commercial containers of each such finished form (e.g., four 100-tablet bottles or six 3-milliliter vials); and
  - e. Expiration date and lot number.
5. For any other controlled substances not in current use (e.g., damaged, defective or impure substances awaiting disposal; substances held for quality control purposes; or substances maintained for extemporaneous compounding) the inventories must include:
- a. The name of the substance,
  - b. The total quantity of the substance to the nearest metric unit weight or the total number of units of finished form, and
  - c. The reason for the substance being maintained by the registrant and whether such substance is capable of use in the manufacture of any controlled substance in finished form.

### E. Investigators who Leave the University

1. Controlled substances obtained pursuant to this policy are the property of the university. Registrants and authorized agents who plan to leave the university must contact their college and/or department prior to their departure to arrange appropriate disposition of the controlled substances and return of any DEA Form 222s to the DEA.
2. In the event of the unexpected or sudden departure of a registrant or authorized agent (e.g., death, suspension, etc.), the college/department must be immediately notified and all unused controlled substances and order forms for controlled substances (i.e., DEA Form 222s) must be immediately secured. If the college/department needs assistance with securing the controlled substances or order forms the items can be submitted to the University Police to ensure temporary secure storage. Transfer of items to University Police should be documented appropriately.
3. The Office of Research Compliance will work with the college/department and University Police if necessary to arrange for and ensure the appropriate disposition of the controlled substances and/or order forms.

### VI. Administration/Use

- A. Registrants and authorized agents must maintain administration/use records documenting the following information on the university controlled substances record (OSU Controlled Substance Form 1.1 or Forms 1.2A and 1.2B, depending upon the needs and preferences of the laboratory):
1. The animal species or cell culture or analytical system in which the controlled substance was administered/used.
  2. The date administered/dispensed.
  3. If not administered/used personally by the registrant, the initials of the person who administered/used the controlled substance.
  4. The name of the controlled substance.
  5. The strength and size of the controlled substance.



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6. The amount administered/used/wasted (number of units or volume).

### VII. Spills/Loss

- A. Breakage, spills, or other witnessed, accidental controlled substance losses do not need to be reported to the DEA. However, any such loss must be documented and witnessed by the registrant or authorized agent on the university controlled substances record (OSU Controlled Substance Form 1.1 or Forms 1.2A and 1.2B, depending upon the needs and preferences of the laboratory).
- B. Controlled substances that can be recovered after a spill, but cannot be used because of contamination (e.g., tablets, powders), must be handled pursuant to the disposal/destruction requirements in this Policy. See Section VIII below.
- C. If the spilled/lost controlled substance is not recoverable (e.g., liquids), the circumstances of the spill/loss must be documented, witnessed by the registrant or authorized agent, and co-signed on the university controlled substances record (OSU Controlled Substance Form 1.1 or Forms 1.2A and 1.2B, depending upon the needs and preferences of the laboratory).

### VIII. Disposal

- A. Registrants and authorized agents should only purchase and store those quantities of controlled substances needed for current research or instructional activities. Damaged, expired, unwanted, unusable, or non-returnable controlled substances must be accounted for, stored, and disposed of in accordance with applicable state and federal regulations.
- B. Disposal of a controlled substance must render it non-retrievable. Though the DEA does not specify destruction methods, it does state, “the process utilized to render a substance ‘non-retrievable’ shall permanently alter the substance’s physical or chemical condition or state through irreversible means and thereby render the substance unavailable and unusable for all practical purposes. A substance is considered ‘non-retrievable’ when it cannot be transformed to a physical or chemical condition or state as a controlled substance or controlled substance analogue.”
- C. There are three disposal options for expired or unwanted controlled substances. Authorized agents should contact the registrant or his/her college and/or department to help determine the correct disposal method. Two employees of the registrant must handle or observe the handling of any controlled substance until it is transferred or rendered non-retrievable.
  1. On-site disposal: Small quantities of controlled substances can be disposed onsite by the DEA registrant or authorized agent using the following procedure:
    - a. Complete the Registrant Record of Controlled Substances Destroyed (DEA Form 41) prior to disposal (see section D below).
    - b. The controlled substance must be rendered non-retrievable by permanently altering the substance’s physical or chemical condition or state through irreversible means and thereby rendering the substance unavailable and unusable for all practical purposes. For a list of on-site disposal methods, see the Office of Research Compliance website ([orc.osu.edu/regulations-policies/controlled-substances/](http://orc.osu.edu/regulations-policies/controlled-substances/)).
  2. Reverse distribution: For large quantities or volumes of controlled substances, 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 depending on the reverse distributor and the substances involved. Contact and cost information for reverse distributors may be obtained from the Office of Environmental Health and Safety ([ehs.osu.edu](http://ehs.osu.edu)).



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3. Contact the supplier: Some suppliers will take back controlled substances for credit. This process may involve the completion of manufacturer-specific return or recall transaction records or DEA Form 222 depending on the supplier and the substances involved.
- D. Registrant Record of Controlled Substances Destroyed (DEA Form 41) must be completed prior to disposing of any controlled substance and a copy must be retained by the registrant or authorized agent for at least five years, pursuant to the statute of limitations and the data retention requirements of the university Research Data policy.
- E. Registrants and authorized agents must maintain disposal records with the following information:
  1. The registrant’s DEA number, name, and address.
  2. If a reverse distribution is done, the reverse distributor's DEA number, name, and address.
  3. The number of units (in finished forms and/or commercial containers) disposed of in any manner, including the manner of disposal.
  4. The date when the products were sent for destruction and left the registrant’s or authorized agent’s inventory.
  5. Any additional documentation recording the exchange of custody.

### IX. Reporting of Theft or Missing Controlled Substance

- A. Registrants and their authorized agents must maintain complete accountability at all times of all controlled substances stored or used in their laboratory. Generation and retention of all records related to the use of controlled substances is essential so that any shortages or missing controlled substances will not go unnoticed. Theft or misuse of a controlled substance is a criminal act. Anyone who has knowledge of theft or misuse must report it to the following agencies, university departments, and individuals:

Agency/Office	Phone	Additional Contact Information
State of Ohio Board of Pharmacy	614-446-4143	614-752-4836 (fax)
DEA Columbus Resident Office	614-255-4200	614-469-5788 (fax)
University Police	614-292-2121	<a href="http://dps.osu.edu/police">dps.osu.edu/police</a>
College and/or department of the registrant		
Registrant		
Office of Research Compliance	614-292-4284	<a href="mailto:controlledsubstances@osu.edu">controlledsubstances@osu.edu</a>

- B. Federal regulations require that registrants notify the DEA Field Division Office in their area, in writing, of the theft or significant loss of any controlled substance within one business day of discovery of such loss or theft. The registrant must complete a Report of Theft or Loss of Controlled Substances (DEA Form 106) and submit this report to the Ohio DEA office. Simultaneous with notification of the DEA, copies of DEA Form 106 must also be submitted to the college and/or department of the registrant (to the vice dean for research or college research officer) as well as the Office of Research Compliance. Registrants and authorized agents must keep one copy of any DEA Form 106 submitted to the DEA for at least five years.
- C. 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 by registrants at [deadiversion.usdoj.gov/21cfr\\_reports/theft/index.html](http://deadiversion.usdoj.gov/21cfr_reports/theft/index.html). Copies must also be submitted to the college and/or department of the registrant as well as their responsible program administrators if applicable, and the Office of



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

### X. Exempt Chemical Preparations

- A. Exempt chemical preparations are controlled substance preparations that do not present any potential for abuse and are intended for laboratory, industrial, educational, or special research purposes only and not for administration to a human or animal.
- B. Investigators may order controlled substances in the forms described on the DEA exempt chemical preparation list without a DEA registration pursuant to [21 CFR §1308.24](#). For a complete list of chemical preparations and suppliers, see [deadiversion.usdoj.gov/schedules/exempt/exempt\\_chemlist.pdf](http://deadiversion.usdoj.gov/schedules/exempt/exempt_chemlist.pdf).
- C. These preparations are exempt from the controlled substances storage and security requirements outlined in Procedures Section IV above, as well as the maintenance of records and reporting requirements outlined in Procedures Sections V-IX above.
- D. Labeling of Exempt Chemical Preparations
  - 1. The label of an exempt chemical preparation must be prominently marked with the preparation’s full trade name or other description and the name of the manufacturer/supplier, in such a way that the product can be readily identified as an exempt chemical preparation.
  - 2. The label and labeling must also include in a prominent manner the statement "For industrial use only" or "For chemical use only" or "For in vitro use only—not for human or animal use" or "Diagnostic reagent—for professional use only" or a comparable statement warning the person reading it that human or animal use is not intended.
  - 3. The symbol designating the schedule of the controlled substance is not required on the label of the exempt chemical preparation, nor is it necessary to list all ingredients of the preparation.

### Responsibilities

Position or Office	Responsibilities
Investigators, registrants, and authorized agents	<ol style="list-style-type: none"> <li>1. Maintain and retain appropriate records and inventories of all controlled substances used in her/his research or instruction at the university. Provide controlled substance documentation to the state, federal and university oversight entities listed in this policy.</li> <li>2. Complete training before being involved in controlled substance use in research.</li> <li>3. Ensure that training records related to your registration are maintained.</li> <li>4. Follow requirements to purchase/order controlled substances from university-based pharmacies and non-university pharmacies or distributors.</li> <li>5. Store all controlled substances in a locked steel cabinet or a locked substantially constructed cabinet. Provide effective controls against theft.</li> <li>6. Maintain up-to-date physical inventories of all controlled substances in their laboratories and follow all inventory requirements.</li> <li>7. Follow requirements for administration/use documentation.</li> <li>8. Document spills/losses as required.</li> <li>9. Account for, retain, and dispose of damaged, expired, unwanted, unusable, and non-returnable controlled substances in accordance with state and federal regulations; maintain disposal</li> </ol>



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Position or Office	Responsibilities
	<p>records as required. Contact the college and/or department to help determine the correct disposal method.</p> <ol style="list-style-type: none"> <li>10. Maintain complete accountability at all times of all controlled substances stored or used in their laboratory.</li> <li>11. Report theft/misuse of controlled substances to the agencies listed in this policy.</li> <li>12. Follow requirements for exempt chemical preparations, if applicable.</li> <li>13. <i>Investigators seeking to become registrants:</i> <ol style="list-style-type: none"> <li>a. Follow the requirements for registering with the university, the Board of Pharmacy, the DEA, and any requirements for renewals and changes in registration.</li> <li>b. Notify the college and/or department prior to registering with the Board of Pharmacy and/or DEA and of any changes in registration.</li> <li>c. Provide copies of licenses and registrations to college and/or department.</li> </ol> </li> <li>14. <i>Registrants and investigators:</i> follow transfer/disposal requirements prior to leaving the university, license termination, or making changes to the registration.</li> <li>15. <i>Authorized agents:</i> follow requirements to become an authorized agent.</li> </ol>
College and/or department of the registrant	<ol style="list-style-type: none"> <li>1. Monitor and oversee of this policy as it applies to registrants and their agents.</li> <li>2. Monitor the registration, recordkeeping, inventory, security, and disposal of controlled substances used in research by their investigators.</li> <li>3. Audit all registrants on an annual basis. Conduct additional audits to determine if corrective action has resolved any found deficiencies.</li> <li>4. Conduct off-cycle audits at college/department discretion.</li> <li>5. Provide appropriate training on the use of controlled substances in research and/or ensure that all registrants and authorized agents have undergone such training (see required list of training topics).</li> <li>6. Designate a responsible program administrator(s) as necessary to oversee training, auditing, etc.</li> <li>7. Notify Office of Research Compliance of serious and/or recurring issues of noncompliance; review issues of noncompliance arising from those audits, and determine and enact corrective action plans in consultation with Legal Affairs and applicable university units.</li> </ol>
Office of Environmental Health and Safety	<ol style="list-style-type: none"> <li>1. Perform annual inspections of laboratory safety and security.</li> <li>2. Maintain contact and cost information for reverse distributors.</li> </ol>
Office of Research Compliance	<ol style="list-style-type: none"> <li>1. Monitor and oversee this policy as it applies to registrants and their agents.</li> <li>2. Review issues of noncompliance arising from annual reviews conducted by the college and/or department of registrants.</li> <li>3. Provide assistance to university investigators holding individual DEA research registrations and Terminal Distributor Licenses (i.e. registrants).</li> <li>4. Maintain and update website with policy and supplemental information.</li> </ol>
University Police	<ol style="list-style-type: none"> <li>1. Work with the Office of Research to temporarily and securely store controlled substances and order forms when needed.</li> </ol>

### Resources

**Forms** – Used to log the purchasing, administering, dispensing, and inventory of controlled substances possessed by university investigators:



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**OSU Controlled Substance Forms** may be downloaded: [orc.osu.edu/regulations-policies/controlled-substances/](http://orc.osu.edu/regulations-policies/controlled-substances/)  
[OSU Controlled Substance Form 1.1](#), Controlled Substances Usage Log  
[OSU Controlled Substance Forms 1.2A, 1.2B](#): Controlled Substance Dilution and Administration Logs (to be used together)  
[OSU Controlled Substance Form 2](#), Individual Drug Log  
[OSU Controlled Substance Form 3](#), Controlled Substances Authorized Agent List  
[OSU Controlled Substance Form 4](#), Controlled Substance Program Security Release  
[OSU Controlled Substance Form 5](#), Purchasing/Receiving Log  
[OSU Controlled Substance Form 6](#), Record of DEA Form 222 Use (Optional)  
 DEA Order Forms Request (for DEA Form 222), [deaddiversion.usdoj.gov/online\\_forms\\_apps.html](http://deaddiversion.usdoj.gov/online_forms_apps.html)  
 Registrants Inventory of Drugs Surrendered (DEA Form 41), [deaddiversion.usdoj.gov/21cfr\\_reports/surrend/index.html](http://deaddiversion.usdoj.gov/21cfr_reports/surrend/index.html)  
 Report of Theft or Loss of Controlled Substances (DEA Form 106), [deaddiversion.usdoj.gov/21cfr\\_reports/theft/index.html](http://deaddiversion.usdoj.gov/21cfr_reports/theft/index.html)  
 TTTD License Application form, [pharmacy.ohio.gov/Documents/Licensing/TDDD/Apps/Limited%20License%20Application.pdf](http://pharmacy.ohio.gov/Documents/Licensing/TDDD/Apps/Limited%20License%20Application.pdf)

### Manuals

DEA Practitioner's Manual (August 2006), [deaddiversion.usdoj.gov/pubs/manuals/pract/index.html](http://deaddiversion.usdoj.gov/pubs/manuals/pract/index.html)  
 PDF version for printing, [deaddiversion.usdoj.gov/pubs/manuals/pract/pract\\_manual012508.pdf](http://deaddiversion.usdoj.gov/pubs/manuals/pract/pract_manual012508.pdf)

### Controlled Substances Links

Code of Federal Regulations Schedule of Controlled Substances, [deaddiversion.usdoj.gov/21cfr/cfr/2108cfrt.htm](http://deaddiversion.usdoj.gov/21cfr/cfr/2108cfrt.htm)  
 DEA Security Regulation (21 CFR §§1301.71 -1301.76), [deaddiversion.usdoj.gov/21cfr/cfr/1301/1301\\_71.htm](http://deaddiversion.usdoj.gov/21cfr/cfr/1301/1301_71.htm)  
 U.S. Department of Justice Drug Enforcement Administration Office of Diversion Control, [deaddiversion.usdoj.gov/index.html](http://deaddiversion.usdoj.gov/index.html)

### Other University Policies, [policies.osu.edu/](http://policies.osu.edu/)

Research Data policy, [orc.osu.edu/files/2011/01/ResearchDataPolicy.pdf](http://orc.osu.edu/files/2011/01/ResearchDataPolicy.pdf)

### Other Information

College/Department Registration Holder List, [orc.osu.edu/regulations-policies/controlled-substances/](http://orc.osu.edu/regulations-policies/controlled-substances/)

## Contacts

Subject	Office	Telephone	E-mail/URL
Policy questions	Office of Research Compliance	614-292-4283	<a href="mailto:controlledsubstances@osu.edu">controlledsubstances@osu.edu</a> <a href="http://orc.osu.edu/regulations-policies/controlled-substances/">orc.osu.edu/regulations-policies/controlled-substances/</a>
Policy questions	College of Medicine, Office of Research	614-688-9301	<a href="mailto:labcompliance@osumc.edu">labcompliance@osumc.edu</a> <a href="http://medicine.osu.edu/research/compliance/controlled_substances/pages/index.aspx">medicine.osu.edu/research/compliance/controlled_substances/pages/index.aspx</a>
Purchasing	Purchasing Department, Office of Business and Finance	614-688-8200	<a href="http://purchasing.osu.edu">purchasing.osu.edu</a>
Purchasing – Wexner Medical Center	Department of Pharmacy, Wexner Medical Center	614-293-4717	
Purchasing – Veterinary Medical Center	Veterinary Medical Center Pharmacy	614-292-1010	
Registration, agent authorization, training, recordkeeping, storage and security, disposal	College and/or department of the registrant		<a href="http://orc.osu.edu/regulations-policies/controlled-substances/">orc.osu.edu/regulations-policies/controlled-substances/</a>
Temporary securing of controlled substances and/or order forms	University Police	614-292-2121	<a href="http://dps.osu.edu/police">dps.osu.edu/police</a>

## History

Issued: 05/12/2010 Individual Investigator Use of Controlled Substances in Research  
 Revised: 12/15/2010



# **Individual Investigator Use of Controlled Substances in Non-Therapeutic Research**

## **University Policy**

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Revised: 06/01/2016 Renamed Individual Investigator Use of Controlled Substances in Non-Therapeutic Research