

Policy

Individual Investigator Use of Controlled Substances in Research

Office of Research/College of Medicine/OSU Medical Center

Applies To

This Policy applies to all Ohio State University faculty and research staff members who hold individual federal Drug Enforcement Administration (DEA) Research Registrations as well as Ohio State Board of Pharmacy licenses to specifically use Controlled Substances in animal research. This Policy does not apply to Ohio State University faculty and staff who are licensed practitioners in the State of Ohio and hold current DEA registrations for the use of Controlled Substances in clinical treatment associated with human subject research or veterinary clinical trials.

Policy

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Controlled Substances are drugs which are regulated by the DEA and the Ohio State Board of Pharmacy because of potential for abuse. Controlled Substances may be used in Institutional Review Board (IRB) approved research involving the use of human subjects by university faculty and staff who are licensed healthcare practitioners in the State of Ohio and hold current DEA registrations. Controlled Substances may also be used in Institutional Animal Care and Use Committee (IACUC) approved veterinary clinical trials by university faculty and professional staff members who are licensed veterinarians in the State of Ohio and hold a DEA Controlled Substance Registration for veterinary use.

DEA regulations and State Pharmacy Board rules also allow faculty and staff researchers (Investigators) to obtain and use Controlled Substances in IACUC-approved animal research or Institutional Biosafety Committee (IBC) approved research with cell culture systems. In order to do so, Investigators must either: 1) hold a current individual DEA Research Registration or 2) conduct the animal research as an “agent” (as defined in this Policy) of a university official or faculty researcher, who holds a current DEA and State Pharmacy Board Research Registration.

This Policy describes the responsibilities of the university and Investigators who use Controlled Substances in animal research and, specifically, Investigators’ responsibilities to comply with State of Ohio and DEA requirements concerning the administration, handling, storage, destruction and/or transfer of Controlled Substances used in research.

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Definitions

Term	Definition
Agents	Authorized co-Investigators or lab staff acting directly on behalf of an Investigator holding a DEA research registration, or acting on behalf of the Senior Director of Pharmaceutical Services at The Ohio State University Medical Center.
Controlled Substances	Drugs that are regulated by the federal Drug Enforcement Administration and the Ohio State Board of Pharmacy because of potential for abuse. See Policy Details, DEA Controlled Substance Schedules, below for a description of the different categories and examples of Controlled Substances.
DEA	The federal Drug Enforcement Administration.
DEA Research Registration	A special DEA license that allows non-practitioner Investigators to obtain and use Controlled Substances in animal research.
Investigator	An Ohio State University faculty researcher or staff member researcher.
Practitioner	An Ohio State University 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 his/her professional practice.
Non-practitioner	A university investigator who conducts animal research at the university and does not have a practitioner's license.

Policy Details

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I. Scope of Use of Controlled Substances in Research by Practitioners, Investigators and Agents

Practitioner

A licensed healthcare or veterinary medicine practitioner is permitted to dispense or administer a Controlled Substance in the course of his/her 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 research, Investigators who are licensed practitioners must also hold a current DEA Research Registration or be an 'Authorized Agent' as described in the Policy below.

Investigators

Practitioner and non-practitioner Investigators may be registered as 'researchers' under the DEA regulations. With a (current) DEA Research Registration, Investigators may purchase and use/administer Controlled Substances in research on animals. Investigators with DEA Research Registrations may not, however, use Controlled Substances in research involving the use of human subjects, or dispense or write prescriptions with a Research Registration. Note that in order to obtain a DEA Research Registration, an Investigator must also obtain a separate State Board of Pharmacy Terminal Distributor License.

Investigators with DEA Research Registrations may only use Controlled Substances pursuant to an Ohio State University institutional animal care and use committee (IACUC) approved protocol, which defines the specific agent(s), dosage(s) and method(s) of administration of Controlled Substances used in the research protocol. Investigators must also follow any additional state or federal restrictions on the use of non-controlled therapeutic agents. For example, federal law restricts Xylazine Hydrochloride, a non-controlled anesthetic/sedative, to use only by or under the order of a licensed veterinarian.

Authorized Agents

Agents may also use Controlled Substances in animal research under an Investigator's Research Registration if they are specifically listed on an Ohio State University Controlled Substances Authorized Agent List (OSU **DEA Form 3**). See the 'Storage and Security Processes and Employee Authorization Documentation' section of the procedures below. Agents using Controlled Substances are also required to comply with the terms of this policy and the procedures within. Before receiving final institutional approval to use controlled substances under this policy, Agents must attend an orientation session provided by the University's Office of Research Compliance, College of Medicine Office of Research (COM Office of Research), or Ohio State University Medical Center Department of Pharmacy.

II. DEA Controlled Substance Schedules

Controlled Substances are designated by the DEA as Schedule I - V (C-I, C-II, C-III, C-IV and C-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. Refer to 21 CFR 1308 for the schedules of Controlled Substances.

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A. Schedule I Controlled Substances

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), marijuana, and methaqualone.

B. Schedule II Controlled Substances

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, fentanyl, morphine, phencyclidine (PCP), cocaine, methadone, and methamphetamine.

C. Schedule III Controlled Substances

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, anabolic steroids, codeine and hydrocodone with aspirin or Tylenol[®], and some barbiturates are examples of Schedule III Substances.

D. Schedule IV Controlled 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, Darvon[®], Talwin[®], Equanil[®], Valium[®], and Xanax[®].

E. Schedule V Controlled Substances

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

III. Monitoring and Inspection

The COM Office of Research, the University's Office of Research Compliance and the Ohio State University Medical Center Department of Pharmacy are jointly responsible for monitoring the recordkeeping, inventory, security, and disposal of Controlled Substances used in research by Ohio State University Investigators. Reviews will be conducted on an annual or bi-annual basis to assure university compliance with DEA and State Board of Pharmacy regulations and this Policy.

IV. University Registration Requirements

Investigators holding current individual DEA Research Registrations and Ohio State Board of Pharmacy Terminal Distributor Licenses must notify the COM Office of Research, which shall serve as the primary point of contact for Investigators and Agents under this Policy. Investigators who intend to register with the State Board of Pharmacy and the DEA for new Research Registrations and Terminal Distributor Licenses must first

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notify COM Office of Research prior to registering with the Ohio Board of Pharmacy and/or the DEA. The DEA generally requires that Investigators first obtain a Terminal Distributor License from the Ohio State Board of Pharmacy before the agency will issue a DEA Research Registration.

V. Recordkeeping Requirements

Every university Investigator holding a DEA Research Registration and an Ohio State Board of Pharmacy Terminal Distributor License is responsible for maintaining appropriate records and inventories of all Controlled Substances used in their research at the university. Investigators who obtain and use Controlled Substances as Agents under the College of Medicine's DEA Research Registration, which is held by the Senior Director of Pharmaceutical Services, or as Agents under DEA Research Registrations held by any other Ohio State University college, department or unit, are also responsible for maintaining appropriate records and inventories of 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 (2) years from the date of such inventory or records, for inspection and copying by authorized employees of the DEA. This Ohio State University Policy requires registered/licensed Investigators to retain Controlled Substance records for five (5) years following the date of such inventory or records, in view of the statute of limitations as well as the data retention requirements of the Ohio State University Research Data Policy.

Ohio State University 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. The Ohio State University Medical Center Pharmacy will be responsible for maintaining DEA Form 222s for all Controlled Substances purchased through the Medical Center Pharmacy under the College of Medicine's DEA Research Registration. Investigators using the Medical Center Pharmacy are responsible for maintaining copies of the university 100-W and eRequest forms used for each Controlled Substance purchase. Investigators who purchase Controlled Substances from outside pharmacy vendors/suppliers and use their own DEA Research Registration 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 either separately from all other records of the registrant/licensee or in such form that the information required is readily retrievable from the ordinary business records of the registrant. "Readily retrievable" means that Schedule III, IV, and V records can be separated out from other records in a reasonable time.

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, the Office of Research and the College of Medicine.

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VI. Corrective Measures

Failure of Investigators and Agents 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, including loss or limitation of an investigator's privilege to conduct animal research at the institution.

Procedures

Issued: 09/20/2010
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1. Purchasing Records

It is strongly recommended that all university Investigators purchase Controlled Substances through the Medical Center Department of Pharmacy.

Controlled Substances Purchased from Ohio State University Pharmacies

Investigators holding current DEA Research Registrations may purchase Schedule II – IV Controlled Substances from the Medical Center Pharmacy Controlled Substance Office or Investigators may use the College of Medicine's DEA Research Registration, which is held by the Senior Director of Pharmaceutical Services, The Medical Center Pharmacy Controlled Substance Office will maintain purchasing records for Controlled Substances ordered by Investigators through the Pharmacy. Investigators using their own DEA Research Registration are responsible for maintaining the DEA Form 222s for Schedule II Controlled Substances. Note that the Medical Center Pharmacy cannot provide some veterinary agents, such as Xylazine Hydrochloride, which can only be obtained and used under the direction of a licensed veterinarian.

Investigators holding a DEA Research Registration may receive Controlled Substances by providing the following to the Medical Center Pharmacy:

- An approved University eRequest Form that includes the following information:
 - Name of individual picking up (this person must be on the approved list)
 - Location (must match location on the list of approved sites)
 - Item number, quantity, name and estimated price of the Controlled Substance(s) you are purchasing (this information can be obtained by contacting the College of Medicine Office of Research)
- A DEA Form 222 (only required for Schedule II Controlled Substances)
- A copy of the Investigator's current DEA Research Registration (for the Pharmacy File)
- A current Ohio State University ID
- A copy of OSU DEA Form 5, Ohio State University Controlled Substances Authorized Agent List, (for the Pharmacy file). Only those listed on the Authorized Agent List or the investigator will be permitted to receive Controlled Substances from the Pharmacy.

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Investigators may use and receive Controlled Substances under the College of Medicine's DEA Research Registration by providing the following to the Medical Center Pharmacy:

- An approved University eRequest Form that includes the following information:
 - Name of individual picking up (this person must be on the approved list)
 - Location (must match location on the list of approved sites)
 - Item number, quantity, name and estimated price of the Controlled Substance(s) you are purchasing (this information can be obtained by contacting the College of Medicine Office of Research)
- A current Ohio State University ID
- A copy of OSU DEA Form 5, Ohio State University Controlled Substances Authorized Agent List (for the Pharmacy file). Only those listed on the Authorized Agent List or the investigator will be permitted to receive Controlled Substances from the Pharmacy.

Controlled Substances Purchased from Non-University Pharmacies or Distributors

Investigators are responsible for obtaining and maintaining the following information for all Controlled Substance purchased from non-Ohio State University pharmacies or distributors:

- A copy of the invoice
- A copy of the purchase order
- A copy of the shipping document
- A copy of the packing slip
- The name, address, and DEA number of the company from which the Controlled Substance was purchased
- The name of the Controlled Substance purchased
- The size and strength of the Controlled Substance purchased
- The amount purchased (which should match the amount received)

The purchasing record (invoice, purchase order, shipping document, or packing slip) must be annotated with the handwritten date of receipt. Investigators purchasing Schedule II Controlled Substances from non-university pharmacies or distributors are required to maintain a copy of the invoice and individual DEA Form 222 for each purchase. Investigators purchasing Schedule II Controlled Substances from non-university sources must also complete a Record of DEA Form 222 Use (**OSU DEA Form 2**) to maintain accountability for all DEA Form 222's used. The date and amounts received entries on OSU DEA Form 2 should then match the date and quantity received entries on the Controlled Substances Record (**OSU DEA Form 1**) for each drug purchased.

2. Inventory Records

Maintaining an accurate inventory for Controlled Substances is one of the most important aspects of the State Board of Pharmacy and DEA enforcement programs and the university's compliance program. In following best research practice and to avoid Board of Pharmacy and DEA audit red flags, Investigator Controlled Substance inventories should only include the minimum amount necessary for research use. Inventory maintenance is the key to the loss detection, theft, and the diversion of Controlled Substances. Investigators must maintain an up-to-date inventory of the physical inventory of Controlled Substances in their laboratories.

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All Investigators are required to maintain an Ohio State University Controlled Substance Record (**OSU DEA Form 1**) for each Controlled Substance used in their laboratories (or a substantially similar form in paper or electronic format that provides the same information). The form meets DEA requirements for Controlled Substance inventory, administration, and use documentation requirements. Complete DEA inventory requirements can be found at the following site:
http://www.deadiversion.usdoj.gov/21cfr/cfr/1304/1304_11.htm .

3. Administration/Use/Waste Records

As noted above, Investigators must maintain administration/use records containing the following information:

- The animal species or cell culture system in which the investigator administered/used the Controlled Substance
- The date administered/dispensed
- If not administered/used personally by the registered investigator, the initials of person who administered/used under the direction of the investigator
- The name of the Controlled Substance
- The strength and size of the Controlled Substance
- The amount administered/used/wasted (number of units or volume)

Investigators must use the OSU Controlled Substances Record (**OSU DEA Form 1**) to document the above information.

4. Storage and Security Processes and Employee Authorization Documentation

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. This includes limiting the number of keys and 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. Developing a key accountability standard operating procedure is recommended. If combination locks are used, combinations must be changed whenever there is turnover of any employee who has knowledge of the combination and access to the Controlled Substances. In addition to key/combination access control, only authorized personnel should be allowed in a university laboratory where Controlled Substances are used or stored.

Authorized Agents who use Controlled Substances under an investigator's Research Registration must be documented on the Ohio State University Controlled Substances Authorized Agent List (**OSU DEA Form 3**), which is copied and forwarded to COM Office of Research), along with a completed and signed Ohio State University Controlled Substance Program Security Release (**OSU DEA Form 4**) for each individual listed on the OSU DEA Form 3. Keep **ONLY** a copy of the OSU DEA Form 6 with the Controlled Substance inventory. As noted in Section 1, only Authorized Agents will be allowed to receive Controlled Substances from the Medical Center Pharmacy. Investigators should forward a copy of OSU DEA Form 3 to the Medical Center

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Pharmacy Controlled Substance Office for the Pharmacy's file. The Pharmacy will not distribute Controlled Substances to any individual not specifically included on OSU DEA Form 3.

Non-laboratory visitors entering areas where Controlled Substances are used or stored must always be asked to provide identification and an explanation of why they are there. When maintenance work is done in the Controlled Substance storage area, the research staff must maintain adequate observation

5. DEA Ordering Forms

To order Controlled Substances from internal (OSU Medical Center Pharmacy Controlled Substance Office) or non-university pharmacies or distributors, Investigators must hold an Ohio State Board of Pharmacy Terminal Distributor License and a DEA research registration. The Controlled Substance Ordering Form (DEA Form 222) is a paper-based form used to order Controlled Substances, which is required for ordering Schedule I and II drugs. It is requisitioned directly from the DEA and is required to be filled out in triplicate. The DEA Form 222 also allows the exchange of 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).

Schedule I or II registrants can request official DEA Form 222 on-line at the following DEA site:

<https://www.deadiversion.usdoj.gov/webforms/orderFormsRequest.jsp>.

You will receive the maximum number of order form books allowed for your business activity.

Schedule III, IV, and V drug orders do not require a DEA Form 222. These drugs can be ordered directly from the manufacturer. However, you may be asked to provide a copy of your DEA Research Registration before your order will be prepared and shipped.

As noted in Section V, Recordkeeping Requirements, The Ohio State University Medical Center Pharmacy will be responsible for obtaining and maintaining DEA Form 222s for all Controlled Substances purchased through the Medical Center Pharmacy. The Medical Center Pharmacy will also maintain accountability of all DEA Form 222's used for internal Pharmacy purchases for Investigators and Agents.

As noted above, Investigators purchasing Controlled Substances from suppliers external to the University must obtain and maintain DEA Form 222s for all non-medical Center Pharmacy Controlled Substance purchases. Investigators must also use the Ohio State University Record of DEA Form 222 Use (**OSU DEA Form 2**) to track and maintain accountability of all DEA Form 222's used for external purchases of Schedule I or II Controlled Substances.

Note: If an Investigator's DEA Research Registration of Terminal Distributor License terminates (because the Investigator dies, discontinues his/her research, or changes the name or address as shown on his registration) (**NOTE – DEA Research Registrations are address specific**) or is suspended or revoked as to all Controlled Substances listed in Schedules I and II for which he/she is registered, all unused Controlled Substances and order forms for such Controlled Substances must be provided to the Ohio State University Police Department.

6. Disposal, Loss Records and Transfer of Investigators from the Institution

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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 (2) copies of the form must be sent to the local Ohio DEA branch and one (1) copy must be retained by the investigator for at least 5 years.

Investigators must maintain disposal records with the following information:

- The Investigator's DEA number, name, and address
- If a reverse distribution (see below) is done, the reverse distributor's DEA number, name, and address
- 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.

Investigators must use the Ohio State University Record of DEA Form 41 Use (**OSU DEA Form 5**) to maintain an inventory of all DEA Form 41's used to dispose of Controlled Substances.

Disposal Options

There are three disposal options for expired or unwanted Controlled Substances. The COM Assistant Vice President or the Medical Center Pharmacy should be contacted to help determine the correct disposal method.

1. **Contact the Supplier:**

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

2. **On-site Disposal:**

Small quantities (less than one (1) pound) can be disposed onsite by the DEA registrant using the following six-step Controlled Substance disposal procedure:

- i. Contact the COM Office of Research with a Controlled Substance disposal request.
- ii. Complete the Registrants Inventory of Drugs Surrendered (DEA Form 41) prior to disposal.
- iii. Inform COM Office of Research when the DEA Form 41 has been completed and is ready for review.
- iv. COM Office of Research will forward this form to the DEA with a projected two (2) week disposal date.
- v. At the end of the waiting period arrangements will be made for an Ohio State Police Officer and COM Office of Research representative to be present as witnesses to the disposal, verify the DEA Form 41 and inventory records.
- vi. COM Office of Research will forward two (2) copies of the DEA Form 41 to the Agent in Charge of Ohio DEA, and provide one (1) copy for the researcher's inventory records.

3. **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,

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re-sale or destruction at a hazardous waste incinerator. This process may involve the completion of DEA Form 222 or DEA Form 41. Contact information for reverse distributors may be obtained from the COM Office of Research.

Transfer of Investigators from the Institution

Controlled Substances purchased by Investigators conducting research on animals are the property of the Ohio State University. Investigators holding individual DEA Research Registrations and Investigators holding Controlled Substances as Agents who plan to leave the university (e.g. accept a position at another university, company or retire) must contact the COM Office of Research or the Medical Center Pharmacy prior to their departure to arrange appropriate transfer or disposal of the Controlled Substances.

7. 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 6 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.

8. 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:

Ohio State Board of Pharmacy	(614) 446-4143 (phone)	(614) 752-4836 (facsimile)
DEA Columbus Resident Office	(614) 255-4200 (phone)	(614) 469-5788 (facsimile)
Ohio State University Police Department	(614) 292-2121 (phone)	
College of Medicine Office of Research	(614) 292-0220 (phone)	

In addition to the immediate phone reporting, a Report of Theft or Loss of Controlled Substances (DEA Form 106) must be completed and submitted to the Ohio DEA office. Investigators must keep one (1) copy of any DEA Form 106 submitted to the DEA for at least 5 years.

On-line reporting to the DEA is also necessary if small quantities of Controlled Substances become unaccounted for on a re-occurring basis. The on-line reporting process can be accessed at http://www.deadiversion.usdoj.gov/21cfr_reports/theft/index.html. Investigators should print and keep one (1) copy of any online DEA Form 106 submitted in their Controlled Substance inventory records.

9. Other Pertinent Record Information

- Maintain current, complete and accurate records to reflect Controlled Substances:
 - Received (Purchased)

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- Sold (Administered & Dispensed)
- Otherwise disposed of
- Theft or loss
- Separate records are required for each research location
- 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).

Responsibilities

Position, or Office	List of Responsibilities
Investigators	Investigators holding or administering holding Controlled Substances under DEA research registrations and Ohio State Pharmacy Board Terminal Distributor licenses have primary responsibilities for: <ul style="list-style-type: none"> • Ensuring the appropriate purchase, use/administration, storage, destruction, and transfer for Controlled Substances used in the investigator’s laboratory • Maintaining all required Controlled Substance recordkeeping • Providing Controlled Substance documentation to the state, federal and university oversight entities listed in this Policy
Agents	Agents administering Controlled Substances under the direct supervision or authority of an Investigator holding a DEA research registrations and Ohio State Pharmacy Board Terminal Distributor licenses have responsibilities for: <ul style="list-style-type: none"> • Ensuring the appropriate delegated use/administration, storage, destruction, and transfer for Controlled Substances used in the Investigator’s laboratory • Providing Controlled Substance documentation to the state, federal and university oversight entities listed in this Policy
COM Office of Research	The College of Medicine Office of Research is responsible for: <ul style="list-style-type: none"> • Monitoring and oversight of this Policy as it applies to College of Medicine Investigators and their Agents • Conducting annual or bi-annual reviews of COM Investigators and joint reviews with the Office of Research Compliance of non-COM Investigators holding DEA research registrations and Terminal Distributor Licenses to assure compliance with this Policy • Providing assistance to College of Medicine Investigators holding DEA research registrations and Terminal Distributor Licenses • Providing assistance to College of Medicine and non-College of Medicine Investigators holding DEA research registrations and Terminal Distributor Licenses on the disposal of Controlled Substances • Maintaining a list of reverse distributors for disposal of Controlled Substances
Office of Research Compliance	The Ohio State University Office of Research Compliance is responsible for: <ul style="list-style-type: none"> • Monitoring and oversight of this Policy as it applies to non-College of Medicine Investigators and their Agents • Conducting annual or bi-annual reviews of non-COM Investigators and joint reviews with the COM Office of Research of COM Investigators holding DEA research registrations and Terminal Distributor Licenses to assure compliance with this Policy • Providing assistance to university Investigators holding DEA research registrations and

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	Terminal Distributor Licenses
Department of Pharmacy Ohio State University Medical Center	The Department of Pharmacy at The Ohio State University Medical Center is responsible for: <ul style="list-style-type: none"> • Holding a Research Registration on behalf the College of Medicine and the Ohio State University Medical Center, under which Ohio State University Investigators may use Controlled Substances as Agents in approved animal research, pursuant to this Policy. Providing assistance to the Ohio State University College of Medicine Office of Research and the Ohio State University Office of Research Compliance in their joint monitoring and oversight of this Policy as it applies to all Ohio State University Investigators and their Agents Providing assistance to university Investigators holding DEA research registrations and Terminal Distributor Licenses.

Resources

1. Forms

These forms will be used to log the purchasing, administering, dispensing, and inventory of Controlled Substances possessed by OSU Investigators holding DEA Research Registrations.

- OSU DEA Form 1- Controlled Substances Record
- OSU DEA Form 2 -Record of DEA Form 222 Use
- OSU DEA Form 3 - Controlled Substances Authorized Agent List
- OSU DEA Form 4 - Controlled Substance Program Security Release
- OSU DEA Form 5 - Record of DEA Form 41 Use
- [Registrants Inventory of Drugs Surrendered \(DEA Form 41\)](#)
- [Report of Theft or Loss of Controlled Substances \(DEA Form 106\)](#)
- [DEA Order Forms Request \(for DEA Form 222\)](#)

2. Manuals

- [DEA Practitioner's Manual \(August 2006\)](#)
 - [PDF Version for Printing](#)

3. Controlled Substance Links

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

Contacts

Individual or Office	Office	Telephone	E-mail/URL
Robert Weber, RPh., PharmD., M.S., Senior Director, Pharmaceutical	Department of Pharmacy Ohio State University	(614) 293-4717	Robert.Weber@osumc.edu

Policy

Individual Investigator Use of Controlled Substances in Research
Office of Research/College of Medicine/OSU Medical Center

Services	Medical Center		
Cecil Smith, Ph.D., Assistant Vice President	College of Medicine Office of Research	(614) 292-0220	Cecil.Smith@osumc.edu
Todd Guttman, M.D.,J.D., Associate Vice President	Office of Research	(614) 292-4283	Todd.Guttman@orc.osu.edu

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