

I. Introduction

Certain research activities require the use of controlled substances. Controlled substances are identified in the schedules contained within the "Controlled Substances Inventory List," published by the U.S. Drug Enforcement Administration (DEA). When conducting research with controlled substances, University employees must comply with federal and state laws and regulations regarding their use, DEA and the Kansas Board of Pharmacy registration; storage requirements; inventory maintenance; disposal; and reporting and record keeping, in accordance with Title 21, Code of Federal Regulations (CFR), Part 1300-1308 and the Kansas Statutes Annotated (KSA) 65-4101 through 4165.

II. Exclusions

This policy does not apply to controlled substances dispensed by a practitioner to a patient in the course of professional practice as authorized by his/her license.

This policy does not cover teaching activities performed within a clinical environment. However, clinical teaching activities must still comply with DEA and state regulations.

III. Definitions

- 1) **Controlled substance:** A drug or other substance, or immediate precursor, included in schedules I, II, III, IV, or V. The term does not include distilled spirits, wine, malt beverages, or tobacco.
A list of controlled substances is available on the DEA website at:
https://www.deadiversion.usdoj.gov/schedules/orangebook/c_cs_alpha.pdf
- 2) **DEA Controlled Substances Registration Certificate:** allows the holder to use controlled substances as specified by the certificate issued by the DEA. The holder of the certificate is accountable to the regulations set forth in 21 CFR 1300-end.
- 3) **Department of Environmental Health & Safety:** refers to the Kansas State University, Department of Environmental Health & Safety.
- 4) **Disposal:** refers to disposal of controlled substances that are in the original container or original form and that are outdated, surplus or no longer intended for use.
- 5) **Drug Enforcement Administration (DEA):** the section of the United States Department of Justice that establishes regulations for the handling and use of controlled substances.
- 6) **Orphaned controlled substance:** a controlled substance that has been abandoned and the researcher who obtained the substance is not known. It may also be a substance that existed before the DEA began controlling the substance, and therefore, it was never registered with the DEA.

IV.Procedures

1) Registration

Anyone intending to use controlled substances for research or teaching must be registered with DEA and the Kansas Board of Pharmacy. The registrant shall purchase controlled substances using his/her own registration number. The registrant shall not purchase controlled substances for other personnel.

Researchers should use the DEA Form 225. You may fill out the form on-line at <https://www.deadiversion.usdoj.gov/webforms/jsp/regapps/common/newAppLogin.jsp>. Select form 225. Then under "Select One Business Activity", select "Researcher." State personnel are not required to pay the registration fee. This is stated in Section 6 of the form.

Register with the Kansas Board of Pharmacy using the Research and Training Institution form at <https://pharmacy.ks.gov/resources-consumer-info-2/forms>

2) Use/Disposition Records

The registered user must document all actions taken with the controlled substance, which includes receiving, using, diluting/combining, transferring or disposing of expired and waste-controlled substances. Record the use of controlled substances on disposition records.

3) Inventory

Every two years, registered users must complete an inventory to compare the actual count of controlled substances to the amount in the written disposition records. More frequent inventories are recommended for laboratories using schedule II drugs, higher volumes, multiple controlled substances, or those labs with many authorized users.

4) Maintaining Registrations

Researchers must renew their DEA and Kansas Board of Pharmacy registrations annually.

5) Labeling

If controlled substances are removed from their original packaging and compounded, diluted or combined, each new container must be labeled and tracked. The label must include: the name of the controlled substances, the lot number, the final concentration, the amount per container and the expiration date.

6) Storing and Securing

Controlled substances must be stored in a sturdily constructed, locked cabinet separate from other drugs or materials.

7) Disposing of Controlled Substances

Controlled substances that are outdated, surplus or contaminated must be disposed of according to federal regulations. One option is to send these items to a reverse distributor. The list of these distributors is available on the Environmental Health and Safety webpage at: <https://www.k-state.edu/safety/docs/reverse-distributor-registrants.pdf>. This is a fairly easy process and the reverse distributor will more than likely assist you through the process.

Important: If you are a registered user with the DEA, you must dispose of your controlled substance per DEA policy. The KSU EH&S department may not pick up or dispose of any controlled substance that belongs to a DEA registered user. If you have an orphaned controlled substance, contact EH&S at 2-5856.

8) Reporting Theft or Loss

If you suspect a theft, immediately notify the K-State Police and EH&S. The DEA requires that theft or loss of controlled substances be reported on DEA Form 106 Report of Theft or Loss of Controlled Substances. The form is available below in the DEA Links section.

If a container of a controlled substance is broken, document this in the disposition record and have a witness sign and date it, if possible. Complete a DEA Form 41 for the amount of the substance lost and write "unintentional destruction" on the form. Signatures of the person who broke the bottle, the witness and the Registrant are required on Form 41. Mail the original to the DEA and file a copy with your controlled substance records.

9) Retaining Records

Controlled substance records must be maintained for at least 5 years.

Relevant Federal and State Regulations Concerning Controlled Substances

- Federal regulation: Title 21, Code of Federal Regulations, part 1300:
<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcr/CFRSearch.cfm?CFRPart=1300>
- Kansas Controlled Substance Act and Regulations:
https://pharmacy.ks.gov/docs/librariesprovider10/statues-regulations/full-version-pdf.pdf?sfvrsn=66fca701_29

V. DEA Links

The following are links to DEA manuals and forms:

- [Main DEA webpage](#)
- [List of DEA controlled substances](#)
- [DEA Example Form 41 Registrants Inventory of Drugs Surrendered](#)
- [DEA Example Form 106 Report of Theft or Loss of Controlled Substances](#)
- [DEA Order Forms Request \(request the form to order controlled substances here\)](#)
- [DEA Form 225 Renewal Application for DEA Registration](#)

VI. Frequently Asked Questions

Q: How do I dispose of my controlled substance?

A: You may dispose of out-of-date, damaged, or otherwise unusable or unwanted controlled substances, including samples, by transferring them to a registrant who is authorized to receive such materials. These registrants are referred to as Reverse Distributors. The list of Reverse Distributors is available on the Environmental Health and Safety website at: <https://www.k-state.edu/safety/docs/reverse-distributor-registrants.pdf>

Schedule I and II controlled substances should be transferred via the DEA Form 222, while Schedule III–V compounds may be transferred via invoice. The registrant should maintain copies of the records documenting the transfer and disposal of controlled substances for a period of 5 years. There may be a charge when you send controlled substances to a reverse distributor. Cost depends on the type and quantity of substance.

You may also try contacting the manufacturer to request authorization to return the substance directly to them.

Q: How do I dispose of an orphaned controlled substance (see above for a definition of orphaned substance)?

A: If your laboratory discovers a controlled substance and it is not known who was registered to possess that substance, call EH&S for disposal at 2-5856. Alert the EH&S person that you talk to that you have a controlled substance that needs to be picked up. EH&S personnel are not allowed to pickup these substances; however, we do have procedures in place to allow for the pickup and disposal of orphaned controlled substances.

Q: What should I do if I discover a theft or loss?

A. Registrants must notify the K-State Police and the DEA field office in their area of the theft or significant loss of any controlled substances upon discovery. The registrant must also complete DEA Form 106 documenting the loss or theft.

Summary of Controlled Substances Act Requirements

	Schedule II	Schedule III & IV	Schedule V
<i>Registration</i>	Required	Required	Required
<i>Receiving Records</i>	Order Forms (DEA Form-222)	Invoices, Readily Retrievable	Invoices, Readily Retrievable
<i>Distribution Between Registrants</i>	Order Forms (DEA Form-222)	Invoices	Invoices
<i>Security</i>	Locked Cabinet or Other Secure Storage	Locked Cabinet or Other Secure Storage	Locked Cabinet or Other Secure Storage
<i>Theft or Significant Loss</i>	Report and complete DEA Form 106	Report and complete DEA Form 106	Report and complete DEA Form 106

Note: **All records** must be maintained for 5 years.

VII. Questions

Direct questions to EHS by phone: 785-532-5856 or email: waste@ksu.edu