

draft

Working with Controlled Substances in Research

Resources and Links

Regulatory Officials

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[NC Controlled Substance Act](#)

[DEA Online Forms](#)

[DEA Security Regulations](#)

[DEA Controlled Substances
Security Manual](#)

[Security Questionnaire](#)

BACKGROUND

Principal Investigators and authorized staff must maintain detailed storage and use records, and follow special controlled substance disposal procedures.

PURCHASING CONTROLLED SUBSTANCES

To order a controlled substance you must first have a DEA license. The Controlled Substance Ordering Form (DEA Form 222) is a paper-based form used to order controlled substances. 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 registered party.

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 Registration before your order will be prepared and shipped.

Controlled substances should be ordered through the WFUHS Purchasing Department or, in some cases, the NCBH Pharmacy.

STORAGE AND SECURITY CONTROLS

All DEA registrants must provide effective controls and procedures to guard against theft and diversion of controlled substances.

Security requirements vary by drug schedule. Schedule I and II controlled substances are subject to the highest security requirements, and must be stored separately from other drugs in an approved safe. Schedule III through V substances must also be stored separately from other drugs in a secure locked location. Regardless of schedule, all controlled substances must be kept locked in their storage location except for the actual time required for authorized staff to remove, legitimately work with, and replace them.

EXPORT

Federal law prohibits the export of controlled substances unless certain requirements are met, including, in most cases, export and import permits. Licensed brokers are available for transport of controlled substances. WFUHS EH&S can provide assistance in arranging for any necessary transport of controlled substances.

AUTHORIZED STAFF

Principal Investigators may authorize members of their laboratory staffs to work with controlled substances under their license/registration, provided staff members have been listed on the license and registration applications.

RECORDKEEPING

Principal Investigators must maintain complete and accurate inventory records for all controlled substances. These records must be kept separately from all other records and documents, in or near the primary work area, and be readily available for inspection during regular work hours or at any other reasonable time. Records must be in written, typewritten, or printed form. The use of codes, symbols, or foreign languages in identifying a controlled substance or person in the record is prohibited.

[Records and Reports of Registrants US DEA](#)

All records must be maintained by Principal Investigators for at least three years from the date of the last recorded purchase, transfer, use, or other transaction. The recordkeeping system must include *at least* the following information maintained as prescribed in state and federal controlled substance laws and regulations:

Receipt of Controlled Substance. A separate and current record of the receipt of controlled substances, indicating:

- date received,
- name and address of supplier,
- the type, strength or concentration,
- and amount of the controlled substances received.

[Receipt Log](#)

Each record must be signed by the person receiving the controlled substance. DEA Forms 222 and invoices should be retained.

Use of Controlled Substances.

Schedule I:

- Schedule I controlled substance records need to be maintained in a bound notebook (recommendation).
- The **records** should include the following information:

- Name of the drug
- Source (vendor)
- Date of expiration of the drug
- Date of receipt
- Date of use (or withdrawn for use)
- Protocol or project for which it is being used
- Animal (if applicable) for which it is being used
- Person dispensing
- Quantity (cc or ml or grams) of drug dispensed
- Quantity remaining in the vial/bottle/box

[Use Log](#)

Schedule II-V:

- Schedule II-V controlled substance records can be maintained in three-holed loose leaf binder. A suggested template is available (see left hand column).
- The **records** should include the same information referenced under Schedule I.

[Inventory Form](#)

EH&S Waste Program
Information

Inventory of Controlled Substances. It is recommended that semi-annual audits of inventory occur for all controlled substances. The DEA requirement is less stringent (every 2 years). The six month period allows for any discrepancies or problems to be easily discovered and resolved.

DISPOSAL

Controlled substances from non-human research work may only be disposed

- under witness from the State DHHS (Drug Control Unit) or Federal DEA,
- through a reverse distributor by documented return to the supplier or manufacturer,
- or as otherwise authorized or directed by regulatory agency personnel.

Expired material, unused or unwanted product, or neat waste must be accumulated and stored under lock and key until ready for disposal. The North Carolina DHHS Drug Control Unit, Federal DEA, or WFUHS EH&S must be contacted to arrange for a disposal visit or permission to otherwise dispose of controlled substances.

SPILLS

Breakage, spills, or other witnessed controlled substance losses do not need to be reported as lost. This type of loss 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 (tablets), must be placed in the disposal/destruction waste stream. If the spilled controlled substance is not recoverable (liquids), the registrant must document the circumstances in inventory records and witnesses must sign.

REPORTING LOSS, DESTRUCTION, THEFT OR UNAUTHORIZED USE

Any losses of any controlled substance, including thefts, unauthorized uses, or unauthorized destruction must be reported to WFUBMC Security and WFUHS EH&S immediately upon discovery. Registrants must also document the incident in writing for submittal to the State DHHS Drug Control Unit (within 72 hours) and Federal DEA (within one business day). The written statement must describe the kinds and quantities of controlled substances in question, and the specific circumstances involved. The registrant should retain a copy of the statement for at least three years.

ABANDONED CONTROLLED SUBSTANCES

Under no circumstances are controlled substances to be abandoned by a DEA registrant. However, occasionally, faculty will leave without appropriately disposing or transferring all controlled substances from their lab. Under these circumstances, the department responsible for the lab will need to contact the North Carolina DHHS Drug Control Unit to arrange for appropriate disposal.