Procedures Regarding the Use of Controlled Substances in Non-Clinical Research

September 1, 2022

Definitions

"Controlled substance" means a drug or other substance, or immediate precursor, included in schedule I, II, III, IV, or V as defined by 21 USC 812: Schedule of controlled substances

“Authorized Agent” means individuals authorized by the registrant to engage in registered activities, if such individual is acting in the usual course of his/her business or employment.

“Registrant” means any individual or entity registered or licensed with the federal Drug Enforcement Administration (DEA) and the State of Illinois to engage in specific activities with specific controlled substances.

“Registered activities” means an individual or entity holds a valid federal and State of Illinois registration or license to engage in certain specific activities with specific controlled substances.

Procedures

Any individual conducting research utilizing a controlled substance must contact cs-compliance@northwestern.edu to notify the Controlled Substance Compliance Coordinator of the intent to obtain and use controlled substances in addition to complying with the following requirements:

I. Registration
   - A. Register with the Illinois Department of Professional Regulations by submitting an Illinois Other Controlled Substances Licensure Application (IL486-2249).
   - B. After approval of the state registration, register with the Drug Enforcement Administration.
   - C. Notify the Controlled Substance Compliance Coordinator (cs-compliance@northwestern.edu) upon approval of the controlled substance registrations.

II. Authorized Use
   - A. The Registrant is responsible for ensuring compliance with all controlled substance regulations pertaining to inventory, record keeping, and security.
   - B. The registrant must screen employees and students before authorizing them to work with controlled substances according to 21 CFR 1301.90. See III below.

III. Authorized Agent Questionnaire
   - A. The registrant must obtain the following information in writing from any proposed authorized agents:
     - i. Within the past five years, have you been convicted of a felony, or within the past two years, of any misdemeanor or are you presently formally charged with committing a criminal offense? (Do not include any traffic violations, juvenile offenses or military convictions, except by general court-martial.) If the answer is yes, furnish details of conviction, offense, location, date and sentence.
     - ii. In the past three years, have you ever knowingly used any narcotics, amphetamines or barbiturates, other than those prescribed to you by a physician? If the answer is yes, furnish details.

B. The registrant must advise the proposed authorized agent that any false information or omission of information in response to these questions will jeopardize his or her position with respect to employment.
C. The registrant must retain copies of the responses for a minimum of two years following the cessation of controlled substance activity.

IV. Purchasing
A. Ordering of controlled substances must comply with the policies and procedures established by Procurement and Payment Services.

V. Record Keeping Requirements
A. The registrant must maintain the following records at the registered location:
i. Employee questionnaires
ii. Executed order forms (222 forms) and invoices for all orders of controlled substances
iii. Inventory records
iv. Usage records
v. Disposal records
vi. Reports of theft or significant loss (if any)
B. All records must be maintained for at least five years from the date of such record.
C. Records for Schedule I and II controlled substances must be maintained separately from all other records.
D. Records of schedules III-V controlled substances must be kept separate from all other records or readily retrievable.

VI. Inventory Requirements
A. After receiving DEA registration, the registrant must take an initial inventory, even if there are no stocks of substances on hand.
B. The registrant must conduct a complete and accurate record of all controlled substances on hand at least every year.
C. The inventory must include the name, address, and DEA registration number of the registrant.
D. The inventory must be taken either as of opening of business or as of the close of business on the inventory date and it must be indicated on the inventory.
E. For each controlled substance in finished form, the inventory must include:
i. The name of the substance;
ii. Each finished form of the substance (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter);
iii. The number of units or volume of each finished form in each commercial container (e.g., 100-tablet bottle or 3-milliliter vial); and
iv. The number of commercial containers of each such finished form (e.g. four 100-tablet bottles or six 3-milliliter vials).
F. For each controlled substance in unfinished form, the inventory must include:
i. The name of the substance; and
ii. The total quantity of the substance to the nearest metric unit weight.
G. The authorized individual(s) who conduct the inventory should sign and date the inventory.
H. For Schedule I and II controlled substances, the inventory must be based on an exact count or measure of the contents in the container.
I. For Schedule III-V controlled substances, the inventory can be based on an estimated count or measure of the contents in the container (unless the container holds more than 1,000 tablets, in which case the exact number should be counted).
J. For substances that are awaiting disposal, the inventories should include:
i. The name of the substance;

ii. Total quantity of the substance to nearest metric unit weight or total number of units in finished form and
iii. Whether the substance is capable of use in the manufacture of any controlled substance in finished form.

VII. Controlled Substance Tracking

A. The registrant must maintain, on a current basis, a complete and accurate record of each controlled substance acquired, used in research, transferred to other registrants, or sent for disposal.
B. For each controlled substance acquired, a log containing the follow information must be maintained:
    i. Name of the controlled substance;
    ii. The concentration and volume of substance or if in unfinished form, the metric unit weigh of the container;
    iii. Each time substance is removed from the container, a record of,
        1. The date
        2. Intended use (e.g., cell culture, *in vitro* experiment)
        3. Quantity removed
        4. Balance remaining in container
        5. Initials or signature of individual removing substance
C. If unfinished controlled substances are formulated into solution or finished products are diluted or mixed with other substances, a log consistent with VI.B. must be maintained for each solution, dilution or mixture.

VIII. Security

A. Controlled substances must be stored in a securely locked, substantially constructed cabinet in compliance with 21 CFR 1301.75.
B. Keys allowing access to controlled substances must remain in the possession of the authorized users and not stored unsecured in the laboratory.
C. Any diversion, theft or significant loss of controlled substances must be reported to the local DEA office in writing within one business day, and the online DEA Form 106 must also be completed and submitted. Send a copy of the Form 106 and the printed name of the person who signed the form to the state Division of Professional Regulation - Drug Compliance Unit in the Department of Financial and Professional Regulation, within one business day after the DEA notification.
D. Prior to reporting to the DEA, the registrant must immediately notify the Controlled Substance Compliance Coordinator (cs-compliance@northwestern.edu) of any actual or suspected diversion, theft or significant loss.
E. In addition to reporting to the DEA, the registrant must immediately notify University Police of any diversion, theft or significant loss.

IX. Disposal

A. Unused, unwanted, or expired controlled substances must be transferred to a DEA licensed reverse distributor for disposal.
B. All controlled substances for disposal must be appropriately secured until packaged and transferred for disposal.
C. Documentation, on the appropriate log, to record the disposal is required.
D. Contact Research Safety for guidance on proper disposal.