



Safety and Risk
Management

Controlled Substances Program

This document provides guidance for WCU personnel who utilize controlled substances in teaching, research, and pharmacy. This procedure is in place to ensure compliance with requirements from the U.S. Drug Enforcement Administration (DEA) and the North Carolina Department of Health and Human Services, Drug Control Unit (NC-DCU).

Revision Date: June 2022

EMERGENCY TELEPHONE NUMBERS

	<u>Phone</u>	<u>Hours</u>
Safety and Risk Management Office <ul style="list-style-type: none"> • Work Related Injuries <i>(Normal Business Hours)</i> • Gas Leaks or Odors • Chemical Spills • General Inquiries 	828-227-7443	8:00am - 5:00pm Monday-Friday
University Police Department <ul style="list-style-type: none"> • Work Related Injuries <i>(After Normal Business Hours)</i> 	Police Services – 828-227-7301 Emergency Line – 828-227-8911	24 hours
Fire or Smoke	911 or University Police 828-227-8911	24 hours
Medical Emergencies	911 or University Police 828-227-8911	24 hours
NC Poison Control Center	1-800-84 TOXIN (1-800-848-6946)	24 hours

Table of Contents

Section 1: Definitions	3
Section 2: Overview	3
2.1 Schedules	3
Section 3: Controlled Substances Program Requirements.....	4
3.1 Registration.....	4
3.2 Ordering.....	5
3.3 Storage and Security.....	5
3.4 Use	6
3.5 Disposal.....	6
3.6 Recordkeeping.....	6
Section 4: Chemical Control Program.....	7

Section 1: Definitions

Definitions for selected terms used in this policy are included below. For a complete list of definitions please refer to [Title 21 United States Code \(USC\) Controlled Substances Act, Section 802](#).

Administer: Direct application of a controlled substance to the body of a patient or research subject by (a) a practitioner (or, in his presence, by his authorized agent), or (b) the patient or research subject at the direction and in the presence of the practitioner, whether such application be by injection, inhalation, ingestion, or any other means.

Dispense: Deliver a controlled substance to an ultimate user or research subject by, or pursuant to the lawful order of, a practitioner, including the prescribing and administering of a controlled substance and the packaging, labeling or compounding necessary to prepare the substance for such delivery. The term “dispenser” means a practitioner who so delivers a controlled substance to an ultimate user or research subject.

Distribute: Deliver (other than by administering or dispensing) a controlled substance or a listed chemical. The term “distributor” means a person who so delivers a controlled substance or listed chemical.

Practitioner: A physician, dentist, veterinarian, scientific investigator, pharmacy, hospital, or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices or does research, to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research.

Section 2: Overview

Controlled substances are any drugs or chemical substances whose possession and use are regulated under the [United States Controlled Substances Act](#) (U.S. CSA) and the [North Carolina Controlled Substances Act](#) (NC CSA). These chemicals have stimulant, depressant, or hallucinogenic effects on the higher functions of the central nervous system, and tend to promote abuse or physiological/psychological dependence.

Because of their potential for abuse, controlled substances have specific regulatory requirements for the acquisition, storage, security, inventory/recordkeeping, disposal, and importing or exporting.

2.1 Schedules

Substances regulated under the U.S. CSA are listed in one of five schedules. **Schedule I** have the most restrictions and include substances with a high potential for abuse, no currently accepted medical use in treatment in the U.S., and a lack of accepted safety protocols for use

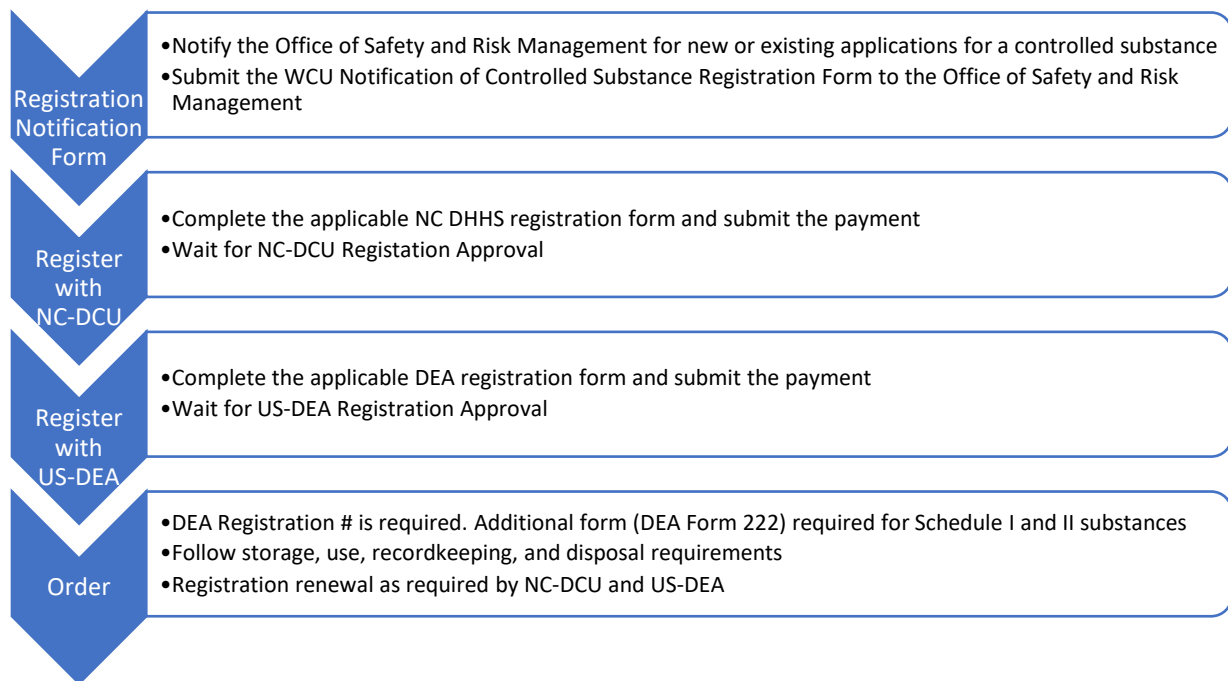
under medical supervision. **Schedules II through V** include substances with decreasing potential for abuse; currently accepted use in treatment or acceptable medical use in the U.S.; and decreasing risks for physical or psychological dependence accordingly. Refer to Part 1308 – Schedules of Controlled Substances on the [DEA website](#) for more information and the current list of controlled substances for each schedule.

North Carolina CSA has added a **Schedule VI** which includes substances with no currently accepted medical use in the United States, or a relatively low potential for abuse in terms of risk to public health and potential to produce psychic or physiological dependence liability based upon present medical knowledge, or a need for further and continuing study to develop scientific evidence of its pharmacological effects. A current list of substances is available under NC Controlled Substances Act [G.S. 90-94](#).

Section 3: Controlled Substances Program Requirements

3.1 Registration

Registration for all controlled substances is required at the State level (NC-DCU) and at the Federal level (US-DEA). The registration process and compliance requirements are detailed in the following flow chart:



Step 1: New and/or existing users of controlled substances at WCU must notify the Office of Safety and Risk Management. Please submit the Notification of Controlled Substance Registration Form (available on the Safety Office website) to the [Lab Safety Officer](#). For questions call 828-227-7443.

Step 2: Register with the North Carolina Department of Health and Human Services, NC-Drug Control Unit. Complete the applicable registration form and submit the payment by following the instructions provided on the [NC Controlled Substances Regulatory website](#).

Step 3: Once the initial registration with NC-DCU is approved and certification of registration is granted, you will need to register with the US-Drug Enforcement Administration (DEA). Registration is submitted online at the [US-DEA website](#).

Registration Renewal: NC-DCU requires annual renewal for all types of registration. However, the renewal for Federal DEA is based on the type of application. Refer to the DEA website for forms and renewal periods for the different types of application.

Departmental Registrants: Departments may register with NC-DCU as a research facility, which will allow them to share controlled substances within the department and for research purposes only. Departmental registration would still require a specific person as applicant/registrant who would be responsible for the proper use, storage, disposal, and recordkeeping for federal and state requirements. If a department performs research in more than one building, NC-DCU may require separate registrations for each building. **Note:** Schedule I and VI substances require **individual** registration and cannot be shared with other individuals. Registration cannot be transferred to a new person once a registrant leaves campus.

3.2 Ordering

Once registration at the State and Federal level is complete, and you have received your registration number for controlled substances, you may proceed with ordering. Note that NC-DCU and the US-DEA can send out inspectors to verify that adequate security is in place before registration is approved. For any controlled substance ordering, the DEA registration number will be required. For ordering Schedule I and II substances, you must use the official Order Form – DEA 222. Forms and information are available from the [US-DEA Registration website](#). Only registered individuals can order controlled substances.

3.3 Storage and Security

The registrant is responsible for managing the controlled substances in accordance with all regulatory requirements including security, inventory, and recordkeeping.

Security: All controlled substances must be kept under lock and key and be accessible only to authorized personnel. Storage cabinets must be built into the structure of the building or essentially immovable with doors that cannot be forced open or easily removed at the hinges. Schedule I and VI substances should be stored separately from other schedule substances and regular laboratory chemicals should not be stored with any controlled substance. Schedule I

and II substances have the highest security requirements and must be stored in an approved safe, steel cabinet, or vault.

Schedule I substances may not be issued to or used by anyone other than the registrant. If additional personnel need to use the schedule I substance, they must register individually with NC-DCU and DEA.

In the event that controlled substances are lost, stolen, or used in an unauthorized manner, the registrant must immediately contact campus police (x8911) and the Office of Safety and Risk Management (x7443). You may be required to submit DEA Form 106: Report of Theft or Loss of Controlled Substance.

3.4 Use

The individual registered person retains all liabilities for the substance. Transferring controlled substances (Schedule II – V only) from a registered to a non-registered user is only allowed if authorized previously in the registration terms. Transferring these substances to other DEA-registered individuals requires extra filing with the State DEA office, and is discouraged. Note: Schedule I and VI substances require individual use only and cannot be shared within a department.

3.5 Disposal

Controlled substances that are expired, unused, or contaminated must be stored securely until ready for disposal. For disposal, the registrant must contact an NC-DCU agent at 919-733-1765 or NCCSAREG@dhhs.nc.gov, who is required to be present when the substances are destroyed.

Only the registrant individual can perform disposal. If the registrant is not available to perform the disposal (for example the registrant has left the institution), contact the NC-DCU for guidance.

Breakage and Spillage of Controlled Substances: When there is breakage, damage, spillage, or some other form of destruction, and the substance is recoverable, disposal must be followed as stated above. If the substance is not recoverable, the registrant must document the circumstances in their inventory records. Two individuals who witnessed the event must also sign the inventory records.

3.6 Recordkeeping

Registrants must maintain complete and accurate inventory records for all controlled substances. These records must be in or near the primary work area, separate from all other records and documents, and available for inspection during regular work hours. Maintain the records for a period of at least 3 years from the date of last entry. In the event of an audit by

DEA or NC-DCU, you will need to produce these records. Records must include the following information:

- Receipt of controlled substance indicating the date received, name and address of supplier, type, strength, and concentration of substance, and amount received. The receiving person must sign each record.
- Current record for the storage and use of each substance indicating the starting quantity, use date, building and room, specific research experiment or analysis, type and strength used, and the quantity used. This record will provide a substance balance log sheet.
- Initial and biennial inventory record to include the name of each substance, form of substance (solid, inhalant, etc.), number of units or volume, and number of containers. Substances awaiting disposal must also be included on the inventory until they are disposed.

Section 4: Chemical Control Program

The DEA's Chemical Control Program is intended to disrupt the illicit production of controlled substances by preventing diversion of chemicals used to make drugs. The production of illegal drugs such as methamphetamine, cocaine, heroin, and MDMA (ecstasy) requires enormous quantities of precursor chemicals. The Chemical Control Program aims to deny precursor chemicals to drug trafficking organization while at the same time ensuring an adequate supply for commercial licit markets. DEA registration, record keeping, and suspicious order reporting requirements apply to importers, exporters, manufacturers, distributors and certain retailers of these [listed chemicals](#).