


Maintain Security and Storage Controls for Controlled Substances Used in Research

The controlled substances licensee/registrant is responsible for applying effective internal controls to guard against theft and diversion of controlled substances; including screening personnel who may come in contact with substances and properly storing and securing the substances per schedule requirements.

Authorized Agents and Authorized Personnel

Authorized Agents are designated by the licensee/registrant to oversee drug ordering, receiving, distribution to authorized personnel for research use, witnessing of drug waste and maintaining access to the safe of locked cabinet. Keep agent status to a minimum number of staff to mitigate the risk of drug diversion.

Authorized Personnel are faculty, staff, and/or students who are allowed to administer or handle controlled substances for research purposes under the authority and supervision of the licensee/registrant or authorized agent, when the licensee/registrant is unavailable.

 The licensee/registrant holds ultimate responsibility for restricting access to the controlled substances. The licensee/registrant is **required** to:

1. Keep an updated [Authorized Personnel Log](#) on file that lists the authorized agents and authorized personnel at a registered location.
2. Complete and keep on file a signed [UM-Authorized Personnel Screening Statement Form](#) for **each** authorized individual. This form is based on the screening questions outlined in [Title 21, CFR, 1301.90](#) and helps ensure U-M is compliant with [Title 21, CFR.1301.769\(a\)](#).

Denying access

Deny access to controlled substances to any individuals with a known/confirmed:

- Controlled substance abuse problem (unless the individual is actively enrolled in a health professional recovery program with a current monitoring agreement).
- Suspended, revoked, denied, or surrendered-for-cause controlled substances license/registration.
- Current sentence for the conviction of a crime that involves controlled substances.

Secure Storage Requirements

Controlled substances must be stored with the following requirements to ensure compliance with [Title 21, CFR.1301.72](#):

- Schedule I-II: Securely locked, substantially constructed safe or steel cabinet that is anchored to a wall or the floor
- Schedule III-V: Securely locked, substantially constructed safe or steel cabinet that is anchored in a way to prevent removal from the area

Note: Schedule I-V substances can be stored together as long as security measures meet Schedule I-II requirements

- Controlled substances requiring refrigeration must be locked in a container securely fastened within a refrigeration unit unless the refrigeration unit can be locked from the outside.



Portable storage boxes or storage in high-activity areas (e.g. corridors) are not allowed

Best Practices

Best practices include:

- Not leaving controlled substances unattended
- Ensuring two levels of security (e.g. locks) are in place and always used
- Resetting locks, keys, or combinations when:
 - Authorized Personnel leave the lab, department, or University
 - Loss/theft is suspected or reported
- Maintaining controlled substances in their original packaging