

## Maintain Security & Storage Controls for Controlled Substances Used in Research

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The controlled substance 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 or 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.1301.76\(a\)](#).

### 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 substance 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
- Note: Schedule I-V substance **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:

- Anchoring *portable* safes, steel cabinets, or refrigerators to the wall or floor for schedule III-V controlled substances.
- 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 (e.g., graduate, terminate employment, etc.)
  - Loss/theft is suspected or reported
- Maintaining controlled substances in their original packaging