CMU CENTRAL MICHIGAN UNIVERSITY | Office of Research Compliance

Registration Options for Principal Investigators

A Non-Practitioner Researcher must obtain each the following for their laboratory location:

- State of Michigan controlled substance research license (Schedule II-V)
- DEA 225 researcher registration (Schedule II-V)

A Practitioner-Researcher with a current DEA practitioner registration (for prescribing) must choose one of the following options:

1. Change the address on their current State of Michigan controlled substance license and DEA practitioner registration to correspond with the laboratory address where controlled substances are stored and administered.

(Preferred option) Obtain a separate State of Michigan controlled substance research license (Schedule II-V) and a DEA 225 researcher controlled substance registration (Schedule II-V).

Separate Registrations for Separate Locations

Each Principal Investigator that stores, receives, or administers controlled substances at their laboratory location must be licensed with the State of Michigan and registered with the DEA at that location.

State of Michigan and DEA Regulations Regarding Registered Locations

MI R 338.3132
(2) A separate license is required for each principal place of business or professional practice. A principal place of business or a professional practice is the physical location where controlled substances are manufactured, grown, cultivated, processed, or by other means produced or prepared, distributed, stored, or dispensed by a licensee.
(3) If a principal place of business or professional practice consists of multiple locations, then each location shall obtain a separate controlled substance license if controlled substances are received, stored, administered, or dispensed at that location.

C.F.R. 1301.12 (a)
A separate registration is required for each principal place of business or professional practice at one general physical location where controlled substances are manufactured, distributed, imported, exported, or dispensed by a person.

An individual possessing a State of Michigan controlled substance license and DEA registration will assume all liability for controlled substances stored and administered at their licensed and registered location. As a result, the Detroit DEA office strongly discourages Principal Investigators from assuming responsibility for large units or departments due to the potential risk of noncompliance with record keeping and loss of controlled substances through accounting errors or theft.

Each Principal Investigator must possess an individual State of Michigan controlled substance license and a DEA registration for their principal place of business (laboratory) if controlled substances are stored and administered at that location. All controlled substances must be ordered using the Principal Investigator's DEA registration corresponding to the laboratory location.

Research staff within their laboratory would be granted authorized agent status working under the Principal Investigator's registered and licensed authority.

The street address and laboratory room number on the State of Michigan controlled substance license and DEA registration must match and be the exact address where controlled substances will be delivered and stored. Vendors will only ship to the location printed on a DEA Certificate of Registration.

UPS, FedEx, or other shipping companies must deliver controlled substances directly to the registrant or an authorized agent at the registered address.

Controlled substances cannot be left outside of laboratories with other packages.

License and registration renewals will be sent to the laboratory location.

Authorized Agents

MI § 333.7303(3) The following persons need not be licensed and may lawfully possess controlled substances or prescription forms under this article: (a) An agent or employee of a licensed manufacturer, distributor, prescriber, or dispenser of a controlled substance if acting in the usual course of the agent's or employee's business or employment.
C.F.R 1301.22(a) The requirement of registration is waived for any agent or employee of a person who is registered to engage in any group of independent activities, if such agent or employee is acting in the usual course of his/her business or employment.

Since authorized agents are not licensed and registered individuals, the act of administering controlled substances must be performed under the authority and in the presence of a State of Michigan controlled substance licensee and DEA registrant.

- Authorized agents must follow all state and federal regulations governing controlled substances.
- Authorized agent access to controlled substances should be kept to a minimum.
- The licensee - DEA registrant must screen all authorized agents.
    - Authorized Agent Screening Statement
    - Screening statements must be kept with the Registrant's records and should not be sent to the DEA or State of Michigan
- A registrant shall not allow employees or graduate students to become authorized agents if the following are known:
    - The individual has a controlled substance abuse problem unless enrolled in a health professional recovery program under a current monitoring agreement.
    - The individual had a controlled substance license, which was suspended, revoked, denied, or surrendered for cause.
    - The individual has a controlled substance license issued by the State of Michigan or another state, which is under suspension or revoked for a violation that involves controlled substances.
    - The individual has been convicted of a crime that involves controlled substances and is currently under sentence for that conviction.
- A list of authorized agents with access to controlled substances must be kept current and must be updated when an employee leaves or is transferred.
    - Authorized Agent Log
    - The Authorized Agent log remains with the registrant and is not sent to the State of Michigan or DEA.
- Only the registrant and authorized agents are allowed access to the storage cabinet or safe where controlled substances are stored.

- Only the registrant or an authorized agent is allowed to receive controlled substance orders and reconcile controlled substance shipments from outside vendors into the general inventory.

Regulations Regarding Administration of Controlled Substances by Authorized Agents

Title 21 USC § 802 (2) The term "administer" refers to the 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.

MI R 333.7103 (1) “Administer” means the direct application of a controlled substance, whether by injection, inhalation, ingestion, or other means, to the body of a patient or research subject by a practitioner, or in the practitioner's presence by his or her authorized agent, or the patient or research subject at the direction and in the presence of the practitioner.

Since authorized agents are not licensed and registered individuals, the act of administering controlled substances must be performed under the authority and in the presence of a State of Michigan controlled substance licensee and DEA registrant.

Key permanent University employees, such as laboratory managers, may also obtain separate individual state controlled substance licenses and DEA registrations if the Principal Investigator on the IACUC protocol(s) travels frequently or is not routinely present at the registered location where controlled substances are administered.

State of Michigan controlled substance licenses and DEA registrations acquired by key permanent staff may only be used for administration purposes when the primary Principal Investigator is not present. Non-licensed and non-registered employees or students will work as authorized agents under the authority of the licensed and registered laboratory manager.

Controlled Substance Usage Records

The registrant for each registered location must maintain complete, current, and accurate usage and administration records if controlled substances are stored, delivered, or administered at that location.

Title 21 CFR, Section 1304.22: Records for manufacturers, distributors, dispensers, researchers, importers and exporters

Refer to Michigan CS Administrative Rules R 338.3153 Invoices, acquisition, dispensing, administration, and distribution records for additional information.

Usage and administration records of controlled substances listed in Schedules I and II shall be maintained **separately** from all other records of the registrant.

Usage and administration records of controlled substances listed in Schedules III, IV, and V shall be maintained either separately from all other records of the registrant or in such form that the information required is readily retrievable from the ordinary business records of the registrant.

All usage and administration records must be maintained for **at least 2 years** from the date of such records and be readily retrievable for immediate inspection and copying by authorized employees of the DEA and Michigan Bureau of Health Investigations. Five years is recommended for record retention.

Readily retrievable means that certain records are kept in such a manner that they can be separated out from all other records in a reasonable time and/or records are kept on which certain items are asterisked, redlined, or in some other manner visually identifiable apart from other items appearing on the records.

All usage and administration records must be stored in a secure location at the registered site preferably locked in a cabinet or safe.

Usage Records

Controlled substances must be tracked from acquisition to administration (to a research subject or usage in an *in-vitro* or chemical process) or disposal.

It is recommended to keep all usage and administration records in standard binders (Schedule I and II records separated from Schedule III-V records) and to securely store the binders in a locked cabinet or drawer.

- A separate usage form should be used for each unique vial or container
- Registrants may develop their own forms or logs to document administration or usage provided a controlled substance can be tracked from acquisition to research subject, experimental endpoint, transfer, or disposal.

Compounded solutions containing a controlled substance prepared within the laboratory should be labeled with the following:

- Name of the controlled substance(s)
- Lot number(s)
- Date vial opened or prepared
- Final concentration(s) and amount(s) per container
- <7 day expiration date, unless product stability data suggests otherwise

Routine Auditing of Controlled Substances Records

- Registrants or authorized agents are encouraged to perform weekly to monthly audits of their controlled substance inventory to accurately track inventory and avoid discrepancies.
- One authorized agent and an authorized agent witness must complete the inventory audit.
- At the conclusion of the audit, the authorized agent shall document the date, their initials, and a statement indicating the records to be accurate or reason for discrepancy.
- Registrants must review records that fail to reconcile in an attempt to identify recording errors or missing transactions. Inventory discrepancies are generally due to:
    - Mathematical errors
    - Non-recorded administration or dispensing transactions
    - Errors in receiving and general inventory updates

Theft or Loss of Controlled Substances

Significant losses or theft must be reported **immediately** to the DEA and State of Michigan Bureau of Health Professions Investigation Division. In addition, the Central Michigan University Police Department and the Office of Research Compliance must be contacted.

- The registrant should provide initial notification in writing of the loss or theft to the DEA Detroit Field office. Immediately fax to the Detroit field office.

Detroit DEA Field Office
431 Howard Street
Detroit, MI 48226
Phone: (313) 234-4000
Fax: (313) 234-4149

- Use online DEA Form 106: Report of Loss or Theft to follow up with the faxed report
- In addition to the DEA, loss or theft must be reported to the State of Michigan Bureau of Health Professions Investigation Division
- All in transit losses and lost DEA Form 222s must be reported to the DEA.

During initial inquiries into the incident, registrants must complete an online DEA Form 106: Report of Theft or Loss of Controlled Substances Form 106. A report must still be filed if lost or stolen material is recovered. Contact the Michigan Bureau of Health Professions Investigation Division at (517) 373-1737 orbhpinfo@michigan.gov for questions regarding theft or loss and submission of DEA Form 106 to the State of Michigan.

Minor discrepancies in inventory **that are not attributed to theft or loss** can be reconciled on the inventory report with proper notation. A DEA Form 106 does not need to be submitted for this purpose. However, the DEA should be contacted for guidance on how to proceed with such matters. The DEA recommends a registrant should determine significant loss in relation to controlled substance activity, patterns or trends of loss, and loss of controlled substances with high risk of diversion. Refer to the DEA Office for Diversion Control for more information.

Storage Requirements

C.F.R Section 1301.75 Physical security controls for practitioners

(a) Controlled substances listed in Schedule I shall be stored in a securely locked, substantially constructed cabinet.
(b) Controlled substances listed in Schedules II, III, IV, and V shall be stored in a securely locked, substantially constructed cabinet.
(c) This section shall also apply to non-practitioners authorized to conduct research or chemical analysis under another registration.
(d) Carfentanil, etorphine hydrochloride, and diprenorphine shall be stored in a safe or steel cabinet equivalent to a U.S. Government Class V security container.

Multiple companies and manufactures sell safes and cabinets for this purpose. Examples include:
Grainger
SelectLocks - Locking medicine and storage cabinets

Controlled substances requiring refrigeration may be stored in a locked container securely fastened within a refrigeration unit.
Health Care Logistics - Refrigerator storage lock boxes

- The cabinet or safe should be bolted, strapped, or otherwise securely fastened to the floor or wall in such a way that it cannot be readily removed.
- The storage container should be designed such that disassembly or forced entry should be clearly visible.
- The storage cabinet or safe must be securely locked at all times and only unlocked for removing or storing controlled substances.
- Only a minimum amount of controlled substances should be stored

Keys

- A wall mounted combination lock key storage unit is recommended to store keys when not in use. Access to the key storage unit is restricted to authorized agents.
- The locks on storage rooms and cabinets must be reset or rekeyed if an authorized agent resigns, is terminated, or a loss or theft is suspected. For this reason, combination locks are preferred.
- Double locking is not required. Locks must be reset or rekeyed if keys are lost. Stolen keys must be reported.
- The controlled substance storage location must have minimal traffic flow and be locked when the registrants or authorized agents are not present.
- Portable storage boxes and outside laboratory corridor storage are not allowed.
- Controlled substances should be stored in their original labeled container and separated from other chemicals or non-controlled drugs.
- Schedule I and II controlled substances should be stored separately or on a separate shelf from Schedule III-V controlled substances.
- The DEA and Michigan Bureau of Health Professions will make the final determination for necessary storage and security requirements during their application review.