Baystate Health

Fact Sheet

Massachusetts Controlled Substances Registration (MCSR) for Researchers

In Massachusetts, all drugs used in research interventions are legally classified as controlled substances, including those in Schedules I through VI and Investigational New Drugs (INDs). According to 105 CMR 700.009, any Principal Investigator conducting such research is required to obtain a Massachusetts Controlled Substances Registration (MCSR) Research License.

Under Massachusetts law updated in **2018**, a Principal Investigator (PI) must obtain an individual **Massachusetts Controlled Substances Registration (MCSR)** Research License if their research meets both criteria:

- **IND Requirement**: The study involves an **Investigational New Drug (IND)**, regardless of whether the IND is held by the PI, a sponsor, or a pharmaceutical company.
- **Storage Location**: The IND drug is physically stored at a Massachusetts site, such as an **Investigational Pharmacy**, radiology department, or research office.

Note: If the IND drug is shipped directly to participants and is **not stored** within Massachusetts, the PI is not required to hold an individual license.

Unlike clinical MCSR licenses, which are valid for two years, the **MCSR Research License** is an **annual registration** that must be renewed every year when the study drug is being dispensed.

The requirements for obtaining an individual versus an institutional license depend on the type of drug being studied:

- **IND-Exempt Drugs (Umbrella License)**: For research involving study drugs that meet IND exemption criteria, institutions may obtain an "umbrella" MCSR research license. PIs conducting research *only* with IND-exempt drugs can be covered under this institutional license, which must also be renewed annually.
- **Schedule I, II, or III Drugs (Individual License Required)**: PIs must obtain their own **individual MCSR Research License** if the study involves any Schedule I, II, or III drug. This individual requirement applies even if the drug otherwise meets the criteria for IND exemption.
- **Research Involving INDs**: Any PI conducting a study that includes an IND must obtain an individual license; once a PI has an individual license, it covers all their drug studies, including those that would otherwise fall under an umbrella license.

How to Apply for an Individual MCSR Research License

PIs who are required to have a MCSR Research license must apply, renew, and if needed, amend all licenses online through the MDPH eLicensing System. Instructions on how to do this are summarized below with step by step instructions also provided at this MDPH website.

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1. Create an account The first time a PI uses the online system to apply for a new or to renew a MCSR Research License they will need to create an account. To create an account:
    - go to https://HealthProfessionLicensing.mass.gov and select 'create an account.'
    - fill in the required fields and create a password [at least ten characters with a lower- and upper-case character and a number]
    - verify the email address by entering the verification code that will be emailed to the PI.
2. Link any previous professional license to the created account
    - Log into the system and select the "Link License to My Account" button and provide information for the subsequent screens that will appear.
    - If the system requests a PIN#, the PI should call the Help Desk at 617-973-0935 so they can look up the PIN#. Linking any previous license with the created account will only need to be done once.

Once an account is created, in the future the PI can just 'log in' to use the system with their username and password. Consult the Health Professions Licensing System User Guide to reset the password, update profile information, and read notifications.

New License: If the PI needs to apply for a new, individual MCSR Research License for IND-related research, they will need to gather the following items to answer the questions and enter the information into the online application form:

- Massachusetts Board of Registration License Number
- DEA Federal Controlled Substance Registration Number (if possessed)
- Business Address (Under the applicable law and regulations, the address used for the MCSR license must be the PI's principal place of business or professional practice).
- Primary telephone number
- Primary email address
- Social Security number (Required by M.G.L. c. 30A, s. 13A)
- The names of all study IND/s being dispensed and the names and schedules for all non-IND drugs being dispensed in the PI's current research studies.

Renewal License: MCSR Research Licenses expire in 12 months and need to be renewed annually. In the online system the license can be renewed up to 90 days before the expiration date. To **renew** an individual MCSR Research License for IND-related research, the PI must gather the same items listed above, log into their created account and follow the instructions, upload required attachments, and submit payment for the renewal fee of $150. The PI will receive an email renewal notice per their MCSR's renewal cycle with guidance on renewing the MCSR Research License in the online licensing system.

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Amended License: If a PI starts another drug study with an IND while their license is current, they need to **amend** their license as soon as possible. A license can be amended as many times as needed during the year.

- The license does not need to be amended if the PI starts a non-IND drug study during the license period. Instead that non-IND study drug/s can be added to the annual renewal application when submitted.
  - Amend immediately → new IND study
  - Wait until renewal → non-IND drug added
- To amend a license the same process is followed for a new or renewal license except *there is no fee to amend the license*.

- Processing may take between 5-10 business days from the receipt of the completed application to issuing a new, renewal, or amended MCSR Research License. If a PI or system user encounters a problem or has any questions they can email MCSR@Massmail.State.MA.US or during weekdays from 9a to 5p they can contact the eLicensing Support Help Desk at 617-973-0935 or the MCSR Board at 617-973-0949.

Desk Audits and Onsite Inspections

Submission of a new or renewal application can result in the request for additional information for a desk audit or onsite inspection. The additional information can include:

- Brief Project/Study Overview
- Organizational Chart
- Location Overview, including:
  - Floor Plan and Square Footage
  - General Hours of Operation
  - Visitor Policy (i.e.: access to building: escorted, non-escorted, etc.)
  - Other occupants, who are they?
- Supplier Information:
  - Source of Research Drug
  - Name or person ordering.
- Process of Ordering
  - Process of Receiving/Deliveries
  - Process for Reverse Distribution/Destruction
- Security Standard Operating Procedures and Policies
  - Access to the facility (individualized key cards, keys, etc.)
  - Access to limited areas/lab within facilities (Individualized key cards, keys, etc.)
  - Storage of controlled substances:
  - Safe/steel cabinet
- Security of storage area (if applicable surveillance cameras, motion sensors, contact switches, glass break detectors, panic buttons, etc.)
  - Alarm Company Information
  - Who will be contacted if a breach occurs?

- Recording Keeping:
    - How, where and for how long the records will be kept (bounded logbooks, electronic system, etc.)

If a PI receives a request from the MDPH for any additional information, forward that email to the Chief Research Compliance Officer who will assist with preparing documents to respond to the request.

Research License versus the standard Clinical License:

Feature	Researcher MCSR (Research)	Clinical MCSR (Practitioner)
Duration	1 Year (Annual Renewal)	2 Years
Renewal Trigger	Required every year drug is dispensed	Standard cycle
Who is included?	Individual PI & those identified as handling the study product	Individual Practitioner
Coverage	A separate registration is required at each location the registrant distributes or dispenses controlled substances or uses controlled substances in research.	A separate registration is required at each place of business or professional practice where the applicant distributes or dispenses controlled substances, or uses controlled substances in clinical care, teaching or chemical analysis.
Modifications	Must file an amendment if the authorized staff listed or location of product distribution or dispensing is changed.	Amendment filed if the location of business or practice is changed.

Resources

- Massachusetts law: Title 105 CMR 700.009
- https://www.mass.gov/how-to/researcher-mcsr
- https://www.mass.gov/how-to/how-to-amend-your-researcher-mcsr
- Health Professions Licensing System User Guide https://www.mass.gov/info-details/health-professions-licensing-system-user-guide
- Health Professions Licensing Portal https://healthprofessionlicensing.mass.gov/login-register
- HELP Desk at helpdesk@MassMail.state.ma.us or 617-973-0935.
- DPH Check a License https://checkahealthlicense.mass.gov/