Massachusetts Controlled Substances Registration (MCSR) for Researchers

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Didn’t we use to…

- The State updated its regulations in October 2018. This included four changes to the MCSR for research:
  1. Clarified DCP’s authority to regulate research drugs and defined “research drugs”
  2. Added eligible applicants - both the PI and the supervisor/department chair/etc.
  3. Clarified that a researcher must have an MCSR before procuring, possessing, and storing drugs to conduct research
  4. Added that an application can be for multiple research projects as long as all required information for each study is included

What are Research Drugs?

Research Drugs are defined as:

- An Investigational New Drug (IND) as defined in 21 C.F.R. 312.3

Or

- Any scheduled drug in a research study or project where it will be administered or dispensed

Who Are Eligible Applicants?

Eligible Applicants include:

- Supervisor, or Department Chair, or Chief Academic Officer

And

- Principal Investigator for research involving an Investigational New Drug (IND)

So Should My PI Get an MCSR for Research

If the research involves FDA-approved drugs or drugs with an IND-Waiver: can be Supervisor, or Department Chair, or Chief Academic Officer

If the research involves an Investigational New Drug (IND): must be the Principal Investigator regardless of who holds the IND.

Doesn't My PI Already Have an MCSR?

- **The MCSR for Researchers is separate from the MCSR for Practitioners**. All MDs who prescribe Schedule II-VI medications in Massachusetts must have a Massachusetts Controlled Substances Registration (MCSR) for Practitioners.
- The Massachusetts Department of Public Health maintains a list of all active MCSR holders: https://www.mass.gov/files/documents/2019/08/29/mcsr-list-of-registered-individuals.pdf

So How Do I Get an MCSR for Researchers?

- Application, downloaded from Mass.gov (https://www.mass.gov/how-to/apply-for-or-renew-a-podiatrist-optometrist-researcher-or-veterinarian-mcsr)
- $150 fee payable to Commonwealth of Massachusetts
- Copy of DEA Researcher Registration for Schedule II-V drugs
- Copy of IRB or IACUC approval letter for human/animal research
- Copy of FDA Form 1572 for any human research involving an IND
- Mail the original signed application, fee and supporting documents

Commonwealth of Massachusetts
Department of Public Health, Bureau of Health Professions Licensure
Drug Control Program
239 Causeway Street, Suite 500, Boston, MA 02114
Telephone 617-973-0949 Fax 617-753-8233

Application for Massachusetts Controlled Substances Registration to Use Controlled Substances and Investigational New Drugs in Research

Please be sure to:

- Submit completed application – front and back.
- Attach the *Additional Documents Required to be Submitted with Your Application*. See list on page 3.
- Enclose check or money order for $150 made payable to "Commonwealth of Massachusetts".
- Have the form signed (not initialed) and dated.
- Mail to the address above.

Incomplete applications will be returned causing a delay in issuance of the MCSR. Only send copies of supporting documents. Originals will not be returned. For further information, visit: http://www.mass.gov/dph/dcp

Application Type: (Please select one) ❑ New ❑ Renewal ❑ Amended Information *(No fee)*

In the boxes below enter the requested information.

1) Degree:

2) Board of Registration in Medicine No. (If possessed):

3) DEA Controlled Substance Registration No. (If possessed):

4) Name of (Select one): ❑ Principal investigator ❑ Department head

First: Middle:

Last: Suffix: (Jr., Sr., II, III)

5) Company, department, and location where drugs will be stored: (Submit a separate application for each location where drugs are stored. If no drugs are being stored, you do not have to register. Registrations are not transferable from one individual to another or from one location to another. Applications with a P.O. Box number and no street address cannot be processed.)

City State ZIP

6) Mailing address (If different from Company, department, and location where drugs will be stored) :

City State ZIP

7) Business Telephone No.:

8) Social Security No.: (Required by M.G.L. c. 30A, s. 13A)

9) E-mail address: (Optional)

10) Select ONLY the drug Schedules currently in use:
List the name of EACH specific drug used. Include attachments if more space is needed.

- ❑ IND _____
- ❑ I _____
- ❑ II _____
- ❑ III _____
- ❑ IV _____
- ❑ V _____
- ❑ VI _____

(Schedule VI includes all prescription drugs not in Schedules II-V.)

11) What is the source of the Controlled Substances and/or INDs supplied to/obtained by the researcher?

_____

_____

12) Has the study been approved by an Institutional Review Board (IRB) or Institutional Animal Care and Use Committee (IACUC)? Please attach copy of approval letter. ❑ Yes ❑ No

13) For what purpose will the Controlled Substances and/or INDs be used? Please be specific.

_____

_____

_____

14) Describe, in detail, the manner in which the Controlled Substances and/or INDs be secured.

_____

Exact location: _____

_____

Construction of storage area: _____

_____

Accountability system: _____

_____

Names of all individuals (including P.I. and sub-investigators) permitted access: _____

_____

15) Have you ever been convicted of any violation of State or Federal law relating to the manufacture, possession, distribution or dispensing of controlled substances? ❑ Yes * ❑ No

16) Has any previous professional license or registration held by you under any name or corporate name or legal entity been surrendered, revoked, suspended or denied or is such action pending? ❑ Yes * ❑ No

* If you answered "Yes" to Question No. 15) or No. 16), a letter must be attached setting forth circumstances of such action(s).

I hereby certify that the information on this application is true to the best of my knowledge, and that I will comply with the laws of the Commonwealth of Massachusetts and all applicable rules and regulations promulgated by the Department

How Do I Fill Out Some of The Form Sections?

- Where will drugs be stored? UMass Memorial Medical Center IDS, ACC Building, AC6-201, 55 Lake Avenue North, Worcester, MA 01655
- Attach a list of each drug currently in use
- Source of Controlled Substances is the Investigational Drug Service Pharmacy
- Individuals permitted access are the PI and Sub Investigators along with the IDS staff: Nitasha Sanil, RPh; Craig Dooley, Pharm D; Delila Katz, Pharm D; Cynthia Rup, CPhT

What If Something Changes?

Submit an amended application.

- Uses the same form as the application
- There is no fee associated with an amendment
- Can be:
  - e-mailed to **MCSR@massmail.state.ma.us**,
  - faxed to (617) 753-8233
  - or mailed to Drug Control Program, 239 Causeway St., Suite 500, Boston, MA 02114

What Do I Do Once I Get the Registration?

The Office of Clinical Research will track the licenses within the OnCore Clinical Trial Management System

Please forward copies of the registration to clinicalresearch@umassmed.edu

Who Can I Contact?

- For a copy of the application pre-filled with details regarding the Investigational Drug Service Pharmacy (IDS): Ann Han, Clinical Research Navigator. Ann.han@umassmed.edu direct line 508-856-1960
- For policy questions or clarifications: Danielle Howard, Director Clinical Research Operations. Danielle.howard@umassmed.edu