State of Michigan Controlled Substance Research License Application Instructions

Important: You must receive your license from the state <u>before</u> applying with the DEA. Once approved, the SOM research license must be renewed biennially.

- 1. Complete, print and sign the **SOM** application form:
 - Check the box to apply for Schedule 2-5 Research
 - Business name = University of Michigan + department name
 - Business address = address of <u>storage location</u> including building name, <u>room</u> <u>number</u>, street address, city, state and zip code
 - Federal employer number = 386006309
 - Fee = check payable to "State of Michigan." The fee amount is listed on the application
- 2. Provide requested information to be included with application (click here for examples):
 - Credentials to conduct proposed research
 - Protocol if the proposed research
 - · List of controlled substances & doses to be used
 - · Procedures for storage and security
 - o Confirmation of storage and use location
 - · List of other staff/persons involved



3. PREVENT DELAYS - SEND APPLICATION TO CS MONITOR FOR REVIEW!

Discrepancies that appear insignificant or irrelevant may take WEEKS or even MONTHS to resolve by the State. To prevent these delays, send your application materials to the CS Monitor for a quick review before mailing to the State of Michigan

4. Mail the State of Michigan application form, requested attachments, <u>AND</u> a check to:

Michigan Department of Licensing and Regulatory Affairs Bureau of Health Care Services Health Licensing Division PO Box 30670 Lansing, MI 48909

- **5.** After you receive the State of Michigan confirmation packet (includes Livescan Request form and Customer ID number), complete the fingerprinting requirement as instructed:
 - Include U-M's Agency ID Number (71734K) when scheduling an appointment
 - Bring the completed Livescan Request Form (provided by the SOM with fingerprinting instructions) and a valid form of photo identification (e.g., driver's license, state or federal identification) to the fingerprinting appointment.

Important checkpoints:

The SOM application process can take several months, but the state has been known to misplace applications or fingerprinting information:

- If you submitted your SOM application over three months ago, and have not been contacted by the state, contact them at (517) 335-0918 to request a status update.
- If you completed your fingerprinting requirements over three months ago, and have not been contacted by the state, contact them at 517-335-2044 and request an update on your application.

EXAMPLE

State of Michigan Controlled Substance Research License Application Requested Attachments

1. Credentials to conduct the proposed research

See attached curriculum vitae.

Attach your CV as another page to your application.

2. Protocol of the proposed research

In simple terms, what is the overall scope of your research and why do you need controlled substances?

EXAMPLE (do not include proprietary research information): The primary goal of my research program is to learn how to build neural prosthetic systems for disabled patients. We currently understand enough about the electrical signals associated with cortical neurons to "read out" information about when and where monkeys will move their arms. By passing these signals through electronics and algorithms of our own design, we can control prosthetic devices such as prosthetic arms with merely the mental intention to move. A secondary basic neuroscience goal is to understand how the primate brain orchestrates movements. To achieve this end, we perform cranial implants in rhesus macaque monkeys. Lastly, to improve upon the signal longevity and fidelity that we read out, we are developing new electrodes that we evaluate in both rats and mice. Animals are given appropriate anesthetic and analgesic drugs as listed below before, during, and after these surgeries. All animal use protocols are approved by the University of Michigan institutional care and use committee.

3. List of controlled substances and doses to be used

Name of drug, concentration, vial size (if applicable), dose (animal), # of containers to be used/year.

EXAMPLE: Ketamine, 100mg/ml, 5ml vial, 80-100mg/kg (mouse), x3 vials/year Buprenorphine, 0.3mg/ml, 1 ml vial, 20-40 mg/kg (rat), x10 vials/year

4. Procedures for storage and security of drugs

List type of storage, heavy or anchored, key/combination securely stored. List U-M security measures.

EXAMPLE: The controlled substances will be stored in a small safe anchored to the wall in the procedure room. The key to the safe will be stored in a key lock-box in the lab. Security measures include:

- · Limited, authorized access only
- · Minimal traffic flow
- Lab locked after-hours and on the weekends
- 24/7 availability of the U-M Department of Public Safety and Security (DPSS)

4a. Storage and use location

List the location where the drugs will be stored and used. For the <u>use</u> location, the generic building location is sufficient.

EXAMPLE: The controlled substances will be stored at 12345 MSRB III, 1150 W. Medical Center Dr. Ann Arbor, MI 48109. They will be used in building MSRB III, 1150 W. Medical Center Dr. Ann Arbor, MI 48109.

5. List of other staff/persons involved

List the name and job titles of staff who will handle the controlled substances in any way (pick up the drug from pharmacy, administer, open the safe, dispose through EHS, etc.).

Example:

- Jane Doe-Lab manager
- John Smith-Postdoctoral research fellow
- Candy Cane-Lab assistant