MICHIGAN CONTROLLED SUBSTANCE RESEARCH LAB, ANALYTICAL LAB, OR INSTRUCTIONAL ACTIVITY LICENSING GUIDE

OVERVIEW:

The controlled substance research lab, analytical lab, or instructional activity license type allows a licensee to conduct chemical analysis, research, and instructional activity with a controlled substance.

NOTE: The content contained below is a general overview of licensing requirements. Links to access the Public Health Code and Administrative Rules for this profession can be found at the end of this guide.

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LICENSURE REQUIREMENTS CHECKLIST

APPLICATION AND FEES

- ☐ Online Application For a Controlled Substance Research Lab, Analytical Lab, or Instructional Activity License – Complete all fields, answer all questions, and upload any supporting documentation.
- ☐ Online application can be completed by visiting **www.michigan.gov/miplus**.
- ☐ This license may be obtained by an individual or other business entity (partnership, cooperative, association, private corporation, other legal entity, or governmental entity).

☐ Application Fee for Controlled Substance Research Lab, Analytical Lab, or Instructional Activity License (Application fee + 2-year license fee): (Must be paid by Visa, Mastercard, Discover, or American Express credit or debit card.):
Contolled Substance Schedule 1 Research Laboratory: $176.40
Controlled Substance Schedule 2-5 Research Laboratory: $176.40
Controlled Substance Schedule 1 Instructional Activity: $176.40
Controlled Substance Schedule 2-5 Instructional Activity: $176.40
Controlled Substance Analytical Laboratory: $176.40

REQUIREMENTS FOR THOSE APPLYING FOR A SCHEDULE 1 RESEARCH LABORATORY LICENSE (Includes Instructional Activity)

☐ The applicant's credentials to conduct the proposed research.

☐ The protocol and description of the nature of the proposed research that contains the following information:

- Investigator information:
  - Name, address, and DEA registration number, if any.
  - Institutional affiliation.
  - Qualifications, including a curriculum vitae and an appropriate list of publications.
- Research project information:
  - Title of project.
  - Statement of purpose.
  - Name of the controlled substance or substances involved and the amount of each needed.
  - Description of the research to be conducted, including the number of species of research subjects, the dosage to be administered, the route and method of administration, and the duration of the project.
  - Location where the research will be conducted.
  - Statement of the security provisions for storing the controlled substances in accordance with R 338.3143 and for dispensing the controlled substances in order to prevent diversion
  - If the investigator desires to manufacture any controlled substance, a statement of the quantity to be manufactured and the sources of the chemicals to be used.
- Authorization information:
  - Institutional approval.
  - Approval of a Human Research Committee for human studies.
  - Indication of an approved active Notice of Claimed Investigational Exemption for a New Drug (number).
  - Indication of an approved funded grant (number), if any.

☐ A list of the controlled substances and doses to be used.

☐ Procedures for storage and security of drugs.

☐ A list of other staff/persons involved in the proposed research.

REQUIREMENTS FOR THOSE APPLYING FOR A SCHEDULE 2-5 RESEARCH LABORATORY LICENSE (Includes Instructional Activity)

- ☐ The applicant's credentials to conduct the proposed research.
- ☐ The protocol and description of the nature of the proposed research that contains the following information:
  - Investigator information:
    - Name, address, and DEA registration number, if any.
    - Institutional affiliation.
    - Qualifications, including a curriculum vitae and an appropriate list of publications.
  - Research project information:
    - Title of project.
    - Statement of purpose.
    - Name of the controlled substance or substances involved and the amount of each needed.
    - Description of the research to be conducted, including the number of species of research subjects, the dosage to be administered, the route and method of administration, and the duration of the project.
    - Location where the research will be conducted.
    - Statement of the security provisions for storing the controlled substances in accordance with R 338.3143 and for dispensing the controlled substances in order to prevent diversion
    - If the investigator desires to manufacture any controlled substance, a statement of the quantity to be manufactured and the sources of the chemicals to be used.
  - Authorization information:
    - Institutional approval.
    - Approval of a Human Research Committee for human studies.
    - Indication of an approved active Notice of Claimed Investigational Exemption for a New Drug (number).
    - Indication of an approved funded grant (number), if any.
- ☐ A list of the controlled substances and doses to be used.
- ☐ Procedures for storage and security of drugs.
- ☐ A list of other staff/persons involved in the proposed research.

REQUIREMENTS FOR THOSE APPLYING FOR A SCHEDULE 1 INSTRUCTIONAL ACTIVITY LICENSE

- ☐ The applicant's credentials to conduct the proposed instructional activity.
- ☐ A course outline for the proposed instructional activity.
- ☐ A list of the controlled substances and doses to be used.
- ☐ Procedures for storage and security of drugs.
- ☐ List of other staff/persons involved in the proposed instructional activity.

REQUIREMENTS FOR THOSE APPLYING FOR A SCHEDULE 2-5 INSTRUCTIONAL ACTIVITY LICENSE

- ☐ The applicant's credentials to conduct the proposed instructional activity.
- ☐ A course outline for the proposed instructional activity.
- ☐ A list of the controlled substances and doses to be used.
- ☐ Procedures for storage and security of drugs.
- ☐ List of other staf/persons involved in the proposed instructional activity.

REQUIREMENTS FOR THOSE APPLYING FOR AN ANALYTICAL LABORATORY LICENSE

- ☐ The applicant's credentials to conduct the proposed chemical analysis.
- ☐ The protocol and description of the nature of the chemical analysis that contains the following information:
    - Investigator information:
        - Name, address, and DEA registration number, if any.
        - Institutional affiliation.
        - Qualifications, including a curriculum vitae and an appropriate list of publications.
    - Chemical analysis project information:
        - Title of project.
        - Statement of purpose.
        - Name of the controlled substance or substances involved and the amount of each needed.
        - Description of the chemical analysis and instructional activity to be conducted, and the duration of the project.
        - Location where the chemical analysis will be conducted.
        - Statement of the security provisions for storing the controlled substances in accordance with R 338.3143.
        - If the investigator desires to manufacture any controlled substance for analytical or instructional purposes, a statement of the quantity to be manufactured and the sources of the chemicals to be used.
    - Authorization information:
        - Institutional approval.
        - Approval of a Human Research Committee for human studies.
        - Indication of an approved funded grant (number), if any.
- ☐ A list of the controlled substances and doses to be used.
- ☐ Procedures for storage and security of drugs.
- ☐ A list of other staff/persons involved in the proposed chemical analysis.

REQUIREMENTS FOR THOSE APPLYING FOR RELICENSURE

- A controlled substance lab license may not be relicensed. If your license has lapsed and you wish to obtain another one, you must apply for a new research lab, analytical lab, or instructional activity license by visiting **www.michigan.gov/miplus.**

REQUIREMENTS FOR THOSE APPLYING FOR RELOCATION

- A controlled substance laboratory with a current Michigan controlled substance lab license that is moving the laboratory to a new address must complete the Online Application For a Controlled Substance Lab License – Complete all fields, answer all questions, and upload any supporting documentation. Online application can be completed by visiting **www.michigan.gov/miplus.**

- Be sure to select "yes" to the question "Is this an existing Michigan licensee that is changing location?" and provide the current Michigan licensee number and proposed date of relocation.

RENEWAL REQUIREMENTS CHECKLIST

- Online Application for a Controlled Substance Research Lab, Analytical Lab, or Instructional Activity Renewal – Can be completed by visiting **www.michigan.gov/miplus**.

- Controlled Substance Lab Renewal Application Fee: $165.40 (Must be paid by Visa, Mastercard, Discover, or American Express credit or debit card)

- Renewal Cycle: 2 years

HELPFUL RESOURCES AND FORMS

- By visiting www.michigan.gov/pharmacy you can access the following helpful resources:

Resources:
- Public Health Code (See Articles 7 and 15)
- Administrative Rules for Pharmacy

FREQUENTLY ASKED QUESTIONS

1. How can I contact the Board of Pharmacy, Licensing Division?

Email (Questions): BPLHelp@michigan.gov
Email (Submit Documents): BPLData@michigan.gov
Phone: (517) 241-0199
Mailing Address: Bureau of Professional Licensing
Board of Pharmacy

PO Box 30670
Lansing, MI 48909

2. How long are Controlled Substance Lab license types valid?

Controlled Substance Lab licenses are valid for 2 years.

3. How do I verify my Michigan Controlled Substance Lab license?

Certified license verification requests must be obtained from the Michigan Board of Pharmacy. You must submit your request via the MiPLUS system at www.michigan.gov/miplus. There is a $15.00 fee for certification processing for each address you list. Please note, if you submit both a USPS mailing adddress and an email address for the same recipient, you will be charged $30.00 since you have requested your certification to go to two different addresses. Normal processing time for verifications being sent by email is the same day, verifications being mailed are sent the next business day.

Licenses may also be verified online on the Bureau's License Verification website free of charge. You may need to confirm with the recipient if verifying a license on this website is acceptable or if a certified license verification is needed.

4. How will I know when I need to renew? Can I renew my license early?

You will be sent a renewal notification to both your mailing and email address on record approximately 90 days prior to the expiration date of your license. You will not be able to renew before that time. It is your responsibility as a licensed health professional to renew your license on time. **Failure to receive the renewal postcard, email notification, or to notify the Department of an address change does not exempt you from renewing your license on time.**

5. Is there a grace period for my renewal?

Yes, there is a 60-day grace period in which you may renew your license. However, if you renew during the 60-day grace period, there is an additional $20.00 late fee for each license type when you renew your license(s).

6. What happens if my license expires?

If your license is not renewed within the 60-day grace period after your expiration date, your license will lapse. The expiration date will reflect the original expiration date – it will not include the grace period. For example: If your license expires January 31, you have until April 1 to pay your renewal fee. If you do not renew by April 1, the end of the 60-day grace period, your license is considered lapsed as of January 31.

7. How long will you keep my licensure application on file?

Your application and fee are valid for two years. If you fail to meet the licensure requirements within that time period, your application and fees are no longer valid.

8. How long does it take to process my application for licensure? Once processed, how long before I receive my license?

Applications are reviewed in the order by date received. The average time to receive a new license is 4 to 6 weeks and could be sooner if all required documents are received with the application. Once all the

required information is submitted and accepted your license will be issued. If all licensure requirements are not met upon application review, you will receive an email requesting any outstanding items needed to complete your application. Once you are approved for licensure, it takes approximately 7 to 10 business days to receive the license by mail, if requested. Immediately upon license issuance a PDF of the license will also be sent to the email address provided on the application.

9. How do I apply for a (Drug Enforcement Administration) DEA registration?

The State of Michigan and the DEA are two separate entities. The DEA is federally administered and regulated. If you have any questions concerning your DEA registration, you should visit their website at www.dea.gov or contact them directly at (800) 882-9539.

You must obtain a Michigan controlled substance license prior to a DEA registration.