

Frequently Asked Questions About Research Licenses

Applicants and licensees are required to comply with the Cannabis Control Commission's (Commission) governing laws available at MassCannabisControl.com and are encouraged to consult their counsel with regards to compliance. These frequently asked questions are intended to anticipate and answer common questions and are not intended to modify any legal rights and obligations.

Revised July 2021

1. What is a Marijuana Research Facility?

A Marijuana Research Facility is a Marijuana Establishment (ME) licensed by the Cannabis Control Commission (Commission) that can conduct research involving marijuana for a wide array of purposes.

2. Do you need to obtain a license from the Commission to become a Marijuana Research Facility?

Yes. Marijuana Research Facility licenses are available to any academic institution, nonprofit corporation, or domestic corporation or entity authorized to do business in the Commonwealth that is interested in either conducting research involving cannabis directly or permitting external researchers with an approved Research Permit to conduct research involving cannabis within approved facilities.



3. Does a Marijuana Research Facility need to obtain any other permissions from the Commission prior to performing research?

Yes. In addition to all applicable inspections of any building that will be used as the licensed premises of a Marijuana Research Facility and compliance checks for other requirements, the Commission must approve the entity's relevant Research Permit application prior to the commencement of any research study.

4. What is the difference between a Research License and a Research Permit?

Once an entity has been granted a Marijuana Research Facility license, it will then be required to obtain a Research Permit from the Commission. A Research Permit means a certificate from the Commission to conduct a specified research study over a specified and finite period.

For clarity, a Marijuana Research Facility license generally allows research to be performed at an identified location. The Research Permit identifies the type of research study to be performed at the licensed premises of a Marijuana Research Facility.

5. What information needs to be submitted to the Commission to obtain a Marijuana Research Facility License?

Generally, all Marijuana Research Facility applicants will need to comply with the same application requirements for other MEs. Some requirements include, but are not limited to, the following:

- Certification of a Host Community Agreement;
- Identification of a proposed location and property interest documentation (e.g. lease, binding permission to use the premises, title to the property, etc.);
- Conduct a Community Outreach Meeting;
- List all Persons or Entities Having Direct or Indirect Control;
- List all capital contributors and upload any loan/management agreements;
- Provide background authorization forms for applicable persons;
- Supply and upload compliant summaries of plans, policies, and procedures for security, inventory, quality control and testing, storage, etc.; and
- Supply and upload a Diversity Plan and Plan to Positively Impact Disproportionately Harmed People (formerly called Positive Impact Plan).



6. What information needs to be submitted to the Commission to obtain a Research Permit?

All Research Permit applicants will need to submit the following requirements that include, but are not limited to, the following:

- The name and curriculum vitae (CV) of each investigator and sub-investigator, including the licensed physician serving as principal investigator who leads the research project and monitors animal/human subjects (if applicable);
- The Institution Review Board (IRB) Institution utilized for ethics review of research involving human subjects (additional information below about IRBs), if applicable;
- The Institutional Animal Care & Use Committee (IACUC) Institution utilized for ethics review of research involving animal subjects (additional information below about IACUCs), if applicable;
- Information on the research project including the following: publication-ready summary of the research project to be conducted, along with a detailed research protocol, safety and disposal protocols, articulated goals of the research project, and start/end dates;
- A description of the project funding or resources that includes the sources of the funding and an attestation that the project is adequately funded or resourced;
- Detailed information about any human participants, if applicable;
- Detailed information about any animal participants, if applicable;
- The quantity of marijuana or marijuana products anticipated to be needed over the duration of the research project;
- The Independent Testing Laboratory where the marijuana or marijuana products will be tested; and
- The name and license number (or application number) of the Marijuana Research Facility where the project will take place.

7. What is the Commission's review process for Research Permits?

Once the licensee or their external researchers submit a Research Permit application to the Commission, it will be reviewed by staff based on the order in which it was submitted. If more information is required, the applicant will receive a notice seeking further information so the Commission may complete its review.

It is pertinent that any research projects involving human subjects supply all necessary IRB details and any study involving animal subjects supplies all necessary Institutional Animal Care and Use Committee (IACUC) details to the Commission. These include: (1) name of



institutional IRB and/or IACUC; (2) contact information for IRB and/or IACUC and lead contact at IRB and/or IACUC with whom the licensee will be working, and (3) current status of IRB and/or IACUC approval. Commission staff need to see final IRB approval before any research will be approved to commence.

8. I have a Research Permit granted by the Commission and I am ready to begin my research project. Where do I acquire the cannabis to be used in the study?

There are three (3) ways for a Marijuana Research Facility licensee to obtain marijuana:

- If the Marijuana Research Facility licensee is also licensed as a Marijuana Cultivator and/or Marijuana Product Manufacturer, it can obtain its own marijuana or marijuana products from those licenses;
- Marijuana or marijuana products can be sourced directly from an external Medical Marijuana Treatment Center, Marijuana Cultivator, Marijuana Product Manufacturer, Marijuana Microbusiness, or Craft Marijuana Cooperative licensed by the Commission; or
- If the cultivation or product manufacturing of marijuana or marijuana products is the subject of the research project, and the approved Research Permit allows it, the licensee may cultivate and/or produce marijuana or marijuana products if it first executes an agreement to do so in conjunction with another licensee authorized to perform those activities. This does not allow for home grown marijuana. All activities must take place at a licensed facility.

9. My research project involves human subjects. Are there any additional special requirements that are involved in these types of studies?

Yes. During the research project, all marijuana or marijuana products used in research and consumed by human subjects must comply with the following:

- Be adequately described in the Informed Consent Form;
- Tested in accordance with 935 CMR 500.160 prior to consumption by human subjects; and
- Recorded in the Commission's seed-to-sale tracking system, Metrc.

Please note the following requirements for human or animal participants:

- IRB approval of the project before a Research Permit is granted (applicable to human subject-involved research);



- One or more licensed physicians in good standing must monitor the participants (applicable to human subject-involved research);
- Other than a survey-only research project, human participants in research conducted by a Marijuana Research Facility licensee where consumption of Marijuana or Marijuana Products is a component must reside in the Commonwealth;
- Any research project with human subjects are participants must identify the (1) name of IRB; (2) contact information for IRB and study IRB contact, and (3) current status of IRB approval. Approved Research Permits will need IRB approval before research may commence;
- The number, ages, and demographic of the participants;
- The number of Registered Qualified Patients (if any);
- “Vulnerable” cohorts (pregnant/breastfeeding women, minors, disabled veterans, etc.) and applicable safety precautions for these cohorts;
- A copy of each individual’s Informed Consent Form or Waiver of Consent;
- Documentation showing that the process of obtaining Informed Consent complied with the Research Licensee’s other IRB, institutional, industry, or professional standards;
- Institutional Animal Care and Use Committee (IACUC) approval of the project before a Research Permit is granted (specific to animal subjects research); and
- One or more licensed veterinary doctors in good standing to monitor participants (applicable to animal subjects research).

10. What do I need to do once my research project has concluded?

Once the research project concludes, the Marijuana Research Facility licensee or external researchers utilizing the Research Permit must provide a final synopsis of the project specific to the Commission and the work undertaken as it aligns with the Research Permit:

- No peer review publication: If the licensee or researchers do not intend to publish their work in a peer review journal, all copies of all final reports, findings, or documentation regarding the outcomes of approved research projects receiving a Research Permit must be submitted to the Commission.
- Peer review publication: If the licensee or researchers intend to submit any part of their work to a peer review journal, it is acceptable to submit all papers, findings, and documentation to the Commission after it is accepted for publication.



11. Is the information I send to the Commission after my study has concluded considered private?

No. Any records or documentation received by the Commission becomes a public record and may be disclosed pursuant to the Public Records Law, M.G.L. c. 66, § 10 and M.G.L. c. 4, § 7, cl. 26, or other compulsory legal process, or at the Commission's discretion.

As with all communication with the Commission, you should consider any conversations you have with us, or any material you provide to us, to be subject to a public records request or other compulsory legal process.

12. Other types of Marijuana Establishments require inspections by the Commission. Can Marijuana Research Facility licensees also be inspected at any time?

Yes. The Commission, or its representatives, may conduct announced or unannounced inspections at any time. Additionally, Marijuana Research Facility licensees can expect an inspection after provisional licensure and final licensure as part of the regular licensing application process.

13. Does a business need to have a Research License prior to applying for a Research Permit?

No. However, Research Permit applicants are encouraged to wait to submit all necessary information for their research projects until a business has obtained all the necessary approvals to be a fully operational Marijuana Research Facility.

14. Are there any limitations on ownership or control relating to the Marijuana Research Facility licenses?

Yes. An entity is limited to holding no more than three (3) Marijuana Research Facility licenses. Additionally, a Marijuana Research Facility licensee may hold or obtain other licenses for Marijuana Cultivation, Marijuana Product Manufacturing, and Marijuana Retail, for example.



15. Can my business obtain a Marijuana Research Facility license if it, or the people/entities with ownership or control over it, have interests in other licenses?

Yes, subject to the ownership and control limits highlighted above. However, a Marijuana Research Facility licensee cannot be, or have financial interest in, an Independent Testing Laboratory license.

16. Are Research Permits only available to Marijuana Research Facility licensees or license applicants?

No. Research Permits are separate from Marijuana Research Facility licenses. However, in order for a Marijuana Research Facility licensee to conduct research, it must first obtain a Research Permit.

17. What are the application and license fees associated with a Marijuana Research Facility license?

The Marijuana Research Facility application fee is \$300 and annual license fee is \$1,000. Please note all applicable application and license fee waivers for Economic Empowerment Priority Applicants, Social Equity Program Participants, and Disadvantaged Business Enterprises apply.

18. Are there any costs associated with a Research Permit?

The Research Permit application fee is \$1,000 and annual permit fee is \$1,000. Please note that all applicable application and permit fee waivers for Economic Empowerment Priority Applicants, Social Equity Program Participants, and Disadvantaged Business Enterprises apply.

19. Can a Marijuana Research Facility Licensee hold more than one Research Permit?

Yes. However, a Marijuana Research Facility licensee with more than one (1) Research Permit must physically separate all marijuana or marijuana products used in one research project from another to ensure a clear boundary between projects.



20. Can Marijuana Research Facility licensees work with other Marijuana Research Facilities?

Yes. One or more Marijuana Research Facility licensees may enter into agreements to conduct research jointly on an identified research project, provided that research activities authorized under the Research Permit must be conducted at only one (1) identified licensed Marijuana Research Facility. The Marijuana Research Facility licensee must disclose to the Commission all contracts or agreements with other Marijuana Research Facility licensees in furtherance of a research project.

21. Will I need to renew my Marijuana Research Facility license?

Yes. Like all Marijuana Establishments, the Marijuana Research Facility license will expire one year after the date of issuance of the provisional license and annually thereafter. The licensee is required to complete a renewal application no later than 60 calendar days prior to the expiration date.

22. Will I need to renew my Research Permit?

Yes. The Research Permit will be renewed at least annually, or sooner depending on the nature and duration of the approved research project.

23. I applied for a Marijuana Research Facility license some time ago. What can I expect?

Commission staff will review all previously submitted Marijuana Research Facility license applications in the order in which they were originally received.

Staff will notify the applicant by email if more information is required. Once staff find the application complies with Commission regulations, background checks and municipal notification will occur. Once the Commission has received all required reports and responses, the application will be recommended for provisional licensure.

24. Is there a difference between applying for a Marijuana Research Facility license and any other Marijuana Establishment?

No, with one exception. A research compliance plan will be required by Marijuana Research Facility applicants to demonstrate their comprehension of and compliance with the operational requirements for the license.



25. Is a Marijuana Research Facility licensee required to comply with the same requirements as other Marijuana Establishments (e.g. security, storage, inventory, and other requirements)?

Yes. All Marijuana Research Facility applicants are encouraged to review the Commission's [Guidance on Licensure](#) and regulations before starting a license application to comply with all requirements for licensure.

26. Can a Marijuana Research Facility licensee transport marijuana?

Yes. A Marijuana Research Facility licensee must comply with all transportation requirements relating to its vehicles, agents, storage, and security, among other requirements. All applicants and licensees must comply with 935 CMR 500.105(13) for all transportation requirements.

27. Is a Marijuana Research Facility licensee required to have all marijuana tested by an Independent Testing Laboratory?

No, however, prior to consumption by human or animal subjects, all marijuana or marijuana products used in research must be tested by an Independent Testing Laboratory and pass all required tests.

28. Who must register as an Agent under a Marijuana Research Facility license?

All individuals engaging in research at the Marijuana Research Facility must be registered with the Commission as Marijuana Establishment Agents.

29. Once approved, how long is the Agent's registration valid for?

The initial agent registration is valid for one (1) year and is required to be renewed by the Marijuana Research Facility. Upon renewal, the agent registration is then valid for a three (3) year period and will be required to be renewed triennially going forward.



30. What is an IRB?

An “Institutional Review Board” or “IRB” is a specifically constituted administrative body designated by a Marijuana Research Facility licensee to review and oversee the design and methods of a research project, and where human or animal subjects are a component of the research, to protect the rights and welfare of those recruited to participate.

31. What is Informed Consent?

Informed Consent means the consent obtained by a Marijuana Research Facility licensee from potential participants in a research project that also explains the risks and potential benefits of the study, and the rights and responsibilities of the parties involved. All marijuana or marijuana products used in research and consumed by human or animal subjects must be adequately described in the Informed Consent Form.

32. What is an IACUC?

An “Institutional Animal Care & Use Committee” or “IACUC” is an administrative body designated by a Marijuana Research Facility licensee to review and oversee the design and methods of a research project and, where vertebrate animal subjects are a component of the research, to protect the rights and welfare of animals in research and testing.

33. What is a Waiver of Consent?

Waiver of Consent means the document signed by potential participants, or the legal guardians of potential participants, that waives one or more elements of consent.

34. Are the human subjects of a research study required to be 21 years of age or older?

Yes, unless the subject is a currently a Registered Qualifying Patient registered by the Commission and under medical supervision.

35. Can a Marijuana Research Facility sell its marijuana to other licensees?

No.



36. Can subjects of a research study consume marijuana?

Yes, however, a Marijuana Research Facility licensee may only allow consumption of marijuana on its premises by a study participant if it is part of a permitted research project; otherwise the consumption of marijuana or marijuana products is not allowed.

37. What is a Marijuana Research Facility licensee required to do with marijuana once its research, or the need for the marijuana, is over?

All unused marijuana and marijuana products must be recorded as waste in the Commission's seed-to-sale system once the research project is done. Unused marijuana cannot be sold or transferred to other Marijuana Establishments or Medical Marijuana Treatment Centers. All waste must be disposed in accordance with 935 CMR 500.105(12).

38. Can a Research Licensee be colocated with another Marijuana Establishment and/or Medical Marijuana Treatment Center?

Yes, if the Marijuana Research Facility and the colocated Marijuana Establishment or Medical Marijuana Treatment Center are commonly owned and clearly physically separated.

39. Are there limitations on how a Marijuana Research Facility licensee or Research Permit holder can advertise for a particular study?

All licensees, including those with Marijuana Research Facility licenses and Research Permits, are required to comply with all advertising requirements.

Advertising means a form of marketing communication that employs a sponsored, non-personal message to sell or promote a Marijuana Establishment's Brand Name, Marijuana Establishment Branded Good, service, product, or idea.

Please see 935 CMR 500.105(4) for additional information.

40. Does the Commission vote on Marijuana Research Facility licenses and Research Permits at its public meetings?

All licenses, including a Marijuana Research Facility license, will be approved by the Commission at a public meeting. The Commission's Executive Director approves research permits and they do not require a vote of the Commission prior to issuance.

