



NYS Cannabis Research License *Frequently Asked Questions*

Do I Need a NYS Cannabis Research License?

1. If I have a research project already in progress, do I need to obtain a Cannabis Research License?

Research projects that are already funded, are under contractual agreements with research partners, or have IRB/IACUC approval prior to September 13, 2023, do not require a Cannabis Research License. Any new research projects initiated after September 13, 2023, will require a Cannabis Research License. Other exceptions may apply. Please contact research@ocm.ny.gov for further questions.

2. Do I need a Cannabis Research License if my research project uses federally sourced cannabis?

No. Principal investigators (PIs) using, or seeking to use, federally sourced cannabis DO NOT need a Cannabis Research License or any approvals from the state prior to applying for it. This includes product obtained through the National Institute on Drug Abuse's Drug Supply Program and product obtained from a source which is registered to cultivate cannabis by the Drug Enforcement Administration. However, once federal approval is received, the PI must send a copy of their federal approval to the Office at research@ocm.ny.gov.

3. Do federally funded research projects require a Cannabis Research License?

No, federally funded research projects do not require a Cannabis Research License. This includes research by individuals registered with the Drug Enforcement Administration and Food and Drug Administration to conduct cannabis research. However, if the study requires the possession of cannabis or cannabis products, the PI must send a copy of their federal approvals or award letter to the Office at research@ocm.ny.gov.

4. According to the research flowchart, all studies that require IRB approval also require a Cannabis Research License. Are there any exceptions?

No, all observational research involving NYS regulated products that requires IRB approval also requires a Cannabis Research License, unless otherwise approved by the Board.

5. My research project is studying cannabis product obtained from unregulated sources or people that are using unregulated products. Do I need a Cannabis Research License?

The Office does not regulate research involving cannabis and cannabis products that are obtained from sources not registered, licensed, permitted, or authorized by the Office.



6. Do I need a Cannabis Research License for Research and Development (R&D)?

Licensees, permittees, and registrants of the Cannabis Control Board performing R&D within the scope of their existing (non-research) license type do not require a NYS Cannabis Research License.

Other business or entity types not currently regulated by the Office require a Cannabis Research License to do R&D with cannabis, cannabis products, or cannabis related products.

7. If there are two or more researchers leading a study together, are they all required to get a Cannabis Research License?

No, the Office only allows one individual to serve as the principal investigator for each study. If multiple researchers are leading the study, the group must identify which individual will serve as the project's PI. This person will be the primary point of contact for the Office and is responsible for ensuring that the research study is being conducted in accordance with all applicable regulations. Other "lead" investigators should be listed on the application as co-principal investigator (co-PI) or sub-investigator (sub-I).

8. The principal investigator of the research project I am working on is in a different state. I oversee a part of the project at a location in NY. Do I need a Cannabis Research License?

In instances where the principal investigator is not in New York State but a co-investigator or sub-investigator oversees a component of the study in NY, the Office requests that the person responsible for overseeing the research activities in NY obtains a Cannabis Research License. This individual will assume the responsibilities of the principal investigator as outlined by the Cannabis Research License regulations Part 132.

9. Is a Cannabis Research License required for studies with hemp?

Research with hemp that has less than 0.3% Δ -9-Tetrahydrocannabinol (THC) does not require a NYS Cannabis Research License.

Emergency Cannabinoid Hemp Regulations Part 114.1(ag) defines total Δ 9-*Tetrahydrocannabinol concentration* to mean Δ 9-Tetrahydrocannabinol + (0.877 x tetrahydrocannabinolic acid).

Application and Licensee Requirements

10. Can I conduct multiple projects on the same Cannabis Research License?

Yes, the Cannabis Research License is issued to an individual, not to a project. An individual serving as PI for multiple projects must list all projects on the research license application.

11. Can I add a new project after my initial application has been approved?



Yes, after the initial approval a PI may apply at any time to have a new project added. The fee for amending the license to add a new project is \$150.00.

12. For a project with multiple study sites, does each site need a separate Cannabis Research License?

No. A Cannabis Research License is issued to the PI who may list multiple sites or affiliations under a single license provided that the contracts are in place and submitted to OCM for review prior to the approval of a Cannabis Research License.

13. How much does a Cannabis Research License cost?

The application fee is \$250.00. If approved for a license, an additional fee of \$500.00 is required to obtain the license. If you would like to renew your license, an additional \$200.00 is required along with the renewal application.

14. The Cannabis Research License regulations state that my application and licensing fee can be waived by the Office. How do I obtain a waiver from the Office?

If you would like to request a waiver due to financial hardship or based on the size, scope, or duration of the proposed research project, please contact the Office research@ocm.ny.gov.

15. Do I apply for a Cannabis Research License in my name or my institution's name?

Applications for a Cannabis Research License are issued in the name of the person who will be principal investigator. If the PI is conducting research with cannabis or cannabis products on the property of a site they do not own, the host institution or entity must attest that they are aware and approve of the research being conducted at their site on the application.

16. Can an institution hold a license to cover multiple PIs?

No. An institution may not hold a license; a license is granted to an individual PI to perform a research project at the institution. The PI holding the license is responsible for the study's conduct. If multiple individual projects are planned at one location, each PI leading a project must apply for a Cannabis Research License.

17. If I do not have full funding in place prior to starting my research project, can I still apply for a Cannabis Research License?

Yes. The Office asks that a description of the existing funding, and/or a plan for acquiring any necessary funding be included on the license application.

Permitted Activities of the Licensee

18. What activities would be considered outside the scope of my existing (non-research) license, permit or registration?



An unrelated activity type, such as a processor looking to perform laboratory analysis, or a licensee exceeding the cultivation canopy for research purposes. If you are still unsure, please contact the Office at research@ocm.ny.gov.

19. If I get a Cannabis Research License, will it help me get or entitle me to other licensure within OCM?

No, individuals interested in licensure outside the scope of their Cannabis Research License must apply separately for the specific license they are seeking within OCM.

20. Are human interventional studies permitted?

The Office does not prohibit principal investigators from performing human interventional studies; however, your IRB will likely require you to receive the appropriate federal approvals to perform the research. Please note, studies using federally sourced cannabis do not need to obtain a Cannabis Research License.

21. Are individuals required to be 21 years of age or older to participate in a research project?

Individuals may be under the age of 21 if they are certified patients in the Medical Cannabis Program. Researchers must obtain informed consent by the legally authorized representative for subjects under the age of 18.

Observational research studies assessing the use of unregulated cannabis products by persons under 21 do not require a research license.

22. Is advertising of research projects to recruit participants permissible?

Yes, advertising for the purpose of recruiting research participants is permissible with appropriate IRB approvals.

23. Can non-residents of NYS be research subjects?

It depends. The Office only regulates research activities that are performed within NYS. In addition, cannabis products cannot cross state lines, therefore it is recommended that participants are residents or living within NYS for the duration of the research project.

Contracts and Agreements

24. Am I required to submit the Affiliated Organization Attestation form when applying for a Cannabis Research License?

As outlined by Part 132.3(a)(7)(iii), if working within an organization, the principal investigator must submit an attestation to the Office. An Affiliated Organization Attestation is only required for studies that plan to have cannabis or cannabis products on the organization's property. However,



if the PI owns the property or is the owner, president or chief executive officer of the organization, an attestation is not required.

25. How do I know if my study requires IRB approval?

If you are unsure if your proposed study requires IRB approval, you can contact your selected IRB, or any local IRB, and request they review your proposal. They will inform you if the IRB review process is necessary or if your study is exempt from IRB oversight.

26. Can researchers work directly with licensed cultivators or processors?

Yes, a Researcher may contract with a processor or cultivator to produce cannabis or cannabis products specific to the researcher's needs. Please note that any cannabis used for human consumption MUST be tested by a laboratory permitted by the Office and pass all [testing requirements](#) set forth by the Office.

27. Will OCM provide funding to researchers?

Funding opportunities are currently not available. Should any opportunities become available, the Office will notify the public. To receive notifications from OCM, visit our webpage [here](#) and sign up for updates with your e-mail address.

Handling Cannabis Products

28. Can principal investigators dispense cannabis directly to research subjects?

A principal investigator, with IRB approval, can dispense cannabis to a research subject in accordance with the research project that was approved by the Cannabis Control Board. Typically, this is permitted when the principal investigator is also operating at an approved designated caregiver facility.

29. Are academic institutions allowed to obtain cannabis for research and educational purposes?

OCM does not prohibit the use of cannabis for research on college and university campuses; however, these institutions may have their own policies and requirements in place. Review the college or university's policies on cannabis possession and use on campus before applying for a license to conduct research on a campus.

30. Where can NYS licensed researchers obtain cannabis or cannabis products for research purposes?

Cannabis may be purchased directly from an adult-use or medical dispensary. Researchers may also contract with other Cannabis Control Board approved licensees, entities, and permittees to acquire, by sale or donation, cannabis for research purposes. The transaction amount may not exceed the possession limit of 3 ounces of cannabis and 24 grams of concentrate. If the transaction amount will exceed the possession limit, the researcher must have a formal



contractual agreement in place with the Cannabis Control Board-approved licensee, entity, or permittee. Agreements must include, at a minimum, the principal investigator's name, Cannabis Research License number, research site address, the amount of cannabis being purchased, and a copy of the Cannabis Research Licensee's NYS approval letter.

31. Where can research subjects participating in observational studies obtain cannabis and cannabis products?

Research subjects participating in an observational study may purchase cannabis products from an adult-use dispensary or a medical dispensary (if they are a patient in the Medical Cannabis Program). Regular purchase and possession limits apply. Medical patients may purchase a 60-day supply from medical dispensaries and 3 ounces of cannabis or 24 grams of concentrate may be purchased from adult-use dispensaries.

32. How will I know what products the research subjects in my observational study are purchasing from dispensaries?

Cannabis Research Licensees can work with dispensaries to designate and label specific products for research subjects. When purchasing products from designated dispensaries, research subjects will need to inform the dispensary pharmacist or dispensary employee of the specific study they are participating in to ensure they are purchasing investigational products specific to that study.

Additionally, Cannabis Research Licensees may request a report with the dispensing history of study subjects if the subject has provided informed consent for the sharing of this information.

33. Do I need a cultivator license to grow cannabis for agricultural research?

Cannabis Research Licensees may cultivate their own cannabis for research purposes without a cultivator license. All cultivation activities must remain consistent with the research activities approved by the Board during the application process and comply with all applicable NYS rules and regulations.

34. Are there any canopy restrictions for doing agricultural research?

There are no set canopy restrictions, however, during the application process the PI must justify their proposed canopy size based on the scope and goals of the proposed research project. The PI must not then exceed the approved canopy size.

35. What do I do with cannabis waste generated as a result of research?

For waste disposal, researchers must abide by Part 125.11 of the Adult Use Cannabis regulations.

36. For agricultural research, are there any restrictions or requirements related to pesticide use?

For research projects that require the use of pesticides, researchers must abide by Part 123 and Part 125 of the Adult Use Cannabis regulations.



License Approvals, Denials, and Renewals

37. Can I apply for a Cannabis Research License before the IRB/IACUC reviews or gives final approval on my research project?

Yes, you may apply for a Cannabis Research License and submit to your IRB/IACUC at the same time or without final IRB/IACUC approval in place. The Office requires the submission of the IRB/IACUC approval status along with the application. At a minimum, you must have initiated your IRB/IACUC submission at the time of license application. Please note, the Office may begin to review your application materials but will not approve you for a license until we receive the final IRB/IACUC approval.

38. How long will it take the Office to review and approve my application for a Cannabis Research License?

The Office's review will not begin until all required materials are submitted. After all application requirements are fulfilled by the applicant, the Office anticipates 90 days to review, process, and approve applicants for a Cannabis Research License. The only exception is for IRB/IACUC approval submissions. However, in some instances, the approval process may take longer. If you do not hear from the Office within 90 days, please contact research@ocm.ny.gov for a status update.

39. If my application is denied, may I apply again?

If your application is denied, you may apply again. However, any deficiencies identified on the initial application will need to be addressed in order for the Cannabis Control Board to consider the application for approval. Applicants *may* be subject to an additional application fee.

40. Will I be charged an additional fee for applying again after my initial application is denied?

If your application was denied because it was incomplete or missing information, applicants may submit again with corrections within 30 days without an additional fee.

41. Will my Cannabis Research License expire?

Yes, Cannabis Research Licenses expire 2 years after the date of initial license approval. Researchers who want to continue their projects beyond the 2 years must submit an application to renew no more than 6 months but no less than 4 months prior to the expiration date. The renewal period is active for 2 years after date of approval. The Cannabis Research License does not require renewal if the researcher is no longer in possession of cannabis or cannabis products.

Still have questions?

Email: research@ocm.ny.gov