NEW YORK STATE OF OPPORTUNITY. | Office of Cannabis Management

Cannabis Research License Application Instructions

Overview

9 NYCRR Part 132, titled the Cannabis Research License, adopted by the Cannabis Control Board (Board), states that a Cannabis Research License shall be required to conduct research studies with cannabis, cannabis derived products, or cannabis related products in New York State. The Cannabis Research License application is now open, and applicants may now apply for the Cannabis Research License. This document provides instructions on how to complete the application. The Cannabis Research License regulations can be found here. Any questions about the Cannabis Research License application can be sent to: research@ocm.ny.gov.

Application Submission Instructions

The Cannabis Research License application will be accepted by the Office on a rolling basis. Upon receipt of the non-refundable $250 application fee, the Office will review completed applications.

If approved for a Cannabis Research License, the non-refundable $500 license fee must be sent to the Office within ten (10) business days from the notification of application approval. The application and license fees must be paid by certified checks, each made payable to the New York State Office of Cannabis Management. Applicants should include the applicant's name and date of application submission on the memo line on the certified check. Checks should be mailed to:

New York State Office of Cannabis Management
Attention of: Licensing - Research
P.O. Box 2071
Albany, NY 12220

Important Notices

1. This application is to be completed based on the facts and circumstances related to the applicant.

2. The Office is not responsible for any costs incurred by the applicant in connection with the application.

3. At any time during the application review, the applicant may withdraw the application. Withdrawal of an application must occur prior to an application's approval or denial. Withdrawal of an application is without prejudice to

submission of an application at a later date. If an applicant wishes to submit an application at a later date, a new application will need to be submitted to the Office with the non-refundable $250 application fee.

4. Application processing shall not constitute an acknowledgment that the requirements for licensure have been satisfied by the applicant. Licensure of an application does not constitute Office approval for any submitted information or documents.

5. The applicant shall be under a continuing duty to report to the Office any change in facts or circumstances stated in the application or any newly discovered or occurring fact or circumstance which is required to be included in the application.

6. Applicants who are awarded a license may not transfer their license.

7. The applicant shall verify the truth and accuracy of the information and documentation submitted in its application. Any material omissions, errors, or misrepresentations, or a failure to provide requested information, may result in the rejection of the application or other action as may be allowed by law. The Office may, in its discretion, reject an application if it determines that information contained therein is not true, complete, and accurate.

8. An applicant that is issued a Cannabis Research License is responsible for ensuring implemented study protocols and standard operating procedures are compliant with all applicable statutory and regulatory requirements.

9. Applications should be completed with accuracy. Applicants are encouraged to save relevant records and copies of the submitted application and all attachments. The Office may interview any applicant and any affiliated entities or individuals identified in the application.

10. The Office may contact any applicant for the purpose of clarifying any item submitted in its application or to request additional information to ensure mutual understanding. This contact may include written questions, interviews, site visits, or requests for corrective pages in the application. Responses must be submitted to the Office within the time specified in the request. As applicable, clarifications will be treated as addenda to an application. Failure to comply with a request for additional information may result in the application being automatically withdrawn.

11. Any person who knowingly makes any materially false statement in the application may be subject to application denial, suspension or revocation of a registration, and a civil penalty of not more than two thousand ($2,000) dollars.

12. An application may be denied if the applicant or any of its associated parties named on application are under investigation by the Office or if the applicant or any parties named on the application are not in good standing with the Office.

Acceptance of Applications

The Office will only review information and documentation included in the application and will consider the criteria set forth in Section 38 of the Cannabis Law and 9 NYCRR Part 132 in making any determination or recommendation regarding the application to the Board. The application should demonstrate how the applicant will meet the applicable criteria, including but not limited to the items listed below in *Criteria for Consideration*.

The Office will not consider any application that does not contain all required fields, attestations, attachments, and the application fee. The Office may contact the applicant to request missing content and will not process the application until all required fields, attestations, attachments, or application fee are received.

If deficiencies are found in the application, the Office may contact the applicant to address such deficiencies. The applicant will have thirty (30) days to address any deficiencies identified by the Office. Failure to correct any deficiencies or submit requested information to the Office within thirty (30) may result in the application being sent to the Board with recommendation for denial. Applications will be reviewed in the order in which they are received, unless required content is missing or deficiencies must be corrected for sufficient review.

Key Terms

For the purposes of completing this application, the following key terms shall mean:

Applicant: An individual applying for a Cannabis Research License issued by the Board pursuant to Section 38 of the Cannabis Law, who shall also be the principal investigator.

Cannabis-derived product: Concentrated cannabis or cannabis-infused products for use by a cannabis consumer or research participant.

Cannabis-related product: A product that may be synthetically produced to mimic or produce similar effects to cannabis.

Canopy: An area to be calculated in square feet and measured using clearly identifiable boundaries of all areas that will contain non-immature cannabis, which shall be vegetative or flowering plants, excluding seedlings or small clones, including the space(s) within 3 the boundaries.

Curriculum vitae (CV): A detailed document highlighting academic and professional accomplishments.

Human subject or research participant: An individual participating in a research project whose data, information, or biospecimens may be collected through intervention or through interaction with the individual.

Investigational product (IP): The cannabis, cannabis-derived product, or cannabis-related product being studied or used by a human subject in an approved research project.

Key personnel: Staff, other than the principal investigator, participating in a research project who is delegated to perform research tasks.

Office: The New York State Office of Cannabis Management.

Principal investigator (PI): The applicant or research licensee, who shall also be the primary individual overseeing a research project and responsible for all activities conducted under the Cannabis Research License.

Research: A systematic investigation, including but not limited to, research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

Research project or study: A formulated plan of action to perform research and the execution of such plan.

Criteria for Consideration

Applicant Information

All applications must be submitted in the name of the applicant. The Cannabis Research License is issued to the individual responsible for the operational oversight and conduct of the research project (the principal investigator). All applicants must be twenty-one (21) years of age or older and be a citizen or lawful permanent resident of the United States.

Applicants that hold an existing registration, permit, or license with the Office of Cannabis Management (i.e.: registered organization, cannabis laboratory, cultivator, processor, retailer, microbusiness, etc.) must provide their entity name, license type, and license number. Such applicants must describe how the proposed research activities go beyond the scope of their current authorized activities.

Research Site Information

Applicants must provide the intended research site name and location where the proposed research will be performed, including GPS coordinates. This information must be provided for each site where research project activities will be conducted. All sites listed must be located within New York State.

Affiliated Organization Attestation

If the applicant is conducting the research in their professional capacity (i.e.: faculty member, staff, researcher) within an affiliated organization (i.e.: academic institution, hospital, business entity.), an attestation of the affiliated organization's support must be submitted with this application. The affiliated organization attestation will be completed in PDF form and uploaded with the application. This form must be signed by an authorized representative of the organization. An Affiliated Organization Attestation is not needed if:

- The research project does not require the possession of cannabis or cannabis products on the organization's property;
- The PI is also the owner, president, or chief executive officer of the organization; or
- The research is not taking place on the organization's property.

Proposed Research Project Information

Applicants may submit multiple projects under the same application, provided the applicant is serving as the principal investigator for each of the projects. Applicants working on other licensed research projects, but not serving as the principal investigator for such projects, should not list those projects on the application. Applicants submitting multiple research projects must submit the required information for each research project. Each project will be reviewed separately and must meet the requirements set forth in the application. At least one of the submitted projects must be approved to obtain a license. If a research project submitted with an application is not approved it will not be listed as an approved study under the license.

Applicants must select a research project type and intended operating activities. Multiple project types and operating activities may be selected in an application for a single research project. The applicant must also upload a description of the research for each research project that is being proposed. The description must include:

Project Title

Abstract (400 words or less): A brief description of the purpose, methods, and intended outcomes of the proposed research.

Research Project Narrative: A description, including study design, of the research to be conducted (maximum 3 pages). PDFs of relevant publications or articles authored by the applicant or key personnel may be included as supplemental information.

Key Personnel: A list of all key personnel and their roles. Key personnel include but are not limited to co-principal investigator(s), sub-investigator(s), licensed physician(s), research staff, and any other individuals who will contribute to the scientific development or execution of the project in a substantive way. A curriculum vitae (CV) or resume of all key personnel must be provided.

Investigational Product(s) (IP): A description of investigational products to be used in the study including cannabis, cannabis-derived products, or cannabis-related products. The applicant may acquire investigational products by sale or donation from other licensees, permittees, or registrants of the Board. If the amount needed for the project will exceed 3 ounces of cannabis and 24 grams of concentrated cannabis, a formal contract or agreement is required in accordance with the contract and agreements section of the application. Provide the following information:

- Type of investigational products to be used for the research project.
- Amount or quantity anticipated to be needed over the duration of the research project, including justification for the amount to be grown or purchased by the applicant.
- Source, including the licensed entity's name, license number, address, and, if available, the date of sale to the applicant.

If cannabis is proposed to be **cultivated**, **propagated**, or **harvested**, the proposed canopy size for the cultivation space (e.g., square footage, indoor/outdoor, etc.) must be provided along with information detailing how the canopy size or purchased cannabis products are consistent with the project scope and goals.

Funding: A description of any existing or anticipated funding sources for the research project. Plans for how the applicant intends to obtain funding to support the proposed research project are also acceptable. Plans should include specific grants or funding opportunities the applicant plans to apply for.

Disposal: A plan for the disposal or donation of investigational product waste generated from the research project.

Location: Provide the location(s) the research project will be performed.

Review Board Approvals

If conducting animal research, the applicant must upload approvals or conditional approvals from the Institutional Animal Care and Use Committee (IACUC).

For clinical or human observational studies where there will be direct interaction with human subjects, the applicant must upload Institutional Review Board (IRB) approvals or

conditional approvals. If there will be direct interaction with human subjects but the principal investigator believes the study does not require IRB review, they must provide documentation of an exemption by an IRB. Applicants must also provide the following:

- A description of all proposed human subjects, including but not limited to ages, demographics, and details on those deemed vulnerable participants (children, prisoners, pregnant women, mentally disabled persons); and
- A copy of the approved Assent(s) or Informed Consent Form(s).

Contracts and Agreements

The applicant must submit disclosures of all contracts and agreements between the applicant and research partners, vendors, or contractors. This may include any individual or entity licensed, permitted, or registered with the Board involved in the research project. Such agreements should describe the responsibilities and duties of each party with respect to the research project. Letters of intent will be accepted to fulfill this requirement.

Storage and Security Plan

For applicants using investigational product, a storage and security plan must be submitted and include a description of how investigational product will be safeguarded from diversion, theft or loss, including any security measures for storing all investigational product the licensee will have in possession. The plan should also list any key personnel who will have access to the investigational product. Failure to provide a sufficient security plan may result in application denial.

Summary of Document Uploads

All uploads must be labelled appropriately with the PI last name, protocol number, and the document type (i.e. **PI Last Name_Protocol 1_Project Description** OR **PI Last Name_Protocol 2_Storage**). The following document uploads must be included with the submitted application:

- ✓ Project description (mandatory)
- ✓ IACUC documents (applicable for animal research studies only)
- ✓ IRB documentation (applicable for human observational and clinical research studies only)
- ✓ Affiliated organization attestation (applicable for applicants working within an organization they do not own or at a research site they do not own)
- ✓ Contracts and agreements (applicable for applicants working with external research partners, vendors, or contractors)
- ✓ Storage and security plan (applicable for applicants handling investigational products)

Attestations

Applicants are required to attest to the following:

- The applicant will maintain and make available to the Office all required documentation.
- The applicant will submit all required reports, project amendments, review board documents, copies of publications and other materials required by the Office.
- The applicant will report serious adverse events, inventory discrepancies, events related to storage or security breaches, to the Office in a timely manner.

The applicant must provide a final electronic signature attesting that all information included on the application, and all submitted documentation, is true, complete, and accurate.

Disclosure of Application Materials

Freedom of Information Law ("FOIL"): The Office's records are subject to disclosure under the Freedom of Information Law. Trade secrets or confidential information that would cause substantial injury to the competitive position of a business are exempt from disclosure under the Freedom of Information Law. To claim this exemption, an applicant must submit a written request to the Office and identify the specific information they are seeking to protect from disclosure.

After receipt of this request, the Office will make a determination as to whether to withhold the information from disclosure. If the Office denies the exemption request, the applicant has the right to appeal this determination. (See Public Officers Law Section 89(5)).

Please note that the licensees name, license number, study title, and abstract may be published on the OCM website or on other office materials.