New York State Cannabis Research License Application

Thank you for your interest in conducting cannabis research in New York State. Under the requirements of section 38 of the Cannabis Law, the Office of Cannabis Management (the Office) developed Part 132, the Cannabis Research License regulations. The Office is now accepting applications for researchers to become cannabis research licensees. To ensure your application is reviewed in a timely manner, please review all submission requirements before beginning your application.

A PDF version of the application is available to review here: NYS Cannabis Research License Application

General Application Information

1. An application fee of **$250.00** is required along with the completion of this form. Applicants that are approved for a Cannabis Research License must submit a license fee of **$500.00** within **ten (10) business days** of the notification of approval in order to receive the license.

All fees are non-refundable and must be a certified check. Do not send cash or a credit card number. Please include applicant name and date of application submission on the memo line on your certified check. All required fees must be mailed directly to:

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

2. Upon receipt of the application and application fee, an administrative member of the Office will conduct a preliminary review of the application and notify the applicant of any deficiencies or concerns using the e-mail address provided at the start of this application. Applications will not be reviewed unless the application fee is received by the Office.

3. At any time during the review of an application prior to approval or denial, the applicant may withdraw the application. Withdrawal of an application is without prejudice to re-filing the application. If an applicant wishes to resubmit an application at a future time, a new application will need to be submitted to the Office with the non-refundable application fee.

4. All applications will be assessed for completion, accuracy, and proof of adequate credentials.

5. The Board will approve or deny a research application after the application review is completed.

6. Applicants will be contacted by e-mail to notify them of approval or denial of the application. Upon notification, applicants will have ten (10) business days to submit their license fee of $500.

7. **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)).

If you have any questions regarding your application, please email research@ocm.ny.gov.

Applicant Information

Applicant Name:

Please note that the applicant must be the individual serving as the principal investigator (PI) of the project(s).

First: *

MI:

Last: *

E-Mail Address: *

Phone Number: *

(###) ###-####

Mailing Address: *

City: *

State: *

Zip Code: *

Other Name/Alias:

Date of Birth: *

Applicants must be 21 years of age or older.

MM/DD/YYYY

Business Website URL:

(E.g.: http://www.example.com)

Citizenship

Are you a citizen or lawful permanent resident of the United States? *

No

Yes

Representation

Are you being represented by an attorney or other representative? *

No

Yes

Name of Attorney or Representative *

First Name: *

Last Name: *

E-mail Address: *

Phone Number: *

(###) ###-####

Business Address: *

City: *

State: *

Zip Code: *

Existing Registration, Permit or License

Do you currently hold an existing license, permit, or registration with the Office of Cannabis Management (i.e., Testing Laboratory, Cultivator, Processor, Registered Organization, etc.)? *

No

Yes

Entity Information: *

Entity Name:

License Type:

License Number:

Please describe the research activities to be conducted that do not fall within the scope of the activities authorized under your current cannabis license, permit, or registration (i.e., activities not authorized by the current cannabis license, activities exceed canopy size, etc.): *

Research Site Information

Provide the intended research site name and location where the proposed study will be performed, including GPS coordinates. This address cannot be a PO BOX or place of residence.

Site Name: *

Site Address: *

GPS Coordinates (Latitude and Longitude): *

City: *

State: *

NY

Zip Code: *

Site Mailing Address (If different from Site Address)

City:

State:

NY

Zip Code:

Do you have an additional research site to submit? *

No

Yes

How many additional research sites do you need to submit? *

Additional Research Site Information

Provide information about the additional intended research site where the proposed study will be performed. The site address cannot be a PO BOX or place of residence.

Site Name: *

Site Address: *

GPS Coordinates (Latitude and Longitude): *

City: *

State: *

NY

Zip Code: *

Site Mailing Address (If different from Site Address)

City:

State:

NY

Zip Code:

Affiliated Organization Attestation

If working within an organization, an attestation of support from the affiliated organization is required to be submitted along with this application. This attestation is not required if:

- 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.

NYS Cannabis Research License Application Organization Attestation

Label PDF attachment: "PI Last Name_Organization Attestation"
(e.g., Doe_Organization Attestation)

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Proposed Research Project Information

How many research projects are being proposed? *

Research Type *(Select all that apply)*: *

- [ ] Animal
- [ ] Human Observational
- [ ] Clinical
- [ ] Agricultural
- [ ] Genomic
- [ ] Lab-based (chemical potency/composition)
- [ ] Other - Write In (Required) *

Intended Operating Activities *(Select all that apply)*: *

- [ ] Outdoor cultivation
- [ ] Indoor cultivation
- [ ] Mixed light cultivation
- [ ] Drying/curing
- [ ] Laboratory testing
- [ ] Processing
- [ ] Waste rendering
- [ ] Dispensing of investigational products (IP) to research subjects
- [ ] Administration of investigational products (IP) to research subjects
- [ ] Other - Write In (Required)

*

Attach a description of the proposed research to be conducted. Please ensure the requested information is provided in a clear, concise, and accurate manner to facilitate the timely review of the Cannabis Research License application.

If multiple research projects are being proposed in this application, please provide the following information in a separate document for each research project:

- Project Title

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

- 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 any 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 the personal possession limits of 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 this application. The IP description must include the following information:
    - Type of investigational products (i.e., whole flower, ground plant products, cannabis concentrate, cannabis placebo, etc.) 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**, provide a site plan and the proposed canopy size for the cultivation space (e.g., square footage, indoor/outdoor, etc.). Provide 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.

*

Using the following the format, label PDF attachment sequentially for each project document being submitted: "PI Last Name_Project #_Description"
(e.g., Doe_Project 1_Description)

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Upload any approvals, conditional approvals, or continuing review documents that have been received by the IACUC for the research project(s).

*

Using the following format, label PDF attachment sequentially for each project document being submitted: "PI Last Name_Project #_IACUC"
(e.g., Doe_Project 1_IACUC)

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Upload any approvals, conditional approvals, exemptions, or continuing review documents that have been received by the Institutional Review Board (IRB) for the research project(s). The following information must also be provided:

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

*

Using the following format, label PDF attachment sequentially for each project document being submitted: "PI Last Name_Project #_IRB”
(e.g., Doe_Project 1_IRB)

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Contracts and Agreements

Provide a copy of any contracts and agreements between the applicant and any research partners, vendors, or contractors. This includes individuals or entities licensed, permitted, or registered with the Board involved in any aspect of the research project(s). Letters of intent will be accepted to fulfill this requirement.

Using the following format, label PDF attachment sequentially for each project document being submitted: "PI Last Name_Project #_[Contract Name]”
(e.g., Doe_Project 1_[Contract Name])

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Storage and Security Plan

Provide a security plan for how investigational products (IP) will be safeguarded against diversion, theft, or loss, including any security measures for storing all investigational products the licensee will have in their possession. This plan should include a list of any key personnel who will have access to the investigational products. Failure to provide a sufficient security plan may result in application denial.

Using the following format, label PDF attachment sequentially for each project document being submitted: "PI Last Name_Project #_Storage"
(e.g., Doe_Project 1_Storage)

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Reporting Requirements

I attest that I will maintain and make available to the Office, upon request, the following documentation:

- Inventory tracking records, including any cultivated, produced, purchased or donated investigational product (IP);
- IP dispensing logs, if applicable;
- IP disposal records;
- List of research subjects; and
- Adverse events that occur during study participation.

*

Initials:

I attest that I will submit the following:

- Annual report(s) to the Board;
- IRB determinations, including amendments and continuing reviews (within 10 business days of receipt);
- Substantial changes to the research project(s);
- Copies of any publications about the research project(s); and
- A synopsis of the research project(s) at study closure.

*

Initials:

I attest that I will notify the Office in a timely manner of the following incidents:

- Serious adverse events that occur during trial participation (within 24 hours of PI awareness);
- Inventory discrepancies;
- Diversion, theft, loss or unauthorized destruction of IP;
- Loss or unauthorized alteration of IP or human subject records;
- Any event or incident that is reported to duly authorized law enforcement by way of a signed statement (within 24 hours of discovery of the event); or
- Discovery of the following (within 1 business day):
  - Alarm activation (not including planned or accidental activations) or event that requires public safety personnel;
  - Security breaches; and
  - Security alarm system failures lasting longer than 8 hours.

Notification should be sent by email to research@ocm.ny.gov. *

Initials:

Record Retention

I attest that I am aware I must maintain copies of all documents and correspondence sent to or from the Office for at least seven (7) years.
*

Initials:

Attestation

By signing below, I attest that all information included on this application, and all documentation accompanied therein, is true, complete, and accurate. I am aware that any false statements, inaccuracies, or omitted information may be grounds for denial of a NYS Cannabis Research License.

*

Clear

Sign name using mouse or touch pad

Signature of

Thank You!

Thank you for submitting your application. A copy of your completed application will be emailed to you.