The Office of Cannabis Management (OCM)
Interim Cannabis Research Guidance

Thank you for your interest in conducting cannabis research in New York State (NYS). For far too long, performing cannabis related studies has been a challenge due to its Schedule I designation under federal law. The Office of Cannabis Management (OCM) is committed to furthering the scientific knowledge base about cannabis and supporting researchers in these efforts.

Despite the Schedule I categorization federally, NYS has de-scheduled cannabis as a controlled substance. Section 38 of the Cannabis Law provides for the ability to obtain a Cannabis Research License for qualified researchers. OCM is currently working on developing cannabis research regulations to provide a framework for the research license. Until regulations are adopted, researchers are limited in the research activities they may conduct.

The following is a list of the type of research actions that are *currently* permitted in NYS, prior to the adoption of the cannabis research regulations and Cannabis Research License:

1. **The research study is conducted using federally sourced cannabis supplied by the National Institute on Drug Abuse (NIDA) Drug Supply Program.** Researchers seeking to use federally-sourced cannabis must obtain a Schedule I research registration from the DEA. Review the DEA's pre-application checklist to ensure all the steps necessary to complete the registration have been addressed. The checklist and information about obtaining a Schedule I research registration can be found by visiting the link here and selecting the option for "new application" and "form 225". Some of the requirements needed to submit a DEA registration application include:
    - **a.** Study protocol
    - **b.** Institutional Review Board (IRB) approval for human subject studies and Institutional Animal Care and Use Committee (IACUC) approval for animal studies
    - **c.** Curriculum Vitae (CV) for each investigator working on the studies/projects
    - **d.** Evidence that Schedule I security requirements will be met, as outlined by the Controlled Substances Act
    - **e.** Institutional authority to conduct research with a Schedule I controlled substance
    - **f.** If obtaining cannabis from an external source, a DEA registration number of the source

    The DEA has published a Researcher's Manual that provides guidance on the statutory and regulatory requirements for prescribing, administering, and dispensing controlled substances. The manual can be found here: CSA Researcher's Manual

    Please note: *NYS no longer mandates State level approvals or authority, including from the Department of Health, Bureau of Narcotic Enforcement (BNE), to be granted, in order to pursue a DEA Schedule I research registration for cannabis. This was a requirement of NYS BNE prior to cannabis being de-scheduled in NYS.*

    For questions and information about the DEA's process for research with federally-sourced cannabis, please contact a DEA Registration Program Specialist by visiting Diversion Field Office Contact Search.

2. **The research activity is being conducted by an entity with an existing license, permit, or registration granted by OCM.** This includes, but is not limited to, registered organizations, conditional licensees, and permitted laboratories. The research activities conducted by these entities must fall under the purview of the license, permit, or registration type, and is within the framework of the Marihuana Regulation and Taxation Act (MRTA) and any corresponding regulations.

3. **The research project is a Human observational study in which research subjects use cannabis, but the researchers do not procure or dispense the cannabis and cannabis is not used at the research site.** These studies may require the approval of an Institutional Review Board (IRB) if personal health or identifying information is being collected. OCM does not house an IRB and researchers seeking IRB approval will be required to contract with their own institutional IRB or with a local IRB. For more information, please visit FDA IRB FAQs.

4. **The research project uses FDA approved drugs such as Marinol (dronabinol), Syndros (dronabinol), Cesamet (nabilone), and Epidiolex, provided that studies meet the IRB requirements, as referenced above.** Epidiolex, which is a highly purified CBD drug, does not require a DEA registration to be obtained for research. The FDA approved synthetic cannabis-related drug products must be obtained by using the DEA registration and by obtaining a license from NYS BNE.

FDA Approved Drug Names	Product Type	FDA Schedule	NYS BNE License Required	DEA Registration Required
Epidiolex	Purified CBD	V	No	No
Syndros	Synthetic THC	II	Yes	Yes
Cesamet	Synthetic THC	II	Yes	Yes
Marinol	Synthetic THC	III	Yes	Yes

5. **The research is with parts of the Cannabis sativa L. plant which are excluded from the Federal Controlled Substances Act definition of *marijuana.*** This includes the mature stalks of the plant; fiber produced from such stalks; oil or cake made from the seeds of such plant; any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks (except resin extract), fiber, oil, or cake; and the sterilized seed of the plant which is incapable of germination.

6. **The research is on hemp plants so long as the Delta-9 Tetrahydrocannabinol (THC) concentration does not exceed 0.3% by dry weight.** The August 21, 2020, DEA Interim Final Rule allows for research without a Schedule I license if the end product of the cannabis plant being researched has less than 0.3% Delta-9 THC. https://www.govinfo.gov/content/pkg/FR-2020-08-21/pdf/2020-17356.pdf.
    a. A research hemp license issued by the Department of Agriculture and Markets, authorizes the growth or cultivation of hemp for scientific, academic, or commercial research purposes but does not authorize hemp to move into commerce or to be processed for human consumption.

b. Currently, hemp research involving cannabinoids, including Cannabidiol (CBD), may be conducted without the need for an OCM research license, even if the researcher does not know if the product was derived from hemp or a cannabis plant.

Please monitor the OCM website and sign up for our mailing list to receive automatic updates from the Office. For questions specific to research, please contact us at research@ocm.ny.gov.

Additional Helpful Resources:

CSA Researcher's Manual

Cannabis Research Registration with the DEA

NIDA Drug Supply Program

Cannabis Research (cogr.edu)

FDA Regulation of Cannabis and Cannabis-Derived Products, Including Cannabidiol (CBD) | FDA

Federal Register: Implementation of the Agriculture Improvement Act of 2018

Cannabis and Cannabis-Derived Compounds: Quality Considerations for Clinical Research (fda.gov)