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Medical Marijuana Program Research Guidance

Thank you for your interest in conducting research with approved medical marijuana products produced by registered organizations (ROs) in New York State. Research is essential to advancing knowledge of medical marijuana, and ultimately improving patient outcomes. This guidance document provides information that individuals or entities interested in conducting research with approved medical marijuana products need to be aware of.

1. **Federally funded research involving clinical studies with human subjects using medical marijuana products requires Institutional Review Board (IRB) approval.** Title 21 of the Code of Federal Regulations (CFR) § 312.1 provides the requirements governing the use of investigational new drugs and requirements for submission of an Investigational New Drug Application (IND) to the FDA. However, researchers may request that the FDA waive applicable requirements in Title 21 CFR Part 312 through an IND submission pursuant to 10 CFR § 312.10. The FDA may grant a waiver if it finds that the sponsor's noncompliance would not pose a significant and unreasonable risk to human subjects of the investigation. Typically, federally funded researchers are required to use federally supplied marijuana from the National Institute on Drug Abuse (NIDA), nevertheless researchers may pursue a federal waiver to show that the researchers are not trying to bring a new product to market.
2. **Title 5-A of Article 33 of the New York State Public Health Law** (PHL) only authorizes certified patients, designated caregivers (or facility caregivers), and registered organizations to lawfully possess approved medical marijuana products. Individuals and institutions who do not fall into one of these three categories do not have the authority to possess approved medical marijuana products on behalf of patients enrolled in the study. For information on becoming a facility caregiver, please visit: https://www.health.ny.gov/regulations/medical_marijuana/caregiver/, or complete the following form: <https://www.health.ny.gov/forms/doh-5256.pdf>.
3. **Pursuant to Article 24-A of the PHL, all human research in New York State must be reviewed and approved by either an IRB or a Human Research Review Committee (HRRC). For research that is not federally funded, an HRCC can be used in lieu of an IRB.** Please visit <https://health.ny.gov/professionals/irb/faq.htm> for frequently asked questions related to IRBs and HRRCs.
 - a. Public or private institutions interested in conducting human research involving approved medical marijuana products, obtained from NYS ROs, who do not already have a HRRC can apply to the Department of Health to establish a human research review committee at the researching institution.
 - b. The HRRC would review the proposed research protocols to ensure the requirements of PHL § 2444(2) are met, including a determination of the following:
 - i. necessity;
 - ii. that the rights and welfare of human subjects are adequately protected;
 - iii. that the risks to human subjects are outweighed by the potential benefits;
 - iv. that voluntary informed consent is to be obtained by methods that are appropriate;

- v. that the persons proposed to conduct the research are appropriately competent and qualified.
4. Pursuant to [Title 10 NYCRR § 1004.10\(b\)\(3\)](#), registered organizations are prohibited from distributing products or samples at no cost, except as may be allowed by the Commissioner of Health. A request for prior written approval may be submitted by an RO to the Department of Health to authorize products to be provided at no cost for participants who are enrolled in a study.
5. [Title 10 NYCRR § 1004.21\(b\)](#) states that no person associated with an RO shall enter into any agreement with a registered practitioner or health care facility concerning the provision of services or equipment that may adversely affect any person's freedom to choose the dispensing facility at which the certified patient or designated caregiver will purchase approved medical marijuana products. However, this regulation does not apply to research studies approved by an IRB or HRRC.
6. [Title 10 NYCRR § 1004.22\(a\)\(1\)](#) states that a practitioner that is registered with the Department of Health to certify patients for medical marijuana shall not directly or indirectly accept, solicit, or receive any item of value from a registered organization. However, this regulation does not apply to research studies approved by an IRB or HRRC, where the item of value is necessary to conduct the research.

Questions? Contact the Medical Marijuana Program at mmp@health.ny.gov.