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Marijuana-related Research

Definition

Marijuana, as defined by National Institute on Drug Abuse (NIDA), is the mixture of the dried leaves and flowers of *Cannabis*, the hemp plant. The main psychoactive chemical in marijuana, responsible for most of the intoxicating effects of marijuana, is *delta-9-tetrahydrocannabinol* (THC), found in resin produced by the leaves and buds primarily of the female cannabis plant. The plant also contains more than 500 other chemicals, including more than 100 compounds that are chemically related to THC, called cannabinoids.

Law and Policy Framework

With legalization laws in effect at the State level, some researchers in Colorado are interested in studying marijuana. While Colorado has legalized marijuana for medicinal and recreational purposes at the State level, marijuana remains classified as a Schedule I controlled substance under the <u>Federal Controlled Substances Act</u>. Further, import/export of marijuana across state lines and/or country boundaries is illegal under federal law, unless expressly permitted by the Drug Enforcement Agency (DEA) to obtain marijuana from the approved source.

The University of Northern Colorado prohibits the **unlawful** possession, use, or distribution of drugs, alcohol, and other controlled substances by all members of the University community (students, faculty, staff, alumni, and guests). See Board Policy Manual 2-1-501 and University Regulations 3-11-104.

UNC Adopted Procedures

The University of Northern Colorado has completed registration with the US Drug Enforcement Agency (DEA) to procure and possess marijuana for *research purposes* in limited locations on campus. The DEA license granted to UNC carries stringent requirements and limitations that researchers are required to follow, otherwise jeopardizing the license for the entire university.

The process by which a researcher obtains permission to conduct marijuana-related research varies according to the nature of the study:

- A. **Basic Research** For research that **does not** involve human subjects or animals, yet is directed toward greater knowledge or understanding of the fundamental aspects of marijuana, the researcher must:
 - Obtain a registration from the DEA. The application process is handled through UNC's
 Purchasing & Contracts Office. Researchers may not contact the DEA directly to request
 a license. (Note: Once the application has been received by the DEA, it will take several
 months to obtain the license. Plan your research timeline accordingly.)
 - Once the license has been obtained, all orders will be processed through UNC's Purchasing & Contracts Office. Your main point of contact will be UNC's <u>Chief</u> <u>Procurement Officer</u> (CPO). The CPO will assist with the completion of the required DEA

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paperwork and obtain the required internal signatures for acquiring marijuana from an approved source.

- Carefully follow all applicable DEA regulations and guidelines for storage, handling, inventory, and use of the marijuana. Contact the CPO with any questions to ensure compliance.
- B. **Human Observational Studies** Human observational studies are those where subjects use marijuana, but the researcher does not procure the marijuana for the subjects, and the marijuana is not used or consumed on a UNC campus. For such human observational studies, the researcher must:
 - Obtain approval from UNC's Institutional Review Board (IRB)
- C. **Human Subjects Studies** (other than observational) Under federal law, marijuana research involving human subjects requires multiple tiers of approvals from the Food & Drug Administration (FDA), the Drug Enforcement Administration (DEA), the Department of Health and Human Services (DHHS), and an Institutional Review Board (IRB). Because of the complex requirements, UNC faculty interested in pursuing marijuana research involving human subjects must contact UNC's Assistant Vice President for Research for guidance.
- D. **Animal Studies** A researcher who wishes to use marijuana in research involving animal studies must:
 - Obtain approval from UNC's Institutional Animal Care and Use Committee (IACUC)
 - Obtain a registration from the DEA. The application process is handled through UNC's Purchasing & Contracts Office. Researchers may not contact the DEA directly to request a license. (Note: Once the application has been received by the DEA, it will take several months to obtain the license. Plan your research timeline accordingly.)
 - Once the license has been obtained, all orders will be processed through UNC's Purchasing & Contracts Office. Your main point of contact will be UNC's <u>Chief</u> <u>Procurement Officer</u> (CPO). The CPO will assist with the completion of the required DEA paperwork and obtain the required internal signatures for acquiring marijuana from an approved source.
 - Carefully follow all applicable DEA regulations and guidelines for storage, handling, inventory, and use of the marijuana. Contact the CPO with any questions to ensure compliance.

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Industrial Hemp-Related Research

Definition

Industrial hemp, as defined by Colorado Department of Agriculture, is a plant of the genus Cannabis and any part of the plant, whether growing or not, containing a delta-9 tetrahydrocannabinol (THC) concentration of no more than three-tenths of one percent (0.3%) on a dry weight basis.

Law and Policy Framework

Section 7606 of the Agricultural Act of 2014 ("Farm Bill") legalized the growing and cultivating of industrial hemp for research purposes in States where such growth and cultivation is legal under State law, notwithstanding existing Federal statutes that would otherwise criminalize such conduct. The statutorily sanctioned conduct, however, was limited to growth and cultivation by an **institution of higher education** or State department of agriculture for purposes of agricultural or other **academic research** or under the auspices of a State agricultural pilot program for the growth, cultivation, or marketing of industrial hemp. As a result of Section 7606 of the Farm Bill, in 2016 the U.S. Department of Agriculture (USDA) in consult with the U.S. Drug Enforcement Administration (DEA) and the U.S. Food and Drug Administration (FDA), published a <u>Statement of Principles on Industrial Hemp</u> to inform the public how Federal law applies to activities associated with industrial hemp.

The legitimacy of industrial hemp research is additionally covered by <u>7 US Code section 5940</u>, which provides that an institution of higher education may grow or cultivate industrial hemp if certain conditions are met. Specifically, (1) if the industrial hemp is grown or cultivated for purposes of research conducted under an agricultural pilot program or other agricultural or academic research; and (2) the growing or cultivating of industrial hemp is allowed under the laws of the State in which such institution of higher education is located and such research occurs.

In the State of Colorado, statutory authority for the Industrial Hemp Program is provided in <u>Colorado</u> <u>Revised Statutes</u>, <u>Article 35</u>, <u>Article 61</u>. Rules promulgated to administer and enforce the Colorado Industrial Hemp Regulatory Program Act are provided in 8 CCR 1203-23.

UNC Adopted Procedures

University of Northern Colorado is registered with the Colorado Department of Agriculture (CDA) to plant and harvest industrial hemp for research purposes, in a limited area on campus, in accordance with Section 7606. The CDA reserves the right to inspect and approve any facilities in which industrial hemp is cultivated, grown, or studied. Registrants that participate in voluntary private testing are not exempt from being selected for sampling from the CDA. Review the CDA website to understand the differences between voluntary testing and CDA mandatory testing.

A researcher who wishes to conduct industrial hemp-related research must, at minimum:

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- Review Colorado Department of Agriculture's <u>rules pertaining to administration and enforcement</u> of the Industrial Hemp Regulatory Program Act
- Review and sign UNC's Industrial Hemp Research Agreement
- Consider the funding source(s) for proposed research. Researchers may not use Federal funds
 for, or in relation to, any hemp research without prior written permission from the Assistant Vice
 President for Research. If a researcher contemplates Federal funding to support hemp research,
 consult with UNC's Assistant Vice President for Research to discuss feasibility and to determine
 if a DEA license must be pursued through UNC's Chief Procurement Officer.

If research will involve **planting** seeds, a research must:

- Through UNC's Office of Research, complete and submit a <u>pre-planting report</u> to CDA prior to planting any seeds
- o Through UNC's Purchasing and Contracts office, procure CDA Approved Certified Seed
- Through UNC's Office of Research, complete and submit a <u>planting report</u> to CDA within
 10 days after planting any Cannabis AND/OR 10 days after emergence of any volunteer
 cannabis plants in a registered land area that the registrant chooses to cultivate and not
 destroy

If research will involve **harvesting** any part of the hemp plant, a researcher must:

Through UNC's Office of Research, submit a harvest which includes a statement of the intended use of all Industrial Hemp cultivated within the registered land area and the harvest date(s) and location of each variety cultivated within a registered land area. Note: Industrial Hemp Rule 3.6.3 requires that a registrant notify the Commissioner immediately of any changes in the reported harvest date(s) in excess of 5 days. If any such changes are made the Commissioner may require additional testing prior to harvest.

If research will involve **human or animal subjects,** the researcher must contact UNC's <u>Assistant Vice</u> <u>President for Research</u> for guidance.

The importation of viable industrial hemp seed across State lines and Country boundaries is illegal under the Federal Controlled Substances Act. Contact UNC's <u>Chief Procurement Officer</u> to confirm compliance.

Contacts for Cannabis-related Research at UNC

Assistant Vice President for Research, UNC Office of Research research@unco.edu | (970) 351-1907

Chief Procurement Officer, UNC Purchasing and Contracts purchasing@unco.edu | (970) 351-2287