



GUIDANCE REGARDING RESEARCH INVOLVING MARIJUANA AND HEMP

This guidance document is intended to provide information about conducting research with marijuana and hemp at the University of Colorado Boulder (CU Boulder). As the regulatory environment is complex, it is recommended that researchers contact the Controlled Substances Program in the Office of Research Integrity (ORI) if they have any questions about research involving marijuana or hemp.

Marijuana and hemp research involving CU Boulder faculty, staff and students is guided by a March 11, 2014, memorandum from CU President Bruce Benson.¹ In brief, President Benson's memorandum states that marijuana-related research must conform with federal and state laws as well as University of Colorado ("University") policies. Federal law makes a key distinction between the controlled substance "marijuana" and the lower-THC form of the plant "hemp." For most research involving marijuana (as opposed to hemp), researchers must obtain a Drug Enforcement Administration (DEA) Schedule I registration². DEA registrants may only receive marijuana from other DEA registrants, or from facilities licensed by the DEA to produce marijuana.

DEFINITIONS

Hemp: The Agriculture Improvement Act of 2018 (AIA; Public Law 115-334), amended the definition of cannabis ("marijuana") in the Controlled Substances Act (CSA) to exclude hemp. The AIA redefined hemp as "the plant *Cannabis sativa* L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis (7 U.S.C. § 1639o)."

Marijuana ("marihuana"): is listed as a Schedule I controlled substance under the CSA³ and defined as "all parts of the plant *Cannabis sativa* L., whether growing or not; the seeds thereof; the resin extracted from any part of such plant; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or resin. The terms "marihuana" and "marijuana" do not include— (i) hemp, as defined in section 1639o of title 7; or the mature stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture, or

¹ [marijuana-research-memo.pdf \(colorado.edu\)](#)

² Researchers must also possess a Schedule I research registration to conduct research on any synthetic equivalent cannabinoids (e.g., delta-8-THC, delat-10-THC) derived from non-hemp materials.

³ The Department of Justice is in the process of re-scheduling marijuana, these guidelines will be updated once this process is completed.



preparation of such mature stalks (except the resin extracted therefrom), fiber, oil, or cake, or the sterilized seed of such plant which is incapable of germination (21 U.S.C. §§ 802(16)(A),(B)).

GUIDANCE

Questions related to the control status of the cannabis plant, its derivatives, or its components can be directed to DEA's Diversion Control Division, Drug & Chemical Evaluation Section. Information can be found on the DEA's Diversion Control Division website or questions can be emailed directly to their mailbox at DPE@dea.gov.

One exception to the DEA registration requirement applies to "Human Observational Studies," in which research subjects use marijuana but the researcher does not procure the marijuana and the marijuana is not used on any University of Colorado campus. To comply with the Drug Free Schools and Communities Act, observational studies may not recruit University of Colorado students nor University of Colorado employees as subjects, regardless of campus.

A second exception to the DEA registration requirement involves certain research involving *hemp*.⁴ The Agriculture Improvement Act of 2018 and the Colorado Department of Agriculture (CDA), together, allow institutions of higher education in Colorado to cultivate, as well as to conduct research on hemp grown under a registration from the CDA's *Research and Development Hemp Program*. To register with this program, contact [Thomas Heddleston](#) of the Office of Research Integrity.

Permissible hemp research ranges from basic scientific research on plant materials (e.g., genetic sequencing) to applied scientific research). Research with human subjects that uses hemp products (as defined by the AIA of 2018) may require a researcher to submit an Investigational New Drug (IND) Application to the Food & Drug Administration and verify that any product used meets the definition of hemp.

Researchers may also conduct research involving hemp by obtaining hemp, or derivatives thereof, from commercial entities. If researchers seek to conduct research in collaboration with a hemp business, the hemp business or entity must:

1. Be registered with the Colorado Department of Agriculture's Hemp Program;
2. Have a federally insured bank account; and

⁴ <https://www.ams.usda.gov/sites/default/files/media/2018FarmBill.pdf>



3. Not work with the Marijuana Industry.⁵

If a hemp business meets these criteria, CU Boulder may enter into agreements to perform sponsored research and services, conduct collaborative research and development, and transfer materials pursuant to approved research, collaborative, or other agreements.

In significant part, the CU Boulder has established these criteria to comply with all applicable laws and regulations as a precondition to receiving a contract or a grant from a federal agency such as the National Science Foundation or the National Institute of Health.

These laws include the Drug Free Workplace Act, the Drug Free Schools and Communities Act, and the Federal Acquisition Regulations. The implementing regulations of the Drug Free Schools and Communities Act state that recipients of federal funds must put into place “standards of conduct that clearly prohibit, at a minimum, the unlawful possession, use, or distribution of illicit drugs and alcohol by students and employees on its property or as part of its activities.”⁶

The University understands that the State of Colorado and the other states have state-level laws in place that appear to conflict with federal law. A core purpose of this Guidance and the accompanying FAQs is to address questions directed towards facilitating research with Hemp and hemp-derived products that complies with federal and state law. Concurrently, the University only allows researchers to conduct business with entities that comply with federal law, as the University is obligated to promote research in compliance with all applicable laws.

Please contact Thomas Heddleston in the Office of Research Integrity to apply for a Research and Development Hemp Registration with the CDA if you intend to cultivate hemp as part of your research (or for more information about this process).

⁵ For the purposes of this guidance, “Marijuana Industry” means a Direct Beneficial Owner of a Retail Marijuana Establishment or a Medical Marijuana Business as these terms are defined in Colorado Senate Bill 16-040; or a commercial grower, processor, distributor or seller of Marijuana.

⁶ 34 CFR § 86.1; 21 U.S.C. §§ 812(b)(1), (c)(10)



FREQUENTLY ASKED QUESTIONS (FAQs)

Research Involving Marijuana:

1. *How is marijuana defined and how does it differ from hemp?*

Marijuana is listed as a Schedule I controlled substance under the Controlled Substances Act (CSA) and refers to the plant *Cannabis sativa* L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of more than 0.3 percent on a dry weight basis. Under the CSA, Schedule I is the most restrictive status, thus according to federal law, marijuana is in the same category as MDMA, heroin, LSD, and psilocybin mushrooms.⁶

2. *Can CU Boulder researchers perform marijuana research?*

Yes, but only under certain conditions. Human observational studies may be conducted without a DEA registration, but all other research requires a DEA Schedule I registration. In addition, research involving humans requires IRB approval (and likely FDA IND approval), and research involving animals requires IACUC approval.

3. *What are human observational studies?*

Human observational studies are those where subjects use marijuana, but the researcher does not procure the marijuana for the subjects and in which the marijuana is not used/consumed on CU Boulder's campus.

4. *How can I locate DEA-approved sources of cannabis products?*

In general, the DEA only approves of transfers of controlled substances between DEA registrants. Currently there are eight primary providers of DEA-approved marijuana for research purposes. A list of marijuana plant material currently available from the NIDA Drug Supply Program can be found at [DEA-Approved Bulk Cannabis Suppliers | NCCIH \(nih.gov\)](#).

5. *Can CU Boulder researchers provide marijuana samples, extracts, and derivatives to other labs at CU Boulder or entities external to the university?*

A qualified no, unless such transfer occurs with another Schedule I holder, and is otherwise permissible under state and federal law.



6. *How can a CU Boulder researcher apply for Schedule I registration?*

Individual PIs may register with the DEA for a Schedule I Researcher registration by following the guidance provided at <http://www.colorado.edu/innovate/controlled-substances>.

7. *How long does it take to obtain DEA approval for a Schedule I controlled substance?*

The approval process is lengthy, often taking four to six months. Researchers interested in performing marijuana research should apply early in the research process. Grants awarded for marijuana research will be declined if the Schedule I registration is not in place at time of award.

8. *Can CU Boulder researchers perform research related to marijuana that does not require the handling of marijuana material?*

Yes, analysis of existing data, literature reviews, and observational studies (see Question 21) are allowable without a Schedule I registration as long as marijuana does not come into the possession of the researcher. Researchers should consult ORI to determine if their research protocols are compliant.

9. *How should CU Boulder researchers dispose of unwanted marijuana obtained for research purposes?*

All DEA-controlled substances must be disposed of through CU's Environmental Health and Safety program See <http://www.colorado.edu/innovate/controlled-substances/policies-guidelines> for more information.

10. *Can CU Boulder accept philanthropic or research funding from the Marijuana Industry?*

No, CU Boulder does not accept funding from the Marijuana Industry due to federal laws and regulations including those related to banking.

11. *Are there any research centers at CU that are promoting collaborative marijuana research?*

CU's Center for Research and Education Addressing Cannabis and Health (CU REACH) promotes multidisciplinary research devoted to the development of evidence-based knowledge regarding the effects of marijuana and hemp. Please visit: <https://www.colorado.edu/center/reach/> to learn more.



Research Involving Hemp:

12. *What is the definition of Hemp?*

The Agriculture Improvement Act of 2018 (AIA; Public Law 115-334), amended the definition of cannabis (“marijuana”) in the Controlled Substances Act (CSA) to exclude hemp. The AIA redefined hemp as “the plant *Cannabis sativa* L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis (7 U.S.C. 1639o).” The Colorado Department of Agriculture uses this same definition.⁷

13. *How are the concentrations of THC and other cannabinoids measured for Colorado regulatory purposes? Who does it and how is that arranged?*

The Colorado Department of Agriculture (CDA) may sample registrants’ hemp crops 30 days prior to harvest and test for THC content only. It does not test for any other cannabinoids; but, under certain circumstances, the CDA tests for the presence of certain pesticides. The CDA offers a program called “Performance-based sampling” for researchers cultivating hemp with a Research and Development Registration that streamlines THC-testing requirements for approved researchers (See 8 Colo. Code Regs. § 1203-23:4.8 [Code of Colorado Regulations \(coloradosos.gov\)](http://coloradosos.gov)).

14. *Is hemp legally different than marijuana?*

Yes. Marijuana remains a Schedule I controlled substance; Schedule I substances are subject to the most intense scrutiny by the DEA. On the other hand, hemp cultivation is regulated by the U.S. Department of Agriculture (USDA) and the Colorado Department of Agriculture (CDA). Under the federal AIA of 2018 and Colorado’s Research and Development Hemp Program, institutions of higher learning have broad latitude to cultivate and research hemp (including its constituent compounds) *without* a DEA Schedule I license.

15. *Does the definition of “hemp” include hemp-derived products that include cannabidiol (CBD) or other cannabinoids?*

The key defining characteristics of hemp is that it is *Cannabis sativa* L. that does not exceed a THC concentration of more than 0.3% on a dry weight basis. If an extract does not exceed this criterion, it qualifies for treatment as hemp.

⁷ 8 Colo. Code Regs. § 1203-23:1



16. What kinds of research involving hemp may be performed at CU Boulder?

CU Boulder Researchers do not need a DEA Schedule I registration to cultivate or conduct research on hemp or hemp-derived products and may conduct a wide variety of research on hemp and hemp-derived products. Researchers may cultivate hemp by first registering with the CDA and reporting all planting and harvesting activities to the CDA and USDA (with assistance from CU's Controlled Substances in Research Program).⁸

17. Are there steps I have to take before engaging in research using actual hemp or hemp- derived materials?

Researchers using hemp in their research should indicate so on the "Controlled Substances Used for Research" section (on page 3) of CU's Office of Contracts and Grants Proposal Submission Request (PSR) form by checking the box labeled "Industrial Hemp or CBD." Researchers should also verify that any vendor providing hemp can certify that it meets the definition of hemp (less than .3% THC). Please contact Thomas Heddleston of the Controlled Substances in Research Program for any further questions on this topic.

18. Can I grow hemp for research purposes?

Yes, but doing so requires that the Controlled Substances program registers the land area of the cultivation site with the CDA and the USDA's Farm Services Administration, after verifying that the site meets all University Requirements, as specified in the [Hemp Cultivation SOP Document](#). Please coordinate registration applications with Thomas Heddleston who will file applications and required planting and harvest reports.

19. If I want to grow hemp for research purposes, where can I obtain viable hemp seed?

CDA does not sell or supply seed. All hemp fields, regardless of source of seed or clones, will be subject to inspection and sampling to verify THC levels. Colorado does not mandate the use of Certified Hemp Seed or Certified Hemp Clones. A grower may use any seed source they choose; however, it is recommended that when buying Open-Source Seed that the

⁸ According to NIH's National Institute on Drug Abuse: "If a hemp product fits the definition of a drug under the Federal Food Drug and Cosmetic Act (21 U.S.C. 9) and its use fits the definition of an interventional investigation with humans, an IND for drugs containing hemp is likely to be required. Questions about INDs for particular protocols should be directed to the FDA." (<https://nida.nih.gov/research/resources-grants-contracts/faqs-conducting-research-with-cannabis-hemp>).



appropriate due diligence is conducted.⁹

20. What do I do if the hemp I grow has THC concentration that exceeds the limit of 0.3% on a dry weight basis?

Any plants with THC concentrations exceeding the 0.3% limit must be reported to the CDA. If the CDA tests the crop and it exceeds the 0.3% limit, it likely will destroy the crop.

21. Can CU Boulder researchers use non-CU subcontractors to grow hemp for research purposes?

Yes, but the subcontractor or researcher must (1) be registered with the Colorado Department of Agriculture's Hemp program; (2) have a federally insured bank account; and (3) certify that they do not work with the Marijuana Industry. Contact Thomas Heddleston for more information about developing an MOU with subcontractors for this purpose.

22. Can CU Boulder researchers obtain hemp products from third-party suppliers for research purposes?

Yes. Researchers are not required to hold a Schedule I research registration to conduct research on hemp-derived products as long as the product(s) contain no more than 0.3% delta-9 THC on a dry weight basis.

23. Can CU Boulder researchers perform hemp research in a paid or unpaid sabbatical situation in a foreign country whose laws permit hemp research in any capacity?

Yes.

24. Can CU Boulder researchers perform hemp research funded by industry?

Yes, but only if the funder meets the criteria described in Question 11 and the arrangement includes an MOU involving sponsored research or services. (CU does not accept gifts or funding from the Marijuana Industry due to federal regulations and laws, including the Drug Free School Zones Act, Drug Free Workplace Act, and the Bank Secrecy Act.)

25. If I perform research on hemp or hemp products, am I free to provide those results to the sponsor?

Intellectual assets, including publications, knowledge, and licensed rights to resulting intellectual property, may always be provided as is standard operating procedure for research universities. Hemp and associated

⁹ <https://ag.colorado.gov/plants/hemp/certified-hemp-seed-or-clone>



materials, but not viable seeds, may be provided to the sponsor. (See answer to Question 12 above).

26. *Can CU Boulder license intellectual property rights resulting from hemp research?*

Yes.

27. *Can a CU Boulder researcher who maintains a DEA Schedule I registration handle hemp materials falling under the CDA's Research and Development Hemp Program in the same facility?*

Yes, provided that all Schedule I rules and protocols are followed for materials categorized as a Schedule I controlled substance.

28. *How should CU Boulder researchers dispose of unwanted hemp materials?*

Currently, the only process for destruction of materials is composting or burial. If researchers apply for the CDA's Performance-Based Sampling status, they will need to provide a detailed disposal plan and to document all hemp disposal activities.

29. *Are there any opportunities to pursue funding for hemp and marijuana research for CU Researchers?*

The Institute for Cannabis Research, based at Colorado State University-Pueblo awards funding to researchers from various fields to study hemp and marijuana annually. Please visit <https://www.instituteofcannabisresearchcolorado.org/research-projects/> for more information.

For additional questions, please contact the Office of Research Integrity:

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