

## GUIDANCE REGARDING RESEARCH INVOLVING MARIJUANA AND INDUSTRIAL HEMP

Marijuana research involving CU-Boulder faculty, staff and students is guided by a March 11, 2014 memorandum from CU President Bruce Benson<sup>1</sup>. 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. For most research involving *marijuana*, researchers must obtain a DEA Schedule I registration. In addition, research involving animals or humans require approval from the campus IACUC or IRB, respectively. DEA registrants may only receive marijuana from other DEA registrants, or from National Institute on Drug Abuse (NIDA) approved sources.

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 the campus. To comply with the Drug Free Schools and Communities Act, observational studies may not recruit CU students or employees as subjects.

As second exception to the DEA registration requirement involves certain research involving *industrial hemp*. Industrial hemp is legally defined as *Cannabis sativa L* that contains not more than 0.3% THC on a dry weight basis. The Federal Farm Bill allows institutions of higher education in Colorado to cultivate, as well as to conduct research on, industrial hemp grown under a registration permit from the Colorado Department of Agriculture's Industrial Hemp Pilot Program. Seeds or clones for growing industrial hemp must be obtained from the Colorado Department of Agriculture (CDA) through the Office of Research Integrity. For more information on registering with this program, contact Ann Bennan in the Office of Research Integrity (contact information follows after the FAQs).

Research permissible under the Industrial Hemp Pilot Program ranges from basic scientific research on plant materials (e.g., genetic sequencing) to applied scientific research with animal models (with IACUC approval). Permissible research does not include human clinical trials, as such research may require a researcher to submit an Investigational New Drug Application to the Food & Drug Administration and obtain the cannabis from Drug Enforcement Administration approved sources, among other requirements.

Researchers may also conduct research involving industrial hemp by obtaining the hemp, or derivatives thereof, from commercial entities. To conduct business with an industrial hemp entity or organization, the entity must:

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<sup>1</sup> <http://www.colorado.edu/innovate/sites/default/files/attached-files/marijuana-research-memo.pdf>

1. Be registered with the Colorado Department of Agriculture's Industrial Hemp Pilot Program.
2. Have a federally insured bank account.
3. Not work with the Marijuana Industry.<sup>2</sup>

If an industrial hemp business meets these criteria, CU Boulder researchers 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 University has established these criteria because it endeavors 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."<sup>3</sup>

The University would like to remind its research community that *marijuana*, which is distinguished from *industrial hemp* legally, remains a Schedule I controlled substance under the Controlled Substances Act, the most restrictive status under federal law, along with ecstasy, heroin, LSD and hallucinogenic mushrooms.<sup>4</sup> This designation is federal law regardless of whether you personally do or do not think it makes sense.

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 FAQs is to address questions directed towards facilitating research with industrial hemp, which, under certain circumstances, is compliant with and legal under federal law. Concurrently, the University seeks to avoid doing business with entities that do not comply with federal law, as the University strives to promote research in compliance with all applicable laws.

Please contact Ann Bennan in the Office of Research Integrity for more information, including registering with the CDA and for agreement templates (contact information follows after the FAQs).

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<sup>2</sup> 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.

<sup>3</sup> 34 CFR § 86.1 (2016)

<sup>4</sup> 21 U.S.C. §§ 812(b)(1), (c)(10) (2016)

## FREQUENTLY ASKED QUESTIONS (FAQs)

### RESEARCH INVOLVING INDUSTRIAL HEMP:

1. *What is the definition of industrial hemp?*

The definition of Industrial Hemp under Colorado law 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."<sup>5</sup>

2. *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' industrial hemp crops two weeks prior to harvest and test for THC content only. It does not test any other cannabinoids; but, under certain circumstances, the CDA tests for the presence of certain pesticides. (See <https://www.colorado.gov/pacific/agplants/industrial-hemp>. Click "CDA Policy for Industrial Hemp Inspection, Sampling.")

3. *Is industrial 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. In Colorado, industrial hemp cultivation is regulated by the Colorado Department of Agriculture (CDA); under the U.S. Farm Bill and Colorado's Agricultural Pilot Programs, institutions of higher learning have broad latitude to cultivate and research industrial hemp, including its constituent compounds, *without* a DEA Schedule I license.

4. *Does "industrial hemp" include "extracts" that include cannabidiol or other cannabinoids?*

The key defining characteristics of industrial hemp are that it is *Cannabis sativa L.* that does not include THC at a concentration of more than 0.3% on a dry weight basis. If the extract meets that criterion, it would qualify for treatment as industrial hemp.

5. *What kinds of research involving industrial hemp may be performed at CU-Boulder?*

Pursuant to the Federal Farm Bill, research can be conducted *without* a DEA Schedule I registration for growth, cultivation, and market analyses (i.e. economic/agronomics) of industrial hemp. CU-Boulder researchers may also conduct "academic research" on any application or subject matter using hemp, other than use with humans, with the additional caveat that use with animal models requires IACUC approval.

6. *Can I do hemp research under a DEA Schedule I registration?*

Yes, but the research must then be conducted in conformance with DEA requirements for

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<sup>5</sup> 8 Colo. Code Regs. § 1203-23:1

research with marijuana (see the next section of FAQs).

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

Please contact Ann Bennan or Jon Reuter in the Office of Research Integrity (contact information is provided at the end of this document) before undertaking such research. They can alert you to any issues that may exist. This will also allow us to keep track of hemp research being conducted for our own analysis as there are frequent inquiries about research of this nature.

8. *Can I grow industrial hemp for research purposes?*

Yes, but this requires registration of the cultivation site on the University's CDA registration or a separate CDA registration for your specific location, if necessary. Please coordinate registration applications through Ann Bennan.

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

At this time, viable hemp seed should be obtained only from the CDA under its license with the DEA. The Office of Research Integrity will order and obtain the seed from the CDA for distribution to faculty having registered locations on the University's CDA registration(s).

10. *What do I do if the industrial 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.

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

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

12. *Can CU-Boulder researchers obtain hemp products from third parties for research purposes?*

A qualified yes. Hemp materials and products, other than viable seeds, that contain a THC concentration of less than 0.3% on a dry weight basis are not subject to the Controlled Substances Act if the materials and products are cultivated pursuant to the Farm Bill and Colorado's Agriculture Pilot Program. In addition, the third party must be registered with the CDA and its activities must have a research purpose. Thus, a researcher is permitted to receive and perform research on such materials and products from parties with which it enters collaborative research focused agreements processed through the Office of Research Integrity.

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

Yes.

14. *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 Work Place Act and the Bank Secrecy Act.)

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

16. *Can CU-Boulder license intellectual property rights resulting from industrial hemp research?*

Yes.

17. *Can a CU-Boulder researcher who maintains a DEA Schedule I registration handle industrial hemp materials falling under the CDA's Industrial Hemp Pilot 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.

18. *How should CU-Boulder researchers dispose of unwanted industrial hemp materials?*

Currently, the only process for destruction of materials is burial/composting.

19. *Has CU formed a joint research institute with Colorado State University?*

Yes, CU and CSU have developed a framework for a joint hemp research institute now called the Colorado Partnership for Hemp Research (CPHR), to legally, jointly perform hemp research and support graduate student engagement in such research.

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## RESEARCH INVOLVING MARIJUANA:

### *20. 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 first requires DEA Schedule I registration. In addition, research involving humans requires IRB approval, and research involving animals requires IACUC approval.

### *21. 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 the University's property.

### *22. 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 the primary provider of marijuana for research purposes is the University of Mississippi, although in principle material (including extracts but excluding seeds) could be obtained in transfers from other DEA registered entities. A list of marijuana plant material currently available from the NIDA Drug Supply Program can be found at <https://www.drugabuse.gov/researchers/research-resources/nida-drug-supply-program-dsp/marijuana-plant-material-available-nida-drug-supply-program>.

### *23. 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.

### *24. 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>. Please be sure to provide Ann Bennan with a copy of your registration application or renewal so that the campus can keep track of DEA registered research.

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

The approval process is lengthy, often requiring six to twelve months. Researchers interested in performing marijuana research should apply as soon as possible, and should make sure that the application fully addresses all questions. Grants awarded for marijuana research will be declined if the Schedule I registration is not in place at time of award.

26. *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.

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

All DEA-controlled substances must be disposed of through a “reverse distributor.” See <http://www.colorado.edu/innovate/controlled-substances/policies-guidelines> for more information.

28. *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.

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

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Regulatory Compliance - Controlled Substances Used for Research Program

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