

**COGR**

Council On Governmental Relations

# Cannabis Research

## Frequently Asked Questions

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### *Of Important Note*

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*This FAQ is provided as an educational tool with the understanding that COGR is not providing legal advice, and cannot and does not warrant the legal sufficiency of any of the information presented in this FAQ. Nothing in this FAQ shall be deemed to supplant any federal/ state/ local laws or institutional policy. Any research activity that involves restricted materials of any kind should be done in accordance with these laws/policies and with the advice of your institution's legal counsel.*

## Table of Contents

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- I. Introduction
- II. Definitions
- III. Cannabis Research—Marijuana
- IV. Cannabis Research—Industrial Hemp
- V. FAQs about the University of Mississippi Program
- VI. Helpful Resources

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## Forward

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The Council on Governmental Relations (COGR) is an association of 185+ leading research universities and their affiliated academic medical centers and research institutes. One of COGR's important activities is helping to develop educational materials that reflect the mutual interest and separate obligations of research institutions and federal and other sponsoring agencies.

This FAQ is an illustration of such activity and has been compiled to help research administrators navigate the complex landscape of cannabis and hemp research.

# I. Introduction (Background)

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The Controlled Substance Act (CSA) creates a comprehensive federal framework that categorizes drugs and other controlled substances into five “schedules.” At the high end of the spectrum, and most tightly regulated, are Schedule I controlled substances, which are those substances that: (1) have a high potential for abuse; (2) have no currently accepted medical use in treatment in the United States; and (3) have a lack of accepted safety under medical supervision. The Food and Drug Administration (FDA) published the results of a comprehensive review of the safety and efficacy of cannabis in the Federal Register on August 12, 2016 and recommended that cannabis remain Schedule I. A federal court recognized in 2017 that “there is a serious debate in the United States over the efficacy of marijuana for medicinal uses,” but nonetheless upheld the Drug Enforcement Agency’s (DEA) refusal to change marijuana’s classification as a Schedule I controlled substance. As such, it remains illegal under federal law for any person to import, manufacture, distribute, possess, or use marijuana. The Department of Justice recently issued a memorandum denying that “any state or local law provides a legal defense to a violation of federal law, including any civil or criminal provision of the [Controlled Substance Act].”

Under the federal Drug Free Schools and Communities Act, institutions of higher education have an obligation to comply with federal drug laws as a condition of receiving grant funding or other financial assistance under any federal program. Consequently, conducting unapproved marijuana-related research could adversely affect an institution’s ability to seek federal research funding or federal financial aid. To prevent this possibility, all marijuana-related research must be conducted in strict compliance with federal, state, and local laws as well as institution policies. Notwithstanding the CSA’s general prohibition upon any marijuana-related activities, federal law provides the FDA with the ability to approve research using Schedule I controlled substances. Currently, across the United States, more than 100 researchers have obtained registrations to conduct marijuana-related research, including clinical studies involving the effects of smoked marijuana.

A 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 (and state departments of agriculture) to cultivate, as well as to conduct research on, industrial hemp grown pursuant to a state Industrial Hemp Pilot Program. Permissible research does not include animal or human clinical trials that require a researcher to submit an Investigational New Drug Application (IND) to the FDA, as such research may require a researcher to obtain the cannabis from DEA approved sources, among other requirements.

# II. Definitions

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The following definitions are provided for the purposes of this document. Definitions are subject to change at any time due to the political nature of cannabis research. Readers are cautioned to seek legal definitions as needed from other sources.

1. *Marijuana and cannabis* are 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. Such term does not include 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 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. Code § 802)
2. *Cannabinoid* is one of over 100 chemically related compounds contained in the cannabis plant. The predominant cannabinoids of research interest are delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD).
3. *THC (delta-9-tetrahydrocannabinol)* is a cannabinoid commercially available as an active pharmaceutical ingredient in FDA approved drug products including Marinol® capsules and generic equivalents. (<https://pubchem.ncbi.nlm.nih.gov/compound/Dronabinol>). The generic drug name for THC is Dronabinol.
4. *CBD (Cannabidiol)* is a cannabinoid currently undergoing clinical evaluation as an active pharmaceutical ingredient for the treatment of refractory epilepsy and other conditions. (<https://clinicaltrials.gov/ct2/results?cond=&term=cannabidiol&cntry=&state=&city=&dist=>)
5. *DEA Registration*. The DEA grants different types of registrations for Schedule I drugs depending on the intended purpose of the applicant. The types of registrations include “manufacturing,” “research,” and “chemical analysis.” See [https://www.deadiversion.usdoj.gov/21cfr/cfr/1301/1301\\_13.htm](https://www.deadiversion.usdoj.gov/21cfr/cfr/1301/1301_13.htm) and <https://www.deadiversion.usdoj.gov/drugreg/categories.htm>.
6. *Marijuana research* is defined as research that involves the growth, production, procurement, possession, distribution, administering, or use of marijuana. It does not refer to observational research or other research (e.g., policy research).
7. *Observational research* is defined as research about marijuana and its legalization that does not involve the growth, production, procurement, administration, or use of any cannabis product by the researcher, but may include studies where subjects use marijuana and the researcher does not procure the marijuana and the marijuana is not used/consumed on campus property. Note that “participants” in states not allowing use under state law are at risk of prosecution under both state and federal law.
8. *Industrial hemp* is defined in [Title 7 U.S. Code §5940](#) (the “Farm Bill”) as “the plant *Cannabis sativa* L. and any part of such plant, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis.” There may be different definitions of “industrial hemp” in applicable state laws, and a substance defined as “industrial hemp in the federal Farm Bill may still be defined as “Marihuana” in the federal CSA.

9. *Pilot Program* is a requirement under the Farm Bill in order to allow industrial hemp to be grown or cultivated in a state. The state must (1) establish a program allowing for cultivation 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 or state department of agriculture is located and such research occurs. The DEA has interpreted this as requiring a state to have a registration and memorandum of understanding (MOU) with private growers, although the MOU requirement is generally just the registration and series of state controls and monitoring that is done pursuant to that registration
10. *Processed industrial hemp* generally refers to hemp that has been harvested and decorticated, and does not include any living hemp plants, viable seeds, leaf materials, floral materials, or delta-9-THC content above 0.3%.
11. *Viable seeds* are those that are not sterilized and can be used to grow plants.

### III. Cannabis Research—Marijuana

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1. Can our 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 the appropriate DEA Schedule I registration. In addition, research involving humans requires IRB compliance, and research involving animals requires IACUC compliance. Certain research studies (i.e., clinical trials) may require other approvals, such as FDA. In addition, researchers must abide by all applicable institutional, local, state, and federal policies, statutes, and regulations.

2. Is there any other type of research allowed without Schedule 1 registration by the researchers?

It depends. Certain parts of the *Cannabis sativa L.* plant are excluded from the Federal Controlled Substances Act definition of marijuana, such as 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. Some institutions have interpreted this to allow faculty, staff and students to legally conduct research involving such substances without a DEA license, for example, as may occur when studying industrial products, processed plant materials, and animal feed mixtures made from those portions of the cannabis plant that are excluded from the definition of “marijuana.” Please verify with your institution officials or policies.

In addition, environmental impact studies in which researchers study the impact of marijuana cultivation, for example on wildlife, water resources, or other aspects of the natural habitat; and

policy or legal studies looking at economic, social, political or other issues involving marijuana and marijuana legislation are allowed without Schedule 1 registration—again, provided the researchers are not otherwise violating CSA laws regarding possession, etc.

**Note that the Final Rule released by the DEA articulates the DEA’s position that marijuana extracts such as CBD are subject to Schedule 1 registration.**

3. Can researchers provide marijuana samples, extracts, and derivatives to other labs at their institution or entities external to the university?

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

4. Schedule I Information

- a. 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 (see below for more information), 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/nidadrug-supply-program-dsp/marijuana-plant-material-available-nida-drug-supplyprogram>.

- b. How can a researcher apply to the DEA for a Schedule I registration?

Individual PIs may register with the DEA for a Schedule I Researcher registration by following the guidance provided by their institution.

- c. How long does it take to obtain DEA approval for a Schedule I registration?

The approval process is lengthy, often requiring six to twelve months. Many research activities may be conducted under a Research or Chemical Analysis type of registration, which are easier and faster to obtain than a Manufacturing registration. 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 at most institutions if the Schedule I registration is not in place at time of award.

5. Can researchers accept philanthropic or research funding from the Marijuana Industry?

Due to federal laws and regulations including those related to banking, some institutions do not allow this. Contact the appropriate institutional official, which may include Foundation, Office of Research, and General Counsel/Attorney General. In evaluating requests to accept funding from

such sources, a significant consideration is the need to comply with applicable money laundering laws and laws re: aiding/abetting illegal activities.

6. Can researchers provide consulting services regarding marijuana?

Faculty and staff should seek guidance from their institution. They should be aware they are assuming the same risks as any other state citizen who chooses to engage in such activities, despite the legal status of cannabis use in a state. Consultation for business and agricultural entities growing or selling marijuana may violate federal law, and the individual should obtain private legal advice prior to doing so. Also, because of most institutions' obligation to comply with federal laws, researchers engaging in activities which are not allowed under federal law should make no use of institution resources (not even the usually permissible de minimis or incidental and occasional personal use of resources). Many institutions require researchers to make it clear to all parties that they are conducting such activities as private citizens, not as faculty or staff. Though they may identify themselves as holding an institution position, there should be clear and consistent statements such as: "This work was performed as a private individual, not as a faculty member. No institution resources, facilities, or funds were used. No institution employees or students participated in this research in their roles as an institution employee or student."

7. Can researchers or extension agents provide advice to non-university marijuana growers approved to grow marijuana in their state?

This is generally not permitted, as there is some risk that advice to growers in order to further their business could implicate laws against aiding and abetting a violation of federal law, since it is still illegal to grow marijuana under federal law.

8. Can a researcher perform research involving the direct use of marijuana in non-institutional facilities, since the possession and use of marijuana is prohibited by federal law?

It depends upon your institution's policies. Some institutions may not allow research to be conducted off-campus in non-institutional facilities, if it could not be conducted on campus in institutional facilities, particularly if it would require obtaining DEA approval. But, if your institution's policies allow this, then, yes, **if** the following conditions are met:

- a. The possession is for research exclusively **and** the non-institutional facility has the appropriate DEA approval for Schedule I research, **and the researcher** follows all relevant state and federal regulations and guidelines (including the need for a Schedule I registration).
- b. The researcher must be officially approved by the non-institutional facility, as subject to state and federal rules. Documentation of this approval must be kept by the researcher.



# IV. Cannabis Research—Industrial Hemp

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1. What types of industrial hemp research can be performed at Farm Bill compliant institution?

This will depend on the state and institution. While some states, such as Kentucky or Colorado, have broad research interpretations of the Farm Bill and allow research without a Schedule I registration for any cultivation, growth, or market analysis, or conduct “academic research” on any application or subject matter using hemp, other than use with humans, other states, such as Washington, require specific research purposes to be met. All industrial hemp related activity must follow the laws, regulation, and policies relevant to the institution and the state it is located in.

2. Can a researcher perform hemp research under a DEA Schedule I registration?

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

3. What steps must a researcher take before engaging in research using actual hemp or hemp-derived materials?

Researchers should contact their institutional official before undertaking such research. They can alert you to any issues that may exist. There may be state law requirements such as registration, for example.

4. Can a researcher grow industrial hemp for research purposes?

Yes, but this requires compliance with the state and institutional Pilot Program requirements

5. In order to grow industrial hemp for research purposes, where can viable hemp seed be obtained?

This varies among states, but typically viable hemp seed should be obtained only from the state agency implementing the Pilot Program. See institutional rules, policies, or guidelines.

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

Typically, any plants with THC concentrations exceeding the 0.3% limit must be reported to the state’s department of agriculture, which likely will destroy the crop. However, see the state, agency, and institutional rules, regulations, and policies for specifics.

7. Can researchers use non-institutional subcontractors to grow hemp for research purposes?

Typically, yes, but the subcontractor usually must be registered with the state Industrial Hemp Pilot program. Other requirements may include a federally insured bank account and certification that subcontractor does not work with the marijuana industry.

8. Can researchers obtain hemp products from third parties for research or analytical service purposes?

Contact the institutional official or consult institutional policies. Some interpretations say that 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 the state's Pilot Program. In addition, the third party must be registered with the Pilot Program and its activities must have a research purpose. Other interpretations include, or only allow, processed industrial hemp to be obtained from third parties. All exchange must be compliant with state laws.

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

Generally, yes. Check with institutional policies.

10. Can researchers perform hemp research funded by industry?

Typically, yes, but only if the funder meets state criteria pursuant to the Farm Bill (most institutions do not accept gifts or funding from the Marijuana Industry due to federal regulations and laws, including the Drug Free Schools and Communities Act, Drug Free Work Place Act and the Bank Secrecy Act).

11. Are researchers who perform research on industrial hemp or industrial hemp products 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 it is standard operating procedure for research universities. Industrial hemp and associated materials, other than viable seed at this time, may be provided to the sponsor under most circumstances. Check with the institution and enacting agency for guidelines on raw industrial hemp material transfer regulations.

12. Can institutions license intellectual property rights resulting from industrial hemp research?

Yes, institutions can typically license out intellectual property rights from industrial hemp research.

13. Can a researcher who maintains a DEA Schedule I registration handle industrial hemp materials falling under a state 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. Hemp has been assigned a DEA registration number that should be used by the Schedule 1 holder to report on their activities.

14. Can researchers and/or extension agents provide advice and assistance to non-university hemp growers inside and external to their state?

Researchers and extension agents may provide advice to state farmers cultivating hemp who are registered under the state registration program; however, researchers and agents may NOT assist cultivators of marijuana, or any entity or individual growing hemp outside of that registration program.

15. Can an institution grower obtain viable hemp seed from any source?

In most cases, viable hemp seed should be obtained from the state Pilot program approved source.

16. Can researchers perform market/agronomic studies or literature searches about industrial hemp under an externally funded sponsored project?

Yes. Further, if the researcher is dealing with only data collected and is not engaged in research that deals directly with growing plants, pieces, or parts, compliance with an industrial hemp research Pilot program is generally not needed, but check with state laws to confirm.

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## V. FAQs about the University of Mississippi Program

1. What is the purpose of the marijuana program at the University of Mississippi (UM)?

UM has a contract from the National Institute on Drug Abuse (NIDA) to supply NIDA's Drug Supply Program with cannabis and cannabinoids for use by approved researchers (<https://www.drugabuse.gov/researchers/research-resources/nida-drug-supply-program-dsp/marijuana-plant-material-available-nida-drug-supply-program>). UM collaborates with industrial partners in support of the development and commercialization of FDA-approved pharmaceutical products derived from cannabis. UM's expertise in drug delivery and natural products chemistry is used to develop optimized formulations for evaluation in preclinical models and clinical trials.

2. Why does marijuana grown at the facility look different from marijuana in dispensaries?

Marijuana produced at UM is composed of whole plant material manicured to a uniform particle size because it is required to be standardized in various research protocols.

3. How can researchers request other forms of marijuana?

Researchers should send requests to the project officers of the National Institute on Drug Abuse (NIDA) Drug Supply Program: Robert Walsh, (301) 443-9825, or Rik Kline, (301) 827-5243.

4. How does the University of Mississippi define CBD oil?

For the purpose of the University of Mississippi's R&D program, "CBD oil" is referred to as "CBD extract oral solution." It is prepared from the plant extract, which is formulated for pharmaceutical use, and is suitable for oral administration. The current product version contains 50 mg/ml CBD and not more than 2.5 mg/ml of THC. UM's CBD oil product is prepared from a concentrated extract of Cannabis [CBD-enriched Cannabis extract] with a high ratio of CBD to THC. Note that the term "CBD oil" is used fairly indiscriminately by marketers and users, and may refer either to concentrated oily residues of the plant, or to many derived products with different oils added. These products may vary highly in CBD content, quality, purity and in the content of other cannabinoids.

5. Can UM analyze an external researcher's marijuana samples?

Yes, but only if the researcher maintains a DEA Schedule-I registration that allows transfer of materials between registrants.

## VI. Helpful Resources

21 CFR Part 1308. *Establishment of a New Drug Code for Marijuana Extracts*. Available at:

[https://www.deadiversion.usdoj.gov/fed\\_regs/rules/2016/fr1214.htm](https://www.deadiversion.usdoj.gov/fed_regs/rules/2016/fr1214.htm)

7 U.S.C. § 5940 (2014). Available at: <https://www.congress.gov/bill/113th-congress/house-bill/2642/text>

81 FR 53395. *Statement Of Principles On Industrial Hemp*. Available at

<https://www.federalregister.gov/documents/2016/08/12/2016-19146/statement-of-principles-on-industrial-hemp>.

Benson, B. and O'Rourke, P. Memo to University of Colorado Research Faculty. University of Colorado, Denver, CO. March 11, 2014.

<https://www.colorado.edu/researchinnovation/sites/default/files/attached-files/marijuana-research-memo.pdf>

Colorado State University. *Hemp & Marijuana Research Frequently Asked Questions and Guidelines*. Colorado State University, Fort Collins, Co. <https://source.colostate.edu/wp-content/uploads/2014/11/Hemp-and-Marijuana-Research-FAQs-and-Guidelines-may-2017.pdf>

The University of Mississippi National Center for Natural Products Research, School of Pharmacy. *Marijuana Research: Frequently Asked Questions*. University of Mississippi, University, MS. <http://pharmacy.olemiss.edu/marijuana/>

University of California Research Policy Analysis and Coordination.. *Guidance Memo 17-01: Information for Researchers on the Effect of Proposition 64 on Marijuana Research at the University of California*. University of California, Oakland, CA. <https://researchmemos.ucop.edu/php-app/index.php/site/document?memo=UIBBQy0xNy0wMQ==&doc=3663>

University of California, Davis. *Frequently Asked Questions Regarding Marijuana Research at UC Davis*. UC Davis, Davis, CA. [http://campuscounsel.ucdavis.edu/local\\_resources/docs/FAQ-on-Marijuana-Research.pdf](http://campuscounsel.ucdavis.edu/local_resources/docs/FAQ-on-Marijuana-Research.pdf)

University of Colorado, Boulder. *Guidance Regarding Research Involving Marijuana and Industrial Hemp*. University of Colorado, Boulder, Boulder, CO. [https://www.colorado.edu/researchinnovation/sites/default/files/attached-files/ucb\\_hemp\\_marijuana\\_faqs\\_guidance.pdf](https://www.colorado.edu/researchinnovation/sites/default/files/attached-files/ucb_hemp_marijuana_faqs_guidance.pdf)

Washington State University. *Washington State University Guidance on Cannabis Research, Teaching, and Outreach Activities For WSU faculty, staff, and students involved in research and extension*. Washington State University, Pullman, WA. [https://research.wsu.edu/office-research/policies/cannabis\\_guidance/](https://research.wsu.edu/office-research/policies/cannabis_guidance/)