

**July 24, 2018**

**To:** Vice Chancellors for Research, Research Compliance Advisory Committee Members, Contracts and Grants Directors

**Subject: Updated** Information for Researchers on Conducting Marijuana Research at the University of California

### **Purpose**

The purpose of this memo is to provide information for University of California (UC) researchers and research administrators regarding legal and policy issues related to marijuana research conducted at the UC. This memo updates and expands upon guidance originally issued to address the effect of Proposition 64 (the Marijuana Legalization initiative passed by the voters in November 2016), and describes under what circumstances campuses must consult with the Office of the President's Research Policy Analysis and Coordination (RPAC) office in regards to marijuana research. Please note the legal and regulatory landscape related to marijuana research is a dynamic area. As such, the most current information is available at the following link: <https://www.ucop.edu/research-policy-analysis-coordination/policies-guidance/cannabis/index.html>.

**Please note:** Federal law defines marijuana to include **all parts of the plant Cannabis sativa L.** (except for excluded parts of the plant explained in section II of this Guidance memo). For the purposes of this Guidance memo, the term "marijuana" is intended to refer to all parts of the cannabis plant, as federally defined.

### **Background**

**Federal Law:** The federal [Controlled Substances Act](#) creates a comprehensive federal framework that categorizes controlled substances into five "schedules." "Schedule I" is the most strictly regulated category. Marijuana is categorized as a Schedule I drug by the DEA. This means that federal regulations do not permit the use, production, processing, sale or growth of marijuana, though there are limited exceptions for research. One such exception permits marijuana research conducted under a Schedule I registration from the DEA, and in compliance with all rules applicable to Schedule I research. Under federal rules, only marijuana obtained from a federally-approved source may be used for research (currently, this means marijuana obtained through the National Institute on Drug Abuse (NIDA) , and marijuana research protocols for both clinical and nonclinical research must be reviewed and approved by the federal Food and Drug Administration (FDA)). A second exception allows certain research involving "industrial hemp," a low-THC variety of the Cannabis sativa plant. Information on conducting industrial hemp-related research can be found in section IV of this

Guidance memo.

In addition to the Controlled Substances Act, which has broad applicability, universities (like UC) receiving federal funds are also obligated to comply with the [Safe and Drug-Free Schools and Communities Act](#) and the [Drug-Free Workplace Act](#). These federal laws require UC to implement policies that prohibit the unlawful manufacture, distribution, dispensing, possession, or use of any controlled substance at UC. Failure to comply could put federal funding at risk.

**State Law:** On November 8, 2016, California voters passed Proposition 64, which changed state law to allow adults aged 21 years or older to grow, possess and use marijuana (now generally referred to in state law as “cannabis”) for nonmedical (sometimes referred to as “recreational”) purposes, with certain restrictions. (Possession, cultivation and use of marijuana by patients for the patient’s personal medical use upon recommendation by a licensed physician has been permissible under state law since 1996, pursuant to passage of a previous voter initiative, Proposition 215.)

Proposition 64 created two new taxes, one levied on cultivation and the other on retail sales. Revenue from the taxes will be spent on drug research, treatment, enforcement, and health and safety grants addressing cannabis, youth programs, and prevention of environmental damage resulting from illegal cannabis production.

Once certain prerequisites have been met, Proposition 64 will provide \$12 million per year over 10 years for a total of \$120 million for specified research related to legalized cannabis use. Of the \$12 million, Proposition 64 earmarks \$2 million per year to UCSD’s Center for Medicinal Cannabis Research and directs that \$10 million annually be provided to “a public university or universities in California” (as selected by the Bureau of Cannabis Control, formerly the Bureau of Medical Cannabis Regulation, established under Proposition 64) to research and evaluate the implementation and effect of Proposition 64. The Proposition does not specify the process or mechanism for determining the research to be funded with the \$10 million.

Proposition 64 did not change existing California state rules that require researchers to obtain approval from the Research Advisory Panel of California (RAPC) (within the state Attorney General’s office) before conducting research projects that involve use of marijuana (as with other research that involves Schedule I or Schedule II controlled substances).

## Guidance

### 1. General Guidance on Conducting Marijuana Research

**As noted above,** UC research involving possession, use, distribution or cultivation of marijuana must comply with all applicable University, local, state, and federal policies, statutes and regulations. This applies to any research conducted in the United States under the auspices of the University of California, regardless of whether or not the research is conducted on a UC campus or UC property.

Applicable rules include, but are not limited to the federal Controlled Substances Act, applicable DEA, FDA and NIDA policies and regulations, the University’s Policy on Controlled Substances ([BFB-BUS-50](#)), and California state rules that require researchers to obtain approval

from the Research Advisory Panel of California (within the state Attorney General's office) before conducting research in California that involves use of Schedule I or Schedule II controlled substances (see Health & Safety Code Sections §11480 and §11481 and guidance on [the RAPC website](#)).

In addition, though this Guidance memo pertains only to use of marijuana in University research, it should be noted that the University has also posted "[UC Guidance on Use and Possession of Marijuana on UC Property](#)," which states that marijuana remains prohibited on all University property and at all University events, except for approved academic research. This Guidance memo provides links at the end of the document to some of the resources available regarding applicable policies and laws in this area.

## **2. Requirements for Conducting Marijuana Research**

As defined in the federal Controlled Substances Act (21 U.S.C., Chapter 13, §801 et seq.), the term marijuana (or "marihuana") means: "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."

Marijuana (including "derivatives" of the marijuana plant) is controlled under Schedule I. In addition, DEA separately lists under Schedule I both THC and "Marijuana Extract" (defined by DEA as "an extract containing one or more cannabinoids that has been derived from any plant of the genus Cannabis...").

As has previously been the case, UC researchers wishing to conduct marijuana research must obtain the marijuana through NIDA, submit an investigational new drug (IND) application to the FDA (if there are human research participants involved), obtain FDA approval (for both clinical and nonclinical research) and register with and obtain a Schedule I registration from the DEA to conduct the research. Researchers who wish to conduct research that involves obtaining a Schedule I Controlled Substance like marijuana should consult with their campus Controlled Substances Program Administrator or other responsible officer designated by the campus Chancellor or Lab Director about applying for a DEA registration/license.

UC researchers interested in conducting work with Marijuana Extract, including Cannabidiol (CBD), must obtain a Schedule I registration, or, in cases where the Marijuana Extract is derived from part of the cannabis plant not included in the Controlled Substances definition of "marihuana" contact the campus Controlled Substance Program Administrator before proceeding with research involving substances derived from those parts. Campuses are encouraged to contact UC Office of the President's Research Policy Analysis & Coordination (RPAC) Office, which may seek advice from the Office of General Counsel (OGC) as needed, regarding questions about Marijuana Extracts.

## **3. Allowable Research Not Requiring a Schedule I DEA Registration**

Research about cannabis that does not involve the direct use, possession, distribution, or

cultivation of cannabis in a research procedure does not require a DEA registration or approval by the Research Advisory Panel of California, and is not subject to the additional rules that apply to marijuana research. This can include observational studies, policy research, and environmental impact studies. However, all the usual requisite approvals for research must be obtained (including IRB and/or IACUC review, where applicable, for studies involving human subjects or animals). Examples might include: surveying individuals about their use of, and experiences with, cannabis; analyzing public records of arrests for cannabis use or distribution; studying the effects of interventions for individuals who use, but wish to moderate or discontinue their use of cannabis; and obtaining symptom rating diaries from individuals who, on their own, obtain and use cannabis with the hope of alleviating those symptoms.

As noted above, the Federal Controlled Substances Act excludes from the definition of marijuana certain parts of the *Cannabis sativa L.* plant, such as the mature stalks of the plant, fiber produced from such stalks, and sterilized seeds incapable of germination. Thus, UC faculty, staff and students may legally conduct research involving such substances without a DEA registration but, in light of evolving understandings about “Marijuana Extract” rules, must consult with their campus Controlled Substance Program Administrator before proceeding with research involving substances derived from those parts. Campuses are encouraged to contact RPAC in regards to such research.

Finally, it should be noted that there are some FDA-approved drugs (e.g., Marinol, Syndros) containing a synthetic form of THC (dronabinol) that are regulated as Schedule II or III controlled substances. In addition, on June 25, 2018, FDA approved Epidiolex oral solution for the treatment of seizures associated with two rare and severe forms of epilepsy, Lennox-Gastaut syndrome and Dravet syndrome, in patients two years of age and older. This is the first FDA-approved drug that contains cannabidiol, a purified drug substance derived from marijuana. Given FDA’s approval of Epidiolex, DEA is required to make a scheduling determination. As of the publishing of this Guidance memo, DEA has not issued such a scheduling determination. Researchers who have questions about the DEA scheduling status of a substance they wish to obtain for research should consult with their campus Controlled Substance Program Administrator.

#### **4. Industrial Hemp-Related Research**

The plant material known as “industrial hemp” is derived from the same *Cannabis sativa L.* plant as psychoactive marijuana, but unlike psychoactive marijuana, industrial hemp has traditionally been used for manufacturing purposes rather than for psychoactive or therapeutic effects.

Because the federal Controlled Substances Act definition of marijuana applies to the plant *Cannabis sativa L.*, and because industrial hemp comes from that same plant, industrial hemp is included in the CSA definition of marijuana.

However, the Agricultural Act of 2014 (commonly known as the “Farm Bill”) contained a section (“Legitimacy of Industrial Hemp Research,” Section 7606) that amended federal law (Title 7, U.S. Code, Section 5940) to allow institutions of higher education and state departments of agriculture to grow and cultivate industrial hemp “for purposes of research conducted under an agricultural pilot program or other agricultural or academic research” in states where that is permissible (which includes California), **notwithstanding** the Controlled

Substances Act, the Safe and Drug-Free Schools and Communities Act or other Federal law.

“Industrial hemp” is defined in 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.”

While a Schedule I DEA registration appears not to be necessary for an institution of higher education or a state department of agriculture to cultivate industrial hemp for research purposes under the Farm Bill, the Farm Bill did not alter the existing federal requirement to obtain a federal DEA import registration in order to import non-sterilized hemp seeds or plants from abroad for use in research.

Importing from abroad, under a DEA import registration, is a clearly permissible avenue for obtaining viable industrial hemp seed and cultivars for use in industrial hemp cultivation conducted pursuant to the Farm Bill. Federal guidance has been less clear about the extent to which it is permissible to obtain such material domestically – there is [federal guidance](#) suggesting that interstate transport of such materials is not permitted. UC researchers who wish to obtain industrial hemp seed or cultivars for use in research should do so under a DEA import registration, or must contact UCOP’s RPAC office to discuss whether other options may be available.

California state law allows cultivation of industrial hemp (see Health & Safety Code 11018.5, and Food and Agricultural Code 81000 et seq., both amended by Prop 64) and provides for registration of commercial growers in the state. An “established agricultural research institution,” including an institution of higher education, is exempt from state registration requirements, and may grow industrial hemp without authorization from the state.

As of the publication of this Guidance memo, the California Department of Food and Agriculture had not established a state research “pilot program,” as permitted by the federal Farm Bill. Therefore, the only entities in California currently authorized under the federal Farm Bill to cultivate industrial hemp for research are institutions of higher education.

Any researcher who wishes to pursue research that involves cultivation of industrial hemp should, prior to commencement of any such research, consult with their campus Controlled Substance Program Administrator to ascertain whether and how their protocol may be subject to the Federal Controlled Substances Act (including DEA import requirements), the University’s Policy on Controlled Substances (BFB-BUS-50), or other UC policies.

## **5. Research Funding**

UC researchers may wish to pursue funding opportunities related to cannabis research. For funding opportunities with extramural sponsors, the campus Contracts & Grants Office (C&G) or Sponsored Projects Offices (SPO) are authorized to submit or negotiate proposals to external sponsors for possible contracts, grants or cooperative agreements. The C&G/SPO ensures that each proposal meets the requirements of the University, sponsor and applicable federal and state rules and regulations. For gift funding, researchers should work with campus external relations and development offices.

In addition to the standard issues that may arise for any funded research (e.g., intellectual property rights), the following issues should be considered and addressed before applying for or accepting cannabis-related funding:

- a. **Research activities.** Under the federal Safe and Drug-Free Schools and Communities Act and Drug-Free Workplace 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. As such, research with marijuana must comply with the guidelines and procedures described in this Guidance memo.
- b. **Source of funding.** Potential sponsors of cannabis-related research may include federal or state agencies, non-profit organizations, industry and private individuals. **Before applying for and before accepting non-governmental research funding, whether through a grant or a gift, that comes from individuals or entities (e.g., companies, associations) whose funding is known to be directly derived from cannabis activities that appear to fall outside of what is permitted under federal law (for example, from the sale of cannabis by growers legally licensed in the state of California) researchers must consult with their campus C&G/SPO or external relations/development office, who in turn must contact the UCOP's RPAC office, which may seek advice from OGC as needed.** In evaluating requests to accept funding from such sources, a significant consideration is risk associated with potential federal criminal and civil enforcement.

## 6. Working with the Cannabis Industry

- a. **University Work:** Because some parts of the cannabis industry are engaged in activities (e.g., sale, cultivation, distribution) that are criminally prohibited under federal law, there are concerns about conducting transactions, including unfunded collaborations, with this industry. As such, before conducting work for or with cannabis entities, campuses must consult with the UCOP's RPAC office, which may seek advice from the OGC as needed. For activities such as agricultural cooperative extension or advising for cannabis producers, contact [UC ANR Risk and Safety Services](#).
- b. **Outside Work:** UC faculty and staff may be asked, or may seek opportunities, to engage in paid outside research or other work for the marijuana industry, in a private consulting capacity. Examples might include: business consulting, analyzing data, agricultural research/advice on how to improve cannabis cultivation. Paid outside work related to marijuana must comply with standard UC policies and procedures governing these activities including but not limited to:
  - [APM 025](#)
  - [APM 670](#)
  - [APM 671](#)
  - [Regents Standing Order 103.1\(b\)](#)
  - UC Contracts & Grants Manual [Chapter 1-800: Conflict of Interest | UCOP](#); [Chapter 2-600: Award Acceptance and Administration | UCOP](#); and [Chapter 7-200: Types of Allowable Costs | UCOP](#)

Some of these outside work activities, though legal under California state law, may not be allowable under federal law (or not allowable without a Schedule I DEA registration) and fulfillment of other federal requirements. In such circumstances, UC faculty and staff should be aware that they are assuming the same risks as any other California state private citizen who chooses to engage in such activities. Also, because of UC's obligation to comply with federal laws, UC faculty and staff engaging in activities which are not allowed under federal law should make no use of UC resources (not even the usually permissible *de minimis* or incidental and occasional personal use of UC resources). Finally, UC faculty and staff should make it clear to all parties that they are conducting such activities as private citizens, not as UC faculty or staff. Though they may identify themselves as holding a UC position, there should be clear and consistent statements such as:

"This work was performed as a private individual, not as a UC faculty member. No UC resources, facilities, or funds were used. No UC employees or students participated in this research in their roles as a UC employee or student."

## **7. Growing/Manufacturing Marijuana for Research**

On August 12, 2016, the DEA announced (via publication of a [Federal Register notice](#)) a policy to expand the number of institutions licensed under the Controlled Substances Act to grow/manufacture marijuana for research determined by the Department of Health and Human Services to be scientifically meritorious. The DEA stated that its intent was to provide researchers with a more varied and robust supply of marijuana for research. At present, only one entity is authorized to produce marijuana to supply to researchers in the United States - the University of Mississippi - operating under a contract with NIDA. The DEA's new policy will allow additional entities to apply to become registered with the DEA so that they may grow and distribute marijuana to researchers for legitimate research purposes. However, as of the date of the issuance of this Guidance memo, DEA has yet to approve any of the applications it has received in response to its 2016 policy announcement.

## **8. Other UC Policies and Guidance on Cannabis Related Activities**

- [UC Policy Against Substance Abuse](#)
- [UC Smoke and Tobacco Free Policy](#)
- [BFB-BUS-50: Controlled Substances](#)
- [UC Guidance on Use and Possession of Marijuana on UC Property](#)

## **9. Other References and Resources**

- [Controlled Substances Act \(21 U.S.C., Chapter 13, §801 et seq.\)](#) and related regulations ([21 C.F.R. § 1300](#) et seq.)
- California Health & Safety Code §§ [11213](#), [11480](#), [11481](#)
- [Establishment of a New Drug Code for Marijuana Extract \(21 CFR Part 1308\)](#)
- [DEA Clarification of the New Drug Code \(7350\) for Marijuana Extract](#)

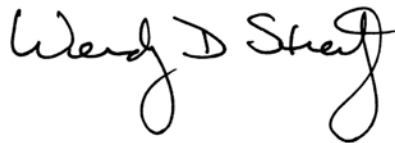
- ["Legitimacy of Industrial Hemp Research" \(7 U.S.C., Section 5940\)](#) and [Statement of Principles on Industrial Hemp \(81 FR 53395\)](#)
- [DEA Internal Directive Regarding the Presence of Cannabinoids in Products and Materials Made from the Cannabis Plant](#)
- [COGR FAQs](#)

## Contact

Contact Research Policy Analysis & Coordination if you have questions about the guidance provided above or about specific marijuana-related research at UC. Contact the Office of General Counsel if you need legal advice. Points of contact in each of those offices are listed below.

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