

Information for Researchers on the Effect of Proposition 64 on Marijuana Research at the University of California

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Summary

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 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, and enforcement, health and safety grants addressing marijuana, youth programs, and prevention of environmental damage resulting from illegal marijuana production.

Proposition 64 will provide \$12 million per year over 10 years, (from FY 2018-19 to FY 2028-29) for a total of \$120 million for specified research related to legalized marijuana use. Of the \$12 million, Proposition 64 earmarks \$2 million per year from a tax 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 Marijuana 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.

It is important to understand that, notwithstanding Proposition 64 (and Proposition 215 before it), cultivation, possession, distribution or use of marijuana for recreational or medical purpose remains illegal under Federal law, with limited exceptions (including an exception that permits certain research conducted in compliance with applicable regulations and policies of the federal Drug Enforcement Agency (DEA), Food and Drug Administration (FDA) and National Institute on Drug Abuse (NIDA)). University of California (UC) research remains subject to the same federal rules and regulations as before the passage of Proposition 64. There is no provision for the legal use of marijuana for research at UC except as already established and in compliance with DEA, FDA and NIDA policies 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.

In addition, though this document 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,” (available here: <http://www.ucop.edu/marijuana-and-drug-policy/>) which states that marijuana remains prohibited on all University property and at all University events, except for approved academic research. This guidance document provides links to some of the resources available regarding applicable policies and laws in this area.

Introduction

The passage of Proposition 64 in 2016 amended California state law to permit the use, sale, processing and production of marijuana for nonmedical purposes in addition to already-permitted medical uses. An increasing number of states have legalized marijuana for medical and/or recreational use. Consequently, we anticipate there will be expanded interest in, and opportunity for, marijuana research. UC's role as the research arm of the State and our research community's expertise in diverse fields makes UC a likely location for such research.

Definition of Marijuana Research

For the purposes of this informational document, 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) for which a researcher does not grow, produce, procure, possess, distribute, or administer marijuana. 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."

Background

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, except for medical or research use conducted under special licensing requirements established by the DEA, usually involving NIDA as the source of the marijuana and FDA for approval for use of marijuana with humans. While the current U.S. Department of Justice (DOJ) has indicated that it will not focus its prosecutorial resources on the sale or use of medical marijuana in states where a well-regulated legal framework has been established, no exemption from the federal law has been granted to any state. There will be a new federal administration in place beginning in 2017, and its prosecutorial focus with regard to marijuana laws is unknown.

Significantly, UC is the recipient of considerable federal funding for research, education, capital projects and healthcare. Accepting this funding obligates UC to comply with the federal [Safe and Drug-Free Schools and Communities Act](#) and the [Drug-Free Workplace Act](#). These federal laws together prohibit the unlawful manufacture, distribution, dispensing, possession, or use of any controlled substance at UC. Unlike DOJ's stance on enforcement of DEA regulations, there has been no statement from the

current or incoming federal administrations suggesting that enforcement of the Drug-Free Schools or the Drug-Free Workplace Acts will be relaxed.

Consequently, despite California's decriminalization of marijuana under state law, there is as yet no provision for the legal use of marijuana in research at UC except as already established and involving compliance with DEA, FDA, and NIDA policies and regulations. This prohibition extends to any research conducted under the auspices of UC, regardless of whether or not the research is conducted on a UC campus or property.

Basic Guidance

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), and register with and obtain a license 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 Officer or other responsible officer designated by the campus Chancellor or Lab Director about applying for a DEA registration/license.

Researchers must abide by all applicable University, local, state, and federal policies, statutes and regulations, including but not limited to the federal Controlled Substances Act, the University's Policy on Controlled Substances ([BFB-BUS-50](#)), and California law (Health & Safety Code Sections §11480 and §11481) that requires that certain studies involving Schedule I and II Controlled Substances be submitted to and approved by the Research Advisory Panel of California. Principal Investigators must follow the guidance on the state's Research Advisory Panel website (<http://ag.ca.gov/research/index.php>).

It should be noted that research about marijuana that does not involve the direct use of marijuana in a research procedure is allowed, provided all the usual requisite approvals for research have been 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, marijuana; analyzing public records of arrests for marijuana use or distribution; studying the effects of interventions for individuals who use, but wish to moderate or discontinue their use of marijuana; and obtaining symptom rating diaries from individuals who, on their own, obtain and use marijuana with the hope of alleviating those symptoms.

Allowable Research Not Requiring a DEA License

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 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." For example, a DEA

license would not be required in order to receive extracted DNA samples of cannabis plants for the purpose of analyses such as genetic sequencing or other genomic research.

Outside Work

UC faculty and staff may be asked, or may seek opportunities, to engage in paid outside research or other work related to marijuana, in a private consulting capacity. Examples might include: consulting, analyzing data, research on cultivation methods, and assessing the impact of marijuana use on medical symptoms. 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 without a Schedule I DEA license 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."

Research Funding

UC researchers may wish to pursue funding opportunities related to marijuana. 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 marijuana-related funding:

1. *Source of funding.* Potential sponsors of marijuana-related research may include federal or state agencies, non-profit organizations, industry and private individuals. Before applying for and before accepting research funding that comes directly from individuals or entities (e.g., companies, associations) whose funding is derived from the marijuana industry (for example, from a professional association of marijuana growers legally licensed in the state of California) campuses must contact the UC Office of the President's Research and Graduate Studies Office, which may seek advice from the Office of General Counsel as needed. 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.

2. *Research activities.* Research with marijuana must comply with the guidelines and procedures described in this informational document
3. *Mechanism of Funding.* The UC campus Sponsored Projects offices (SPO) are the only UC campus entities authorized to submit or negotiate proposals to external sponsors for possible contracts, grants or cooperative agreements. The SPO will ensure that each proposal meets the requirements of the University, sponsor and applicable federal and state rules and regulations. Funders who prefer to use the gift mechanism work with UC campus external relations and development offices. Researchers interested in marijuana research funding are strongly encouraged to use the SPO mechanism rather than a gift mechanism, even for funding that would otherwise meet the criteria for being handled as a gift.

Industrial Hemp-Related Research

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

While the federal Controlled Substances Act does not distinguish industrial hemp from marijuana, the Agricultural Act of 2014 (commonly known as the “Farm Bill”) contains a section {“Legitimacy of Industrial Hemp Research”, Section 7606} that allows institutions of higher education and state departments of agriculture to grow and cultivate non-psychoactive 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.” Any such research would need to be conducted in compliance with applicable State regulations and registration requirements.

The Farm Bill did not alter the existing federal requirement to obtain a federal DEA license in order to import non-sterilized seeds or marijuana plants for use in research.

California state law permits cultivation of industrial hemp (see Health & Safety Code 11018.5, and Food and Agricultural Code 81000 et seq., both amended by Prop 64) and specifies that cultivation, possession, use, and distribution are to be regulated by the Department of Food and Agriculture. However, as of yet, the state Department of Food and Agriculture has not implemented regulations governing registration of hemp crops, and there may be other issues associated with conducting this research that will require a UC protocol to be in place prior to any cultivation of industrial hemp. Thus, any researcher who wishes to pursue research that involves cultivation of industrial hemp should, prior to commencement of any such research, first consult with their campus Controlled Substance Program

Officer to ascertain whether and how their protocol may be subject to the Federal Controlled Substances Act, the University's Policy on Controlled Substances (BFB-BUS-50), or other UC policies.

Growing/Manufacturing Marijuana for Research

On August 12, 2016, the DEA announced (via publication of a Federal Register Notice, available here: (<https://www.gpo.gov/fdsys/pkg/FR-2016-08-12/pdf/2016-17955.pdf>) 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. UC is in the very early information-gathering stages regarding its potential interest and capacity for operating under such a license. It is unclear whether the DEA's policy to expand the number of institutions licensed to grow/manufacture marijuana for medical research will change under the incoming federal administration.

Conclusion

Marijuana research at UC is still subject to the same federal rules and regulations as before the passage of Proposition 64. However, the legal landscape is rapidly changing. This informational document will be revised as needed to include any future changes and to address additional specific issues. The University recognizes and wishes to facilitate the desire of its faculty to conduct marijuana research that has significant scientific merit and/or public health value.

Contact

Contact the UC Research & Graduate Studies office if you have questions about the information 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. Information regarding non-research issues related to the enactment of Proposition 64 will be addressed in separate communications from offices other than Research & Graduate Studies.

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