

To: University of Washington Faculty, Staff, and Students Involved in Research

From: Mary Lidstrom, PhD  
Vice Provost for Research



Date: October 1, 2014

Re: Guidance for Researchers at the University of Washington Concerning Marijuana Research

### **Summary**

Despite Washington State's legalization of marijuana, UW marijuana research is still subject to the same federal rules and regulations as before the passage of Washington State initiative No. 502. There is as yet no provision for the legal use of marijuana in research at UW except as already established and involving compliance with DEA, FDA, and NIDA policies and regulations. This applies to any research conducted under the auspices of the University of Washington, regardless of whether or not the research is conducted on the UW campus.

### **Introduction**

The passage of Initiative Measure No. 502 in 2012 amended Washington State law to permit the use, sale, processing, and production of marijuana for recreational purposes in addition to already-permitted medical uses. Colorado also recently legalized the recreational use of marijuana and a majority of states have legalized its medical use. Consequently, it is anticipated that there will be expanded interest in, and opportunity for, marijuana research. The University of Washington (UW) is a world-class research institution whose robust research community and expertise in diverse areas make it a likely location for such research.

The purpose of this guidance is to inform the UW research community of the University's current position on marijuana research and the conditions under which marijuana research may be conducted. There appears to be disagreement within and between federal agencies about marijuana, which means that there are some issues for which the applicable laws and procedures are not yet clear. This guidance will be updated as laws and policies develop.

### **Definition of Marijuana Research**

For the purposes of this Guidance, marijuana research is defined as research that involves the growth, production, procurement, administration, or use of marijuana. It does not refer to observational research for which the researcher does not grow, produce, procure, or administer marijuana. The term "marijuana" refers to *Cannabis spp*, tetrahydrocannabinol, and any cannabis derivatives or cannabimimetic agents that have been classified by the U.S. Congress as a Schedule 1 drug in the Controlled Substances Act.

## **Background**

Marijuana is categorized as a Schedule I drug by the DEA under the federal Controlled Substances Act. 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 and also usually involving the National Institute of Drug Abuse (NIDA) as the source of the marijuana and the U.S. Food and Drug Administration (FDA) for use with humans. While the U.S. Department of Justice (DoJ) has indicated that it will not focus its prosecutorial resources on the sale or use of marijuana in states where a well-regulated legal framework has been established, no exemption from the federal regulations has been granted to any state.

In addition, the UW is the recipient of considerable federal funding for research, education, capital projects, and healthcare. Accepting this funding obligates the University to comply with the Drug-Free Schools and Communities Act and the Drug-Free Workplace Act. These federal regulations together prohibit the unlawful manufacture, distribution, dispensing, possession, or use of any controlled substance at the University. Unlike the DoJ's stance on enforcement of DEA regulations, there has been no statement suggesting that enforcement of the Drug-Free Schools and Communities Act or the Drug-Free Workplace Act has been, or will be, relaxed.

Consequently, despite Washington State's legalization of marijuana, there is as yet no provision for the legal use of marijuana in research at UW 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 the University of Washington, regardless of whether or not the research is conducted on the UW campus.

## **Basic Guidance**

As has been the case since the 1990s, UW researchers wishing to conduct marijuana research must obtain the marijuana through NIDA, submit an investigational new drug application to the FDA (if using marijuana with human research participants), and register and obtain a site license from the DEA to conduct the research.

In addition, researchers must abide by all applicable University, local, state, and federal policies, statutes and regulations.

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 of the usual requisite approvals for the research are obtained. 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; or 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 Schedule 1 License**

UW faculty, staff, and students may legally conduct marijuana research without a Schedule 1 license when the marijuana exists in the form of industrial products, processed plant materials, and animal feed mixtures made from certain portions of the cannabis plant, to the extent that such products and plant materials contain THC but are not used, or intended, to cause THC to enter the human body. The portions of the cannabis plant that are legal in these circumstances include all portions except: the flower tops (buds), the leaves, the resin of the plant, and the non-sterilized seeds.

For example, a Schedule 1 license would not be required in order to receive extracted DNA samples from cannabis plants for the purpose of analyses such as genetic sequencing or other genomic research.

### **Outside Work**

It is likely that University faculty and staff will be asked, or will seek opportunities, to engage in paid outside research or other work related to marijuana. Examples might include: consulting; analyzing data; research on cultivation methods; or assessing the impact of marijuana use on medical symptoms. Paid outside work related to marijuana must comply with standard University policies and procedures governing these activities:

- Executive Order No. 57 “Outside Professional Work Policy”;
- Administrative Policy Statement 47.3 “Outside Consulting Activities and Part-Time Employment by Professional or Classified Staff Employees”; and
- (for UW Medicine or School of Medicine) UW School of Medicine Policy on Potential Financial Conflicts of Interest for Commercial and Non-Profit Entities.

Some of these activities, although legal under Washington State law, may not be allowable under federal law without a Schedule 1 DEA license and fulfillment of other federal requirements. In such circumstances, University faculty and staff should be aware that they are assuming the same risks as any Washington State private citizen who chooses to engage in such activities. Also, because of the University’s obligation to comply with federal laws, University faculty and staff engaging in activities which are not allowed under federal law should make no use of UW resources (not even the usual allowable *de minimis* use described in APS 47.2, “Personal Use of University Facilities, Computers, and Equipment by University Employees”). Finally, they should make it clear to all parties that they are conducting such activities as private citizens, not University faculty or staff. Though they may identify themselves as having a University position, there should be clear and consistent statements such as: “This work was performed as a private individual, not as a University of Washington faculty member. No UW resources, facilities, or funds were used. No University employees or students participated in this research in their roles as a University employee or student.”

### **Research Funding**

UW researchers may wish to pursue funding opportunities related to marijuana. In addition to the standard issues that may arise for any funding (e.g., intellectual property rights), the following issues should be considered and addressed before applying for 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. Whether researchers may accept funding that comes directly from the marijuana industry (for example, from a professional association of growers legally licensed in Washington State) is a difficult question that should be addressed with the Office of Research before applying for or accepting the funding.

2. *Research activities.* Research with marijuana should comply with the guidelines and procedures described in this Guidance.

3. *Mechanism of funding.* The UW Office of Sponsored Programs (OSP) is the only UW office authorized to submit or negotiate proposals to external sponsors for possible grants, contracts, or cooperative agreements. OSP ensures 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 the UW Foundation (the UW's 501(c)(3) entity) in compliance with UW policy GIM 34 "Guidelines for Classification of Sponsored Projects and Gifts" about classifying external support as either a sponsored project or a gift. Researchers interested in marijuana research funding are strongly encouraged to use the OSP 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**

At this time, the only approved framework for conducting industrial hemp-related research at the UW is the same as for marijuana research. Specifically, the researcher must obtain a Schedule 1 license from the DEA and obtain the hemp seeds or plants from a federally-approved source.

The federal Farm Bill of 2013 contains a section ("Legitimacy of Industrial Hemp Research", Section 7606) that allows growth or cultivation of industrial hemp "for purposes of research conducted under an agricultural pilot program or other agricultural or academic research". However, it requires that the state in which the research will occur must have state laws permitting industrial hemp growth or cultivation, and it requires that sites must be certified by, and registered with, the state's department of agriculture.

None of the laws recently introduced to the Washington State legislature to legalize industrial hemp for research and/or commercial uses have been passed by both the Washington State House and Senate. The Washington State Department of Agriculture maintains that research on industrial hemp is not currently allowed in Washington State without a Schedule 1 license.

### **Conclusion**

UW marijuana research is still subject to the same federal rules and regulations as before the passage of Washington State Initiative Measure No. 502. However, the legal landscape is rapidly changing. This guidance 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. Therefore, the University is working with other institutions to request more regulatory clarity from the federal government.

**Contact**

Contact the Office of Research at [research@uw.edu](mailto:research@uw.edu) or 206-616-0804 if you have questions about this Guidance or about specific marijuana-related research at the UW.