OR/ORSO Guideline 15

Cannabis Research, Teaching, and Outreach Activities

WASHINGTON STATE UNIVERSITY

The Office of Research

Office of Research Support and Operations

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Background

2012: (Marijuana) Washington State Legislature passed Initiative 502 (I-502) legalizing the production, distribution, and consumption of recreational marijuana.

2015: (Marijuana) The Legislature approved Senate Bill SB5121, creating "a marijuana research license that permits a licensee to produce and possess marijuana for limited research purposes."

(Industrial hemp) The Legislature reviewed House Bill HB1552 and Senate Bill SB5012, which would have allowed industrial hemp to be grown, produced, possessed, and commercially traded in the state. These bills did not pass.

2016: (Marijuana) The Washington State Legislature overrode the Governor's veto of Senate Bill SB6177, which modifies marijuana research license provisions. The Liquor and Cannabis Board (LCB) is assigned the lead role of reviewing projects submitted by marijuana research license applicants.

(Industrial hemp) The Washington State Legislature overrode the Governor's veto of Senate Bill SB6206, which establishes the licensed "growing of industrial hemp as a legal, agricultural activity" in conformance with the federal agricultural act of 2014.

2018: (Hemp) The 2018 Farm Bill (Agriculture Improvement Act of 2018) defined hemp (vs. Industrial hemp) as cannabis plant material with nor more than .3% delta-9 THC on a dry weight basis, and includes "all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers."
Hemp (as defined above) was descheduled from the definition of marihuana in the CSA and from DEA oversight, and restrictions were eased regarding interstate commerce.

2019: (Hemp) State Senate Bill 5276 authorized and established a licensing and regulatory program for hemp production in the State of Washington in accordance with the Agriculture Improvement Act of 2018. This bill placed the hemp program under the jurisdiction of the Washington State Department of Agriculture ("Hemp Program") and established the regulatory framework necessary for hemp production within the State

of Washington.

2021-2022: HB 1210
https://app.leg.wa.gov/billsummary?year=2022&billnumber=1210&initiative=false

Replaced the term "marijuana" with the term "cannabis" throughout the Revised Code of Washington.

Because hemp is also a form of the same species (*Cannabis sativa* L.) and could legitimately be called "cannabis", this document will use "high-THC cannabis" in place of "marijuana" and "hemp" will be used for *C. sativa* fitting the definition of the 2018 Farm Bill in guidance from the CCPRO. When the word "cannabis" is used alone, without the "high-THC" modifier, it is a generic usage meaning any form of the species, either high-THC cannabis or hemp or both.

These legislative actions have prompted requests from external parties and stakeholders asking WSU to: i) develop research programs on production systems for high-THC cannabis and hemp; ii) evaluate market potential and profitability of cannabis production; iii) examine individual and social costs associated with increased recreational high-THC cannabis use; iv) provide production-related information in support of cannabis cultivation; v) facilitate student internship and other academic opportunities in the area of cannabis production; and vi) research the health effects of high-THC cannabis and the efficacy of its use for medical purposes. This guidance document serves to answer questions on the status and limitations of cannabis research, teaching, and outreach activities, including restrictions on student internships, at WSU.

Introduction

Despite Washington's legalization of high-THC cannabis for recreational use, WSU research, teaching, and Extension activities are still subject to the same federal rules and regulations as before the passage of I-502. There is no legal provision for the use of high-THC cannabis in research at WSU, except for research that is in compliance with the U.S. Drug Enforcement Administration (DEA) and the U.S. Food and Drug Administration (FDA) policies and regulations. This federal law applies to WSU and to any research conducted by a WSU researcher in the United States, although there may be some differences in law and policy outside the United States. The inconsistency within and between federal and state agencies regarding the legal use and research with high-THC cannabis means that WSU must also look to federal law to guide policies regarding research on, use of and possession of high-THC cannabis. This guidance will be updated as laws and policies develop. In contrast, hemp (also called industrial hemp) may be the subject of research with few restrictions, except that all such research must be carried out under state (Washington State Department of Agriculture) regulatory compliance, per the federal Agricultural Improvement Act of 2018 and associated Washington State laws passed in response to that federal legislation (see *Hemp-Related Research* section of this Guidance further below).

As a land-grant university, part of WSU's mission is to conduct and disseminate research that

benefits the citizens of Washington State. Legalization of high-THC cannabis has significant implications for public health, the economy, and law enforcement. It is within WSU's mission to engage in research and outreach on issues that have significant public health, legal, and economic impact in our state. The purpose of this document is to inform the WSU community of the University's current status regarding cannabis research and outreach and the conditions under which both may be conducted.

(Industrial) Hemp and the 2018 Farm Bill

Prior to enactment of the 2018 Farm Bill, the federal Controlled Substances Act classified hemp as marijuana. The 2018 Farm Bill, passed by Congress on December 12, 2018 and signed by the President into law on December 20, 2018, amended the federal Controlled Substances Act to exclude hemp from the definition of marijuana. The 2018 Farm Bill also created a pathway toward the legalization of hemp, that required States to devise and submit a regulatory plan to the USDA for approval. Washington State followed this process in 2019, passing state Senate bill 5276, which authorized and established a state hemp program. Under this legal framework, a hemp producer license is now required to grow hemp for any purpose within the state. No provision for a hemp researcher license has been included in any legislation passed to date, so any researcher wishing to work on hemp for research purposes only must still perform that work under a valid hemp producer license.

Thus, the 2018 Farm Bill's decriminalization of hemp reduced WSU's legal peril and increased our ability to engage in hemp research and provide extension services to registered hemp growers. Hemp has now been fully "legalized", although hemp research must still be conducted in compliance with both Washington and Federal law, which includes the 2018 Farm Bill and state bill 5276 from 2019 (see Hemp-Related Research section of this Guidance further below).

Importantly, the Farm Bill did not change the authority of the FDA to regulate products containing high-THC cannabis or compounds derived therefrom. Thus, any component or product derived from high-THC cannabis remains a Schedule 1 controlled substance in the view of the federal government. In contrast, current legal interpretation at both the national and state level have led to the conclusion that as long as the delta-9-THC concentration of any product or component obtained from hemp remains at or below 0.3% (on a dry weight basis, and corrected as needed as described in statute), that product or component or derivative thereof remains "hemp" and is therefore not regulated by the FDA, except as may be changed by future legislation or under any other pertinent regulatory framework. Right now, for example, no product from hemp is viewed as a dietary supplement component or food additive. Only specific pharmaceuticals derived from hemp (e.g., Epidiolex™ used to treat certain seizures) are regulated by the FDA.

This guidance will be updated as laws, rules and policies develop. These policies could change at any time

What is Cannabis?

We use *cannabis* to refer to the plant genus Cannabis and includes both high-THC cannabis (legally often called marijuana/marihuana) and (industrial) hemp produced from Cannabis species including *Cannabis sativa* L. This discussion refers to *marijuana* or high-THC cannabis as that form of the plant that is consumed for either its psychoactive properties and/or its medicinal properties, thus with relatively high concentrations of delta-9-tetrahydrocannabinol (THC) (e.g. greater than 0.3% THC concentration).

What is (industrial) hemp?

This guidance uses the definition of Hemp in 2018 Farm Bill, which defines Hemp as the plant *Cannabis sativa* L. and any part of the plant, whether growing or not, that contains a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis. The 2014 farm bill specifically used the term "industrial hemp" to differentiate it from that form of the plant used for medicinal or recreational use (i.e., high-THC cannabis). However, the 2018 farm bill dropped the "industrial" terminology and refers to it instead as "hemp".

What is Cannabis Research?

For the purposes of this document, cannabis research is defined as research that involves the growth, production, procurement, administration or use of high-THC cannabis and/or hemp. The term "cannabis" includes Cannabis spp., cannabinoid compounds (such as tetrahydrocannabinol and cannabidiol), and any cannabis derivatives or cannabimimetic agents whether they have been classified by the U.S. Congress as controlled substances under the Controlled Substances Act, or meet the definition of hemp and have therefore been excluded from the Controlled Substances Act under the 2018 Farm Bill.

Observational research is defined as research about cannabis and its legalization that does not involve the growth, production, procurement, administration or use of any cannabis product.

Summary of the Status of Cannabis-Related Research Activities at WSU

Washington State University faculty may only conduct research that involves the possession, use, or distribution of high-THC cannabis if such research is in compliance with already established guidelines set forth by federal agencies, including the DEA, NIDA, and FDA. In addition, WSU faculty may only perform research that involves the possession, use, or distribution of hemp if such research is in compliance with already established federal guidelines and state law.

Marijuana (high-THC cannabis) is categorized as a Schedule 1 controlled substance by the DEA under the federal Controlled Substances Act. 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 the FDA for use with humans and animals (See HHSD Notice on 6.23.15. Also NIDA's role in providing marijuana for research for requirements). While the U.S. Department of Justice (DOJ) has indicated 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 and there is no legal restriction on the DOJ

changing its focus at any time.

In addition, WSU is the recipient of considerable federal funding for research, education, outreach, and capital projects. Accepting federal 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.

Allowable Cannabis Research at WSU Requiring a Controlled Substances License

WSU researchers wishing to conduct high-THC cannabis (marijuana) research must register and obtain a controlled substances license for cannabis-related drug codes from the DEA to conduct the research, submit an investigational new drug application to the FDA (if using marijuana with human participants), and obtain the marijuana from a DEA-approved distributor. In addition, researchers must abide by all applicable University, local, state, and federal policies, statutes, and regulations.

Hemp-Related Research

For the purposes of this document, hemp research is defined as research that involves the growth, production, procurement, administration or use of hemp.

The legal framework for conducting hemp-related research has changed dramatically in the past few years. Researchers no longer need to obtain a DEA license to work with hemp or any hemp-derived product. Instead, the only requirements for working with hemp or its products are that 1) the material is verified as hemp and not high-THC cannabis (a certificate of analysis is needed for any hemp-related material that is brought into the university to demonstrate that it contains delta-9-THC levels of 0.3% or less) and 2) any researcher wishing to grow hemp for research purposes must do so under a valid WSDA-granted hemp producer license.

Although the 2018 Farm Bill removed industrial hemp from the controlled substances list, it also made hemp production unlawful if done without a USDA license issued under a USDA plan or a state license from a state with a USDA approved hemp production plan. The USDA Agricultural Marketing Service (AMS) was designated as the lead USDA agency to administer the USDA Hemp Production Program. The USDA first published its interim rule for hemp production and then published in 2021 its final rule, which outlined how regulatory compliance is to be monitored. Washington State has a USDA-approved hemp production program that follows those regulatory compliance rules. Thus, growing hemp under license as part of the Washington State Department of Agriculture's industrial hemp research program is authorized as an agricultural activity.

WSU has obtained permission from WSDA to have a single blanket producer license for all hemp-related research performed on university property. All researchers wishing to grow hemp may have their fields/greenhouses/growth facilities registered under that blanket license. Due to the cost associated with obtaining such as license (currently $1200 per license per year), it is advantageous to be included in this blanket license. Dr. David Gang, current CCPRO Director, is the license holder for this blanket license

and any researcher wishing to grow hemp should contact him to be included in the blanket license. It is certainly possible for researchers to obtain their own producer licenses if they do not wish to be included in the blanket WSU hemp producer license, but they must then follow all procedures outlined by the WSDA on the Hemp Program website (https://agr.wa.gov/departments/agricultural-products/hemp) and pay a separate $1200 fee per year.

Any researcher wishing to work with hemp-derived components or materials from hemp plants grown by other individuals, whether within WSU or without, may do so without any need for any regulatory oversight because hemp is now defined as a legal commodity within the United States. Only its growth and production are regulated. Research involving hemp that is not grown by the researcher could include chemical extracts from hemp plants (e.g., full spectrum cannabinoid extracts, terpene extracts) or flower/bud material, leaves, stems, seeds, etc. (this list is not meant to be exhaustive, but is for illustration purposes only, many activities/forms of the plant material can be utilized now in research activities). The only important factor to remember is that any such material must be hemp and not high-THC cannabis (marijuana), i.e., it must have a delta-9-tetrahydrocannabinol concentration of 0.3% or less on a dry weight basis, per statute. If a WSU researcher receives C. sativa derived material that has delta-9-THC levels of greater than 0.3%, regardless of what their supplier told them, they have received high-THC cannabis (marijuana), which is a controlled substance/Schedule 1 drug. Receiving such material is a felony under federal law (although currently not typically enforced as described above). Thus, it behooves the researcher to make sure that the material sent (and received) is in fact hemp. It is the individual researcher's responsibility to determine this. Should high-THC material be received, the simple solution is to destroy it by autoclaving.

Allowable Cannabis Research at WSU Not Requiring a Controlled Substances License

WSU faculty, staff, and students may legally conduct cannabis research without a controlled substances license when the cannabis 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 controlled substances 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.

Observational Research

Research that does not require DEA license and approval for the use of cannabis is allowable, provided it complies with the Drug-Free Schools and Communities Act and the Drug-Free Workplace Act and, provided all of the usual requisite approvals for the research are obtained. This would include approval by the Institutional Review Board (IRB) if the research qualifies as human subject research. If the research includes use of animals, IACUC approval will be necessary. Examples include: education and prevention research (epidemiological research on prevalence and demographics of marijuana use; prevention research on effective communication strategies for parents, schools, and communities; risk and protective factors for high-THC cannabis use and dependence; effective prevention and harm reduction strategies) and research on societal implications of legalization (effects of legalization and community-level policies on crime, public health, and state economy). Data analysis from cannabis studies is also

allowable. The important factor is that no actual physical cannabis plant material or products derived therefrom are handled by the WSU researcher.

Outreach and Extension Related to Cannabis

Until both federal and state laws concur on the cultivation of high-THC cannabis within Washington, WSU cannot provide diagnostic services, recommendations and/or other information regarding the production, management and/or processing of high-THC cannabis. At this time, WSU personnel, including student interns, will not engage in any outreach or Extension activity that supports high-THC cannabis cultivation, should refrain from being in possession of high-THC cannabis for diagnostic purposes, and should not visit sites for the purpose of providing any information or assistance regarding the cultivation of plants. That said, the opposite is true for hemp plants. All of the activities listed above but that involve legal hemp production are allowable.

Creation and dissemination of outreach materials can provide valuable, research-based information to the citizens of Washington State on, for example, the social, pharmacological, and health effects of high-THC cannabis use by adolescents or communicating with adolescents to prevent its use. Translational information of this type should be peer reviewed before dissemination.

Outside Work

It is likely that University faculty and staff will be asked to engage in paid outside research or other work related to cannabis. Paid outside work related to high-THC cannabis must comply with standard University policies and procedures governing these activities: [BPPM 60.44; Faculty Manual (sections IV. D and IV. E).

Some activities, though legal under Washington State law, may not be allowable under federal law without a controlled substances 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 that do not comply with federal law should make no use of WSU resources for those activities. Doing such could be viewed as being a state ethics violation and could be subject to disciplinary action at the state ethics board level. 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 Washington State University faculty member. No WSU resources, facilities, or funds were used. No University employees or students participated in this research in their roles as a University employee or student.” Researchers with questions about potential research activities that might fit under this paragraph’s context should contact the Office of Research for guidance before engaging in said research.

Researchers should also consult with the Office of Research for guidance before engaging in international collaborations that involve cannabis (whether high-THC cannabis or hemp). Note that WSU investigators conducting cannabis research overseas have to comply with the laws of the corresponding jurisdiction(s).

Research Funding

WSU researchers may wish to pursue funding opportunities related to cannabis. 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 high-THC cannabis-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 high-THC cannabis 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. Some WSU campus' have specific requirements and research officers, and we advise additional consultation with these campus and department specific research officers before undertaking cannabis-related projects. The State of Washington does not currently have either a Hemp Commission (for hemp related research) or a Cannabis Commission (for high-THC cannabis related research), although both are being developed at this time and are likely to be established during the next year's legislative session. Once established, WSU researchers will be able to receive funding from either Commission for research activities that fall under the umbrella of legal activities allowable as described in this position statement.

2. *Research activities.* Research with high-THC cannabis (marijuana) should comply with the advice and procedures described in this position statement.

3. *Mechanism of funding.* The WSU Office of Research Support and Operations (ORSO) is the only WSU office authorized to submit or negotiate proposals to external sponsors for possible grants, contracts, or cooperative agreements on behalf of the University. ORSO 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 WSU Foundation [WSU's 501(c)(3) entity] in compliance with the Office of Research Guideline 4 (*Quick Guide for Processing Private Gifts and Private Grants*). Researchers interested in cannabis research funding are strongly encouraged to use the sponsored project mechanism, as much as possible, rather than a gift mechanism, even for funding that would otherwise meet the criteria for being handled as a gift.

Conclusion

WSU high-THC cannabis research is still subject to the same federal rules and regulations as before the passage of Washington State Initiative I-502. As the legal landscape evolves, however, this guidance will be revised and updated. The situation for hemp research has already changed, making such research now fully legal, and only requiring a producer license and associated regulatory compliance as managed by the Washington State Department of Agriculture. The University recognizes and wishes to facilitate the interest of its faculty to conduct cannabis research that has significant scientific merit and public health and/or agricultural commodity value. The University also recognizes its responsibility to the people of the State of Washington to proactively engage in research and outreach on issues that have significant public health and economic impact in our state.

Contact

For questions related to cannabis research activities, please contact Dan Nordquist, Associate Vice

President for Research, at nordquist@wsu.edu or David Gang, Director, Center for Cannabis Policy, Research and Outreach, at gangd@wsu.edu.

References

- I-502 FAQs - http://www.liq.wa.gov/mj2015/faqs_i-502
- 'High THC Concentration Cannabis Policy: Initial Report'
- For requirements related to obtaining and using cannabis for research, see HHSD Notice on 6.23.15 and NIDA's role in providing marijuana for research.

This document incorporates material from the "Guidance for Researchers at the University of Washington Concerning Marijuana Research" memo (dated 10/1/14) with the permission of Mary Lidstrom, Vice Provost for Research at the University of Washington.