

Oregon State University Guidance on Hemp, Marijuana, and Other Cannabis Research and Outreach Activities

For faculty, staff, and students involved in research and extension

The purpose of this document is to provide Oregon State University researchers and staff with guidance on permissible cannabis research and extension activities. This guidance uses the term *cannabis* to refer to *Cannabis* species that include both marijuana/marihuana and industrial hemp. Please see the “What is Cannabis?” section on pp. 3 for further definitions of marijuana and industrial hemp.

OSU has an existing policy on marijuana and industrial hemp research. OSU's policy, https://policy.oregonstate.edu/UPSM/university_policy_marijuana, states:

Oregon State University policy prohibits faculty from conducting research that involves the possession, use, or distribution of marijuana unless such research is in compliance with already established guidelines set forth by federal agencies, including the Drug Enforcement Administration (DEA), Food and Drug Administration (FDA), and National Institute of Drug Abuse (NIDA).

Oregon State University policy allows faculty and students to perform research on industrial hemp in compliance with established federal guidelines outlined by USDA through the 2014 and 2018 Farm Bills.

This guidance clarifies OSU's existing policy with respect to research and extension activities and identifies which campus authority to consult on questions in this area.

Introduction

The Federal and State legal and regulatory landscape for both marijuana and industrial hemp is complex and continually evolving. Where there is inconsistency between Federal and State laws, Federal law applies.

Since 2015, Oregon Law has allowed certain marijuana-related activities, such as recreational use and possession, as set forth in ORS 475B *et. seq.* and its implementing administrative rules OAR 845-025-1000 *et. seq.* Oregon Law also permits the growth, cultivation and sale of industrial hemp in accordance with ORS 571.300 *et. seq.* and its implementing administrative rules OAR 603-048-0010 *et. seq.*

Marijuana

Despite Oregon's legalization of cannabis, OSU research, teaching, and extension activities are still subject to the same federal laws as before. Marijuana and marijuana extracts are classified as a Schedule I controlled substances under the federal Controlled Substances Act (CSA), and these federal laws continue to criminalize the possession, use, distribution, manufacturing, and cultivation 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.

For the past few years, Congress has passed annual appropriations acts that preclude the U.S. Department of Justice (DOJ) from using federal funds to interfere with state medical marijuana laws and programs, but this could change at any time. Moreover, the U.S. DOJ issued a January 4, 2018 memorandum in which it discontinued its policy of refraining from enforcing the CSA for the sale or use of marijuana.

In addition, OSU 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, which requires the University to adopt and implement a drug prevention program that prevents the unlawful possession, use, or distribution of controlled substances—including cannabis—on university property or as part of any of its activities.

Because the use, possession, distribution, and cultivation of marijuana remains illegal under Federal law, OSU prohibits the use of marijuana in OSU research unless the research is conducted in compliance with DEA and FDA regulations and policies.

Industrial Hemp and the 2018 Farm Bill

Prior to enactment of the 2018 Farm Bill, the federal Controlled Substances Act classified industrial 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 will require States to devise and submit a regulatory plan to the USDA for approval. The USDA, however, has not yet begun to accept State regulatory plans for review, and there are several remaining implementation issues that will require further Federal and State rulemaking or guidance through 2019 or beyond before hemp is fully “legalized.”

Thus, while the 2018 Farm Bill’s decriminalization of hemp will reduce OSU’s legal peril and increase our ability to engage in hemp research and provide extension services to registered industrial hemp growers, hemp has not yet been fully “legalized.” Thus, hemp research must still be conducted in compliance with both Oregon and Federal law, which includes the 2014 and 2018 Farm Bills (see Industrial 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 cannabis, or cannabis–derived compounds, regardless of whether they originated from marijuana or hemp.

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

What is Cannabis?

This guidance uses the term *cannabis* to refer to the plant genus *Cannabis* and includes both marijuana/marihuana and industrial hemp produced from *Cannabis* species including *C. sativa*.

Definition of Marijuana

This guidance uses the definition of *marijuana* in the federal CSA. The CSA defines marijuana and cannabis 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. It

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 and marijuana extracts, including cannabinoid compounds such as delta-9 tetrahydrocannabinol (Δ 9THC) and cannabidiol (CBD), are DEA Schedule I controlled substances. CBD derived from the hemp plant, natural sources other than cannabis (e.g., yeast), or as pure compounds from commercial vendors are also subject to the same regulations. A Schedule I DEA license must be obtained before purchasing or using these substances from a commercial vendor, unless the material is specifically designated as an exempt chemical preparation of a Class I controlled substance (such as solutions sold as analytical standards in solvents).

The FDA issued a statement on October 16, 2019 to address the status of cannabis-derived products including CBD. The FDA requires a cannabis product (hemp-derived or otherwise) that is marketed with a claim of therapeutic benefit, or with any other disease claim, to be approved by the FDA for its intended use before it may be introduced into interstate commerce. Cannabis and cannabis-derived products claiming in their marketing and promotional materials that they're intended for use in the diagnosis, cure, mitigation, treatment, or prevention of diseases are considered new drugs or new animal drugs, and must go through the FDA drug approval process for human or animal use before they are marketed in the U.S.

At present, biomedical researchers can obtain pure cannabinoid compounds, including CBD and THC, from several commercial vendors with a schedule I DEA registration but must obtain research grade marijuana and marijuana products from the National Institute on Drug Abuse (NIDA) through the NIDA Drug Supply Program. The research community will need further guidance from FDA, DEA, and NIDA on authorized sources of research-grade materials.

Definition of Industrial Hemp

This guidance uses the definition of Industrial Hemp in 2018 Farm Bill Act, which defines Industrial Hemp as the plant *Cannabis sativa L.* and any part of the plant, whether growing or not, that contains a delta-9 tetrahydrocannabinol (Δ 9THC) concentration of not more than 0.3 percent on a dry weight basis.

For OSU researchers seeking technical guidance on the definition of industrial hemp or whether the substance that they plan to use constitutes industrial hemp, please contact Dr. Jay Noller, Center Director, Global Hemp Innovation Center, at hemp@oregonstate.edu.

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 marijuana and/or industrial 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 Industrial Hemp and have therefore been excluded from the Controlled Substances Act under the 2018 Farm Bill

Summary of the Status of Marijuana–Related Research

Activities at OSU

Allowable Marijuana Research at OSU Requiring a Controlled Substances License

OSU faculty may only conduct research that involves the possession, use, or distribution of marijuana if such research is in compliance with already established guidelines set forth by federal agencies, including the DEA, FDA, and NIDA.

OSU researchers wishing to conduct marijuana research must:

- Register with the DEA and obtain a Schedule I registration number that allows the handling and conduct of research on cannabis and/or its components, <https://www.deadiversion.usdoj.gov/drugreg/index.html>. Researchers holding a DEA Schedule 1 registration number must also register with the Oregon Board of Pharmacy.
- For clinical drug research in human subjects and animals, apply for an investigational new drug (IND) application to the Center for Drug Evaluation and Research. The Institutional Review Board (IRB) provides researchers pursuing research on human subjects assistance with their protocol. For research related to an animal drug, investigators should seek an investigational new animal drug

(INAD) application with the Center for Veterinary Research. The Institutional Animal Care and Use Committee (IACUC) provides researchers pursuing research with animals assistance with their protocol.

- Obtain research-grade marijuana from a DEA-approved distributor. At present, the University of Mississippi is the National Institute on Drug Abuse's approved source of marijuana for research, but DEA recently granted a license that allowed an institution to obtain research-grade cannabis in a form unavailable from the University of Mississippi from a different source.

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

Allowable Industrial Hemp-Related Research at OSU

For the purposes of this document, *hemp research* is defined as research that involves the growth, production, procurement, administration or use of industrial hemp. The term "cannabis" includes *Cannabis sp.*, cannabinoid compounds (such as delta-9 tetrahydrocannabinol and cannabidiol), and any cannabis derivatives or cannabimimetic agents that have been classified by the U.S. Congress as controlled substances under the Controlled Substances Act.

Although the 2018 Farm Bill removed industrial hemp from the controlled substances list, it also made industrial hemp production unlawful if done without a USDA license issued under a USDA plan or in a state without an USDA approved industrial hemp production plan. The USDA Agricultural Marketing Service (AMS) was designated as the lead USDA agency to administer the new USDA Hemp Production Program. The USDA has published its interim rule for hemp production and is accepting applications from states for review and approval to delegate the regulation of hemp from the USDA to states with approved plans. Until state plans are approved and licenses issued under anticipated AMS regulations, growing industrial hemp remains illegal unless done in compliance with the 2014 Farm Bill section 7606, or with a DEA permit. Until the final USDA rule as specified in the 2018 Farm Bill is published by AMS, researchers should do nothing that exceeds the interpretation of the 2014 Farm Bill Section 7606. In other words, researchers for now must continue to follow the guidance received regarding Section 7606 of the 2014 Farm Bill.

OSU faculty may only perform research that involves the possession, use, or distribution of industrial hemp if such research is in compliance with already established federal laws and regulations, state laws and regulations, and OSU standards and policies. Appropriate

methods for waste disposal of remaining portions of the plant must be in place. Researchers should consult with the Environmental, Health and Safety Office for guidance on proper disposal of hemp. <https://ehs.oregonstate.edu/controlled-substances>.

At this time, there are two potential legal and regulatory frameworks for conducting industrial hemp-related research not involving human subjects at OSU:

The first option is for the researcher to obtain a controlled substances license from the DEA and obtain the hemp seeds or plants from a DEA-approved source. In such cases, the researcher would:

- Register with the DEA and obtain a Schedule I registration number for the possession, use, or distribution of industrial hemp in accordance with the DEA requirements for marijuana. Upon receipt of registration number, register with the Oregon Board of Pharmacy.
- For clinical drug research on animals that will be marketed with a claim of therapeutic benefit, apply for an investigational new drug (IND) application to FDA. <https://www.fda.gov/NewsEvents/PublicHealthFocus/ucm421173.htm>.
- Obtain Institutional Animal Care and Use Committee (IACUC) approval if the research involves animals.

The alternative is for OSU researchers to conduct industrial hemp research under the Federal Farm Bills of 2014 and 2018. The U.S. Farm Bill of 2014 allowed an institution of higher education in a state in which such activities are legalized "...to grow or cultivate industrial hemp for purposes of research conducted under an agricultural pilot program or other agricultural or academic research." For an OSU researcher to grow, cultivate, or conduct research on industrial hemp under the Farm Bill, the research must be conducted for the purpose of agricultural or academic research and activities must take place within the state of Oregon. Growing hemp under the Farm Bill requires registration with the Oregon Department of Agriculture (ODA). Section 7605 of the 2018 Farm Bill re-extends these conditions for conducting hemp research and directs the Department of Agriculture to conduct a study of the economic viability of domestic production and sale of industrial hemp which includes a review of agricultural or academic research relating to industrial hemp and state agricultural pilot programs.

Under Oregon law HB 4089, OSU's Dean of the College of Agricultural Sciences is authorized to establish a program for labelling and certification of agricultural hemp seed. At present, however, there is no U.S. uniform standard for certification of hemp seed. Consequently, a DEA import license may be needed to import certified viable industrial

hemp seeds from abroad. Further Federal and state clarification is needed on what will be required to move viable plant tissue, including seeds, from one state to another. Any seeds received or distributed within OSU must be done so through the Oregon State University Seed Testing Laboratory.

OSU's College of Agriculture's program is currently focused on industrial hemp research for the purposes of production of seeds, biomass, fiber, and other industrial products.

If the research involves animals, IACUC approval is also required, and FDA regulations followed for the disposition of research animals.

Examples of industrial hemp research that may be allowed without a controlled substances license include:

- The use of extracted DNA samples from *Cannabis* plants for the purpose of analyses such as genetic sequencing or other genomic research.
- Fiber research on the mature stalks of *Cannabis*, 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.

Observational Research

Observational research for purpose of this guidance is defined as research about cannabis and its legalization that does not involve the growth, production, procurement, possession, administration, or use of any cannabis product. Research that does not require DEA license and approval for the use of cannabis is generally allowable, provided it complies with the Controlled Substances Act and 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 as research subjects, IACUC approval is required. 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 marijuana 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.

Outreach and Extension Related to Cannabis

Until both federal and state laws concur on the cultivation of cannabis within Oregon, OSU cannot provide instruction on how to grow, manufacture or dispense, provide diagnostic services, make recommendations, and/or give other information regarding the production, management, and/or processing of marijuana. At this time, OSU personnel, including student interns, will not engage in any outreach or Extension activity that supports marijuana production, must refrain from being in possession of marijuana for diagnostic purposes, and must not visit sites for the purpose of providing any information or assistance regarding the cultivation of cannabis plants for marijuana production.

Under the Farm Bills of 2014 and 2018, the OSU Extension Service is permitted to provide information to Oregon farmers cultivating hemp who are registered with the Oregon Department of Agriculture (ODA). Extension Service will provide its policies and procedures related to industrial hemp.

Questions from non-OSU marijuana or hemp growers may be referred to the Oregon Department of Agriculture, Oregon Liquor Control Commission (OLCC), and the Oregon Health Authority (OHA) who regulate other aspects of the marijuana industry and links may be provided to their websites.

A large percentage of Extension Service questions relate to production questions including pesticide use recommendations and safety. Although Federal law prohibits talking about marijuana specifically, OSU personnel can answer general crop questions that are also relevant to non-marijuana crops, such as what types of pesticides are safe to use on plants grown for human consumption, what types of insecticides are effective on a variety of crops for controlling a specific pest, or what type of protective personal gear should be worn when handling pesticides. We can also refer them to the ODA website on 'cannabis and pesticides'.

<https://www.oregon.gov/ODA/programs/Pesticides/Pages/CannabisPesticides.aspx> .” For testing or registration of pesticides, refer them to ODA.

Outside Activities/Consulting

It is likely that University faculty and staff will be asked to engage in outside research or other work related to cannabis. Outside work related to cannabis must comply with standard University policies and procedures governing these activities.

<https://facultyaffairs.oregonstate.edu/faculty-handbook/consulting-overload-and-outside-employment-compensation> . In particular, it is recognized that outside activities are undertaken under an employee's own, individual legal agency, and are therefore outside of the legal and business protections normally afforded to employees that protect the employee in the course of performing on-campus activities.

Some activities, though legal under Oregon 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 Oregon 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 cannot make use of any OSU resources for those activities. Finally, they must make it clear to all parties that they are conducting such activities as private individuals, not as University faculty or staff. Although employees 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, and not as an Oregon State University faculty member; No OSU 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 should consult with the Research Office for guidance before engaging in international collaborations that involve cannabis. Note that OSU investigators conducting cannabis research overseas have to comply with the laws of those corresponding jurisdiction(s).

Research Funding

OSU researchers may pursue funding opportunities related to cannabis. In addition to the standard issues that may arise for any funding, the following issues should be considered and addressed before applying for cannabis related funding.

1. *Source of funding.* Potential sponsors of cannabis-related research may include federal or state agencies, non-profit organizations, industry, and private individuals.

OSU researchers should be aware there is potential criminal liability exposure for both the researcher and OSU if OSU researchers accept funding or gifts in kind (that include donated marijuana product) directly from the marijuana industry. Although funding from the hemp industry is permissible with approval, OSU should not accept money with knowledge that the funds are derived from the sale of marijuana. This is because the Controlled Substances Act's definition of conspiracy includes persons who are in the business of cultivating, selling or distributing marijuana, and those that knowingly facilitate such activities regardless of State law.

To avoid potential criminal liability exposure for both OSU and the researcher, researchers may not accept funding or gifts that come directly from the marijuana industry (for example, a professional association of marijuana growers legally licensed in Oregon State or a member of the marijuana industry).

Private funding of cannabis research is a difficult question that should be addressed with the Research Office (RO) before applying for or accepting the funding. The Research Office will evaluate these and other difficult questions on a case-by-case basis, taking into account the research benefits, legal risks to the university and researcher, university reputational issues, and other relevant factors. The Research Office shall consult, as appropriate, with the interested colleges or departments, the College of Agriculture, Faculty Affairs, Office of General Counsel, Office of Government Relations, and Audit Services and Compliance. The RO will also consult with the Provost or President as appropriate on proposed actions that pose a high risk.

2. *Research activities.* Research with cannabis must comply with the advice and procedures described in this guidance.

3. *Mechanism of funding.* The OSU Research Office's Office for Sponsored Research and Award Administration (OSRAA) ensures that each proposal meets the requirements of the University, sponsor, and applicable federal and state rules and regulations. In addition, the Office for Commercialization and Corporate Development (OCCD) negotiates sponsored research agreements partnering with industry.

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. Gift awards must be reviewed and approved by the Research Office the same as with sponsored research mechanisms.

Conclusion

OSU cannabis research is still subject to all applicable federal rules and regulations as it was before the passage of Oregon law. As the legal landscape evolves, however, this guidance will be revised and updated. 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 and help ensure compliance with all laws and regulations.

Contact

For questions related to cannabis research activities, please contact Staci Simonich, Associate Vice President for Research Operations and Integrity, staci.simonich@oregonstate.edu.