Cannabis

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This guidance memo is intended to provide information to Southern Illinois University (SIU) researchers, research administrators, faculty, staff and students regarding legal and policy issues related to research and funding involving cannabis, specifically marijuana.¹

The legal and regulatory landscape relating to research and funding involving cannabis (both industrial hemp and marijuana) is complex. While many states, including Illinois, are legalizing the use of marijuana for medical and recreational purposes, marijuana is still illegal under federal law.

I. Legal Landscape
   A. Federal Law

      The federal Controlled Substance Act (21 U.S.C., Chapter 13, §801, et seq.) defines marijuana (‘marihuana’) as "all parts of the plant Cannabis sativa L., whether growing or not; including 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."²

      The Drug Enforcement Agency (DEA) maintains a Schedule I classification for marijuana, classifying it as a drug with “no currently accepted medical use” in the United States, along with drugs like heroin and ecstasy. As a Schedule I Controlled Substance, the use, possession, distribution, and cultivation of marijuana is illegal under the federal Controlled Substances Act, with limited exceptions (including exceptions that allow

¹ Separate guidance relating to research involving industrial hemp was issued in December 2021.

² The Farm Bill of December 2018 amended the Federal Controlled Substances Act to specifically exclude hemp and hemp derivatives from the definition of marijuana, so hemp plants (often labeled “industrial hemp”) are legal and can be used for research so long as the Delta-9 Tetrahydrocannabinol (THC) concentration does not exceed 0.3% by dry weight. The August 21, 2020 DEA Interim Final Rule allows for research without a Schedule I license if the end product of the plant being researched has less than 0.3% THC. More information on industrial hemp is available in the guidance issued in December 2021.

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certain research that complies with strict federal controls). The Department of Justice (DOJ)/DEA has authority to enforce the Controlled Substances Act, including through civil and criminal penalties.

The FDA also regulates research involving cannabis. The FDA considers cannabis containing more than 0.3% THC to be a regulated drug, and thus requires an individual or an organization wishing to conduct research on cannabis to submit a New Drug Application (NDA) proposing an Investigational New Drug (IND) to the FDA’s Center for Drug Evaluation and Research (CDER), just as any other potential drug research would require.

In addition, universities (like SIU) 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 SIU to implement policies that prohibit the unlawful manufacture, distribution, dispensing, possession, or use of any controlled substance at SIU. Failure to comply could put federal funding at risk.

B. State Law

On January 1, 2020, the Cannabis Regulation and Tax Act became effective in Illinois. The Act changed state law to allow adults aged 21 years or older to possess and use marijuana and those who are registered qualifying patients under the Compassionate Use of Medical Cannabis Pilot Program Act to cultivate a limit of no more than 5 cannabis plants, both of which have certain restrictions.

II. Risks in Accepting Funding from the Marijuana Industry

The marijuana industry consists of entities and individuals that conduct marijuana-related activities that are illegal under federal law. They include, among others, cultivators, manufacturers, distributors, and retailers (e.g., dispensaries) of marijuana. The marijuana industry may also include trade association groups and those organizations that provide ancillary products and services to support federally illegal marijuana-related activities (e.g., lighting or hydroponic equipment companies whose main clientele is the marijuana industry).

Because the marijuana industry consists of entities and individuals that conduct marijuana-related activities that are illegal under federal law, there are concerns about accepting funding from or conducting transactions with members of this industry, either directly or indirectly. Possible legal risks of accepting funding from marijuana entities include:

• Federal criminal charges of money laundering or aiding and abetting and violations of the Controlled Substances Act;

• Risk of federal forfeiture (i.e., funds that are determined to be the proceeds of criminal activities, which could apply if funds donated to a university were
derived from the donor’s sale or distribution of marijuana, and can be seized by the federal government);

• Allegations that the university has violated the Drug Free Schools Act and/or the Drug Free Workplace Act, which could put its federal funding at risk;

• Reputational risks of working with an individuals or entities engaged in illegal activities.

Due to the risks involved with accepting funding from individuals and entities in the marijuana industry, SIU campuses may not accept donations, grants or other funding from entities or individuals known to directly derive most or all of their funding from conducting marijuana-related activities that are illegal under federal law (e.g., sale, cultivation, distribution). This includes grants that are earmarked specifically for the study of the impact of marijuana directly from companies that distribute or manufacture marijuana products or foundations that are created by such companies.

III. Marijuana Research

A. Research Involving the Cultivation, Distribution, Possession or Use of Marijuana

Research involving the possession and use of marijuana in humans and animals is allowable if the researcher has obtained a Schedule I registration with the DEA and approval for their research protocol through scientific review by the U.S. Food and Drug Administration’s Investigational New Drug process. Other standard research approvals from the appropriate institutional review board(s) (IRBs) and Institutional Animal Care and Use Committee(s) (IACUCs) must also be obtained if research involves humans or animals. The approval process may take as long as a year and DEA registration must be completed before research can begin.

In addition, marijuana research requires the researcher to obtain marijuana only from a source approved by the DEA through the National Institute on Drug Abuse (NIDA) Drug Supply Program. At present, only the University of Mississippi is authorized to produce marijuana plant-based products for use by researchers in the U.S. In August 2016, the DEA announced that it would accept applications from other institutions interested in supplying marijuana for federal research. To date, no new approved sources have been announced by the DEA. Researchers are encouraged to refer to the NIDA website (https://www.drugabuse.gov/drug-topics/marijuana/nidas-role-in-providing-marijuana-research) for additional information.

B. Research Not Involving the Cultivation, Distribution, Possession, or Direct Use of Marijuana
The following types of research and other activities are acceptable (as long as the funding is not from a prohibited source), although all normal approvals for research must be obtained, including those for the use of human and animal participants:

1. Surveys of individuals already using marijuana for recreational or medical purposes.
2. Environmental impact studies on the impact of marijuana cultivation on the environment.
3. Research on the socioeconomic effects of marijuana cultivation, sale, or use.
4. Research on policy and legislative issues concerning marijuana.
5. Establishing websites or publishing newsletters through which results of the above referenced research or other information on marijuana may be disseminated.
6. Conducting conferences, seminars, or informal meetings intended to provide objective information to SIU staff and the public on various marijuana-related issues.

IV. Summary for Marijuana (>0.3% THC) Research

- Must obtain DEA Schedule I registration for research projects

- Must obtain cannabis from National Institute on Drug Abuse (NIDA), produced at University of Mississippi (or other sources that may be approved by the DEA)

- Must obtain approval from FDA for clinical and non-clinical research

- Cannot accept research funding from individuals or entities that directly obtain most of their revenue from the cannabis industry in violation of federal law

- May conduct cannabis research that does not involve the direct use, possession, distribution, or cultivation of cannabis (e.g., surveying individuals who use cannabis, analyzing public records, and data)