TITLE 19 – DEPARTMENT OF HEALTH AND SENIOR SERVICES
Division 100 – Division of Cannabis Regulation
Chapter 1 – Marijuana

PROPOSED RULE

19 CSR 100-1.200 Marijuana Research Facilities

PURPOSE: Under Article XIV, Section 2 of the Missouri Constitution, the Department of Health and Senior Services has the authority to create and issue additional licenses intended to facilitate scientific research or education. This rule describes what a research license is authorized to do and the application requirements for such a license.

(1) Definitions.

(A) "Animal Subject" means any animal as defined in the Animal Welfare Act, 7 U.S.C. § 2132 being used as part of an approved research study.

(B) "Assent" means an affirmative agreement to participate in licensed research studies as a human subject, made by a non-emancipated human subject or human subject otherwise not legally able to provide informed consent. A failure to object should not, absent affirmative agreement, be construed as assent.

(C) "Delivery", as used in this rule, means the movement of marijuana to human and animal subjects as part of and in compliance with a department-approved researched study.

(D) "Human subject" means an individual person participating in a research study whose data or biospecimens may be collected through intervention or interaction with the individual.

(E) "Informed consent" means the legally effective knowing permission and agreement of an individual or their legally authorized representative, so situated as to be able to exercise free power of choice without undue inducement or any element of force, fraud, deceit, duress, or other form of constraint or coercion, to engage in licensed research studies as a human subject.

(F) "Institutional Animal Care and Use Committee" (IACUC) means an independent committee that oversees all research with animals. The IACUC requires researchers to give reason to their need for animals in research, ensure they select appropriate species for the research, and use of the fewest number of animals in the research to reach their desired outcome.

(G) "Institutional review board" (IRB) means a human research review committee established and approved under the provisions of Title 45 of the Code of Federal Regulations Part 46 or Title 42 of the US Code section 289, for the purpose of reviewing and monitoring research.

(H) "Non-emancipated human subject" means a human subject under the age of eighteen (18) who has not been emancipated under Missouri law.

(I) "Principal investigator" means an individual who conducts a research study or, in the event of a research study conducted by a team of individuals, is the responsible leader of that team.

(J) "Personally identifiable information" means information that can be used to distinguish or trace an individual's identity, or to contract or locate an individual, either alone or when combined with other information that is linked or linkable to a specific individual.

(K) "Public institution" means any entity established or controlled by the federal government, a state government, or a local government or municipality, including but not limited to an institution of higher education or a public higher education research institution.

(L) "Research study" means a discrete scientific endeavor to answer a research question or a set of research questions.

(2) All activities under this rule must comply with applicable state, tribal, local, and municipal laws and regulations.

(3) Marijuana research facilities, generally.

(A) A marijuana research licensee's authority to engage in activities intended to facilitate scientific research or education related to marijuana product includes the ability to –

1. Acquire and transfer marijuana product from a licensed medical or marijuana facility;

2. Cultivate marijuana;

3. Process or manufacture marijuana product;

4. Store marijuana product on-site;

5. Transfer marijuana product to or from a testing facility or another marijuana research facility;

6. Sell or donate marijuana product to another marijuana research facility;

7. Sell or transfer marijuana seeds and clones produced from a research study to a licensed cultivation facility;

8. Acquire and transfer marijuana seeds from entities not licensed under this chapter if doing so does not violate state or federal law;

9. Perform research on marijuana product;

10. Perform research on animal and human subjects related to the use of marijuana product;

11. Perform testing on marijuana product;

12. Enter into contracts or agreements with a public institution or another marijuana research facility to conduct a research study;

13. Share space with a cultivation facility, manufacturing facility, dispensary facility, or testing facility; and

14. Administer final marijuana product to animal subjects, human subjects above the age of twenty-one (21), or human subjects under the age of twenty-one (21) with a medical marijuana patient identification card, provided that the licensee has met all requirements of this chapter.

(B) A research licensee shall not sell or transfer marijuana product to a cultivation facility, manufacturing facility, or dispensary facility.

(C) A research licensee's authority to perform research on human subjects shall include the administration and delivery of marijuana product to human subjects but shall not include the sale of final marijuana product to consumers, qualifying patients, or primary caregivers.

(4) Research facility and study application process.

(A) Facility and study applications will be considered complete if the application includes all documents required for applications by this rule.

(B) The department will receive applications for all research facility licenses and studies electronically through a department-provided, web-based application system. In the event of application system unavailability, the department will arrange to accept applications in an alternative, department-provided format and will notify the public of those arrangements through its website.

1. The department shall charge each applicant seeking a research facility license and research study approval an application fee to be submitted with the application. The department shall publish current fees, including any adjustments, on its website.

2. Application fees are nonrefundable.

(C) The issuance of a research facility license does not authorize the research facility licensee to begin activities related to marijuana research authorized by the license. A research facility licensee will be granted final approval to operate upon passing a commencement inspection.

(D) A research facility license shall be valid for three (3) years from its date of issuance.

(E) Research facility licenses may be renewed pursuant to the renewal requirements in 19 CSR 100-1.060.

(5) Application requirements. Entities must obtain a license to operate a marijuana research facility in Missouri. Applications for research facility licenses shall include, at a minimum, all of the following:

(A) Name and address of the designated contact for the applicant entity;

(B) Legal name of the applicant entity, including fictitious business names;

1. In the case the group intending to perform marijuana research is part of an entity that performs other non-marijuana related activities, such as a university, an affiliated entity that will be conducting the marijuana research shall be the applicant entity.

(C) All owners of the applicant entity, with ownership percentage, and a visual representation of the facility's ownership structure, if applicable;

(D) Proposed address of the marijuana research facility and –

1. An attestation that the proposed facility location complies with the facility location requirements of this rule;

2. An attestation that the proposed facility location complies with any facility location requirements of the local government;

3. A copy of, and a hyperlink to, all local government requirements for facility location, such as zoning requirements, if applicable. Applicable sections shall be highlighted in the copy of the regulations;

4. An indication of whether the proposed research facility will share a space with another facility;

(E) Proposed blueprints that outline the entire facility and feature all rooms and areas clearly labeled, including purpose and square footage, camera locations, limited access areas, and access permissions;

(F) For research facilities that will be cultivating marijuana, the cultivation practice(s) (indoor, outdoor, greenhouse) used by the facility, and, if using a combination of practices, the ratio of cultivation space limits for each cultivation practice;

(G) An attestation that all individuals subject to analysis for disqualifying felony offenses will submit fingerprints within two (2) weeks after the application submission for a state and federal fingerprint-based criminal background check to be conducted by the Missouri State Highway Patrol;

(H) An attestation that no individual subject to analysis for a disqualifying felony offense has a disqualifying felony offense;

(I) A written plan for documenting all individuals who will have access to the research facility and marijuana product;

(J) A brief description of the research that will be conducted.

(K) An indication of whether the applicant intends to conduct research on human and/or animal subjects;

(L) An indication of whether the applicant intends to sell seeds and clones to a licensed cultivation facility; and

(L) A non-refundable application fee of five hundred dollars ($500).

(6) Research studies

(A) A research licensee shall not conduct any research unless all aspects of its proposed research has been reviewed and approved by the department.

(B) The following must be submitted to the department for review and approval prior to commencing any research study:

1. A description of the research that will be conducted, including –

A. Abstract;

B. Study question;

C. Study rationale;

D. Study protocol, including expected sample sizes and marijuana testing methods if applicable;

E. If the licensee plans to cultivate marijuana, the amount of marijuana to be cultivated with an explanation for that amount;

F. If the licensee plans to sell seeds and clones to a licensed cultivation facility –

(I) The amount of seeds and clones to be sold;

(II) When in the cultivation process the licensee plans to collect the seeds and clones to be sold; and

G. A non-refundable study application fee of two hundred and fifty dollars ($250).

(C) Research submissions must be made through a department provided, web-based system.

(D) The department will communicate in writing to the licensee whether the submission is complete.

1. If deemed incomplete, the department will identify reasons why it determined the submission is incomplete and will return the application for corrections.

2. If deemed complete, the research study will be approved or denied.

(E) Once a research study has been approved, the licensee will receive a research study identification number.

(F) Research studies involving human subjects.

1. A marijuana research licensee shall not conduct any research involving human subjects unless all aspects of its proposed research study have been reviewed and approved by the department's IRB and an IRB that is registered and in good standing with the Office for Human Research Protections, U.S. Department of Health and Human Services, to be the IRB of record.

2. Research study applications shall be submitted following approval by both IRBs and prior to commencing any research study involving human subjects. In addition to the requirements for all research studies, the following must be submitted to the department for review and approval:

A. Evidence of the study's approval by the department IRB;

B. The name of the IRB of record that will review all research studies to be conducted on human subjects;

C. Disclosures of any actual or apparent conflicts of interest between any applicant or agent and any member of the IRB;

D. Attestation that all research studies to be conducted on human subjects will be led by at least one licensed physician in good standing;

E. The name and license number of the licensed physician

F. A plan for obtaining a waiver of consent from both IRBs or informed consent from –

(I) All human subjects that are eighteen (18) years of age or older or are emancipated minors participating in a research study; and

(II) At least one legal representative for each non-emancipated human subject and for each human subject who is otherwise not capable of understanding the information provided and making an informed decision; and

G. A plan for obtaining assent from all non-emancipated human subjects participating in a research study.

(G) Research studies involving animals.

1. A marijuana research facility shall not conduct any research involving animal subjects as defined in the Animal Welfare Act, 7 U.S.C. § 2132 unless the marijuana research facility is registered with the U.S. Department of Agriculture pursuant to the Animal Welfare Act, 7 U.S.C. §§ 2131 et seq.

2. Research study applications shall be submitted following approval by an IACUC that is registered and in good standing with the National Institutes of Health Office of Laboratory Animal Welfare and prior to commencing any research study involving animal subjects. In addition to the requirements for all research studies, the following must be submitted to the department for review and approval:

A. The name of the IACUC that will review all research studies to be conducted on animals;

B. Disclosures of any actual or apparent conflicts of interest between any applicant or agent and any member of the IACUC;

C. Attestation that all research studies to be conducted on animal subjects will be led by at least one licensed veterinary doctor in good standing; and

D. The name and license number of the licensed veterinary doctor.

(7) Application approval and denial process.

(A) Applicants are responsible for submitting a complete and accurate facility and study application as set out in this rule. However, the department may request an applicant to provide additional information or documents needed to determine eligibility for a license by sending the request to the email address of the designated contact associated with the application. If requested, the applicant will have three (3) business days from the date the email is sent to provide the requested information or documents.

(B) If the department determines an application meets all of the license eligibility requirements in this rule and Article XIV, the license will be issued.

(C) An application will be denied if –

1. The application is not complete;

2. The applicant, application, or any proposal in the application, is in violation of any rule in this chapter or Article XIV;

3. The applicant provides false or misleading information in an application; or

4. The applicant fails to timely provide information or records requested by the department.

(D) Any denial shall be issued by the department in writing to the applicant and shall include the specific reasons for the denial and the process for requesting review of the department's decision.

(8) Research facility and licensee requirements. Research facilities and licensees shall comply with the following:

(A) Research licensees and applicants have a continuing duty to provide the department with up-to-date contact information, including the individual who shall be the designated contact for all department communications. Licensees and applicants are deemed to have received all communications and notifications from the department on the date the department sends an email to the email address of the designated contact for the licensee or applicant;

1. The designated contact for a research license and application must be the research facility's principal investigator.

(B) No research facility shall be owned, in whole or in part, by an individual with a disqualifying felony offense;

(C) All employees, contractors, volunteers and owners having access to a research facility shall comply with the facility employment requirements in 19 CSR 100-1.070 and may not have a disqualifying felony offense;

1. An individual performing maintenance work (such as plumbing) or other similar work not related to research, testing, transporting, growing, manufacturing, or dispensing marijuana product at the research facility for no more than fourteen (14) days in a calendar year, is not required to be screened for a disqualifying felony offense. The licensee is responsible for supervising such individuals while they are in the facility.

(D) Research licenses and licensees must comply with the facility security requirements in 19 CSR 100-1.090;

(E) Research licenses and licensees must comply with the location, general operations, and signage requirements in 19 CSR 100-1.100 unless otherwise stated;

1. Consumption of marijuana product on the licensed premises, including in any approved transport vehicles, is prohibited, except as specifically authorized within the context of a department-approved human or animal subject research study;

(F) A research licensee must comply with the business change and notification and reporting requirements in 19 CSR 100-1.100 unless otherwise stated. In addition to these requirements –

1. A research licensee shall notify the department in writing of any changes in intent to conduct research on human or animals subjects.

2. A research licensee shall submit to the department a report annually, beginning one (1) year from receiving approval to operate, detailing the status of any ongoing and/or completed research studies in the previous year;

3. A research licensee shall maintain and provide upon request of the department a written schedule for disposal of marijuana product after it has concluded research on that item;

4. A research licensee must send the department a copy of any report or notification they send to the IRB of record within twenty-four (24) hours of notifying the IRB of record; and

5. A research licensee must send the department a copy of any report or notification they send to IACUC within twenty-four (24) hours of notifying IACUC.

(G) Research licensees that test marijuana product must comply with the certification, facility, and testing requirements in 19 CSR 100-1.110 unless otherwise stated;

1. Marijuana product shall not be administered to any human subject or animal subject as part of a research study until the marijuana product has been tested by a testing or research licensee pursuant to the provisions of 19 CSR 100-1.110, and the research licensee has received verification from the testing or research licensee that the marijuana product has passed mandatory testing.

A. Acceptable limits and deviation from the mean for each analyte in a marijuana product's cannabinoid profile shall follow values in protocols approved by an IRB or IACUC in each department-approved research study.

(H) Research licensees must comply with the following packaging and labeling requirements.

1. All marijuana product shall be produced, packaged, and labeled in a manner that protects public health and is not attractive to children.

A. No marijuana product may be manufactured, packaged, or labeled in a false or misleading manner, such as by inaccurately representing product ingredients.

B. Product packaging and design.

(I) For all marijuana product to be administered to human or animal subjects, packaging, with the exception of marijuana seeds and plants, shall be constructed from FDA-approved food contact substances. Where marijuana product is packaged in a series of containers, the container closest to the product, including methods of administration or wrappers, must be compliant with this requirement, unless the department approves application of this rule to a different container in the series.

(II) All marijuana product packaging, apart from the universal symbol, may only utilize –

(a) Black or white colors and may not use logos or symbols;

(b) Text indicating side effects and behavioral effects of usage; and

(c) A label required by this rule.

(III) Marijuana product packaging must be in compliance with applicable local, state, and federal requirements.

C. Labeling. Except as specifically identified herein, labeling requirements apply to containers, wrappers, packages, and methods of administration that contain marijuana product, except seeds or plants. The labels required herein are not required on the paper for prerolls.

(I) All marijuana product shall be clearly and conspicuously labeled with "Marijuana" as well as a prominently displayed universal symbol in red and white print that consists of the following:

(a) A diamond containing the letters "THC";

(b) The letter "M" located under the "THC" within the diamond; and

(c) For infused products, the number of milligrams of THC in the package, placed directly under the diamond.

(II) The marijuana product container closest to the product shall bear a template label provided by the department that displays only the following information, in the following order, from top to bottom and left to right:

(a) All active and other ingredients, which shall not include groups of ingredients that obscure the actual ingredients, such as "natural flavors" or "botanically derived terpenes" and shall include solvents used in the manufacturing process:

(b) Servings and doses per package for human subjects;

(c) A "best if used by" date;

(d) The license number of the licensed entity from which the final marijuana product originated;

(e) The license number of the research facility;

(f) The department-issued research study identification number;

(g) The testing licensee where the final marijuana product passed mandatory testing;

(h) The state-wide track and trace system tag number associated with the mandatory testing results for the final marijuana product;

(i) The exact total weight of the marijuana included in the package –

I. For dried, unprocessed marijuana, concentrates, prerolls, and infused prerolls, weight shall be listed in grams;

II. For infused products other than infused prerolls, weight shall be listed by milligrams of delta-9-tetrahydrocannabinol;

(j) The exact delta-9-tetrahydrocannabinol (Δ9-THC), delta-9-tetrahydrocannabinolic acid (Δ9-THCA), cannabidiol (CBD), cannabidiolic acid (CBDA), cannabinol (CBN), tetrahydrocannabivarin (THCV), cannabidivarin (CBDV), and delta-8-tetrahydrocannabino (Δ8-THC) per serving/dose, listed in milligrams;

(k) Results of terpene analysis, if tested during mandatory testing;

(l) Instructions for use;

(m) Estimated length of time the serving or dosage will have an effect;

(n) The following warning; "Cognitive and physical impairment may result from the use of marijuana. Keep out of reach of children,"

(o) The statement "Not For Sale or Distribution";

(p) The statement "For Research Purposes Only";

(q) If the marijuana product is not intended for consumption by humans subjects, the statement "Not For Human Consumption"; and

(r) The name and contact information for the licensed physician or veterinary doctor leading the research study.

2. Final marijuana product shall not be packaged in a manner that exceeds three (3) ounces of dried, unprocessed marijuana, or its equivalent.

3. Product packaging may not be designed in a manner such that the required elements for packaging and labeling are easily removed or separated from the package, such as placing required information on part of the package that must be removed in order to access the product.

4. Any violation of this subsection shall be punishable by an appropriate and proportional department sanction, up to and including an administrative penalty of five thousand dollars ($5,000) for each product/packaging category in which a requirement is violated.

(I) Research licensees must comply with the inventory control and seed-to-sale tracking requirements in 19 CSR 100-1.130;

(J) Research licensees must comply with the transportation and storage requirements in 19 CSR 100-1.140 unless otherwise stated;

1. Researchers may only deliver up to six (6) ounces of dried, unprocessed marijuana, or its equivalent, per human subject, in a thirty- (30-) day period.

2. At the time of delivery, licensees must –

A. Require production of a qualifying patient or primary caregiver identification card for human subjects under the age of twenty-one (21);

B. Require production of a valid (not expired) government-issued photo ID confirming the identity and age of the human subject if the human subject is at least twenty-one (21) years of age

C. Require production of a valid (not expired) government photo ID confirming the identity of the parent or legal guardian of all non-emancipated human subjects;

D. Require production of a valid government identification confirming the identity of the human subject if the human subject is a non-emancipated human subject; and

E. Record the delivery of product in the state-wide track and trace system.

(K) Research licensees must comply with the marijuana waste disposal requirements in 19 CSR 100-1.150 unless otherwise stated;

(L) Research licensees that cultivate marijuana must comply with the cultivation facility requirements in 19 CSR 100-1.160 unless otherwise stated;

1. Each research facility utilizing any combination of indoor, outdoor, or greenhouse cultivation practices will be limited to no more than thirty thousand (30,000) square feet of flowering plant canopy space.

(M) Research licensees that manufacture marijuana product must comply with the manufacturing facility requirements in 19 CSR 100-1.170;

(N) If a research licensee is operating in a shared space with a cultivation, manufacturing, dispensary, or testing licensee, the research licensee must ensure that –

1. Unless the research licensee's marijuana product is being tested by the testing licensee, all marijuana product owned by the research licensee shall be physically segregated from product owned or controlled by the cultivation, manufacturing, dispensary, or testing licensee's marijuana product; and

2. Research activities maintain physical segregation from the activities of the cultivation, manufacturing, dispensary, or testing licensee; and

(O) No electronic equipment utilized by a research facility shall collect a research participant's personally identifiable information for use outside of the research study unless the subject has provided informed consent to the release of their personally identifiable information .

(9) Complaints, inspections, and investigations. A research licensee must follow complaints, inspections, and investigations requirements pursuant to 19 CSR 100-1.030 unless otherwise stated.

(A) If the department determines that a research licensee is not in compliance with the department's regulations or a department-approved research study, the department may, without prior notice of violation, impose penalties, including, but not limited to –

1. Suspending the research study;

2. Placing an administrative hold on marijuana product; and

3. Suspending the research license.

(B) If there is a credible and imminent threat to public safety, the department may order the licensed research facility to immediately suspend all or part of the operations, including placing an administrative hold on marijuana product, until the threat has been eliminated. An imminent threat to public safety includes, but is not limited to –

1. A dangerous condition at the facility that is likely to harm employees or the public;

2. A credible report, such as from law enforcement, that diversion or inversion of marijuana product is occurring at the licensed facility;

3. A credible report that a facility's practices are permitting marijuana product to enter the regulated market without being compliantly tested; and

4. A credible report that a facility's practices are not following IRB or IACUC approved protocols.

(10) Appeals. A research facility licensee or applicant may seek review of the following department decisions at the administrative hearing commission, pursuant to the appeals provisions in 19 CSR 100-1.020:

(A) Denial of a research license; or

(B) Any penalties imposed by the department.

AUTHORITY: section 2.4.(1)(g). of Article XIV, Mo. Const.