

R68. Agriculture and Food, Plant Industry.

R68-35. Academic Medical Cannabis Research.

R68-35-1. Authority and Purpose.

Pursuant to Section 4-41a-901, this rule establishes the process by which a research university may obtain, cultivate, process, and possess cannabis for academic medical cannabis research.

R68-35-2. Definitions.

1) "Applicant" means a person from a research university who applies for a research license from the Utah Department of Agriculture and Food.

2) "Batch" means a quantity of:

a) cannabis concentrate produced on a particular date and time, following clean up until the next clean up during which lots of cannabis are used;

b) cannabis product produced on a particular date and time, following clean up until the next clean up during which cannabis concentrate is used; or

c) cannabis flower packaged on a particular date and time, following clean up until the next clean up during which lots of cannabis are being used.

3) "Cannabis" means any part of the marijuana plant.

4) "Cannabis concentrate" means:

a) the product of any chemical or physical process applied to naturally occurring biomass that concentrates or isolates the cannabinoids contained in the biomass;

b) any amount of a natural, derivative, or synthetic cannabinoid in its purified state.

5) "Cannabis Product" means a product that:

a) is intended for human use; and

b) contains cannabis or tetrahydrocannabinol.

6) "Department" means the Utah Department of Agriculture and Food.

7) "License" means a license issued by the Utah Department of Agriculture and Food to a research university granting authorization to obtain cannabis from a cannabis production establishment or another research licensee to cultivate, process, and possess cannabis for research purposes.

8) "Licensee" means a person authorized by the department to obtain, cultivate, process, and possess cannabis for the purpose of research.

9) "Lot" means the quantity of:

a) flower produced on a particular date and time, following clean up until the next clean up during which the same materials are used; or

b) trim, leaves, or other plant matter from cannabis plants produced on a particular date and time, following clean up until the next clean up.

10) "Research" means academic medical cannabis research or the study of cannabis for the purpose of developing useful processes, information, and products.

11) "Research Plan" means a plan stating the objective and purpose of the proposed academic medical cannabis research including each method and procedure for carrying out the research.

12) "Research Location" means the area of a research university where academic medical cannabis research takes place.

13) "Security Plan" means a plan to control and limit unauthorized access to cannabis and methods used to prevent diversion of cannabis.

14) "Total THC" means the sum of the determined amounts of delta-9-THC and delta-9-THCA, according to the formula: Total THC = delta-9-THC + (delta-9-THCA x 0.877).

R68-35-3. Research License Requirements.

1) No applicant may possess any cannabis until the applicant is notified that their research license has been approved by the department.

2) An applicant shall be 21 years of age or older.

3) An applicant shall be employed by a research university.

4) The department may not issue a license to an applicant if they have been convicted of a drug-related felony within the last ten years.

5) An applicant shall submit to the department:

a) the name, email address, and telephone number of the principal investigator responsible for the:

i) procurement of cannabis;

ii) use and secure storage of the cannabis; and

iii) the management of the research;

b) the institution's name and address;

c) the name of each individual with access to cannabis material;

d) a research plan;

e) the research location;

f) the name and address of each cannabis production establishment or licensee from which the applicant intends to obtain cannabis; and

g) a security plan.

6) Each applicant for a license shall submit to the department, at the time of application, from each individual who will handle cannabis as part of the research, a nationwide criminal history from the FBI completed within three months of the application.

7) An applicant shall submit a research license fee as approved by the legislature in the fee schedule.

8) Prior to issuing a license the department shall inspect the proposed research location to determine if the applicant complies with state law and this rule.

9) An incomplete or incorrect application will be rejected and not considered by the department.

R68-35-4. Research Plan Requirements.

1) An applicant is responsible for ensuring that no information is included in a research plan that may compromise the applicant's ability to secure patent, trade secret, or other intellectual property protection.

2) Each research plan shall be submitted by a person who has the legal authority to represent the research university.

3) Each research plan shall be submitted to the department in a legible PDF format.

4) Each individual involved in research shall be considered an agent of the licensee.

5) A research plan is limited to twelve pages, not including references or citations, and should include the following information, in addition to the requirements of Section R68-35-2:

a) the purpose and goal of the proposed research;

b) each key milestone and timeline for the research;

c) background and preliminary studies, if applicable;

d) the amount and type of cannabis to be obtained for the research project including the justification with respect to each milestone task;

e) the anticipated cost of the proposed research project and funding source;

f) personnel that will be involved in the project, including each name and role;

g) facilities, equipment, and other resources required and available for conducting the proposed research project;

h) letters of support, limited to two pages each, confirming the commitment of time and resources from external personnel or organizations if external personnel or organizations will participate in research activities under an approved research project; and

i) any additional information requested by the department.

6) Each license will be issued by the Cannabis Production Establishment Licensing Board.

R68-35-5. Inventory and Recordkeeping Requirements.

1) A licensee shall maintain an organized filing system so cannabis records can be easily obtained when requested by the department.

2) Each record related to research shall be maintained by the licensee and available for inspection by the department for a minimum of two years following the completion of the project.

3) The licensee shall maintain a current inventory and record of the disposition of materials for cannabis, cannabis plant product, cannabis concentrate, and cannabis product on hand.

4) A licensee shall take necessary measures to avoid the diversion of cannabis, cannabis concentrate, or cannabis product.

R68-35-6. Research Limitations.

1) A licensee is restricted to only research specified in an approved research plan.

2) An amendment to an approved research requires the resubmission and approval of the documents listed in Section R68-35-4 and the reason for the amendment.

R68-35-7. Transportation.

1) A printed transport manifest shall accompany each transport of cannabis.

2) The manifest shall contain the following information:

a) the licensee's address and license number of the departure location;

b) the physical address and license number of the receiving location;

c) the strain name, quantity by weight, and unique identification number from the inventory control system of cannabis to be transported;

d) the date and time of departure;

e) the estimated date and time of arrival; and

f) the name and signature of each licensee or agent accompanying the cannabis.

3) The transport manifest may not be voided or changed after departure.

4) A copy of the transport manifest shall be given to the receiving location.

5) The receiving location shall ensure that the cannabis received is as described in the transport manifest and shall record the amount received for each strain.

6) The receiving location shall document at time of receipt any difference between the quantity specified in the transport manifest and the quantity received and recorded. Any difference shall be immediately reported to the department.

7) During transportation, cannabis shall be:

- a) shielded from the public view;
- b) secured; and
- c) temperature controlled if perishable.

8) A licensee shall contact the department within 24 hours if a vehicle transporting cannabis is involved in an accident that involves product loss.

9) A licensee or an agent of a licensee shall occupy each transporting vehicle. No other individual may occupy a transporting vehicle.

R68-35-8. Inspection and Testing.

1) A licensee shall provide the department with written consent allowing a representative of the department or local law enforcement to enter any premises where a licensee possesses or stores cannabis for the purpose of:

- a) conducting a physical inspection; or
- b) ensuring compliance with the requirements of state law and this rule.

2) Cultivation or processing based research that does not involve testing on any human or animal subject, is not subject to the testing requirements of Section R68-29-3.

R68-35-9. Minimum Storage and Handling Requirements.

1) Each storage area shall be maintained in a clean and orderly condition.

2) A licensee shall store cannabis, cannabis concentrate, or cannabis product in a manner so as to prevent diversion, theft, or loss.

3) A licensee shall make cannabis, cannabis concentrate, and cannabis product accessible only to the minimum number of specifically authorized agents of the licensee essential for efficient operation and shall return the cannabis, cannabis concentrate, or cannabis product to its secure location immediately after completion of the process or at the end of the scheduled business day.

4) If a research process cannot be completed at the end of a working day, a licensee shall securely lock the processing area or tanks, vessels, bins, or bulk containers containing cannabis inside an area or room that affords adequate security.

R68-35-10. Cannabis Waste Disposal.

1) A licensee shall dispose of cannabis, cannabis concentrate, or cannabis product if research is discontinued for any reason.

2) Solid and liquid waste generated during research shall be stored, managed, and disposed of in accordance with applicable state law and rules under Title R68.

3) Wastewater shall be disposed of in compliance with applicable state law and rules under Title R68.

4) Cannabis waste shall be rendered unusable prior to leaving the research location.

5) Cannabis waste, that is not designated as hazardous, shall be rendered unusable by grinding and incorporating the cannabis waste with other ground materials so the resulting mixture is at least fifty percent non-cannabis waste by volume or other methods approved by the department before implementation.

6) Material used to grind and incorporate with cannabis fall into two categories:

- a) compostable; or
- b) non-compostable.

7) Compostable waste is cannabis waste to be disposed of as compost or in another organic waste method mixed with:

- a) food waste;
- b) yard waste; or
- c) vegetable-based grease or oils.

8) Non-compostable waste is cannabis waste to be disposed of in a landfill or another disposal method, such as incineration, mixed with:

- a) paper waste;
- b) cardboard waste;
- c) plastic waste; or
- d) soil.

R68-35-11. Security Plan.

1) A licensee's security plan shall conform to the following requirements:

a) a licensee shall provide effective controls and procedures to guard against theft and diversion of cannabis;

b) a licensee shall store cannabis in a securely locked, substantially constructed cabinet;

c) a licensee shall not employ, as an agent or employee who has access to cannabis, any person who has been convicted of a drug-related felony in the last 10 years or is not at least 21 years of age; and

d) a licensee shall notify the department of any theft or significant loss of any cannabis within 24 hours from the discovery of the loss or theft.

R68-35-12. Renewal.

- 1) A licensee shall resubmit each document required in Sections R68-35-3 and R68-35-4, with updated information, before December 31st of each year including a report detailing the progress of the research.
- 2) The department may deny a renewal for incomplete documentation.
- 3) The department may deny renewal for any licensee that has violated any portion of this rule or state law.

R68-35-13. Violations.

- 1) It is a violation for a licensee to store or process cannabis, cannabis concentrate, or cannabis product on a site not approved by the department as part of the license.
- 2) It is a violation for a licensee to process cannabis, cannabis concentrate, or cannabis product from a source that is not licensed by the department.
- 3) A licensee's research for the U.S. Drug Enforcement Administration (DEA) or another law enforcement agency is exempt from Subsections R68-35-13(1) or R68-35-13(2).
- 4) A licensee shall maintain each requirement of their security plan and may not allow unsupervised public access to an area where cannabis, cannabis concentrate, or cannabis product is stored or processed.
- 5) A licensee may not deny an official of the department access for sampling or inspection purposes.
- 6) It is a violation of this rule to handle or possess cannabis without a license from the department.
- 7) It is a violation for a licensee to employ a person under the age of 21 in the processing or handling of cannabis or a cannabis product.
- 8) It is a violation to fail to keep a record required by this rule.
- 9) It is a violation to allow an employee that has been convicted of a drug-related felony in the last ten years access to cannabis or cannabis product.
- 10) It is a violation to operate outside of the scope of the research project approved under the license.
- 11) It is a violation to make changes to a research plan or research location without prior approval from the department.

R68-35-14. Violation Categories.

- 1) Public Safety Violations: Each person is fined \$3,000- \$5,000 per violation. This category is for violations that present a direct threat to public health or safety including:
 - a) cannabis sold to an unlicensed source;
 - b) cannabis purchased from an unlicensed source;
 - c) refusal to allow inspection;
 - d) unauthorized personnel on the premises;
 - e) permitting criminal conduct on the premises; or
 - f) engaging in or permitting a violation of the Title 4, Chapter 41a, Cannabis Production Establishments, that amounts to a public safety violation as described in this Subsection.
- 2) Regulatory Violations: Each person is fined \$1,000-\$5,000 per violation. This category is for violations involving this rule and other applicable state rules under Title R68 including:
 - a) failure to follow approved security plan;
 - b) failure to keep and maintain records;
 - c) failure to follow transportation requirements;
 - d) failure to follow the waste and disposal requirements; or
 - e) engaging in or permitting a violation of Title 4, Chapter 41a, Cannabis Production Establishments. this rule, or other applicable state rules under Title R68 that amounts to a regulatory violation as described in this subsection.
- 3) Licensing Violations: Each person is fined \$500 - \$5,000 per violation. This category is for violations involving research license requirements including:
 - a) an unauthorized change to the research plan;
 - b) failure to notify the department of changes to the research plan;
 - c) engaging in or permitting a violation of this rule or Title 4, Chapter 41a, Cannabis Production Establishments that amounts to a licensing violation as described in this Subsection; or
 - d) failure to respond to a violation.
- 4) The department shall calculate penalties based on the level of violation and the adverse effect or potential adverse effect at the time of the incident giving rise to the violation.

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