GRAMA Claim of Business Confidentiality

Pursuant to Utah Code Section 63G-2-305(1) and (2), and in accordance with Section 63G-2-309, __Univ of Utah - Center for Human Toxicology_____ (company name) asserts a claim of business confidentiality to protect the following information submitted as part of a Request for Proposals.

- ☐ non-public financial statements
- ☐ specific employee name and contact information
- ☐ specific customer information, client lists, or subscription lists
- ☒ other (specify):

Research plan is redacted as it is confidential.

This claim is asserted because this information requires protection as it includes:

☒ trade secrets as defined in Utah Code Section 13-24-2 ("Trade secret" means information, including a formula, pattern, compilation, program, device, method, technique, or process, that: (a) derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable by proper means by, other persons who can obtain economic value from its disclosure or use; and (b) is the subject of efforts that are reasonable under the circumstances to maintain its secrecy.)

☐ commercial information or non-individual financial information obtained from a person if: (a) disclosure of the information could reasonably be expected to result in unfair competitive injury to the person submitting the information or would impair the ability of the governmental entity to obtain necessary information in the future; [and] (b) the person submitting the information has a greater interest in prohibiting access than the public in obtaining access.

Following is a concise statement of reasons supporting the claim of business confidentiality:

The research plan contains unpublished data and yet to be funded grant application text.

Signed: Joseph Rowe

On behalf of (company): University of Utah - Center for Human Toxicology

Date: 11/7/2025

Utah Department of Agriculture and Food

4315 S 2700 W
Taylorsville, UT 84129

cannabis@utah.gov 801-982-2375

Academic Medical Cannabis Research Operating Plan Coversheet

In accordance with 4-41a and R66-8 a licensed Utah academic medical cannabis research facility must have an operating plan that describes how the academic researchers will comply with all applicable operating standards, statutes and administrative rules. This document is not intended to be a full comprehensive list of all operating standards, statutes and administrative rules. Medical cannabis research facilities must be familiar with and comply with all operating standards, statutes and administrative rules. Statues and administrative rules change frequently, verify you are using the most up to date form.

Application Type

[X] New Application [ ] Renewal

Business Information

Research University Name:	University of Utah
Physical Address:	30 S 2000 E, Rm 3800, Salt Lake City, UT 84112
Mailing Address:	30 S 2000 E, Skaggs 201, Salt Lake City, UT 84112

Phone Number:	801-587-7595	E-mail:	Joseph.Rower@hsc.utah.edu
Contact Name:	Joseph Rower	Contact Position:	Associate Director, Center for Human Toxicology

Researcher(s) Information

List of personnel that will be involved in the project, including each name and role. R66-8-4.(5)(f).

Principal Investigator(s)		Researcher(s)	
Name:	Joseph Rower	Name:	Cassandra Rice
Phone Number:	801-587-7595	Phone Number:	801-587-7595
E-mail:	Joseph.Rower@hsc.utah.edu	E-mail:	cassandra.rice@utah.edu
Role:	Assoc Director, Center for Human Toxicology	Role:	Asst Director, Center for Human Toxicology
Name:	Chris Reilly	Name:	
Phone Number:	chris.reilly@pharm.utah.edu	Phone Number:	
E-mail:	801-581-5236	E-mail:	
Role:	Director, Center for Human Toxicology	Role:	
Name:		Name:	
Phone Number:		Phone Number:	
E-mail:		E-mail:	
Role:		Role:	
Name:		Name:	
Phone Number:		Phone Number:	
E-mail:		E-mail:	
Role:		Role:	

Academic Research Operating Checklist

Please attach operating plan in designated order in a single PDF limited to 12 pages, not including references or citations

The applicant understands that as an applicant and potential licensee you are REQUIRED to know the current statutory law, administrative rules and Departmental policies and comply in full? _x Yes_____No

The applicant understands that no applicant may possess any cannabis until the applicant is notified that their research license has been approved by the department? R66-8-3.(1) _x __Yes _____No

The applicant understands that they shall be 21 years of age or older and be employed by a research university? R66-8-3.(2)(3) _x Yes _____No

The applicant understands that 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? R66-8-3.(4)&(6) _x _Yes _____No

The applicant understands that an applicant shall submit a research license fee as approved by the Legislature in the fee schedule? R66-8-3.(7) _x Yes _____No

The applicant understands that before issuing a license the department shall inspect the proposed research location to determine if the applicant complies with state law and this rule? R66-8-3.(8) _x Yes _____No

The applicant understands that 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? R66-8-4.(1) _x Yes _____No

The applicant understands that 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? R66-8-4.(1) _x Yes _____No

The applicant understands that each research plan shall be submitted by a person who has the legal authority to represent the research university.? R66-8-4.(2) _x Yes _____No

General Research License Requirements

1. The name, email address, and telephone number of the principal investigator responsible for the: procurement of cannabis; R66-8-3(5)(a)(i). 4-41a-901.(2)(a)

2. The name, email address, and telephone number of the principal investigator responsible for the: use and secure storage of the cannabis; R66-8-3(5)(a)(ii). 4-41a-901.(2)(c)(i)

3. The name, email address, and telephone number of the principal investigator responsible for the: management of the research; R66-8-3(5)(a)(iii). 4-41a-901.(2)(c)(ii)

4. Name, location and description of where the research university intends to conduct the research. R66-8-3(5)(b). 4-41a-901.(2)(a)

5. The the name of each individual with access to cannabis material R66-8-3(5)(c). 4-41a-901.(3)

6. The research university's research plan. R66-8-3(5)(d). 4-41a-901.(2)(b)

7. The research location. R66-8-3(5)(e). 4-41a-901.(2)(b)

8. The name and address of each cannabis production establishment or licensee from which the applicant intends to obtain cannabis. R66-8-3(5)(f). 4-41a-901.(4)(a)(ii)

9. A security plan. R66-8-3(5)(g).

10. 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. R66-8-3(6).

11. Inventory and Recordkeeping plan. R66-8-5.

12. Transportation plan. R66-8-7.

13. Inspection and Testing plan. R66-8-8.

14. Minimum Storage and Handling Requirements plan. R66-8-9.

15. Cannabis Waste Disposal plan. R66-8-10.

Research Plan that is limited to 12 pages, not including references or citations, and should include the following information, in addition to the requirements of Section R66-8-3:

16. The purpose and goal of the proposed research. R66-8-4.(5)(a) 4-41a-901.(2)(b)

17. Each key milestone and timeline for the research. R66-8-4.(5)(b) 4-41a-901.(2)(b)

18. Background and preliminary studies, if applicable;. R66-8-4.(5)(c) 4-41a-901.(2)(b)

19. The amount and type of cannabis to be obtained for the research project including the justification with respect to each milestone task. R66-8-4.(5)(d) 4-41a-901.(2)(b)

20. The anticipated cost of the proposed research project and funding source. R66-8-4.(5)(e) 4-41a-901.(2)(b)

21. Personnel that will be involved in the project, including each name and role. R66-8-4.(5)(f) 4-41a-901.(2)(b)

22. Facilities, equipment, and other resources required and available for conducting the proposed research project. R66-8-4.(5)(g) 4-41a-901.(2)(b)

23. 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. R66-8-4.(5)(h) 4-41a-901.(2)(b)

24. Any additional information requested by the department. R66-8-4.(5)(i) 4-41a-901.(2)(b)

25. Each license will be issued by the Cannabis Production Establishment Licensing Board. R66-6-3(6)

Change Requests (Renewal Applications Only)

26. Attach all approved change requests to the application

Principal Investigator responsible for cannabis procurement, use, storage, and management
Joseph Rower
Joseph.Rower@hsc.utah.edu
801-587-7595

Name, location, and description where the research university intends to conduct research
University of Utah Center for Human Toxicology (CHT)
Skaggs Research Building, Rms 3800, 3861, 3580
Skaggs 3580 is a secure drug storage room where cannabis products will be kept prior to use. Skaggs 3800 and 3861 are lab spaces where cannabis products will be used to conduct study procedures.

Name of each individual with access to cannabis material
Joseph Rower, Cassandra Rice, Chris Reilly
Dr. Rower is the principal investigator of the proposed study and Associate Director of the Center for Human Toxicology. His role on the project is to acquire funding, design studies, and interpret collected data. Dr. Rower will also aid in the preparation of cannabis for administration, as needed.

Dr. Rice is a Research Associate within the lab and will lead proposed animal studies. Dr. Rice will be responsible for preparing cannabis materials for administration, administering cannabis to mice, and will oversee sample collection.

Dr. Reilly is the Director of the Center for Human Toxicology with expertise in inhalation exposures. As Director, Dr. Reilly holds the Center's DEA license. Aside from this, his role will be to guide appropriate inhalation exposure study design.

Name/address of cannabis production establishment/licensee from which applicant intends to obtain cannabis
Cannabis will be obtained directly from the Utah Dept. of Agriculture. The Center for Human Toxicology maintains a close working relationship with Dr. Brandon Forsyth, the state's chemist in charge of cannabis testing within the Dept. of Agriculture. Cannabis materials will be obtained directly from Dr. Forsyth or his delegate from the main Dept. of Agriculture cannabis testing laboratory via hand-to-hand transfer to a named investigator at the CHT (Dr. Rower, Rice, or Reilly). Each material transfer will be accompanied by a detailed manifest describing the exact material and quantity being transferred. An example transfer manifest follows:

Dept. of Agriculture Representative: _____
Signature: _____
Dept. of Agriculture License: _____
Dept. of Agriculture Address: _____
Center for Human Toxicology Investigator: _____
Signature: _____
Center for Human Toxicology License: _____
Center for Human Toxicology Address: _____

Identification #	Item	Unit Size	No. of Units	Total Quantity

Departure Date/Time: _____
Arrival Date/Time: _____

Security Plan
The CHT maintains a DEA schedule 1 license to support ongoing research in the laboratory. Cannabis storage and security will follow established laboratory protocols for storage of other schedule 1 compounds in the laboratory. This includes storage of the compound behind two locked doors and documentation of when and how much compound is used. Skaggs Rm 3580 is designed for secure storage of scheduled compounds – access to the room requires both badge access through the main lab access doors and badge access to the room itself, which is restricted to a limited number of personnel. Moreover, there are two safes within Rm 3580 that will be used to store cannabis products when not in use. As described in the '*Inventory and Recordkeeping Plan*' described below, the quantity of material received and utilized will be documented. We do not expect the risk of theft or diversion. However, in the event cannabis material is stolen, we will follow existing protocols for managing stolen scheduled materials. This includes the investigator (Dr. Rower) immediately notifying UDAF of the theft/diversion and auditing the compound inventory to identify how much and what items were stolen. We plan to use all materials to conduct the planned research. However, in the event material is unused and needs to be discarded, it will be destroyed by adding it to RxDestroyer with two licensed investigators signing that they witnessed the material's destruction.

Inventory and Recordkeeping Plan
As with other scheduled compounds stored and utilized by the CHT, incoming cannabis materials will be recorded by documenting receipt date, receiving personnel, supplier, quantity received, and storage location, and appending this information to the transfer manifest. As material is utilized, the personnel using the material and the quantity used will be documented on this form until the entire quantity is consumed. These records will be stored in a three-ring binder within the CHT's secure file storage space in Skaggs 3580 for at least two years after the material is acquired. The CHT has successfully utilized this approach for maintaining inventory of DEA scheduled compounds for ~40 years. In the event cannabis materials need to be destroyed, the inventory for that item will be appropriately updated to indicate that it was destroyed with countersignatures by two investigators.

Transportation Plan
Cannabis materials will be acquired directly from the Utah Dept. of Agriculture, along with a printed transfer manifest describing the materials being transferred and the individual transporting the material (see example transfer manifest above). Transportation will be arranged by contacting Delia Tracey with the Dept. of Agriculture. A sampling technician in the Dept. of Agriculture, under the direction of Dr. Brandon Forsyth, will transport the designated material from the Utah Dept. of Agriculture facility in Taylorsville directly to the University of Utah for storage. During transport, the cannabis material will be stored in a non-descript and unidentifiable Styrofoam cooler to shield it from public view. Use of a cooler will allow temperature control if needed. The transport vehicle will remain locked during transport and will travel directly from the Dept. of Agriculture to the University of Utah Center for Human Toxicology. In the event the transport vehicle is involved in an accident that results in product loss, the Dept. of Agriculture will be notified within 24 hours.

Inspection and Testing plan
The CHT and Dr. Rower consent to allow inspection of cannabis material storage and documentation by a representative of the Dept. of Agriculture or other law enforcement personnel.

Minimum Storage and Handling Requirements
The CHT will comply with the minimum storage and handling requirements stated in R66-8-9, in accordance with standard laboratory practices used to handle scheduled compounds. This includes maintaining Skaggs 3580 in a clean and orderly condition, storing cannabis in a way that prevents diversion, and allowing access only to necessary personnel. Skaggs 3580 is used to store all scheduled compounds within the CHT's

inventory, however, a specific safe within Skaggs 3580 will be utilized only for storing cannabis materials. Only Drs. Rower, Rice, and Reilly will have the combination for the safe in which cannabis materials are stored.

Cannabis Waste Disposal Plan

It is our anticipation that all cannabis material acquired will be utilized for research purposes. In the event that research is discontinued prior to consuming the acquired cannabis material, the CHT will appropriately dispose of the remaining material. The appropriate manner of disposal will be driven by the type of material remaining and will be coordinated with the University's Environmental Health and Safety office and the Dept. of Agriculture. Waste will be made unusable before disposal. The typical approach utilized within the CHT to destroy material is to add it to RxDestroyer with two licensees witnessing the destruction, prior to removal by EHS personnel.

Funding Source

Dr. Rower is applying for funding from the NIH to support the planned research using cannabis materials. Additional funding for this research has been awarded by the Center for Medical Cannabis Research seed grant.

Letters of Support

No external investigators or organizations will work with the acquired cannabis materials, thus no external letters of support were solicited for this application.