

Cannabis Research Program

Research Office

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University
of Regina

Legislation

- The regulations concerning cannabis research are contained in the
 - Cannabis Act - <https://laws-lois.justice.gc.ca/eng/acts/C-24.5/page-1.html> and the
 - Cannabis Regulations - <https://laws-lois.justice.gc.ca/eng/Regulations/SOR-2018-144/index.html>
- Health Canada oversees the cannabis research licensing process.

Cannabis Definition

- Cannabis – A cannabis plant, or any part of a cannabis plant, including the phytocannabinoids produced by, or found in, such a plant, regardless of whether that part has been processed or not. This includes products such as edibles or oils. It does not include:
 1. a non-viable seed of a cannabis plant;
 2. a mature stalk, without any leaf, flower, seed or branch, of such a plant;
 3. fibre derived from a stalk referred to in item 2;
 4. the root or any part of the root of such a plant.



Cannabis Licence

- The University currently holds an Institutional Research Licence for the Regina campus, Wascana location.
 - Cannabis research is limited to the RIC, Lab Building, and KHS.
 - UR Stores will keep all cannabis in locked storage and distribute when needed by authorized research teams.
- The licence applies in all cases where the researcher is handling, directing, controlling, or distributing cannabis. Some research (e.g, asking participants about cannabis use, where the participants grow or purchase their own product and the researcher is not witnessing the consumption) would not need approval under the cannabis licence. Approval from the REB would still be required.



Related regulations and guidelines

- Clinical trials involving cannabis are regulated by Health Canada and also governed by the Research Ethics policy. RCH-020-010: <https://www.uregina.ca/policy/browse-policy/policy-RCH-020-010.html>
- Cannabis research involving animals is governed by the Care and Use of Animals policy. RCH-020-005: <https://www.uregina.ca/policy/browse-policy/policy-RCH-020-005.html>
- Cannabis research also needs to conform to all other research-related guidelines and policies.

Institutional Cannabis Licence

- All cannabis used for research must be obtained through a legal source, even if the amount you will be handling or distributing is within the permissible amount for personal possession and consumption. UR Stores will be used to purchase all cannabis for research.
- The University's licence does not include permission to grow, cultivate, or develop cannabis.

Institutional Cannabis Licence

- Research is limited to specific locations. If you want to conduct research in a lab other than in RIC, Laboratory Building, and KHS, the University will need to submit an amendment to the cannabis license and have it approved before your research project can be approved.
- All cannabis research projects need approval from the Cannabis Research Committee, and have all other relevant approvals in place before research can begin.

Roles and Responsibilities

- Vice-President (Research) is the Senior Manager for the Cannabis Research Licence and is responsible for appointing the Responsible person to manage the cannabis research program on their behalf.
- Director, Research Office, is the Responsible Person named on the licence. The Director is the point of contact for Health Canada and ensures that activities are conducted in accordance with the licence.



Roles and Responsibilities

- Cannabis Research Committee provides oversight for the development of guidelines and training for the cannabis research program, ensuring compliance with legislative requirements. The Committee reviews cannabis research applications and Standard Operating Procedures (SOPs) from researchers.
- Cannabis Research Coordinator is responsible for providing advice and assistance in all matters related to cannabis research, including additional approvals, as well as creating, updating, and educating on procedures and practices for the use of cannabis in research.

Roles and Responsibilities

- All persons using cannabis for research will:
 - Comply with the Research with Cannabis Policy
 - Submit and have approved the Cannabis Research Application Form before obtaining cannabis for research purposes.
 - Meet all requirements as outlined in the Cannabis Research Program and the conditions in their respective permits.
 - Comply with legislative requirements (Federal/Provincial Acts, regulations, standards and guidelines and Municipal bylaws),
 - Ensure that cannabis is purchased by, stored at, and returned promptly to UR Stores at the end of a session, and that no unauthorized person is given access.



Roles and Responsibilities

- Principal Investigator (PI)
 - Develop and maintain required standard operating procedures for cannabis related activities
 - Provide training on related procedures to all personnel working under the registration or permit
 - Maintain records of cannabis inventory as prescribed
 - Take adequate steps to contain, protect and secure cannabis against loss or theft
 - Restrict access to the cannabis to those with a need to access for the research project
 - Adhere to any other terms and conditions of permits and licences granted

Roles and Responsibilities

- Principal Investigator (PI)
 - Report any loss or theft of cannabis to Campus Security immediately upon discovery. Report spill, loss or thefts of cannabis to the Cannabis Research Coordinator.
 - Maintain, amend, renew and terminate approvals in a timely manner as applicable.
 - Destroy all unused cannabis material through authorized destruction methods outlined in permit upon completion of associated research.
 - Submit annual reporting to the Cannabis Research Coordinator.



Roles and Responsibilities

- UR Stores
 - Purchases the cannabis from legal sources in accordance with amounts approved.
 - Keep cannabis in secure safe when not in use by a researcher.
 - Ensure that researchers have an approved protocol before releasing cannabis from the secure location.
 - Track amounts released to and returned by researchers.
 - Reconcile amounts distributed with amounts returned, used, destroyed, and report anomalies to the Cannabis Research Coordinator.

Roles and Responsibilities

- Campus Security
 - Consult with stakeholders as required regarding appropriate security provisions to be implemented, particularly if alarms, surveillance systems or renovations are considered.
 - Provide advice to the Cannabis Research Committee on safety protocols as required.
 - Investigate any losses/thefts of cannabis.
 - Liaise with law enforcement agencies as required.

Applications

- Researchers must apply to the Cannabis Research Committee far enough in advance of the start of the program of research for the Committee to review and approve and for UR Stores to purchase the cannabis.
- Application details include:
 - Research to be conducted
 - Type and quantity of cannabis to be used
 - Location of use
 - Personnel involved in project



Applications

- Details (continued)
 - Security measures in place for laboratory during experimental sessions
 - Record keeping measures within the lab
 - Destruction procedures
 - Proof of other certifications, if required. E.g. No objection letter for clinical trials, REB approval, PCAC approval.

Amendments

- The following circumstances will require an amendment to the application form:
 - Changes to source of cannabis
 - Changes to amount required
 - Changes to product name
 - Changes to research protocol
 - Changes to location
 - Changes to personnel
- Notifying the University of these changes will ensure that records concerning your research project are up to date and in compliance with all guidelines and the terms of our licence.

Procurement

- All cannabis must be obtained from a legal source through UR Stores.
- The Director, Research Office, will approve a Procurement Form based on amounts described in the Cannabis Research Application Form and any usage to date (for subsequent purchases).
- The approved Procurement Form must be submitted to UR Stores with sufficient notice before the start of the cannabis research to allow for purchase of the product.

Working with Cannabis

- The operation area for a proposed study must be approved at the time of the Cannabis Research Application Form to ensure that the space proposed meets these criteria. Research can only take place in the room(s) listed on the approved permit.
- Access in operations areas must be controlled by requiring laboratory doors to remain closed and locked while cannabis research is taking place. Only those individuals who are listed and approved on the *Cannabis Research Application Form* are permitted within a research space while research with cannabis is ongoing.



Working with Cannabis

- Cannabis will be stored in a locked safe in a locked mechanical room inside of UR Stores.
- Researchers will be provided with the amount of cannabis required for that day.
- Any unused cannabis at the end of the day is to be returned or destroyed following the procedures set out in the *Cannabis Program* and documented on the *Destruction of Cannabis Form*. The *Destruction of Cannabis Form* will be returned to UR Stores to reconcile the amount of cannabis distributed with the amount returned and disposed of at the end of the day.



Record Keeping

- All material is to be requested from a legal source through UR Stores.
- UR Stores will track materials in and out of their facilities on a daily basis (unless there is no cannabis research activity on that day).
- Records must be kept for at least 2 years.

Destruction

- Cannabis is to be destroyed using one of the methods on the following form.
- Destruction must be witnessed by the PI and by a permanent employee of the university. Students can not sign the destruction form.

Reporting

- Principal Investigators need to provide an annual report on their research projects. The information provided will be used to formulate the University's annual report to Health Canada. Researchers will be asked to report on:
 - Changes to the nature of the research
 - Quantity of cannabis approved by the current permit
 - Quantity of cannabis used in the reporting year
 - Quantity proposed for the next year

Equivalent amounts (for relevant forms)

Class of Cannabis	Quantity that is equivalent to 1 g of dried cannabis
Dried cannabis	1 g
Fresh cannabis	5 g
Solids containing cannabis	15 g
Non-solids containing cannabis	70 g
Cannabis solid concentrates	0.25 g
Cannabis non-solid concentrates	0.25 g
Cannabis plant seeds	1 seed

Note: Non-dried cannabis in solid and non-solid forms are considered cannabis concentrates when above 3% THC by weight.

Questions?

- For questions, contact research.office@uregina.ca .