



Cannabis Research Program

Office of Administrative Responsibility: Research Oversight and Compliance Office

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PURPOSE

To facilitate compliance with prescribed requirements for research involving the use, handling, or other manipulation of cannabis plants, seeds, and/or extract products and derivatives referred as cannabis in these guidelines.

SCOPE

This guideline applies to all individuals conducting research activities involving the use, handling, storage or other manipulation of cannabis at the University of Toronto (Campus).

DEFINITIONS

cannabis –

- a cannabis plant,
- a part of a cannabis plant
- any substance or mixture of substances that contains or has on it any part of a cannabis plant
- phytocannabinoids found in a cannabis plant whether produced by the plant or not and whether contained in the plant or not.

cannabis level 1 –

- less than 100g equivalent dry weight cannabis
- no growth

cannabis level 2 –

- 100g-11kg equivalent dry weight cannabis
- 0-15 m² growth area

cannabis level 3 –

- 11kg-600kg equivalent dry weight cannabis
- 15-200 m² growth

production –

- Includes growth, propagation and cultivation of cannabis; extraction of phytocannabinoids from cannabis plants; synthesis of phytocannabinoids.



Responsible Person -

- an individual assigned by the Licence Holder and responsible for activities conducted by the Licence Holder with the authority to bind the University.

GUIDELINE

1. Introduction

The Cannabis Act and Regulations permit various activities involving the use, handling or other manipulation of cannabis.

Research with any amount of cannabis must be conducted under a valid licence delivered by Health Canada. This may be accomplished by conducting the research either:

- at the site of another licensee whose licence type permits the type of research proposed e.g. research involving cultivation conducted on the site of a person with a Cultivation Licence (Standard or Micro-Cultivation), under the terms and conditions of their licence; or
- under a University of Toronto (Campus) Cannabis Research permit in accordance with a University Cannabis Research Licence issued by Health Canada.

As the University transitions to a campus specific licence and internal permitting system, Principal Investigators may continue to work under individual research licences issued for their particular program. Cannabis research to be conducted at sites other than the St. George, UTM or UTSC Campus will require a separate Cannabis research licence (e.g. research stations, or multi-site studies).

2. Responsibilities

2.1 Office of the Vice President, Research and Innovation

- Represent the University (licence holder) and provide a letter in support of an institutional licence
- Act as the Responsible Person for the purposes of the licence and identify an alternate

2.2 Research Compliance Manager

- Consult with stakeholders including Principal Investigators as required regarding appropriate security provisions, operational procedures and licence applications associated with research programs involving cannabis
- Develop and manage research licence applications as the delegated Alternate Responsible Person
- Manage the University of Toronto Cannabis Research Program



- iv. Liaise with regulatory bodies regarding licence applications, and amendments associated with research programs involving cannabis and submit any required reports
- v. Maintain cannabis inventories of all internal permits, including PIs, research type and location

2.3 Principal Investigator (PI)

- i. Apply for a cannabis permit and receive approval before obtaining and/or commencing work with cannabis
- ii. Develop and maintain required standard operating procedures for cannabis related activities
- iii. Provide training on related procedures to all personnel working under the permit
- iv. Maintain records of cannabis inventory as prescribed
- v. Take adequate steps to contain, protect and secure cannabis against loss or theft
- vi. Restrict access to the cannabis to those with a need to access for the research project
- vii. Adhere to any other terms and conditions of permits and licenses granted
- viii. In the event of an extended absence from the University, make alternate arrangements for possession and safekeeping of cannabis including licence/permit amendment as required
- ix. Report any loss or theft of cannabis to Campus Police and the Research Compliance Manager immediately upon discovery. Report spill, loss or thefts of cannabis to the Research Compliance Manager.
- x. Maintain, amend, renew and terminate approvals in a timely manner as applicable
- xi. Permit the Research Compliance Manager, or Inspector to audit all records, locations and inventories of cannabis
- xii. Destroy all unused cannabis material through authorized destruction methods outlined in permit upon completion of associated research.

2.4 Researchers

- ii. Participate in related training as required
- iii. Complete and maintain required records
- iv. Safeguard the cannabis and adhere to access control and security provisions
- v. Report any spills, or losses of cannabis to the PI immediately

2.5 Campus Police

- i. Consult with stakeholders as required regarding appropriate security provisions to be implemented, particularly if alarms, surveillance systems or renovations are considered.



- ii. Investigate any losses/thefts of cannabis.
- iii. Liaise with law enforcement agencies as required.

3. Cannabis Research Registration and Permits

Principal Investigators are required to submit cannabis research applications for registration, review and approval as necessary for all projects involving the handling, use or manipulation of cannabis at University of Toronto (Campus) locations.

Projects involving cannabis levels 1 or 2 may be registered following review and approval by the Research Compliance Manager or delegate. Projects involving cannabis level 3 or lower levels as referred by the Research Compliance Manager are to be reviewed by the Cannabis Research Committee.

Projects completed solely at locations otherwise licensed under the Cannabis Act (e.g. industrial partners with cultivation or processing licences) may be completed under those licences subject to the terms and conditions of the licence and approval of the particular Licence Holder.

Projects requiring other approvals, such as those associated with the use of animals, human subjects, biohazards or radiation must have all approvals in place as needed.

3.1 Amendment

An amendment to a Cannabis Research Permit is required whenever there are changes to the information contained in the permit application. This includes changes to the:

- cannabis described in the Cannabis Research Permit
- maximum quantities of cannabis
- research type
- locations
- principal investigator or designate (including cases of absences > 3 months)

3.2 Renewal

Cannabis Research Permits are renewed annually upon receipt of an annual status report for a maximum of 5 years at which time a new permit application must be submitted.

3.3 Cancellation

Cannabis Research Permits can be cancelled by the PI following appropriate decommissioning of the related spaces and destruction and/or approved transfer of all remaining cannabis materials.

4. Destruction

Authorized destruction methods must render the cannabis unavailable and unusable for subsequent use. Destruction methods to be used for the particular work are to be detailed in the licence application.



For plant material, including seeds, appropriate destruction methods include:

- autoclaving followed by mixing with soil/growth media.
- grinding of plant material and combining with other ground waste material such that the cannabis content is < %50. Other waste material may be soil, cardboard, food waste, or other absorbent material.
- incineration by approved provider

For non-plant material e.g. cannabis oil, an appropriate destruction includes mixing with liquid soap, absorbing with a spill absorbent material and disposing via the University's hazardous waste procedures.

All destruction must be annotated in the appropriate inventory records and explicitly recorded. See section 5.3 for details regarding destruction records.

All destruction must be witnessed by the at least 2 University employees, one of which is the applicable permit holder. Students are not able to act as witnesses for destruction.

5. Security

5.1 Security clearances

Personnel security clearances are not a regulatory requirement of a research licence, however could be included as a condition of permit approval for projects at or above Cannabis level 3.

5.2 Physical security

Research areas are to be designed to prevent unauthorized access.

Storage and cultivation areas are to be restricted access.

Specifications for physical security will depend on the nature and scope of the research involved with consideration of the quantity of cannabis on site. Please see the University of Toronto's Cannabis Security Matrix for security expectations.

6. Records – Cannabis Act and Regulations

Receipt, usage, transfer and destruction/disposal records must be maintained at the site specified in the registration/permit application.

All records are to be in a place, form, and manner that will permit an Inspector to readily examine them. Records must be maintained for at least two years from the date of the making of the record even if the related licence has expired or is terminated.

Examples of records are included in the Appendix. Electronic records may be accepted provided there is a mechanism in place to track changes.

6.1 Receipt Records

Records of receipt must include the following:

- name and address of the person/organization from whom the cannabis was received



- address of location at which it was received
- date received
- quantity received (e.g. number of containers and quantity per container, number of plants, number/weight of seeds, etc.)
- name/description of cannabis material including brand name if applicable
- lot or batch number if known
- form of the cannabis containing drug and its strength per unit if applicable
- intended use

Appendix A contains an example of a suitable receipt record.

6.2 Inventory Records – production

For cannabis production, inventory records to comply with the Cannabis Regulations must include that listed below as applicable. Monthly reporting in accordance with the requirements of the Excise Act may also be required. See Section 6.

- Cannabis plants ○ Date propagated by means other than sowing seeds and the number of new plants propagated
- Cannabis seeds ○ Date seeds are sown and their net weight on that date
- Dried cannabis ○ Date on which drying processes are completed and net weight on that date
- Packaging of cannabis into discrete unit form ○ Date put into a discrete unit form e.g. capsule, the net weight or volume of cannabis in each unit and the number of units
- Cannabis oil/extracts ○ Date produced and net weight or volume
 - In respect to the cannabis used to produce the oil/extract, its description, net weight or volume, its lot or batch number and date produced
- Other ○ Date on which cannabis is otherwise produced (e.g. synthesis), and its net weight or volume on that date.

6.3 Usage records

For cannabis that it being used, records must include the following information:

- lot/batch number or sample identifier as applicable
- particulars of use including description of use, patient and/or project identifier as applicable
- amount used
- amount remaining
- identity of the person using the cannabis (legibly printed name and signature)



Appendix B contains an example of a suitable usage record.

6.4 Destruction records

Destruction records must be kept for any cannabis that is destroyed. Records must include:

- Description of cannabis including brand name, if applicable
- Date of destruction and its pre-destruction net weight (or volume as applicable)
- Address at which the cannabis is destroyed
- Brief description of destruction method
- Names of individuals who witness destruction and their role allowing them to witness such destruction
- Signed and dated statement by two witnesses stating:
 - That they witnessed the destruction
 - That the cannabis was destroyed in accordance with approved method.

See Appendix C for an example of a suitable destruction record.

6.5 Transfer Records

All import, exports, domestic or internal transfers of cannabis materials must be approved by the Research Compliance Manager prior to movement.

7. Reporting and Records – Excise Act

If research involves the growth or cultivation of cannabis plants or production of cannabis oils or concentrates, monthly reporting to Canada Revenue Agency (CRA) will be required under the University's Cannabis Licence. This will first require the research premises to be added to the licence, inclusion of the destruction method to be used and may require an on-site inspection by CRA.

The information to be reported is found on the monthly reporting form. This information must be submitted to the Research Compliance Manager by the 2nd Friday of the month following the end of the reporting period such that it can be collated with records from other University research projects as applicable and provided to CRA in accordance with the University Cannabis Licence.

RELATED EXTERNAL LEGISLATION OR POLICY

- [Cannabis Act](#)
- [Cannabis Regulations](#)
- [Excise Act](#)



LOCATION OF RESEARCH GUIDELINE

This guideline is published at: Environmental Health and Safety Website: ehs.utoronto.ca

APPENDIX

A: Example of a suitable receipt record

Cannabis Receipt Record

Name of supplier:

Address of the supplier:

Name of receiver:

Licence number:

CANNABIS

Date received:

Address where cannabis was received:

Storage location (Building and room):

Description of cannabis material:

Brand name if applicable:

Intended use: Lot/batch
number

Net weight or volume (if
liquid) received

For cannabis containing drug,
indicate form and strength per
unit

Not applicable



B: Example of a suitable usage and transfer record

Cannabis Usage and Transfer Log

Principal Investigator name:

Description/name of cannabis:

Lot number/batch number or sample ID:

Date produced (optional field if produced within the research project at the University):

Identifier of cannabis from which the oil/extract was produced (optional field if form is used to track usage of an extract/oil):

Net starting weight/volume of cannabis: Date of use	Description of Use	Patient or project ID	Quantity Used	Quantity Remaining
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A separate form is to be completed for each container.

*Produced - cultured, dried, synthesized, extracted, or sown. Refer to the Section 4.2 in the Guideline for further information

C: Example of a suitable destruction form

Destruction of Cannabis Form

DESCRIPTION OF DESTRUCTION METHOD

- Plant material - Autoclaved and mixed with soil and/or culture media.
- Plant material – Ground and mixed with at least equal part of other materials. Indicate what other materials used:
- Other – Mixed with liquid soap and absorbed with solid absorbent.



SOP used for destruction:

DESTRUCTION

Description of samples destroyed, including brand name if applicable:

Location (address) of destruction:

Samples destroyed: Sample identification number	Net weight or volume (if liquid) prior to destruction
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WITNESS

I, the undersigned, certify that I am an employee of the University of Toronto (Campus) and that I have witnessed the destruction of the cannabis described above as per the method described above.

Name: _____ Signature: _____ Date: _____

Name: _____ Signature: _____ Date: _____