



Cannabis Research Program

Office of Administrative Responsibility: Office of Research Risk

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PURPOSE

To facilitate compliance with prescribed requirements for research involving the use, handling, or other manipulation of cannabis.

SCOPE

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

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 license. This may be accomplished by conducting the research either:

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



As the University transitions to a campus-wide license and internal permitting system, Principal Investigators may continue to work under individual research licenses issued for their particular program. Cannabis research to be conducted at sites other than the Guelph Campus will require a separate Cannabis research license (e.g. research stations, Ridgetown, or multi-site studies).

2. Responsibilities

2.1 Office of the Vice President, Research

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

2.2 Cannabis Research Committee

- i. Provide oversight for the development and ongoing management of the Cannabis Research Program
- ii. Review Cannabis Research permit applications for Cannabis Security Level 3 and other permit applications as deemed prudent

2.3 Manager, Research Risk

- i. Consult with stakeholders including Principal Investigators as required regarding appropriate security provisions, operational procedures and license applications associated with research programs involving cannabis
- ii. Develop and manage research license applications as the delegated Alternate Responsible Person
- iii. Manage the internal Cannabis Research Program



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

2.4 Principal Investigator (PI)

- i. Apply 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 license/permit amendment as required
- ix. Report any loss or theft of cannabis to the Campus Safety Office immediately upon discovery. Report spill, loss or thefts of cannabis to the Manager, Research Risk.
- x. Maintain, amend, renew and terminate approvals in a timely manner as applicable



- xi. Permit the Manager, Research Risk, 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.

2.5 Researchers

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

2.6 Campus Safety Office

- 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 Guelph locations.

Projects involving cannabis levels 1 or 2 may be registered following review and approval by the Manager, Research Risk or delegate. Projects involving cannabis level 3 or lower levels as referred by the Manager, Research Risk 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 licenses) may be completed under those licenses subject to the terms and conditions of the license and approval of the particular License 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
- 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. Cannabis Research Committee

The Cannabis Research Committee is to be comprised of:

Cannabis Research Program



- faculty representative of the cannabis related research activities at the University including biomedical, plant biology and analysis/assessment.
- faculty not involved in cannabis related research
- representative from the Campus Safety Office
- Manager, Research Risk

5. 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 license 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.
- composting

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 7.5 for details regarding destruction records.

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

6. Security

6.1 Security clearances

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

6.2 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 Guelph's Cannabis Security Matrix for security expectations.

7. 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 license 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.

7.1 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.

7.2 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 8.

- 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.

7.3 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.

7.4 Transfer Records

All import, exports, domestic or internal transfers of cannabis materials must be approved prior to movement. Domestic and internal transfers are approved using the Cannabis Transfer Approval form seen in Appendix E. Imports and/or exports must be accompanied by appropriate import/export permits issued by Health Canada. Note that transfer of plant material or seed may also require an import permit from CFIA or the equivalent authority of the importing country. Import/export permit applications are submitted by the Responsible Person or alternate on the license.



Appropriate chain of custody documentation must accompany all transfer shipments. See Appendix C for an example of a suitable chain of custody record.

7.5 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 D for an example of a suitable destruction record.

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.

production –



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Research Guideline: OR-RR-G-009.1

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

Responsible Person -

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

RELATED EXTERNAL LEGISLATION OR POLICY

- [Cannabis Act](#)
 - [Cannabis Regulations](#)
 - *Research License application guide*
 - *Research License management guide*

LOCATION OF RESEARCH GUIDELINE

This guideline is published at: www.uoguelph.ca/research

REVIEW FREQUENCY

It is the responsibility of the Office of Administrative Responsibility to initiate review of this policy. This guideline is to be reviewed every 5 years.



APPENDIX

A: Example of a suitable receipt record

Cannabis Receipt Record

SUPPLIER AND RECEIVER INFORMATION

Name and address of supplier:

Name of receiver:

License number of receiver:

CANNABIS MATERIAL

Date received:

Address where cannabis was received:

Storage location (Building and room):

Description of cannabis material (including CRA classification if applicable):

Brand name if applicable:

Intended use: Research

Lot/batch number	Net weight (g) or volume (ml) received	For cannabis containing drug, indicate form and strength per unit <input type="checkbox"/> Not applicable

***Maintain all original documentation accompanying shipment.**



B: Example of a suitable usage record

Cannabis Usage 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	Used by (printed name)

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 chain of custody record

Cannabis Program: Chain of Custody form

Part A. Sender and Receiver Information	
<input type="checkbox"/> Sender	Name: University of Guelph
<input type="checkbox"/> Receiver	License:
	Address: 50 Stone Rd. E. Building #:
<input type="checkbox"/> Sender	Name:
<input type="checkbox"/> Receiver	Licence:
	Address:

Part B. Product to be Transferred				
Product Type	Strain	ID Number	Quantity at Sender	Quantity at Receiver (To be completed by receiver upon receipt)
Transfer information		Quantity received		
Completed by:		verified by:		
Initials/Signature and Date:		Initials/Signature and Date:		



Part C. Shipping Information	
Method of Transportation	Date of Shipment
Name of Shipper	Signature of Shipper

Part D. Receiving Information	
Date Shipment Received	
Name of Receiver	Signature of Receiver



D: 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 CRA classification if applicable):

Brand name if applicable:

Location (address) of destruction:

Identification number of samples destroyed	Net weight or volume (if liquid) prior to destruction	Number of plants/seeds, if applicable

WITNESS

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

Name: _____ Signature: _____ Date: _____

Name: _____ Signature: _____ Date: _____



E. Changes from Previous Version

- Update of Campus Police to Campus Safety
- Additional information related to requirements and documentation for transfers of cannabis
- Removal of reference to Excise act and CRA licensing as this is no longer required for Cannabis Research licensees