

Western University Cannabis Research Program Guidance

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Introduction

The Cannabis Act and its Regulations provide, among other things, the framework for legal access to cannabis, and its control. Under this framework anyone who wishes to engage in cannabis related activities, including research, must obtain a license from Health Canada. Applicants and license holders must adhere to relevant federal, provincial, and territory laws, municipal bylaws, and strict regulations on the production, distribution, and sale of cannabis and related activities as outlined by the framework.

Western University ("Western") has obtained an institution-wide cannabis license for research involving cannabis/cannabis related products. Researchers wishing to conduct research activities with cannabis/cannabis related products will be required to register with Western's Cannabis Research Program and obtain a permit prior to conducting any research activities with cannabis/cannabis related products.

This guidance document describes the procurement, use, handling, and storage of cannabis for research purposes conducted at Western. This guidance document does not apply to researchers at Western's affiliated University colleges or hospital sites.

Scope

This guidance applies to all individuals using, possessing, producing, transporting, sending, or delivering cannabis for research purposes at Western. For the purposes of the institution-wide cannabis license, research includes but is not limited to *in-vitro*, *in-vivo*, clinical trials, cannabis product development (not including administration to humans), analysis (if it supports your own research), educational programs, and research with hemp.

Duration of License

Western's cannabis license is effective for periods of five (5) years. Western looks to renew its institution-wide institution cannabis before expiry. Permit approvals issued to researchers will be active until Western's institution-wide cannabis license expiry date. Researchers are responsible for submitting for an extension if their research will extend beyond the license expiry date.

Types of Research with Cannabis

The following are the types of research that are included in the institution-wide cannabis license. Note, this is not an extensive list and researchers are required to contact the Manager, Research Quality & Compliance for further details regarding whether their research requires a licence.

- Clinical Trials. Clinical Trials or interventional studies with cannabis/cannabis related products
 regulated under the Food and Drugs Regulations (FDR), will require a No Objection Letter (NOL) in
 addition to permit approval from Western's Cannabis Research Program.
 - Note: not all interventional studies require an NOL as such, it is recommended that researchers contact the Manager, Research Quality & Compliance to discuss requirements.
- **Observational studies**. Observational studies are non-interventional such as recording observations, analyzing data, etc. These studies do not require an NOL but will require permit approval from Western's Cannabis Research Program.

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- * Western's Institution-wide Cannabis License does **NOT** currently allow for:
 - Non-therapeutic research on cannabis (NTRC). NTRC are interventional, non-therapeutic studies for
 the purposes of, increasing knowledge on cannabis and its non-therapeutic effects; gaining knowledge
 to inform public health and public safety measures, public education, and policy; further research and
 development of cannabis products.
 - If researchers intend to conduct a NTRC study, they will need to obtain an individual license with provision of the license, once approved, to Western's Cannabis Research Program.
 - Analytical testing involving cannabis/cannabis related products as a service. Individuals who wish, for the purposes of testing, to produce, distribute and sell reference standards, and to manufacture or assemble and distribute and sell test kits, to possess cannabis and to alter the chemical properties of cannabis by any means for the purposes of testing will require an analytical testing license.
 - If researchers intend to conduct a study involving analytical testing as a service, they will need to obtain an individual license, with provision of the license, once approved, to Western's Cannabis Research Program

Roles and Responsibilities

Roles relevant to the use, handling, and other management of cannabis at Western are outlined below.

Principal Investigator (PI)

The PI is required to:

- Complete a Cannabis Research Registration Permit Application and submit it to Western's Cannabis Research Program for consultation, review, and approval.
- Maintain up to date records of cannabis inventories, current approved study team members, and destruction.
- Take adequate measures to protect and secure cannabis against theft, inadvertent use, and loss.
- Restrict access to cannabis to only those with a need associated with a licensed activity that falls under the institution-wide cannabis license.
- In the event of an extended absence (> 3 months) from Western, make alternate arrangements for the possession and safekeeping of cannabis including keeping up to date with permit requirements.
 - This includes notifying Western's Cannabis Research program of any changes/updates to the PI.
- Immediately report any loss or theft of cannabis to the Western Special Constable Service (WSCS) and Western's Cannabis Research Program.
- Maintain, amend, and renew permit as required.
- Upon completion of associated research, or when no longer needed; destroy all unused cannabis material through authorized destruction methods outlined in this document.
- Train study team members on the requirements outlined in the permit.

Study Team Members

Complete required records as delegated by the PI.

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- Safeguard cannabis on-site and, adhere to safety precautions as outlined in the initial safety assessment.
- Report any spills or losses of cannabis to the PI immediately.

Responsible Person

The Vice-President (Research) is the Responsible Person (RP) for the institution-wide cannabis license. The RP has overall responsibility for the activities conducted under the licence, has the authority to bind the license holder and will be the main point of contact with Health Canada.

Alternate Responsible Person

The Alternate Responsible Person (ARP) role is held by the Director, Research Ethics and Compliance. The ARP is qualified to replace the RP if required.

Cannabis Research Program

Western's Cannabis Research Program is led by the Manager, Quality & Research Compliance under the auspices of the Research Ethics and Compliance unit of Western Research. The program is in place to oversee all research conducted with cannabis at Western. Responsibilities under this program include:

- Providing training to researchers on the use of cannabis in research at Western.
- Accepting and approving permit applications by researchers.
- Maintaining records of all approved permits.
- Monitoring and inspecting areas where cannabis is stored and used.
- Conducting investigations where contraventions or deviations from activities prescribed in a license have occurred or are suspected to have occurred.
- Updating the RP on the status of the license and permits.
- Liaising with Health Canada regarding:
 - License applications and amendments associated with research projects involving cannabis at Western.
 - o Information or compliance requests.
 - o Clarification of any criteria that is unclear.
 - Reporting to Health Canada as required.

Western Special Constable Service (WSCS)

- Work with the researcher and the Cannabis Research Program to ensure security provisions are in place and implemented.
- Investigate any suspected loss or theft of cannabis.
- Liaise with law enforcement agencies as required.

Safety & Well-being Office

• Responsible for disposal and destruction of controlled substances including cannabis.



Procedures

Submission to Western's Cannabis Research program is required for approval of the use, possession, production, transportation, sending or delivering of cannabis/cannabis related products for research purposes at Western. Researchers are still required to submit to the applicable Western Research Ethics Board (REB) for any studies involving human participants and Western's Animal Care Committee for any studies involving animals.

1. Pre-Application Consultation Meeting:

• Research teams are invited to set up a consultation meeting with the <u>Quality & Research Compliance</u> team prior to submission of the Cannabis Research Registration permit if needed (optional).

2. Application (Submission):

- The PI will submit the Cannabis Research Registration Permit Application via email to the <u>Cannabis</u> Research Program.
 - See template of the Permit Application in <u>Appendix A</u>
 - The full permit application can be found on the Western Research cannabis webpage.

3. Review

- The application is then reviewed by a member of the Quality & Research Compliance team in consultation with related stakeholders such as Western Special Constable Service (WSCS) with regard to security measures, Research Ethics Board (REB)/Animal Care Committee (ACC) to determine if a No Objection Letter (NOL) or Veterinary Drug Experimental Studies Certificate (ESC) is required, and any additional relevant/applicable individuals.
 - NOTE: All regulatory approvals, i.e. No Objection Letter (NOL) and/or experimental Studies
 Certificate (ESC), Research Ethics Board (REB), Animal Use Protocol (AUP), Biological Agents
 Permit Application (BAPA) approval etc. will need to be provided with the permit prior to any
 approvals.
- If not already completed, site security will be initiated by the Manager, Quality & Research Compliance and conducted by WSCS.
- Any changes requested by WSCS will need to be completed and in place prior to issuing the Cannabis permit.

Permit issuance

- A member of the Quality & Research Compliance team will communicate directly with the PI to clarify
 or make any necessary changes. When all expectations have been met, a permit is provided for a
 maximum of five years, renewable.
- Once a permit is in place, the PI is responsible to maintain, amend, and renew permits as required.
 - Any changes to a study which may affect the permit must be submitted to the Cannabis Research Program prior to the initiation of said changes. See <u>Appendix B</u> for an example of the required documentation.



- Of note, if these changes require notification to the REB/ACC this will need to be submitted in addition to notification to the Cannabis Research Program.
- A courtesy notification will be sent to the researcher 30 days before their license will expire as a reminder to renew their license. A PI can reapply up to 30 days in advance of the permit expiry date to avoid a lapse in approval.
 - **Note**, it is still the responsibility of the researcher to keep track of any expiry dates and ensure all approvals are in place and maintained appropriately.

Procurement of Cannabis

All sources of cannabis that will be used for research purposes will be obtained from a legal source, specifically a license holder as defined under the Cannabis Regulations, a retail or online point of sale authorized by a province or territory or a legal foreign source.

All researchers conducting research under the institution-wide cannabis license will ensure:

- That cannabis procured for research purposes under this license is from a supplier/source authorized to distribute to the Research License Holder (this <u>site</u> can be used for reference if needed);
- That the source of their cannabis is from a legal supplier.
- The manufacturer or distributor listed on Western's permit application is used to procure cannabis.

Inventory for cannabis stored at Western

All researchers under Western's institution-wide cannabis license must agree to maintain ongoing individual inventories of cannabis materials to ensure compliance with Western's institution- wide cannabis license.

Western will also maintain a centralized inventory of all cannabis/cannabis related products within the WorkSafe inventory system. Western utilizes WorkSafe as the central inventory of chemicals, and hazardous materials can provide real time updates and changes of materials being used. It is the PI's responsibility to ensure when their product is delivered it is entered into the system.

- If the PI orders cannabis/cannabis related product(s) to be received at one of the Western's four
 receiving locations, a barcode will be created at the receiving location for that product to be tracked in
 WorkSafe.
 - The PI will be required to collect the product at the receiving location as per the normal collection process.
 - Note: this task cannot be delegated, and the PI must collect the product from the receiving area.
- If the cannabis/cannabis related product(s) will be shipped directly to a PI's lab location, the PI is required to contact their department health and safety officer (list of contacts can be found in Appendix G) in order to have the product entered into WorkSafe and to obtain a bar code for tracking purposes. If the department health and safety officer is unavailable, the PI can contact the Manager, Quality & Research Compliance for assistance.
 - The PI will transfer the cannabis/cannabis related product(s) to the controlled location in their inventory so that it is kept private and secure.



Records

Record Keeping

For researchers:

Researchers are required to retain all documents and information related to cannabis research:

- in a manner that will enable an audit of it to be made in a timely manner;
- until the end of the retention period, at least seven years after the completion of the project as per institutional requirements [<u>Faculty Collective Agreement</u> (FCA), Retention of Research and Scholarly Materials].

For the Responsible Person:

The Responsible Person is required to retain a copy of the license and all related documents and information, on the site specified in the license:

- in a manner that will enable an audit of it to be made in a timely manner;
- until the end of the retention period, which is at least seven years after the completion of the project as per institutional requirements (FCA, Retention of Research and Scholarly Materials).

If the Responsible Person ceases to hold a license, they must:

- ensure that the documents and information continue to be retained until the end of the retention period, which is at least seven years after the completion of the project as per institutional requirements (FCA, Retention of Research and Scholarly Materials);
- provide Health Canada with notice, in writing, of the address of the location at which the document or information is retained and of any subsequent change to the address.

For the Cannabis Research Program, it must:

- retain copies of all permit submissions and approvals;
- submit a report to Health Canada annually. In preparing this report, the Cannabis Research Program will confirm with each researcher under the institution-wide cannabis license if there have been any changes in their research.

Institution-wide Records

The Cannabis Research Program will maintain records of all approved permits. All application forms, amendments and related documentation will be stored electronically on Western's server.

Procurement of Cannabis Records

Upon procuring cannabis, the researcher must retain a document that contains:

- Name and address of supplier
- Date received
- Name of receiver



- · Address of where cannabis was received
- Storage location
- Description of cannabis materials including, but not limited to:
 - o Brand name, if applicable
 - Form of the cannabis containing drug received
 - Strength received
- Quantity of cannabis received
- Intended Use

See <u>Appendix C</u> as an example of a Receipt Record that can be used. The records must be retained at least seven years after procurement of the cannabis, in accordance with Western's data retention policy (<u>FCA</u>, Retention of Research and Scholarly Materials).

Storage and Usage Records

Researchers must maintain storage and usage records for cannabis/cannabis related product(s) being used and, these records must include the following:

- Lot/batch number
- Description of use (including patient and/or project identifier if applicable)
- Amount used
- Amount remaining
- Printed name and signature of the study team accessing and using the cannabis/cannabis related products.

See <u>Appendix D</u> for an example of the format to use for a usage record. Usage records must be retained for at least seven years after the completion of the project as per institutional requirements (<u>FCA</u>, Retention of Research and Scholarly Materials).

Destruction

For destruction of all cannabis/cannabis related products, the researcher will send a request to the <u>Safety & Well-being Office</u> (Hazardous Materials/Waste contact) to arrange for a special pickup.

Destruction Records

All cannabis destruction must be recorded, with these records being retained for at least seven years per institutional requirements. See <u>Appendix E</u> as an example of the format for the requirements of a destruction record. Destruction of the materials should be witnessed by the permit holder (typically the PI) and an appropriate Safety & Well-being representative. Students cannot act as witnesses for destruction.

Physical Security

Researchers conducting research under Western's institutional cannabis license will work with Western Special Constable Service (WSCS) and obtain a Campus Safety Provided Through Environmental Design (CSPTED) assessment to determine storage and security requirements in their research space based on the Directive on



Physical Security Requirements for Controlled Substances and Drugs Containing Cannabis. As part of the CSPTED assessment, the CSPTED coordinator determines what the requirements are under this directive based on the type of drug, the quantity and form or concentration. Once the level of security is determined, the CSPTED coordinator factors that into their CSPTED Report. After determining storage, the researcher is responsible for ensuring adequate storage and security conditions.

Access to cannabis is restricted to authorized individuals. Only those with a need associated with a licensed activity that falls under Western's institution-wide cannabis research license and listed on the Cannabis Research Registration Permit Application associated with the project will have access to cannabis storage. Records of the issuing of combinations and keys shall be maintained and available to the Cannabis Research Program. Regulations are periodically updated, and it is the responsibility of the permit holder to understand current requirements.

Western will ensure compliance with Health Canada's <u>Directive on Physical Security Requirements for Controlled Substances and Drugs Containing Cannabis</u> – see Western's Security Matrix.

If a researcher suspects any loss, theft, inadvertent use, or unauthorized access to their cannabis, they must contact WSCS and the Cannabis Research Program immediately for reporting purposes.

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. The reporting form can be found here. This type of research may also be subject to an on-site inspection by the CRA.

Please note that growth and cultivation of plants; or production of cannabis oils is currently prohibited under the Western institution-wide cannabis license.

Monitoring/Oversight

The Manager, Quality & Research Compliance, and WSCS when required, will monitor and inspect areas where cannabis is stored and used on an annual basis to ensure that all procedures approved in the permit are being adhered to. In addition, the Cannabis Research Program will ensure ongoing compliance and will conduct investigations where contraventions or deviations from activities prescribed in a license have occurred or are suspected to have occurred.

In addition to physical monitoring and inspection visits, researchers who hold permits will also be asked to submit an annual form like that provided in <u>Appendix F</u>. If a researcher who holds a permit indicates they will be conducting new research or that their research has changed, the Manager, Quality & Research Compliance will work with them to ensure that all institution-wide permits are in place.

<u>Contact</u>

Western Cannabis Research Program: westerncrp@uwo.ca

Manger Research Quality & Compliance: Karen Gopaul kgopaul2@uwo.ca



1. General Information

APPENDIX A: Cannabis Research Registration Permit Application

Directions

- Email completed form with any accompanying documentation to the <u>Cannabis Research Program</u>.
- In the event of insufficient space, please attach additional pages labelled with the applicable section number.

Renewal/Extension of existing permit Current permit# Proposed start date: Expected completion date: Principal Investigator Principal Investigator Principal Investigator Department Phone E-mail Study Team Members List all personnel involved in the work described in this application (add lines as required). This list must include a designate in the absence of PI. The designate must be a faculty member with research privileges. Students cannot be named as designates. Study team members Department Phone Email Access to cannabis required? I confirm that all personnel involved in the work described in this application are at least 19 years of age 2. Summary of Research Title(s):	Permit Type:				
Expected completion date: Principal Investigator Principal Investigator Principal Investigator Department Phone E-mail Study Team Members List all personnel involved in the work described in this application (add lines as required). This list must include a designate in the absence of PI. The designate must be a faculty member with research privileges. Students cannot be named as designates. Study team members Department Phone Email Access to cannabis required? I confirm that all personnel involved in the work described in this application are at least 19 years of age 2. Summary of Research	\square Renewal/Extension of existing	ng permit	[☐ New permit	
Principal Investigator Principal Investigator Department Phone E-mail Study Team Members List all personnel involved in the work described in this application (add lines as required). This list must include a designate in the absence of PI. The designate must be a faculty member with research privileges. Students cannot be named as designates. Study team members Department Phone Email Access to cannabis required? I confirm that all personnel involved in the work described in this application are at least 19 years of age 2. Summary of Research	Current permit#	ſ	Proposed start o	late:	
Principal Investigator Department Phone E-mail Study Team Members List all personnel involved in the work described in this application (add lines as required). This list must include a designate in the absence of PI. The designate must be a faculty member with research privileges. Students cannot be named as designates. Study team members Department Phone Email Access to cannabis required? I confirm that all personnel involved in the work described in this application are at least 19 years of age 2. Summary of Research	Expected completion date:		E	Expected comple	etion date:
Study Team Members List all personnel involved in the work described in this application (add lines as required). This list must include a designate in the absence of PI. The designate must be a faculty member with research privileges. Students cannot be named as designates. Study team members Department Phone Email Access to cannabis required? I confirm that all personnel involved in the work described in this application are at least 19 years of age 2. Summary of Research	Principal Investigator				
List all personnel involved in the work described in this application (add lines as required). This list must include a designate in the absence of PI. The designate must be a faculty member with research privileges. Students cannot be named as designates. Study team members Department Phone Email Access to cannabis required? I confirm that all personnel involved in the work described in this application are at least 19 years of age 2. Summary of Research	Principal Investigator	Department	Phone	E-mail	
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cannabis required? ☐ I confirm that all personnel involved in the work described in this application are at least 19 years of age 2. Summary of Research	include a designate in the abse	nce of PI. The desi			
2. Summary of Research	Study team members	Department	Phone	Email	cannabis
2. Summary of Research					
2. Summary of Research					
2. Summary of Research					
·	☐ I confirm that all personnel i	nvolved in the wo	rk described in thi	s application are	e at least 19 years of age.
Title(s):	2. Summary of Research				
	Title(s):				



Research type (Select all that	apply)		
☐ Analysis/Assessment	\square Horticultural practices	\square Growing conditions	☐ Plant genetics
☐Pest control	☐ In-vivo (animal research)	☐ Human clinical trials*	
☐ Plant breeding	\square Processing practices		
☐This project involves cultiv	ration, growth and/or propaga	ation	
\Box This project involves synth	esis of cannabinoids		
\Box This project involves produ	uction of cannabis products		
\Box This project involves teach	ing activities		
\Box This project involves the sa	ale of cannabis products		
\square Other. Please describe:			
	ed with Health Canada and, a copy of the		luded with this application.
Objectives/Intent			
	ding procedures, methodolog	gy, inclusion/exclusion crit	teria etc.)
	ding procedures, methodolog	gy, inclusion/exclusion crit	teria etc.)
	ding procedures, methodolog	gy, inclusion/exclusion crit	teria etc.)
	ding procedures, methodolog	gy, inclusion/exclusion crit	teria etc.)
	ding procedures, methodolog	gy, inclusion/exclusion crit	teria etc.)



Other Approvals		
This project involves the use of radioisotopes:	□ No	☐ Yes. If yes, provide permit#:
This project involves the use of biohazards:	□ No	☐ Yes. If yes, provide BAPA#:
This project involves the use of animals:	□ No	☐ Yes. If yes, provide AUP#:
This project involves human participants:	□ No	☐ Yes. If yes, provide REB#:
3. Cannabis Materials		
Select one of the following:		
 □ This project involves the use of approved cult less THC in leaves or flowering heads) □ This project involves the use of cultivars of inc □ This project involves the use of cannabis that 	dustrial help	p only. Cultivars are not approved.
Supplier:		
	ude individu	al foreign source, but not holders of an analytical lals, including those formerly registered under priculations.
Confirm that the intended source(s)/supplier(s) of your cannabis is from a legal supplier.	of cannabis	is authorized to distribute and that the source of
\square Yes, I attest that the source of ca	annabis will	be from a legal source.
\Box The cannabis will be obtained from a licensed license processor).	l source in (Canada (e.g., licensed retailer, license cultivator,
$\hfill\Box$ The cannabis will be imported under a Health required).	ı Canada im	port permit as well as CFIA import permit (if
Provide the source from where your cannabis is	being procı	ured:
Source of procurement (include name and addr	ress)	



Provide information below on the quantity of cannabis materials that will be procured:

	Maximum Quantity at any one time		Description
ТНС		g	
CBD		g	
Plants (for growth/cultivation, including tissue culture)		m2 (of growth area)	
Fresh plant material (for processing, analysis, assessment, etc. not already accounted for above)		g	
Dried cannabis		g	
Oils/extracts/concentrates		g or ml	
Edibles (describe including concentration or amount of THC)		g	
Seeds		Number of seeds	
Other phytocannabinoids not listed above. Specify:		g	

4. Location Campus sites

Please provide information regarding all Western University work locations that will be required for this project.

Building name	Room Number	Purpose



Security Measures

•	·		Service and received your cannabis or	ved a Crime Preven n campus?	tion Through E	invironmental De	esign (CPTED)
☐ Yes. If yes, atta	ach a copy of the a	assessment.	□ No. If n	o, a CPTED will nee	ed to be compl	eted prior to per	mit approval.
Security measure	s to prevent unau	thorized access	(check all that appl	y):			
Location	Physical Security i	measures					
Laboratory	☐ Lab remains locked when not	☐ Access	☐ Access restricted. E- access (key card	☐ Unsupervised access restricted to	☐ Monitored via audible	☐ Alarm monitored via	☐ Monitored via video surveillance
☐ Applicable	occupied		or fob access)	only those involved in the project	alarm	Campus Police	video sai veinanee
□ Not applicable							
Greenhouse	☐ Greenhouse remains locked	☐ Access	☐ Access restricted. E- access (key card	☐ Unsupervised access restricted to	☐ Monitored via audible	☐ Alarm monitored via	☐ Monitored via video surveillance
☐ Applicable	when not occupied		or fob access)	only those involved in the project	alarm	Campus Police	video sui veinance
☐ Not applicable							
Growth chamber	☐ Growth chamber remains	☐ Access restricted. Access	☐ Access restricted. E- access (key card	☐ Unsupervised access restricted to	☐ Monitored via audible	☐ Alarm monitored via	☐ Monitored via video surveillance
☐ Applicable	locked when not occupied	by key.	or fob access)	only those involved in the project	alarm	Campus Police	
☐ Not applicable							
Storage	☐ Lock box	☐ Locked cabinet,	☐ Safe secured to wall or floor	☐ Dedicated locked storage room	☐ Monitored via audible	☐ Alarm monitored via	☐ Monitored via video surveillance

alarm

Campus Police

refrigerator, or

freezer



Storage	Access to storage location restricted to:
Secondary locations	☐ Material will ☐ Other. Describe: remain in the care and control
☐ Applicable	of an individual directly involved in the project
☐ Not applicable	
Other security measures	☐ Additional /alternate physical measures used (if any):



5. Transfer

Please provide information regarding any anticipated transfers of materials to individuals not listed on the application. Leave blank if not applicable. With very limited exceptions, all cannabis materials must be destroyed at the end of the project.

Note that all transfers must be appropriately documented within the inventory and approved in advance.

Name of the Institute or organization	Name of contact	Health Canada License # or Western University Cannabis Research permit #

6. Destruction and Waste Management

Please indicate specific methods used for denaturing/destruction of cannabis waste.

Waste Management

Cannabis materials are to be destroyed prior to disposal using a method approved by Health Canada as part of the University's Cannabis Research License. For each type of material, specify means of destruction to be used.

,,	culture materials	mixed with at	Mixed with liquid soap and solid absorbent	
Plant Material			Not applicable	
Seeds			Not applicable	
Oil/extracts/concentrates	Not applicable	Not applicable		
Cannabinoids	Not applicable	Not applicable		
Other, specify:				



7. Inventory Recordkeeping

Strict ongoing inventories of cannabis materials must be maintained to ensure compliance with the University's
Cannabis Research License. These must be available for inspection upon request.

\square I confirm that I have read and understand Western's Cannabis Research Program Guidance. I
understand my responsibility to ensure that all inventory maintenance procedures are adhered to within
this project.

Record Type	Location of Record	Forms (electronic or hardcopy)
Receipt		
Usage		
Transfer		
Destruction/Disposal		
Other: Describe		



Approval conditions (if any):

Version date: March 25, 2024

Principal Investigator's Certification

I certify that the information provided in this application form is accurate and that any changes will be submitted to the Cannabis Research Program in writing prior to initiation.

I agree to follow all University Cannabis procedures and guidelines as applicable to my project.

I accept responsibility for training of all research, facility and support personnel involved in work described in this application.

I accept responsibility for safeguarding the cannabis from loss, theft or unauthorized access.

Signature	Date
Principal Investigator	
<u>Approval</u>	
Signature	Date
Manager, Quality and Research Compliance	
Approval number:	
Expiry Date:	



Appendix B: Template of Amendment Form (quantity change) for Permit Holders

Permit#	
Amendment Date	
Quantity (New amount of	
cannabis)	
Provide an explanation for	
the change in amount of	
cannabis	
Does this change require	
ethics approval (Human	
and/or Animal)	
 Provide REB or AUP# 	
Description of security	
measures in place for	
storage of cannabis.	



Appendix C: Template of Receipt Record

Receipt Record	
Permit #	
Name of supplier	
Address of the supplier	
Date received	
Address where cannabis was received	
Storage location (building and room)	
Description of cannabis materials including, if	
applicable, brand name.	
 If receiving a drug containing cannabis 	
 – what is the form of the drug and its 	
strength per unit?	
 If receiving cannabis plants or seeds 	
or cannabis that is not of a class set	
out in <u>Schedule 4</u> to the Act – the	
intended use.	
Quantity of cannabis obtained	
Intended use	

^{**}Maintain all original documentation accompanying shipment



Appendix D: Template of a Storage and Use Log

Date of	Lot/batch	Description of	Net starting	Amount	Amount	Used by	Used by
use	number	use (include participant and/or project ID if applicable)	weight/volume of cannabis	used	remaining	(print)	(sign)



Appendix E: Template of a Destruction Record

DESTRUCTION (to be completed by Western's Safety & Well-being Office)

Description of samples destricted Form: Quantity: Include brand name, if application (address) of destruction of method used Date of destruction:	cable: applicable: ction:			
Samples destroyed:				
Sample identification number		Net weight or volume (if liquid) prior to des	truction	
WITNESSES I, the undersigned, certify that I am an employee of Western University and that I have witnessed the destruction of the cannabis described above as per the method described above.				
Name:	_Signature:	Date:		
Name:	_Signature:	Date:		



Appendix F: Template of Annual Reporting Form

Permit #	
Date	
Quantity (initially approved)	
Quantity (last amended if applicable)	
Quantity used since last report	
 Have there been any changes in the initially approved or last amended quantity amount? If yes, include amendment date of approval. If the change in quantity was not submitted as an amendment include a justification as to why. Otherwise please just state no. 	



Appendix G – Departmental Health and Safety Contact Information

<u>Chembio stores</u> (under Science stores)

Engineering Stores (Logistics-Procurement Coordinator)

Biochemistry (Manager, Operations & Safety)

<u>Anatomy and Cell biology</u> and Medical Biophysics (Manager, Operations & Safety for both departments)

Physiology and Pharmacology Laboratory and Facility manager)

Microbiology and Immunology (Laboratory and Facilities manager)

<u>Pathology and Laboratory Medicine</u> (Departmental Technician)

Robarts Research Institute (Martin Awzan)

Version date: March 25, 2024