

Cannabis Licensing Application Guide: Research

**Application Requirements and
Process to Become a Research Licence
Holder under the *Cannabis Act* and**



Government
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du Canada

Canada

FOREWORD

The *Cannabis Act* establishes that an application for a licence must be filed with the Minister in the form and manner specified by the Minister and must include the information required by the Minister. This guide sets out the application process, including the form and manner for submitting an application for a licence, and the information that is required to be submitted. In accordance with the *Cannabis Act*, the Minister may also request any additional information that pertains to the information contained in an application and that is necessary to consider it. It is important to note that in the case where any information required to be submitted is not provided, the Minister may refuse to consider an application.

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Disclaimer

This document should be read in conjunction with relevant sections of the *Cannabis Act* and its Regulations. In the case of any discrepancies between this document and the *Cannabis Act* and its Regulations, the latter shall prevail. In cases of discrepancy between the Cannabis Tracking and Licensing System (CTLS) and the Regulations or guidance, the *Cannabis Regulations* shall prevail.

Publication Date: September 6, 2019

Également disponible en français sous le titre: Guides des demandes de licences liées au cannabis : Recherche

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ISBN: 978-0-660-32701-3

Cat: H134-11/2-2019E-PDF

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Purpose

This document provides information on the application requirements to obtain a licence for research from Health Canada under the *Cannabis Act* and *Cannabis Regulations*.

Background

The Cannabis Act and its Regulations provide, among other things, the framework for legal access to cannabis and control and regulate its production, distribution and sale. Under this framework, a person is required to obtain a licence issued by Health Canada in order to conduct various activities with cannabis, including research. Applicants and Licence Holders are responsible for compliance with the *Cannabis Act* and its Regulations as well as compliance with other applicable federal, provincial and territorial legislation and municipal by-laws.

The *Cannabis Act* establishes that an application for a licence must be submitted to Health Canada in the form and manner specified by the Minister¹ and must include the information required by the Minister. This guide sets out the application process including the form and manner for submitting an application for a research licence and the information that is required.

Health Canada publishes other guidance documents and information on its website that may be used in conjunction with this document to assist you in preparing your application. In order to maintain consistency and transparency, this guide, as well as other guidance documents and information, will be updated, as required, to reflect changes to policies and/or operations.

Scope

This document provides guidance to anyone wishing to apply for a licence under the *Cannabis Act* and *Cannabis Regulations* to conduct activities in relation to research involving cannabis.

For more information on requirements associated with the activities that are not addressed in this guide, applicants may refer to the *Cannabis Act* and *Cannabis Regulations*, additional guidance published on the [Health Canada website](#) or contact Health Canada as outlined at the end of this guide.

This guide does not include information on additional licensing requirements that may be required by the Canada Revenue Agency or provinces and territories.

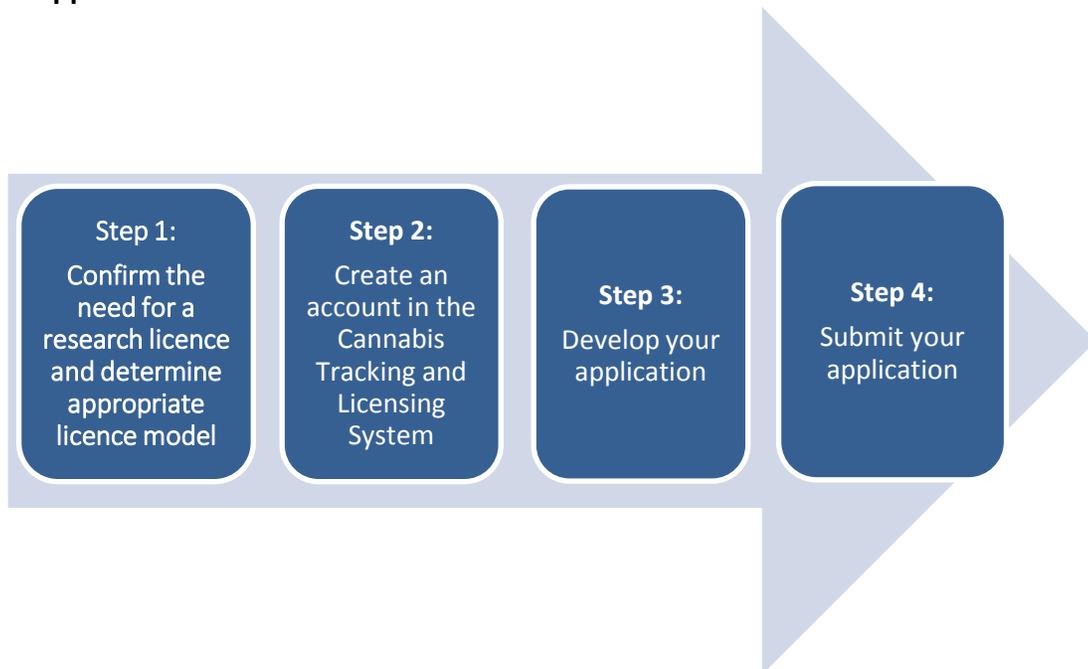
¹ Throughout this guide, there are references to actions that would be taken by the Minister under the *Cannabis Act* and its Regulations, often in the context of decision-making. In many cases, it is anticipated that the decision-making function would not be exercised personally by the Minister, but instead by an official in the Department of Health who is employed in a capacity appropriate to making the decision and who has been delegated that responsibility in accordance with the *Salaries Act*.

Health Canada has established an online licence application system, referred to as the Cannabis Tracking and Licensing System (CTLS), to be used by applicants to apply to Health Canada for a cannabis licence. Applicants should be familiar with the use of this system and should refer to the CTLS User Guide for more information, available upon request from cannabis@canada.ca.

Getting Started: the Application Process

This guide is separated into four steps to help you navigate the application process. The process flow outlined in Figure 1 provides a general summary, with references to the relevant parts of this guide.

Figure 1: Application Process



Step 1: Confirm the need for a research licence and determine appropriate licence model

Is a licence required?

Before applying for a licence, first determine whether a research licence is the appropriate licence for your proposed activities. Research activities can include, but are not limited to, *in vivo* and *in vitro* studies, clinical trials, plant genetics, cannabis product development, and educational programs. If you or your organization holds another licence under the *Cannabis Act*, you may already be authorized to conduct research and development activities under the terms of that licence. Review your existing licence conditions or contact [Health Canada](#) for clarity.

If you wish to carry out analytical testing activities on cannabis (including cannabis products) as a service, you must apply for an analytical testing licence. If you only conduct analytical testing in support of your own research activities, only a research licence is required.



Important: As per the *Cannabis Act*, cannabis (including hemp) means:

- 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, other than a part of the plant referred to in Schedule 2;
- Any substance or mixture of substances that contains or has on it any part of such a plant; or
- Any substance that is identical to any phytocannabinoid produced by, or found in, such a plant, regardless of how the substance was obtained.

The term cannabis DOES NOT include:

- A non-viable seed of a cannabis plant;
- A mature stalk, without any leaf, flower, seed or branch, of such a plant;
- Fibre derived from a mature stalk; or
- The root or any part of the root of such a plant.



Important: If the research being proposed involves the cultivation of industrial hemp plants only (i.e. cannabis plants containing less than 0.3% THC), you may only require an industrial hemp licence to conduct your research. For more information, please see the [Industrial Hemp Regulations](#) and [Industrial Hemp Licensing Application Guide](#).



Important: Research licences cannot be applied for through an amendment to an existing cannabis licence, nor can a new cannabis licence (e.g., for cultivation or processing) be added to a research licence through an amendment. Licence Holders wishing to apply for these licences must submit a new licence application.

Determine licence model

To allow for greater flexibility depending on your organization and the type of research that you wish to conduct, there are three models of research licences that are available:

1. **One project, one site:** One research licence covering one research project, generally with a single research protocol and activities taking place at only one site. If you are a research group that has more than one project, but all under the purview of a single principle investigator in one research area, this model would still apply.
2. **One project, multiple sites:** One research licence covering one research project, but with research activities taking place at multiple sites (e.g., a clinical trial at numerous hospitals).
3. **One institution, one site:** One research licence covering multiple research projects taking place at one institution (e.g., numerous researchers or projects at a single university campus or research hospital; or a large research group performing multiple projects, such as a contract research organization).

Determine what model best suits your proposed research activities prior to starting your application, as the licence model selected will determine the various information requirements as you develop your application.

If your research plans do not fit cleanly within one of the above models, please contact [Health Canada](#) for clarity and to help ensure an appropriate application pathway is developed.



Important: The *Cannabis Regulations* define a **site** as an area that is used exclusively by the Licence Holder and that consists of at least one building or one part of a building.

In practice, a university or college campus could be covered by one institution-wide licence. However, if a university has multiple campuses separated geographically, each campus would require its own licence (but these licences could have the same Responsible Person).



Tip: Individuals affiliated with an institution should check with their institution's administration (e.g. the Vice President's Research Office) prior to applying for a project-based licence, as they may already be covered for their research under an institution-wide licence.



Important: In order for your application to be considered, your facility should be already built.

Step 2: Create an account in the Cannabis Tracking and Licensing System (CTLS)

Health Canada's Cannabis Tracking and Licensing System, or CTLS, is a public facing web application that enables the submission of new licence applications, requests for amendments, and licence renewals in addition to the submission of monthly tracking reports for those Licence Holders required to submit them.

Creating an individual account in the CTLS

In order to submit a licence application in the CTLS, you must first request access. In order to do so, basic information is required including your full name and salutation, email, phone number, date of birth, language preference and security information. Health Canada will then provide an Account ID that can be used to enter the CTLS. You can use the same Account ID for each licence application to which you may be associated.

For more information on the steps to create an account please refer to the [CTLS Getting Started Guide](#) (available on the [Health Canada website](#)).



Tip: Should the CTLS (or internet) not be available to you, you may contact Health Canada directly by phone at 1-866-337-7705 or by email at cannabis@canada.ca for more guidance.

Create accounts in the CTLS for individuals associated with the application. User accounts are also required for additional individuals associated with a research licence application (see Table 1). These individuals must create their own accounts in the CTLS before an application can be completed and submitted to Health Canada.

Table 1: Individuals who require user accounts in the CTLS when applying for a research licence

Role	Account IDs Required	Responsibilities and Qualifications
Licence Holder	Only if the applicant is an individual	<ul style="list-style-type: none">• Overall responsibility for the licence
Responsible Person	For all applicants	<ul style="list-style-type: none">• A Licence Holder must identify an individual, known as the Responsible Person, who has the authority to bind the Licence Holder (often the CEO or Director of the organization, or someone delegated by that person)• The Responsible Person will be the point of contact with Health Canada and through the CTLS• They are responsible for submitting the application• They are responsible for the activities conducted by the Licence Holder• Must have sufficient knowledge of provisions of the Act and Regulations that apply to the holder of a licence <p><i>A qualified alternate Responsible Person may also be identified. This is not yet possible in the CTLS. Instructions for naming an alternate can be found in Step 3.</i></p>
Directors	Only if the applicant is a corporation	N/A
Officers	Only if the applicant is a corporation	N/A



Tip: A single individual may hold one or multiple roles within the company (e.g. be both the Licence Holder and the Responsible Person), for one or more classes of licences at one site, or in some cases, multiple sites, assuming they meet all the requirements.

Creating a corporate profile

An application for a research licence can be created for an individual, an academic institution/research centre, or a corporation. Only applicants that are corporations must ensure that a corporate profile for the organization has been created in the CTLS. Incorporated academic institutions are exempt from having to create a corporate profile.

In order to create a corporate profile, individuals associated with the corporation (i.e. directors and officers) must create user accounts and those Account IDs must be linked to the corporate profile. Once the corporate profile has been created, a new Corporation ID is created for the corporation. This Corporation ID can then be used to create the research licence application, where the corporation can be specified as the Licence Holder.

Creating a corporate profile has some additional requirements, as outlined in Table 2. Some requirements are needed to create a corporate profile in the CTLS, while others are required before an application is submitted.



Tip: If you are applying as an academic institution (e.g. university or college) that is incorporated, you do not need to create a corporate profile.

Table 2: Corporate Profile Requirements

Requirement	Required details to include
The full legal name(s) of the organization	Any other name(s) registered federally or provincially under which the entity intends to do business, if applicable.
The incorporation number	As provided on the certificate of incorporation.
Business address and contact details	The business address and the contact details used for correspondence with the corporation, not the individual applicant (e.g., head office).
Controlling organizations (noted as “Parent Corporation” in the CTLS), if applicable	The Corporation ID of each controlling organization. Note that any controlling organization will be required to create a corporate profile as per these requirements.
Certificate of incorporation	As part of an application, certificate of incorporation documents are required.
Corporate organizational chart	As part of submitting an application, a corporate organizational chart is required. The organizational chart: <ul style="list-style-type: none"> • Must demonstrate the relationships between senior positions within the organization and the various

Table 2: Corporate Profile Requirements

Requirement	Required details to include
	<p>controlling individuals or entities, if applicable.</p> <ul style="list-style-type: none">• Must include all names and titles of senior management positions such as directors and officers of the organization and any controlling individual or entity, if applicable.
Organization personnel	<p>As part of an application, specific organization personnel must be identified. These individuals must have individual CTLS accounts created so that their Account IDs can be associated with the corporate profile.</p> <p>Directors or officers of corporations must be included as part of the corporate profile.</p> <div data-bbox="636 772 1432 1001"><p>Important: The CTLS requires at least one director or officer be named per corporate profile. In the case where there is no director or officer for the organization, the Responsible Person should be identified as an officer in this section of the CTLS.</p></div>



Tip: Changes may be made to the corporate profile before and after an application has been submitted. Changes to the corporate profile will be updated in any associated application that has not yet been granted a licence. If a licence has been granted and there is a change of details in the corporate profile, these changes may trigger an automatic amendment, or may require a notification under Section 34 of the *Cannabis Regulations*.

Step 3: Develop your application

Once you have the appropriate Access IDs to the CTLS, and have determined which licence model you will use, you are ready to start developing your application. There are six main sections of a research licence application:

- I. Licence ownership (Licence Holder)
- II. Mailing address
- III. Site details (including research activities)
- IV. Site personnel
- V. Physical security
- VI. Record keeping

Each of these sections must be complete prior to submitting an application to Health Canada. If your application does not fulfill all of these requirements Health Canada may refuse to consider your application.



Important: Many sections of the application require a document, or several documents, to be uploaded. File names should clearly identify the name of the application requirement outlined in this guide. For example: Research Protocol, No-Objection Letter, etc. A maximum of 5 documents can be uploaded per section, each with a maximum size of 10MB per document. Applicants should combine documents where suitable and minimize extraneous content in order to submit the required documents.



Tip: You are not required to complete the application process in one session. The application may be started in the CTLS and left in Draft status until you are ready to submit.

I. Licence Ownership (Licence Holder)

In this section of the application, you are required to identify the Licence Holder. An application can be created for an individual, an academic institution/research centre, or a corporation. If you apply as a corporation, you must ensure that you have completed a corporate profile for the organization in the CTLS as outlined in Step 2.

Further, a Responsible Person must be designated for all applications. The Responsible Person has the authority to bind the Licence Holder, has overall responsibility for the activities conducted, and is responsible for submitting the application. The Responsible Person is the official point of contact with Health Canada.



Important: As per the *Cannabis Regulations*, you may designate one individual as an alternate Responsible Person who is qualified to replace the Responsible Person. However, in the current version of the CTLS, only one Responsible Person may be designated in the CTLS. To designate an alternate Responsible Person, or to change the Responsible Person after an application has been submitted, email hc.sp-licensing-cannabis-licences-sp.sc@canada.ca with the subject line “Request to add an alternate Responsible Person” or “Request to change Responsible Person” and the application number and details. Health Canada will contact you for additional information, if required.



Important: In order to apply for an institution-wide research licence at a recognized academic institution, a letter of support from a senior member of the institution’s administration (e.g., President, Chancellor, Vice President, or equivalent) must be included with the application in the Record Keeping section. In such cases, please contact [Health Canada](#) if additional information is required.

II. Mailing Address

This section of the application allows you to enter a mailing address identifying a Canadian address where you would like to receive official mailed correspondence (e.g., the licence when issued).

III. Site Details (which includes details on the proposed research activities)

This section of the application seeks information about the site(s) where the proposed research will be undertaken, as well as information on proposed research activities. Table 3 outlines the Site Detail requirements that must be provided as part of a research licence application.

Table 3 : Site Detail Requirements for a Research Licence

Requirement	Required details to include
Complete site address	Primary Canadian site at which the research is proposed to occur (cannot be a P.O. Box) (e.g. for an institution-wide licence, the site could be identified as the main institution address or the office of a senior official such as the Vice President of Research).
 Important: Licensed activities cannot be conducted in a dwelling-house (i.e., a place of residence)	
Research grant identification	The grant number may be provided as additional information, if applicable. This is optional.
Information on cultivation	If cannabis is proposed to be cultivated, propagated or harvested, provide information on where it is proposed to be cultivated, propagated or harvested (e.g. latitude/longitude, indoor/outdoor, buildings and room numbers, etc.).
Identify whether cannabis will be synthesized	Indicate whether cannabis will be synthesized.
Additional site(s) identification FOR PROJECT BASED APPLICATIONS ONLY	For applicants seeking a project-based research licence , if there are additional sites where activities with cannabis are proposed to occur (e.g., processing/extraction of cannabis, clinical trial conducted at multiple hospitals), provide the address of each site as well as the name and contact information of an individual at each site. The address of each additional authorized site will appear on the licence, if it is issued. A document must be uploaded explaining the relationship and interactions between and/or among all sites. This description must indicate if there will be distribution from the primary site to the additional sites, or distribution

Table 3 : Site Detail Requirements for a Research Licence

Requirement	Required details to include
	among the primary site and the additional sites.
Intent to sell	Indicate if there is intent to sell the physical product of the research (e.g., cannabis plants and/or cannabis plant seeds to a licensed cultivator, researcher, or cannabis drug licence).
	<div style="background-color: #e0f2f1; padding: 10px; border: 1px solid #ccc;">  <p>Tip: Distribution to other licence holders and select individuals is permitted for research licence holders and is not considered sale. For more information, see section 28(5) of the Cannabis Regulations.</p> </div>
Research type	<p>Indicate the type(s) of research (e.g., <i>in vitro</i>, <i>in vivo</i> (animal), clinical trial, plant genetics, cannabis product development, non-cannabis product development, other) that is proposed to be conducted with cannabis.</p> <p>More than one type of research may be conducted under a single licence.</p> <p>An example of non-cannabis product development would be research on lights used to grow cannabis plants.</p> <p>For applicants seeking an institution-wide research licence, select all types of research that you expect will be undertaken. For research activities that involve teaching, choose the research type “Other”.</p>
For an <i>in vivo</i> (animal) study: obtain FDA authorization, if applicable	<p>For those conducting research in animals, an Experimental Studies Certificate (ESC) may be required. Examples of when an ESC is required include research conducted in a food producing animal (e.g., dairy cattle, fish, bees, etc.) or trials intended to support the future authorization of a product for use in animals (e.g. a veterinary drug submission).</p> <p>For an <i>in vivo</i> study where authorization under the <i>Food and Drugs Act</i> is required, the ESC must be uploaded as part of the licence application if it is known at the time of application that the ESC is required.</p>

Table 3 : Site Detail Requirements for a Research Licence

Requirement	Required details to include
	<p>Additional information on the ESC can be found in the Experimental Studies Certificate Application Form for a Veterinary Drug</p> <p>For more information regarding animal study authorizations, please consult the Veterinary Drugs Directorate at: hc.vdd.skmd.scdgpps.dmv.cp.sc@canada.ca or</p> <p>Veterinary Drugs Directorate A.L. 3000A Ottawa ON K1A 0K9 Tel: 613-941-8845</p>
<p>For a clinical trial: Obtain No-Objection letter for a clinical trial</p>	<p>Clinical trials conducted with cannabis using human subjects must first have a clinical trial application filed with Health Canada.</p> <p>A copy of the No-Objection Letter must be uploaded as part of the licence application if it is known at the time of application that a No-Objection Letter is required.</p> <p>Additional information on clinical trial application requirements can be found in the Guidance Document For Clinical Trial Sponsors: Clinical Trial Applications as well as on the Health Canada website.</p> <p>For more information regarding clinical trial authorizations, please consult the Office of Clinical Trials at: hc.oct.enquiries-requetes.bec.sc@canada.ca</p>

Table 3 : Site Detail Requirements for a Research Licence

Requirement	Required details to include
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Research protocol	For the purposes of a licence application, a research protocol is a summary of the proposed research to be conducted and the amount of cannabis required for the research. Providing a clear summary document will facilitate the timely review of a research licence application. Please see Appendix B and C templates that may be used to ensure a clear, concise and complete research protocol is submitted.
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For applicants seeking an institution-wide research licence that would cover multiple research projects at the same site (e.g. multiple projects within a single university campus), the research protocol can be broader than individual projects, but should still clearly identify the nature of the proposed research that would be undertaken (e.g., with examples of proposed research activities such as *in vivo* or *in vitro* models, clinical trials, etc.). As part of this document, you are asked to list any frameworks within the institution that will be used to ensure oversight and/or coordination of the various research projects that will be conducted with cannabis at the institution, and adherence to the *Cannabis Act* and its Regulations as well as other regulations that may govern activities performed with cannabis. Examples may include a cannabis research office, research ethics boards, or animal care committees.

The following is a list of requirements to include in your research protocol. Please also refer to Appendices B and C for research summary templates.

Description of research	A brief summary of the types of research activities to be conducted at the site(s). Please include whether studies will involve human subjects (e.g., clinical trials, palatability studies, etc.) and for <i>in vivo</i> research, please be sure to include a list of model organism(s).
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Quantity of dried cannabis (or non-dried equivalent)	For project-based applicants , the maximum quantity of cannabis that is proposed to be possessed or produced by the applicant at any given time (e.g., kilogram, litre or number of plants or seeds, as appropriate), broken down by site (if applicable) as well as the overall total. If cannabis to be used is in non-dried form (e.g., cannabis solid, etc.). See Appendix D for how to calculate equivalent amounts. Note that non-dried cannabis in solid or non-solid forms are considered concentrates when above 3% THC by weight.
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For applicants seeking an institution-wide licence, an *estimate* of the maximum quantity of cannabis that is proposed to be

Table 3 : Site Detail Requirements for a Research Licence

Requirement	Required details to include
	possessed (e.g. grams, kilograms) or produced (e.g. number of plants and/or seeds) by the applicant at any given time is required across all buildings where cannabis is expected to be present. The square footage of grow area would also be acceptable if number of plants is not feasible.
Legal supplier	<p>Attestation that the intended source(s)/supplier(s) of cannabis is authorized to distribute to the Research Licence Holder. For example, suppliers may be a licensed cultivator or processor, a provincially- or territorially-authorized retailer, or a legal foreign source. A legal source does not include holders of a licence for analytical testing, or individuals, including those formerly registered under the <i>Marihuana Medical Access Regulations</i>, <i>Access to Cannabis for Medical Purposes Regulations</i> or currently or formerly registered under the <i>Cannabis Regulations</i>.</p> <p>A Research Licence Holder is authorized to import cannabis from legal foreign sources for medical or scientific purposes if they obtain an import permit from Health Canada for each shipment of cannabis that is imported.</p>
Duration	<p>The duration for which the research licence is sought and a rationale.</p> <p>A research licence may be effective for the duration of the research, up to a maximum of five years. If the research needs to continue past the expiry date of the licence, the Licence Holder may apply for a renewal of the licence.</p>



Tip: You don't need to submit a full research grant proposal or an animal care or clinical trial application. Only the research protocol document **is required**.

IV. Site Personnel

As an applicant for a research licence, you do not have to provide information in the “site personnel” section in the CTLS.

However, keep in mind that, as outlined in Step 2, you do need to identify the individuals that must have CTLS accounts and these individuals will need to create CTLS accounts and provide their Account IDs to you, as the licence applicant (e.g. if applying as a corporation it is necessary to identify directors and officers). Please refer to Table 1 for details.

V. Physical Security

All applications must have a plan for how the operations areas where research activities are proposed to take place are designed in a manner that prevents unauthorized access.

For project-based applications, when quantities of cannabis exceed a total of 1 kg and the applicant is not already a Licence Holder for the cultivation or processing of cannabis, a description of the plan must be provided to Health Canada. This must include a brief description of the site, including its perimeter and the physical security plan for operational and storage areas as well as a brief description of who would have access to operations areas, how access would be controlled to operations area(s), and how storage of the cannabis would be secured.

If the total maximum quantity of cannabis at a site exceeds 11 kg equivalent of dried cannabis, please also include a site plan including clear identification of the perimeter and the delineation of storage and operational areas.

For applicants seeking an institution-wide research licence that would cover multiple research projects at the same site (e.g. multiple projects within a single university campus), a clear framework must be provided to demonstrate how the Responsible Person will ensure that storage and operations areas where any research activities are proposed to take place are designed in a manner that prevents unauthorized access, that security measures are appropriate to the various activities taking place across the institution and that measures are in place to mitigate risk based on the quantities of cannabis present where cannabis research activities will take place within their institution or campus. For example, this may be provided in physical security and record-keeping SOPs that researchers conducting activities under the institution-wide licence must follow to ensure compliance with section 77 of the *Cannabis Regulations*, or a description of other compliance monitoring mechanisms that will be put in place.



Important: Depending on the type of activities proposed to be conducted with cannabis, the quantity of the cannabis on-site and the size of the proposed licence site, additional security measures may be required. Each submission will be assessed on a case-by-case basis.

Table 4 provides a summary of the information that demonstrates how physical security requirements would be met.

Table 4: Physical Security Requirements for Research Licences

Requirement	Required details to include
Prevention of unauthorized access	<p>A description of how the operations areas are designed to prevent unauthorized access to cannabis. Include such details as:</p> <ul style="list-style-type: none">• A brief description of the site, including its perimeter• A brief description of who accesses the operations area(s);• How access to the operations areas are controlled; and• How the storage area is secured. <p>A template can be found in Appendix E.</p> <p>For applicants seeking an institution-wide research licence, if there are varying quantities of cannabis proposed for locations across the institution (e.g. 11 kg of dried cannabis spread across multiple laboratories), a description should be included indicating what measures the institution will take to monitor compliance and mitigate risks based on the quantities of cannabis where cannabis research activities will take place.</p>

Site plan and floor plans IF REQUIRED	<p>The overall site plan must include the following details:</p> <ul style="list-style-type: none">• The perimeter of the site must be clearly identified;• The footprint of any building(s) or units within a building must be clearly identified; and• An indication if the building is a multi-unit building or a stand-alone site (i.e., single unit). If it is a multi-unit building, the site perimeter should be identified accordingly and all units must be labelled with information on their current use (i.e., company name).
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If there are areas (including buildings) that will not be used exclusively by the applicant, these areas must be outside of the proposed site perimeter. If there are areas inside the proposed site perimeter that will be used to conduct activities other than activities with cannabis, these activities must be clearly indicated in an appendix to the site and/or floor plan(s).



Tip: For applicants seeking an institution-wide research licence, a campus map or building site plan can be used. Locations within that institution where research activities with cannabis will be taking place (e.g laboratories) must be indicated, if known at the time of application.

VI. Record Keeping

There are a number of regulatory requirements for record keeping that must be met by a Licence Holder. Table 5 provides a summary of the information that must be submitted as part of a research licence application. The Record Keeping Attestation is found in Appendix F and provides additional details about record keeping requirements for applicants for a research licence.

Table 5: Record Keeping Requirements for Research Licences

Requirement	Required details to include
Copy of government issued identification	In order to verify the identity of the Licence Holder and/or Responsible Person, a copy of government-issued identification must be provided.
Attestation form	Include a signed and completed attestation form found in Appendix F: Record Keeping Attestation.
 Important: There is no specific section in the current version of the CTLS to upload this information. It should be uploaded as an attachment under the “Record Keeping Description” section.	
Letter of support from institution administration IF APPLICABLE	If applying for an institution-wide licence, upload in this section a letter of support for the licence from a senior member of the institution’s administration (e.g., President, Chancellor, Vice President, or equivalent).

Step 4 - Submit your Application

Submitting your application

Once all required information has been entered/uploaded in the CTLS, the application is ready to be submitted.

Use the checklist in Appendix G to ensure that all required pieces have been completed and are included in your submission. Once an application is submitted, no further changes can be made.

Once the application is submitted, it will appear in the “Submitted Licence Applications” section of the CTLS. Each application will have a unique Licence Application ID. All correspondence with Health Canada in relation to the application should include this identifier in the subject title.



Important: If all items included in Appendix G are not included in your submission, the review of your application will be delayed until that information is received via a “request for more information” (see below).

Following submission

Once an application is submitted in the CTLS, there are a series of steps Health Canada undertakes to review the licence and take a decision. A risk-based approach is used to triage applications, depending on a variety of factors such as the maximum quantity of cannabis proposed at the site, or whether multiple projects are part of the application.

Applicants are encouraged to check the status of their application using the CTLS at any time during the application process. Table 6 below provides an explanation of the four categories in the CTLS that denote the status of the application..

Table 6: Application Status

Status	Explanation
Draft	The application has not yet been submitted. Health Canada does not receive, nor process, draft applications. The applicant must complete all sections of the application in order to submit an application for processing by Health Canada.
Submitted	Once the application is received by Health Canada, the application is considered 'submitted' and remains at this stage until the screening of the application commences.
In progress	Health Canada has begun review of the application.
Pending information	A request for more information has been sent to you and Health Canada is waiting for a response.



Important: For assistance related to a specific licence application, an email may be sent to: hc.sp-licensing-cannabis-licences-sp.sc@canada.ca. The email must clearly indicate the application file number, the applicant's name and the subject of the correspondence in the subject line of the email.

Service Standards

Health Canada commits to a non-binding 42 business day service standard for single project applications and up to 180 business days for multiple project or institution-wide applications; these align with service standards that previously existed under the *Narcotic Control Regulations* for s. 56 exemptions or for research with cannabis, respectively.

Administrative procedures

Receiving and responding to a request for more information

Under subsection 62(5) of the *Cannabis Act*, Health Canada may request the submission of any additional information pertaining to an application.

It is the applicant's responsibility to meet all the licensing requirements. If information submitted as part of the application is unclear or requires further detail to show how it meets the requirements, Health Canada will ask the applicant for clarification through a request for more information (RMI). To avoid such a request, ensure your application includes the details noted in this guide and addresses all items in the checklist included in Appendix G.

When an RMI is sent, Health Canada strives to be clear about what information is needed from the applicant and a deadline to respond is provided. If the applicant is unclear about what is required to respond to the request for more information, they may contact Health Canada by email for further guidance (see Contact Information Section of this guide). Note that it is not a requirement to retain the services of a third party (e.g., consultant) to prepare responses to Health Canada.

A request for more information will be emailed to the Responsible Person. The applicant must respond by email within the timeframe requested. Responses should be comprehensive and comment on each of the elements noted in the request for more information. A revised version of the original documents should not be resubmitted unless requested to do so.



Important: Be as specific and as detailed as possible when addressing each question. Incomplete responses may delay processing or lead to a refusal to consider an application. A lack of response to Health Canada's request for more information may also lead to a refusal to consider an application.



Tip: If the applicant wishes another representative to be the primary recipient of communications or receive a copy of all communications, a written and signed consent to Health Canada must be submitted that permits Health Canada to communicate details about the application with another individual. The consent must indicate the name(s) of the individual(s), the application number and be sent to hc.sp-licensing-cannabis-licences-sp.sc@canada.ca from the email address captured within the CTLS for the Responsible Person, with the subject line "Consent to Communicate".

Refusals and withdrawals

Health Canada may refuse to issue a research licence under circumstances set out in the *Cannabis Act* and its Regulations. These include:

- Issuing the licence is likely to create a risk to public health or public safety, including the risk of cannabis being diverted to an illicit market or activity;
- There are reasonable grounds to believe that false or misleading information or false or falsified documents were submitted in, or in support of, the application;
- Within the last 10 years the applicant has contravened a provision of *the Cannabis Act*, the *Controlled Drugs and Substances Act* or the *Food and Drugs Act* or of any regulation made under any of those Acts;
- Within the last 10 years there are reasonable grounds to believe that the applicant has contravened an order or a condition of a licence or permit under the above-noted Acts;
- The applicant is a young person (as defined in the *Cannabis Act*), an individual who does not ordinarily reside in Canada, or is an organization that was incorporated, formed or otherwise organized outside Canada;
- The Minister is of the opinion that it is in the public interest to do so;

- Any prescribed grounds for refusal exist.

In the cases mentioned above, Health Canada may send a Notice of Intent to Refuse. This Notice will provide the applicant with a timeframe within which to respond, after which a Notice of Refusal will be issued.

The Notice of Refusal sets out the specific reasons or deficiencies that resulted in the decision to refuse to consider the application or issue a licence. All decisions to refuse an application are without prejudice to filing a new application for a licence. If an applicant wishes to submit a new application at a future time, it will be processed as such. Information and data submitted to support an application will not be returned to the applicant.

At any time during the review of an application, the applicant may withdraw the application through the CTLS. Withdrawal of an application is without prejudice to re-filing the application. If an applicant wishes to resubmit an application at a future time, the application will be processed as a new application.

Changes to an application/unsolicited information

Once an application is submitted, changes cannot be made to the application within the CTLS. If a change is required, the applicant must contact: hc.sp-licensing-cannabis-licences-sp.sc@canada.ca. The email must clearly indicate the application file number, the applicant's name and the subject of the correspondence in the subject line of the email.

Contact Us

For questions related to a specific licence application, an email may be sent to: hc.sp-licensing-cannabis-licences-sp.sc@canada.ca. The email must clearly indicate the application file number, the applicant's name and the subject of the correspondence in the subject line of the email. Meeting or teleconference requests are evaluated on a case-by-case basis.

For other general questions about the *Cannabis Act* and its Regulations outside of a specific application, including those related to the CTLS, email: cannabis@canada.ca.

Alternatively, the Controlled Substances and Cannabis Branch may be contacted by phone at 1-866-337-7705.

Feedback – Help Us Improve

Health Canada is committed to providing all stakeholders with timely, accurate and reliable information. This includes providing applicants and Licence Holders with the information they require in order to be compliant with the *Cannabis Act* and its Regulations.



Health Canada appreciates receiving your feedback on whether this guide was useful and would welcome your suggestions for improvement. Please send us your feedback by email to: cannabis@canada.ca and indicate in the subject line: “Feedback on Research Application Guide”.

Your feedback will help us improve this guide and better serve all applicants and Licence Holders.

Appendix A: Sales Questionnaire

Questionnaire Regarding Activity of Sale for Research Licence Holders/Applicants

For applicants seeking authorization to sell plants, seeds, or other physical products of research with cannabis, Health Canada requires certain information in order to maintain oversight on what is intended to be sold and ensure that sales stemming from commercialization of research are limited in nature and consistent with the objectives of the *Cannabis Act* and its Regulations.

As part of our review of your request to have the activity of sale added to your research licence, we ask you to complete the following questionnaire:

- Who do you intend to sell to? Be as specific as possible.
[Example: to a holder of a licence for research (insert licence number)]
- What do you intend to sell (cannabis plants and/or cannabis seeds)?
[Example: tissue cultures, cannabis cuttings for clonal propagation]
- What quantity of cannabis do you intend to sell (e.g., number of plants and/or cannabis seeds)?
[Example: 10 plants]
- Is this a one-time sale, or do you intend to make repeated sales of the same or similar products of cannabis research to the same Licence Holder? If repeated sales, include rationale and anticipated frequency of this transaction.
[Example: repeated sales (insert rationale), 4x per year]
- What is the expected value of the cannabis that you intend to sell (e.g., dollar value per cannabis plant and/or cannabis plant seed)?
[Example: \$100/plant]
- When do you intend to make the sale(s)?
[Example: month and year]
- Why are you intending to sell the cannabis?
[Examples: for further research, to commercialize the outcome of research]
- What does the buyer intend to do with the cannabis (if known)?
[Example: propagation of new genetics]

Appendix B: Research Protocol for Project-Based Applications (single or multiple site) (suggested template)

Protocol Title

Outline

[Please include a brief summary of the field of research and the tools used to perform said research with cannabis (e.g., analytical techniques, specify any in vivo or in vitro models to be used). If human subjects are involved with this research, please explicitly state the nature of their involvement]

Is there more than one site for the proposed research? Provide details.

What is the maximum quantity of dried cannabis that will be possessed at all sites at any given time?

[If the quantity of cannabis exceeds 1 kg of dried cannabis or equivalent at any one site and there is no existing cultivation or processing licence at the site, please be sure to include a physical security description with the application. If the quantity exceeds 11 kg of dried cannabis or equivalent at any one site and there is no existing cultivation or processing licence at the site, please be sure to include a site plan with the application.]

What is the duration sought (in years) for the licence application? Please provide a rationale.

[A research licence may be effective for the duration of the research project, up to a maximum of five years. If the research project needs to continue past the expiry date of the licence, the licence holder may apply for a renewal of the licence.]

Do you attest that the source of cannabis is from a legal supplier?

[Suppliers may be a licensed cultivator or processor or a legal foreign source, but not holders of an analytical testing licence. A legal source also does not include individuals, including those formerly registered under prior regulations or currently registered under the Cannabis Regulations.]

Yes, I attest that the source of cannabis will be from a legal source.

Appendix C: Research Protocol for Institution-wide Applications for Multiple Projects at a Single Site (suggested template)

Nature of research performed at the institution

[Please include a brief summary of the various proposed research programs and tools used to perform said research (e.g., identify the principal investigators and their field of research, including any potential in vivo model organisms). If human subjects are to be involved with any research, please outline the scope and nature of any anticipated projects.]

What is the estimated maximum quantity of dried cannabis (or non-dried equivalent - equivalent amounts can be found in Appendix D) that will be possessed at any given time?

[The estimated maximum quantity of cannabis that is proposed to be possessed or produced by the applicant at any given time (e.g., kilogram, litre or number of plants or seeds, as appropriate). The square footage of grow area would also be acceptable if number of plants is not feasible.]

A brief description of institutional frameworks and their involvement to ensure oversight and/or coordination of the various research projects that will be conducted with cannabis at the institution, and adherence to the *Cannabis Act* and its Regulations as well as other regulations that may govern activities performed with cannabis.

[e.g., cannabis research office, animal care committees, research ethics boards, campus security services, etc.]

What is the duration sought (in years) of the licence application? Please provide a rationale.

[A research licence may be effective for the duration of the research project, up to a maximum of five years. If the research project needs to continue past the expiry date of the licence, the licence holder may apply for a renewal of the licence.]

Do you attest that the source of cannabis from a legal supplier?

[Suppliers may be a licensed cultivator or processor or a legal foreign source, but not holders of an analytical testing licence. A legal source also does not include individuals, including those formerly registered under prior regulations or currently registered under the Cannabis Regulations.]

Yes, I attest that the source of cannabis will be from a legal source.

Appendix D: Equivalent Amounts (as per Schedule 3 of the *Cannabis Act*)

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.

Appendix E: Physical Security Plan (suggested template)

For project-based applications: *Required to be submitted if the quantity of cannabis exceeds 1 kg equivalent of dried cannabis at any of the sites within your proposed licence activities and that site does not have a cannabis processing or cultivation licence.*

Description of Site(s)

What physical security measures will be in place to prevent unauthorized access to the operations areas where research with cannabis is conducted?

Who has access to operational and storage areas and how is this access controlled?

How are the storage areas secured?

For institution-wide applications: Description of the frameworks in place to ensure adequate physical security and prevent diversion or inversion of cannabis

[for example, a summary of SOPs or security plans that demonstrate how operational and storage sites to be covered under the licence are designed in a manner that prevent unauthorized access and take into account appropriate measures for various quantities of cannabis kept in operational or storage areas, or other frameworks that researchers will be required to follow to ensure compliance with the Cannabis Act and its Regulations. This should also include a description of any internal compliance monitoring mechanisms and measures in place to mitigate risk based on the quantities of cannabis present at various locations where research with cannabis will take place within their institution.]

Appendix F: Record Keeping Attestation

PART 11 – RETENTION OF DOCUMENTS AND INFORMATION	
APPLICANT INFORMATION	
Applicant Name:	Application Number:
INSTRUCTIONS	
1. Complete the ‘General Information’ and ‘Responsible Person Attestation Signature’ fields in the attestation form provided below. 2. Upload the completed attestation form as an attachment under the ‘Record Keeping Example Section’ in the Cannabis Tracking and Licensing System (CTLS).	
GENERAL INFORMATION	
Please confirm the proposed record keeping method : <input type="checkbox"/> Electronic-based (<i>please specify any record keeping software to be used</i>): <input type="checkbox"/> Paper-based <input type="checkbox"/> Other:	
REGULATORY ATTESTATION	
It is incumbent on the applicants to meet all applicable regulatory requirements pertaining to <i>Part 11 – Retention of Documents and Information</i> of the <i>Cannabis Regulations</i> . Health Canada has identified requirements (see below) for which we would like to emphasize, as these may represent a greater risk in the event of non-compliance.	
REGULATION	
GENERAL PROVISIONS	
221 Manner of Retention	
222 Requirement to continue to retain	
INVENTORY AND DISTRIBUTION	
224 Inventory - cannabis other than oil	
225 Inventory – cannabis oil	
226 Receipt of cannabis	
227 Sale, distribution and export of cannabis	
DESTRUCTION	
229 Destruction	
RESEARCH AND DEVELOPMENT	
237 Research and Development	

RESPONSIBLE PERSON ATTESTATION SIGNATURE

I, the undersigned, attest that:

- **All** applicable documents and information pertaining to *Part 11 – Retention of Documents and Information of the Cannabis Regulations*, as required by the research licence and activities being applied for at the time of licensing, will be retained accordingly for the noted retention period(s) as outlined by the respective regulation(s).
- With respect to section 221 of the *Cannabis Regulations*, **all** applicable documents and information will be retained in a manner that will enable an audit to be made of it in a timely manner.
- All information or documents under section 221 will be retained at the site of the Licence Holder, or, in the case of a person that does not hold a licence, at the person’s place of business, or if they do not have one, at a place of business in Canada.

Responsible Person Name (Printed):

Responsible Person Name (Signature):

Date:

Please review the regulations for the post licensing record keeping and reporting requirements.

Appendix G: Submission Checklist

Research Licence Application Checklist

Licence Ownership

- A copy of the Certificate of Corporation (if applying as a corporation)

Site Details

- Complete address of your research site(s) including:
 - ✓ Unit number, if applicable
 - ✓ Street number
 - ✓ Street Name
 - ✓ City
 - ✓ Province
 - ✓ Postal code
- A list of all the site addresses, if your research is conducted at multiple sites. In the case of an institution-wide research licence application, each building where it is known at the time of application that cannabis will be present within the boundaries of an institution.
- Confirmation that the proposed research site is not a dwelling house (i.e., residential) or an alternative address of your proposed research site
- Sales Questionnaire (if applicable)
- Research protocol(s) as per Appendix B or C
- No Objection Letter (NOL) (for clinical trials only)
- Experimental Science Certificate (ESC) (for *in vivo* animal studies, as applicable)

Physical Security

- For project-based applications, if the quantity of cannabis exceeds 1 kg equivalent of dried cannabis at any of the sites within your proposed licence activities and that site does not share a commercial cannabis processing or cultivation licence, a physical security description for your research site(s) that includes:
 - how the physical security of the proposed research site(s) will prevent unauthorized access to the cannabis;
 - who has access to operational and storage areas and how this access is controlled,
 - how storage areas are secured;
 - a brief description of the sites and their perimeters; and
 - how operational and storage areas are delineated.

See Appendix E for template.
- For project-based applications, if the maximum quantity of cannabis possessed at all sites at any given time exceeds 11kg of dried cannabis (or equivalent in non-dried form) and the site does not have a processing or cultivation licence, a site plan with clear identification of the

operational and storage area(s), with clearly identified perimeters and delineation of operational and storage areas.

- For institution-wide research licence applications, a description of the framework that ensures proper access and control of cannabis is maintained (e.g., summaries of SOPs for physical security, record keeping, etc. that will be required by researchers conducting activities with cannabis).

Record Keeping

- Copy of the Licence Holder / Responsible Person's Government-issued ID (e.g. driver's licence) (if applicable)
- If applying as an academic institution, research hospital or contract research organization, a copy of a Letter of Support from a senior member of the institution's administration (e.g. president, chancellor, vice president or equivalent)
- Record Keeping Attestation