



Health
Canada Santé
Canada

Opioid Response Team
Office of Controlled Substances
April 2018

Application form for an exemption to use a controlled substance for clinical studies (disponible en français)

Privacy Notice

The personal information you provide to Health Canada is governed in accordance with the Privacy Act. The collection of your personal information is authorized under the Controlled Drugs and Substances Act. This information will be used to process your application for an exemption to use a controlled substance for scientific purposes. Information may be used to provide reports to management. The information may also be used for research, planning, audit and evaluation purposes. In limited and specific situations, your personal information may be disclosed without your consent to law enforcement or in accordance with subsection 8(2) of the Privacy Act. Failure to provide the requested information may result in a refusal to process the application. This personal information collection is described online at [Info Source: Sources of Federal Government and Employee Information Health Canada](#). In addition to protecting your personal information, the Privacy Act gives you the right to request access to and correction of your personal information. For more information about these rights, or about our privacy practices, please contact Health Canada's Privacy Coordinator at hc.privacy-vie.privee.sc@canada.ca. You also have the right to file a complaint with the Privacy Commissioner of Canada if you think your personal information has been handled improperly.

1. Application Type

New Extension of exemption period Amendment of a valid exemption	Cancellation of a valid exemption Transfer of controlled substances from one researcher to another within an institution
If this is not a new application, please indicate the current authorization number	

2. Identification**2.1 Principal Investigator**

	Mr.	Mrs.	Dr.
Surname (last name)	Given Name(s)		
Preferred Language of correspondence	French		English

2.2 Title and Qualifications

B.Sc	M.Sc	Ph.D.	M.D.	D.V.M.	D.M.D.	D.D.S.
Practitioner Permit Number	Field of Study					
Telephone Number	Email Address					
Alternate Contact Name						
Alternate Contact Email						

Note: The applicant must be a practitioner

2.3 Address (where the substance will be used)

Institution / Company					
Department		Faculty			
Street Address		Room Number			
City	Province		Postal Code		

2.4 Mailing Address

Same as above address

Institution / Company					
Department		Faculty			
Street Address		Room Number			
City	Province		Postal Code		

3. Project Or Study Description

Project Title (same as protocol)					
Required Documents	Protocol attached Protocol previously submitted, if not amended No Objection Letter issued by the Office of Clinical Trials (NOL)				

Please provide a brief description of the project or study

4. Supplier Of The Controlled Substance

The quantity required is an estimate of quantity needed for a maximum period of one year. Attach additional copies of this page as necessary.

Controlled Substance					
Brand Name		Concentration (if applicable)			
Quantity required for all submitted protocols		Quantity in inventory (from previous exemption if applicable)			
Quantity to be purchased					
Name of Canadian Supplier		Contact Name			
Street Address					
City		Province		Postal Code	
Telephone Number			Email address		

Controlled Substance					
Brand Name		Concentration (if applicable)			
Quantity required for all submitted protocols		Quantity in inventory (from previous exemption if applicable)			
Quantity to be purchased					
Name of Canadian Supplier		Contact Name			
Street Address					
City		Province		Postal Code	
Telephone Number			Email address		

5. Physical Security

Please provide a description of the physical storage and security measures to be used

Note: Security must meet the requirements of the "[Directive on Physical Security Requirements for Controlled Substances](#)", available on the Health Canada website.

6. Declaration

6.1 Application Type: New, Extension or Amendment

I hereby declare that I am the principal investigator and that the controlled substance(s) will be used for clinical studies mentioned in this application. I have read and understand the Directives on Physical Security Requirements of controlled substances and other requirements specified in the Controlled Drugs and Substances Act and its Regulations. The specified requirements are met, or will be met before I commence any activity associated with any exemption issued to me.

I also agree to comply with any terms and conditions that may be specified in any exemption issued to me.

Signature of applicant:

Date:

(YYYY-MM-DD)

6.2 Application Type: Cancellation

I hereby declare that the exemption with authorization number _____, is no longer required.

I attest that the total quantity of controlled substance was used and that there is no remaining inventory.

I attest that there is a quantity of controlled substance remaining and it will be used for the protocol titled _____ under existing authorization number: _____

Signature of applicant:	Date: (YYYY-MM-DD)
-------------------------	-----------------------

6.3 Application Type: Transfer

I hereby certify that I am transferring the controlled substance(s) named in the exemption with authorization number _____ to the applicant taking over responsibility of the controlled substance(s). The quantities being transferred are:

Name of Controlled Substance(s)	Quantity Remaining

Signature of Outgoing Applicant:	Date: (YYYY-MM-DD)
----------------------------------	-----------------------

Signature of Incoming Applicant:	Date: (YYYY-MM-DD)
----------------------------------	-----------------------

7. Submission

Please email this completed Application Form and required documents to the Office of Controlled Substances at hc.exemption.sc@canada.ca or mail to the following address:

**Exemptions Section
Authorizations Division
Office of Controlled Substances
Health Canada
AL 0300B
161 Goldenrod Drwy
Ottawa ON K1A 0K9**

For further information, please contact the Exemptions Section at hc.exemption.sc@canada.ca

Checklist for an application for an exemption to use a controlled substance for scientific purposes

This checklist is provided to assist you in ensuring that all the required information has been included in your application for a scientific exemption. Incomplete applications will be put on hold until the required information is received.

Completed Information

Section 1	Application type
Section 2	Exemptions are issued to the applicant of each protocol. The address on the application is where the substance will be used
Section 3	The project title must be the same as the protocol along with a brief description of the use of the controlled substance
Section 4	Full details concerning the purchase of each controlled substance is required
Section 5	A description of storage and security that will meet the requirements of the “Directive on Physical Security Requirements for Controlled Substances”
Section 6	The declaration must be signed and dated by the applicant, or in the case of a transfer, both the incoming and outgoing applicants, and the original form submitted to our office

Attachments

	A copy of the protocol is attached with the application form or has been previously submitted and the protocol has not been amended
	A copy of the No Objection Letter (NOL) issued by the Office of Clinical Trials of the Therapeutic Products Directorate

Note: Additional copies of sections 4 may be submitted if required.