



Health
Canada Santé
Canada

Protected B (When Completed)
Opioid Response Team
Office of Controlled Substances
April 2018

Application form for an exemption to use a controlled substance for scientific purposes (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.

Canada 

1. Application Type

New Extension (no additional quantities) Extension (additional quantities)	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)	

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 minimum requirement of study for the applicant is a B.Sc. in an appropriate field

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 (where the substance will be shipped)

Same as above address

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

2.5 Storage Address (where the substance will be stored)

Same as above address provided in section 2.3

Same as above address provided in section 2.4

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 Approval of the Animal Care Committee (for in vivo studies)				

Note: A copy of the protocol of the project and the most recent Approval of the Animal Care Committee (if applicable) must be submitted.

Please provide any further information

--

Please provide a brief description of the use of the substance

Please provide the reason for requiring an extension, cancellation or transfer of responsibility (if applicable)

4. In Vivo Administration

In vitro utilization (*Please skip to section 5)	In vivo administration
---	------------------------

When all of the following conditions are met, a subsection 56(1) exemption will not be required:

- The substances will be administered to animals solely by an appropriately licensed veterinarian;
- The animal is a patient of the veterinarian under their professional treatment; and,
- The controlled substance is required for the condition for which the animal is being treated

Administration of the following controlled substances will be performed by a licensed veterinarian, meet the above conditions and therefore do not require a subsection 56(1) exemption:

1	
2	
3	
4	

Animal Species		Number of animals (to be used under this exemption)	
Average Weight per animal		Animal carcasses will be disposed of by:	Incineration Other (please specify below):

4.1 Controlled Substance(s)

Name of Controlled Substance			
Initial Dose		Maintenance Dose	
Frequency of Maintenance Dose		Total Dose per Animal	

Name of Controlled Substance			
Initial Dose		Maintenance Dose	
Frequency of Maintenance Dose		Total Dose per Animal	

5. 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.
- ****Please note that if the substance is unavailable in Canada, the Office of Controlled Substances may import on behalf of the applicant. In such cases, the applicant must provide a copy of the purchase order and a Purolator account number. Importation may take up to 3 months.**

Controlled Substance			*Foreign Supplier	Yes	No
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 Supplier			Contact Name		
Street Address					
City	Province			Postal Code	
Telephone Number			Email address		

***Note:** In the case of a Foreign Supplier, please make sure to fill out Appendix A: Import Order Authorization and Permit Application Form.

Controlled Substance			*Foreign Supplier	Yes	No
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 Supplier				Contact Name	
Street Address					
City		Province		Postal Code	
Telephone Number			Email address		

***Note:** In the case of a Foreign Supplier, please make sure to fill out Appendix A: Import Order Authorization and Permit Application Form.

6. 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.

7. Declaration

7.1 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 scientific purposes 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 Principal Investigator:	Date: (YYYY-MM-DD)
--------------------------------------	--------------------

7.2 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: _____.

I attest that there is a quantity of controlled substances remaining and it will be destroyed.

Signature of Principal Investigator:	Date: (YYYY-MM-DD)
--------------------------------------	--------------------

7.3 Application Type: Transfer

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

Name of Controlled Substance(s)	Quantity Remaining

Signature of Outgoing Principal Investigator:	Date: (YYYY-MM-DD)
---	--------------------

Signature of Incoming Principal Investigator:	Date: (YYYY-MM-DD)
---	--------------------

8. 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

Appendix A: Import Order Authorization and Permit Application Form

The importation process will be initiated once an exemption for research purposes has been granted to the applicant pursuant to subsection 56(1) of the Controlled Drugs and Substances Act. Please ensure that your order is placed with the supplier **prior** to submitting this form. **Note: This request is valid for one shipment only.**

1. Purchaser Information And Shipping Address

Name of Principal Investigator					
Street Address (shipping)					
City		Province		Postal Code	
Country			Name of contact		
Telephone Number			Email address		

2. Order Information

Name of Supplier					
Street Address				City	
Province		Postal Code		Country	
Supplier Contact Name				Telephone Number	
Product Name				Catalogue Number	
Substance Name				Quantity	
Purolator Account Number				Purchase Order (PO) Number	

3. Certification

<p>I hereby certify, that the above mentioned order, of which I am requesting, all costs associated with the importation, including cost of substance(s), customs duties and shipping of permit(s) and substance(s), will be paid by the applicant to the supplier.</p>		
Name		
Signature:		Date (YYYY-MM-DD)

For Office Only

Pursuant to the provision of the Controlled Drugs and Substances Act, application is hereby made for a permit to import the controlled substance listed above.					
HC Authorization Number		Import Permit Number		Valid until	(YYYY-MM-DD)
Port of Entry	Ottawa	Conveyance		Air	
QPIC Signature:			Date	(YYYY-MM-DD)	

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 Principal Investigator 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	Only include the number of animals and dosing information to be used under this exemption. For multi-year protocols, this number is the number to be used in one year.
Section 5	Full details concerning the purchase of each controlled substance is required.
Section 6	A description of storage and security that will meet the requirements of the "Directive on Physical Security Requirements for Controlled Substances".
Section 7	The declaration must be signed and dated by the principal investigator, or in the case of a transfer, both the incoming and outgoing principal investigators, 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.
	In the case of a Foreign Supplier, Appendix A: Import Order Authorization and Permit Application Form is attached.
	The most recent approval or renewal from the Animal Care Committee (if applicable)

Note: Additional copies of sections 4 and 5 may be submitted if required.