APPLICATION FORM FOR AN EXEMPTION TO USE A CONTROLLED SUBSTANCE FOR SCIENTIFIC PURPOSES

(Disponible en français)

1. APPLICATION TYPE

- (•) New
- ( ) Extension (no additional quantities)
- ( ) Extension (additional quantities)
- ( ) Amendment of exemption
- ( ) Cancellation of exemption
- ( ) Transfer of responsibility of the project

2. IDENTIFICATION

A) Principal investigator: Mr. ( ) Mrs. (•) Ms. ( ) Dr. ( )

Surname: _____ Given name: _____ Middle Initials: _____

B) If this is not a new application please indicate the current authorization number

_____

C) Title and qualifications:

(Minimum requirement: B.Sc. in an appropriate field)

B.Sc. ☐ M.Sc. ☐ Ph.D. ☐ M.D. ☐ D.V.M. ☐ D.M.D. ☐ D.D.S. ☐

Licence Number: _____ Field of study: _____

Telephone: _____ Facsimile: _____

E-mail: _____

Alternate contact name: _____

Alternate contact e-mail: _____

D) Address (where the substance will be used)

Institution/Company: _____

Department: _____

Faculty: _____

Street: _____ Room: _____

City: _____ Province: _____ Postal Code: _____

E) Mailing Address: (if different from above)

Institution/Company: _____

Department: _____

Faculty: _____

Street: _____ Room: _____

City: _____ Province: _____ Postal Code: _____

3. PROJECT OR STUDY DESCRIPTION

A) Project Title (Same as protocol)

B) 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 Approval of the Animal Care Committee (if applicable) must be submitted

C) Brief description of the use of the substance:

D) Reason for requiring an extension, cancellation or transfer of responsibility (if applicable)

4. DETAILS OF ADMINISTRATION

In vitro utilization (Go to number 5) ○	*In vivo* administration ○	
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) _____		
1- Name of Controlled Substance:	2- Name of Controlled Substance:	3- Name of Controlled Substance:
Initial dose:	Initial dose:	Initial dose:
Maintenance dose:	Maintenance dose:	Maintenance dose:
Frequency:	Frequency:	Frequency:
Total dose:	Total dose:	Total dose:

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 will 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:	Controlled Substance:	Controlled Substance:
☐ Foreign supplier (see Appendix A)	☐ Foreign supplier (see Appendix A)	☐ Foreign supplier (see Appendix A)
Brand name :	Brand name :	Brand name :
Concentration (if applicable):	Concentration (if applicable):	Concentration (if applicable):
Quantity required for all submitted protocols:	Quantity required for all submitted protocols:	Quantity required for all submitted protocols:
Quantity in inventory : (From previous exemption, if applicable)	Quantity in inventory (From previous exemption, if applicable)	Quantity in inventory : (From previous exemption, if applicable)
Quantity to be purchased:	Quantity to be purchased:	Quantity to be purchased:
Supplier: _____ Address: _____ _____ _____ Telephone: _____ Contact Name: _____	Supplier: _____ Address: _____ _____ _____ Telephone: _____ Contact Name: _____	Supplier: _____ Address: _____ _____ _____ Telephone: _____ Contact Name: _____

6. PHYSICAL SECURITY

Description of physical storage and security measures to be used:
*** Please note: Security must meet the requirements of the "Directive on Physical Security Requirements for Controlled Substances", available on the Health Canada website http://www.hc-sc.gc.ca/hc-ps/substancontrol/substan/securit-eng.php**

7. DECLARATION

7.1 Application Type: New, extension or amendment

I hereby certify 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.

Principal investigator:_____ Date: _____

7.2 Application type: Cancellation

I hereby certify 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 in accordance with the process outlined in section 3.0 in the Guidance Document *"Application to Use Controlled Substances for Scientific Purposes*".

Principal investigator:_____ Date:_____

7.3 Application type: Transfer

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

Name of Controlled Substance(s)	Quantity Remaining
_____	_____
_____	_____
_____	_____

Outgoing Principal Investigator:_____ Date:_____

Incoming Principal Investigator:_____ Date:_____

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 an Scientific Exemption. Incomplete applications will be put on hold until the required information is received.

- ☐ 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. With a brief description of the use of the Controlled Substance.
- ☐ A copy of the protocol is attached with the application form or has been previously submitted if there is no amendment.
- ☐ The approval from the Animal Care Committee (if applicable).
- ☐ 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.

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

Please submit the completed original application form and all accompanying documents to:

National Compliance and Exemption Division
Office of Controlled Substances
Controlled Substances and Tobacco Directorate
Healthy Environments and Consumer Safety Branch
Health Canada AL 0300B
150 Tunney's Pasture Dwy
Ottawa ON K1A 0K9

Note: Faxed applications will no longer be accepted.

For further information, you may contact the National Compliance and Exemption Division by phone at (613) 954-8246 or by e-mail at exemption@hc-sc.gc.ca

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