University of Victoria

Completing an Application Form For An Exemption To Use A Controlled Substance For Scientific Purposes

Introduction

- Health Canada Office of Controlled Substances regulates the use of controlled drugs within Canada.

- The use of controlled drugs is limited to individuals whom have a valid practise or research license and their authorized personnel.

Health Canada

Purpose

- To assist the research community through the process of the controlled drug Scientific Exemption application.

Responsibility

- The licensee is responsible for the following;
  - Obtaining and renewing the Exemption form
  - Acquisition
  - Storage
  - Security
  - Inventory
  - Disposal
  - Record-keeping

Page 1

Page 1 includes sections:

Section 1. Application Type

Section 2. Identification

Section 1-Application Type

Health Canada | Santé Canada

Healthy Environments and Consumer Safety Branch
Direction générale de la santé environnementale et sécurité des consommateurs

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

Indicate appropriate type (most will be “New” or “Extension”)

Section 2, part A & B : Identification

2. IDENTIFICATION

A) Principal investigator: Mr. ○ Mrs. ◉ Ms. ○ Dr. ○

Surname: _____ Given name: _____ Middle Initials: _____

B) If this is n[illegible]new application please indicate the current authorization number

_____

The person who is named as PI on the Animal Use Protocol (AUP)

Section 2, part C: Identification

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: _____

Alternate contact: should be same as listed on AUP

Section 2, part D: Identification

University of Victoria address, include laboratory location (Room #)

D) Address (where the substance will be used)

Institution/Company: _____

Department: _____

Faculty: _____

Street: _____ Room: _____

City: _____ Province: _____ Postal Code: _____

Section 2, part E: Identification

Address where drugs will be received:

University of Victoria
Science Stores
3800 Finnerty Rd.
Petch Building Rm. 168
Victoria, B.C. V8P 5C2

E) Mailing Address: (if different from above)

Institution/Company: _____

Department: _____

Faculty: _____

Street: _____ Room: _____

City: _____ Province: _____ Postal Code: _____

Page 2

Page 2 includes sections:

Section 3. Project or Study Description

Section 4. Details of Administration

Multiple copies of this page can be completed. One for each of the listed protocols in section 3, part a.

Section 3, part A: Project Description

3. PROJECT OR STUDY DESCRIPTION

A) Project Title (Same as protocol)

Must be EXACTLY the same title as current approved AUP

Section 3, part B: Project Description

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

Include "Page 1" of AUP signed by Animal Care Committee Chair.
Contact the ACC Liaison for assistance : acsc@uvic.ca
250-853-3187

Section 3, part C: Project Description

C) Brief description of the use of the substance:

For example; Substances are used for: pain management following surgeries (buprenorphine) and for euthanasia (ketamine).

Section 3, part D: Project Description

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

N/A on initial applications.

Section 4: Project Details of Administration

Number of animals= total number of animals approved on protocol

Use high end of range for species (unless neonates are used)

Carcasses are incinerated

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:

Section 4: Project Details of Administration

Section 15 on AUP.

Refer to next slide

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:

Use highest approved dose

Complete if multiple doses are required

Ex. once, twice, every 6 hours

McGill Controlled Drug Availability

*refer to your protocol for approved drugs and doses

description	Concentration	Size	unit price
Generic: Buprenorphine (Trade name: Buprenex)	0.3 mg/ml	1 ml vial	$9.00
Pentobarbital	54.7 mg/ml	100 ml bottle	$118.00
Generic: Ketamine HCl (Trade names: Vetalar or Ketaset)	100 mg/ml	50 ml vial	$105.00
Generic: Sodium Pentobarbital (Trade name: Euthanyl)	240 mg/ml	250 ml bottle	$70.75
Generic: Sodium Pentobarbital Trade name: Euthansol)	340 mg/ml	250 ml bottle	$83.00

*Contact acsaht@uvic.ca if you would require a drug not listed here

Availability as of Dec 2015

Page 3

Page 3 includes sections:

Section 5. Supplier of the Controlled Substances

If multiple protocols are placed under one exemption, this section should include a consolidation of the total volumes required from each page 2.

Section 6. Physical Security

Section 5: Supplier information

Use information as listed in section 4 and previous slide

# of animals getting drug x total volume used/animal *from all AUP's included in this application

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:

Total quantity to purchase is the minimum quantity available from distributor – may be more than what is required (slide 18)

Section 6: Physical Security

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**

Detail the following;

- Structure used for physical storage
- Lab location (including building and room number)
- Security features (ex. key or fob access to hallway, locking windows)
- Who will have key or code to safe (normally department admin)
- Where will this access information be stored and monitored
- $5000 street value is maximum allowable per storage cabinet/safe

Courier the completed form and supporting documents to:
National Exemption Section
Office of Controlled Substances
Health Canada,
A.L. 0300B
Ottawa Ontario K1A 0K9

Important Notes about Exemptions

- They are only valid for a one year period.
- Licensees are responsible for keeping track of the expiry date and resubmitting forms prior to expiry.
- Renewal applications can take up to 3 months.

Additional Resources: Exemption Form

- Health Canada Office of Controlled Substances website:

http://www.hc-sc.gc.ca/hc-ps/substancontrol/exemptions/applic-scien-eng.php

- Contact AHT Coordinator acsaht@uvic.ca

250-853-3692

Important Notes about Records

- Detailed records must be kept for the controlled substance's life cycle, i.e., from when they arrive until containers are empty or disposed.

- Records must be maintained and available to the Ministry upon request for up to 2 years.

Additional Resources: Required Records

- Animal Care Services guidelines document outlining recommendations for the acquisition, storage, recording, using and discarding controlled substances.
- Template recording forms on website (under 'References and Forms')
- Contact AHT Coordinator acsaht@uvic.ca

  250-853-3692