

INFORMATION FOR FILLING OUT “APPLICATION FORM FOR AN EXEMPTION TO USE A CONTROLLED SUBSTANCE FOR SCIENTIFIC PURPOSES” (a Health Canada document)

Quote from Health Canada website:

<http://www.hc-sc.gc.ca/hc-ps/substancontrol/exemptions/index-eng.php>

“The Controlled Drugs and Substances Act (CDSA) prohibits activities related to controlled substances. Researchers (physicians, veterinarians, and other researchers affiliated to universities and private industry) requiring a controlled substance for research purposes which include in vitro utilization, administration to animals or human clinical trial or for special activities (e.g. testing of water quality, screening for drugs of abuse), must receive an exemption under Section 56 of the CDSA. The exemption allows the individual only to possess a specified quantity of the controlled substance and to administer the controlled substance to human subjects or animals for the purpose of research.”

In order to apply for and receive the required exemption(s) for controlled substances required for your research, you must fill out and submit the form for obtaining scientific exemptions. It is available as a pdf file that can be saved onto your computer. You can find this form on Health Canada’s website at:

http://www.hc-sc.gc.ca/hc-ps/alt_formats/hecs-sesc/pdf/substancontrol/exemptions/scientific-eng.pdf

Copies of the form are also available by emailing veterinaryservices@umanitoba.ca

Information to assist you with filling out the form follows. You may contact Veterinary Services at the following numbers for additional assistance with filling out the form:

Dr. Richard Hodges – 474-6557

Dr. Valerie Smid – 474-6254

The information is arranged according to the corresponding numbered sections on the form for easy reference.

1. Application Type:

There are five categories of application type. Most applications made will fall into the “New exemption” category.

All controlled substances stored or used must be covered under a current exemption. If controlled substances are not used in the year the exemption is applied for, an extension or new application must be applied for or the drug must be properly disposed of. (Please see procedures for disposal at the end of this document).

2. Identification:

Ensure that you fill out all fields of the form as missing or incorrect information may delay or invalidate your application.

3. Project or Study Description:

Provide a brief description of the use of the substance.

Submit one application form for each protocol. All controlled drugs used in the protocol can be requested on one application.

The protocol being referenced needs to be provided. Rather than providing the entire protocol the sections describing the use of controlled drugs and the summary of procedures should be provided along with the approval letter from the PMRC for the protocol. Applications may be submitted prior to approval being obtained from the PMRC but the application will not be finalized until the approval letter is supplied to Health Canada

4. Details of Administration

You are applying for **the amount of each drug to be used in one year** according to the information you supplied in section 3. After a year, you will need to apply for a new exemption.

You will need to provide the number of animals, the dosage and number of doses etc so that the amount required can be calculated.

Make additional copies of this section if required

5. Supplier of the Controlled Substance

You will need to consider the packaging of the drug (example – Euthanyl comes in 250 ml bottles. See list of controlled drugs and available packaging under #5. Description of Storage and Security). You will need to request an exemption for the total amount to be purchased. Veterinary Services cannot sell a part bottle.

You do not need to request a Brand name (e.g. VETALAR) unless you specifically want a certain brand. You may leave this section blank and only indicate the controlled substance name (ketamine HCl). Using the generic name will allow a choice of brand names (which is useful when products are unavailable for some reason). The concentration you indicate will limit the products that may be sold to you, particularly in the case of pentobarbital where there are limited Brand Names to chose from and each Brand name differs in concentration (e.g. 240mg/ml Pentobarbital = Euthanyl, 340mg/ml Pentobarbital = Euthansol, 54.7mg/ml = Pentobarbital sodique). Ketamine has multiple Brand names with the same concentration.

Make copies of section # 5 as required .

“Remaining quantity in inventory” would be zero unless you have some drug left over from previous exemptions. This quantity would need to be indicated and subtracted from the total amount of drug required.

The “Intended Supplier” needs to be indicated in advance in order to obtain your exemption.

Veterinary Services, University of Manitoba, 194 Dafoe Rd., Winnipeg, MB R3T 2N2 has become a supplier of controlled substances with Health Canada. You will be able to obtain controlled substances from us or, if you wish, you may choose another supplier.

6. Description of Storage and Security

Security Requirements for Storage of Controlled Drugs by Investigators Holding Scientific Exemptions

In the review of the Application Form For An Exemption To Use A Controlled Substance For Scientific Purposes, Health Canada officials will review the security requirements of individual laboratories. While there are no written guidelines, Health Canada officials have outlined verbally what is acceptable. While not identical to, it is quite similar to the storage requirements for controlled drugs at Security Level 1 as outlined on page 16 in its [Directive on Physical Security Requirements for Controlled Substances](#).

The following requirements must be met:

A cupboard, refrigerator, a drawer in a steel cabinet or an equivalent may be utilized provided that:

- a) It prevents visualization of the controlled substance
- b) It is fastened to the room’s floor or wall and cannot be removed or is of sufficient weight that it cannot be manually removed.
- c) It can be locked. An approved padlock as per the Directive is not required
- d) It is located in a locked room to which the public does not have access.

Based on the information provided by Health Canada the following amounts of controlled substances may be held under the above security provisions.

- 500 mls of Ketamine (100 mg/ml)
- 500 mls of Euthanyl (pentobarbital 240 mg/ml)
- 45 mls of buprenorphine (0.3mg/ml)
- 1000 mls of Pentobarbital sodique (55-65 mg/kg)
- Other amounts and substances able to be kept are available on request

It is recommended with Veterinary Services acting as a supplier and having access generally within 14 days to controlled substances, that amounts held be kept to a minimum. Health Canada may also place restrictions on how much drug may be held when issuing the exemption.

**LIST OF CONTROLLED SUBSTANCES COMMONLY USED IN THE ANIMAL
RESEARCH SETTING**

Generic name	Brand name(s)	Concentration	Vial/Bottle size
Buprenorphine	<i>Temgesic</i>	0.3 mg/ml	1 ml ampules (box of 5)
Ketamine	<i>Ketalean</i>	100 mg/ml	50 mls
	<i>Ketaset</i>	100 mg/ml	10 mls, 50 mls
	<i>Vetalar</i>	100 mg/ml	10 mls, 50 mls
Pentobarbital sodium (anesthesia and euthanasia)	<i>Pentobarbital sodique</i>	54.7 mg/ml	100 mls
Pentobarbital sodium (euthanasia)	<i>Euthanyl</i>	240 mg/ml	250 mls
	<i>Euthansol</i>	340 mg/ml	250 mls
	<i>Euthanyl Forte</i>	540 mg/ml	250 mls
Thiopental	<i>Thiotal</i>	1 gram of powder (2.5 % solution)reconstituted	40 mls once
	<i>Thiotal</i>	5 grams of powder (2.5 % solution)reconstituted	200 mls once
Diazepam	<i>Diazemuls</i>	5 mg/ml	2 ml ampules (box of 10)
	<i>Diazepam</i>	5 mg/ml	2 ml ampules (box of 10)
Butorphanol	<i>Torbugesic</i>	10 mg/ml	10 ml, 50 ml
Midazolam	<i>Midazolam</i>	5 mg/ml	10 ml

Record Keeping

Record keeping for Controlled Drugs **must be stringent**. The following is required.

- Date purchased, the name and address of supplier, volume and concentration of the drug
- For each dosage administered - date, volume used (or discarded,) animal identification, signature of person administering the drug. This must be done for each dose as used. The record must be completed in pen and ["] marks are not acceptable. Authorities must be able to trace each dose back to a specific animal.
- If the drug is mixed or diluted the amount taken from the vial must be recorded and separate record sheet prepared for the dilution or mixture.

A copy of a suggested controlled drug log is attached. Veterinary Services supplies a log sheet with each controlled substance it supplies.

6. Declaration:

Review the document, and sign.

Destruction of Controlled Substances

Preamble:

Occasionally supplies of controlled drugs will reach their expiry date, or they may no longer be required by a researcher. As controlled drugs their handling, including disposal, is governed by law and falls within the jurisdiction of the Compliance Division of Health Canada. The procedures indicated below have been developed in consultation with them.

Procedures to obtain Authorization for Destruction:

1. Identify unusable Controlled Drugs requiring disposal.
2. Complete a Request for Destruction of Unusable Narcotic and Controlled Drugs Form available from Veterinary Services.

3. Mail or fax a copy to:

Compliance, Monitoring and Liaison Division
Office of Controlled Substances
Drug Strategy and Controlled Substances Program
Health Canada
Address Locator: 3502B
Ottawa, ON K1A 1B9
Tel: (613) 954-1541 Fax: (613) 957-0110

Only once the Letter of Authorization has been received can steps can be taken to destroy the drugs. The authorization is valid for 60 days. If the product has not been destroyed within the 60 days then a new authorization to destroy is required.

Procedures:

1. Letter of Authorization to Destroy the controlled substances must be in your possession.
2. Contact the Environmental Health and Safety Office (EHSO).
3. EHSO will denature the product and remove it. The authorization holder must be present.

4. The following statement should be made on the Authorization of Destruction

The above mentioned substances were denatured by Environmental Health and Safety in my presence and have been removed by them for incineration.

Date:

Authorization holder signature:

Witness name:

Signature:

Below is a suggested form to complete to request an Authorization for Destruction.

**Request for the
Authorization for Destruction of a Controlled or Narcotic Substance**

Compliance, Monitoring and Liaison Division
Office of Controlled Substances
Drug Strategy and Controlled Substances Program
Health Canada
Address Locator: 3502B
Ottawa, Ontario K1A 1B9
Tel: (613) 954-1541 Fax: (613) 957-0110

To Whom it May Concern:

Please consider this request for the destruction of the following controlled or narcotic substances:

Holder of Controlled Substance Exemption Information

Name: _____
Institution: _____
Address: _____
City: _____ Province: _____
Postal Code: _____ EMAIL: _____
Phone #: _____ Fax #: _____
Obtained under exemption
#: _____

Controlled Substances requiring Destruction:

Product Name and Strength	Quantity	Lot #	Expiry Date	Reason for Destruction

Signature

Date

Name

This form may be faxed to: (613) 957-0110

