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. Leo Kenny – 474-8024

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 **must** be provided along with the approval letter from the Animal Care Committee (ACC) for the protocol.

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. This amount should be in mgs or grams.

Make additional copies of this section if required

5. Supplier of the Controlled Substance
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. (See list of controlled drugs and available packaging under #6. Description of Storage and Security).
Once you have chosen the product you wish to use you will need to consider the concentration of the product in order to determine the number of mls required. You will then need to consider the packaging of the drug (example – Euthanyl comes in 250 ml bottles. Veterinary Services cannot sell a part bottle so the amount to be purchased will need to be based on the full bottles. (ie 240 mls required– you request 250 mls to be purchased if the package size is 250 mls and 300 mls if the package size is 100 mls)

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
Telephone: 204-474-6557
Contact Name: Dr. Richard J. Hodges
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.

Recently, Health Canada stopped the sale of buprenorphine and pentobarbital sodique from McGill University to other controlled substances dealers. This means that these products can no longer be obtained by Veterinary Service from McGill for resale to you.
If you require pentobarbital sodique you will need to order and obtain it from McGill University (see information below).
In regards to buprenorphine you have two options for future supplies:

1) Buprenorphine can be ordered as a 10 ml vial under the trade name Vetergesic® and Veterinary Services at the University of Manitoba can be named as your supplier. It has the same concentration of 0.3mg/ml buprenorphine as the Temgesic® product we have been supplying. Please indicate on your exemption application the name Vetergesic® so that Health Canada will know that you require 10 mls of product (smallest size available). While this may mean you have excess product, with sourcing this locally and without shipping from Montreal the price will be more economical although it has a shorter expiry date. It is our intention to begin filling any orders of 10 mls or more of buprenorphine with the Vetergesic® product. I have attached a copy of page 3 of the exemption application form to assist you, in future applications.
2) If you wish to use 1 ml vials of buprenorphine, then you the PI would need to order it directly from McGill University and McGill would need to be named as the supplier on your application for an exemption. Please contact them for further information and to ensure they are able to provide the products you require before naming them in the exemption application.

To order from McGill University:
Contact:
Rosanna Lento
Administrative Coordinator
Comparative Medicine & Animal Resources Centre
McIntyre Medical Building
3655 Promenade Sir-William-Osler, room 1440
Montréal, Québec H3G 1Y6
Tel : (514) 398-8289 (option 1)
Fax : (514) 398-7283
DRSS@mcgill.ca

To name them as a supplier use the following information.

Authorized Dealer
Dr. Jim Gourdon
McGill University, DRSS
Animal Resources Centre
3655 PR. Sir-William-Osler, Room 1440
Montreal, Quebec H3G 1Y6

6. Description of Storage and Security

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 that holding up to $2500 street value is acceptable 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. They will advise if the security you indicated is satisfactory for the amount of drug you are holding and may restrict the amount you can hold at one time.

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	*Temgesic*** (McGill University)	0.3 mg/ml	1 ml ampules (box of 5)
	Vetergesic	0.3 mg/ml	10 ml vial
Ketamine	*Ketalean*	100 mg/ml	50 mls
	Ketaset	100 mg/ml	10 mls, 50 mls
	Vetalar	100 mg/ml	10 mls, 50 mls
Pentobarbital Sodium** (anesthesia and euthanasia)	*Pentobarbital sodique* (McGill University)	*54.7* mg/ml	100 mls
Pentobarbital sodium (euthanasia)	*Euthanyl*	240 mg/ml	250 mls
	Euthansol	340 mg/ml	250 mls
	Euthanyl Forte	540 mg/ml	250 mls
Thiopental	*Thiotal*	1 gram of powder (2.5 % solution)	40 mls once reconstituted
	Thiotal	5 grams of powder (2.5 % solution)	200 mls once reconstituted
Diazepam	*Diazemuls*	5 mg/ml	2 ml ampules (box of 10)
	Diazepam	5 mg/ml	2 ml ampules (box of 10)
Butorphanol	*Torbugesic*	10 mg/ml	10 ml, 50 ml
Midazolam	*Midazolam*	5 mg/ml	10 ml

****These products cannot be purchased from Veterinary Services – our suggested supplier is McGill University**

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.

Mailing
Health Canada recently moved offices and and have updated the application form with their new address. Please note that the address for mailing the application is:

National Compliance and Exemption Division
Office of Controlled Substances
Health Canada
150 Tunney's Pasture Driveway
Tunney's Pasture
AL 0300B
Ottawa ON K1A 0K9

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. The drugs cannot be returned to the dealer. As controlled drugs their handling, including disposal, is governed by law and falls within the jurisdiction of the Compliance Division of Health Canada. The procedure for destruction of controlled drugs as per Health Canada is outlined below.

You are responsible for the destruction of any unused or expired narcotic. The destruction must be witnessed by a member of your research staff who is working on the same research project as specified in this exemption, and who works under your direction and control. The method of destruction used must alter or denature the narcotic in such a way as to make it non-recoverable and thus make their consumption improbable or impossible. You are required to keep and retain for a period of two years from the date of the making of the record, the following information:

- the name, strength per unit, and quantity of any narcotic to be destroyed;
- the date of destruction; and
- the reason for destruction.

Immediately following the destruction, you and the witness are required to sign and print your names on a joint statement indicating that you witnessed the destruction and that the narcotic destroyed has been altered or denatured to such an extent that its consumption has been rendered impossible or improbable.

Suggested example of controlled drug log

Name of Controlled Product: Ingredient: Strength:

Manufacturer: Lot #: Expiry Date:

Date	Amount Received	Amount Used	Balance Remaining	Protocol #	Species	# of animals	Signature	Comments – Animal ID or Group ID