



University Animal Care Committee Standard Operating Procedure

Document No: 14.1	Subject: Management of Controlled Substances	
Date Issued: March 29, 2016	Revision: 2	Page No: 1

Location: Queen's University

Responsibility: Principal Investigators (PI), Research Staff, Veterinary Staff

Purpose: The purpose of this Standard Operating Procedure (SOP) is to describe general laboratory based responsibilities regarding the management of controlled drug use.

1. Introduction and Definitions: Controlled substances are regulated through [Health Canada](#) and the [Controlled Drugs and Substances Act \(S.C. 1996, c.19\)](#). Federal regulations must be followed as well as compliance with Queen's University Environmental Health and Safety guidelines.

2. Materials:

- Valid exemption permit
<http://www.hc-sc.gc.ca/hc-ps/substancontrol/exemptions/applic-scieng-eng.php>
- acceptable storage unit and padlock
- bleach
- glass beaker
- absorbent pads (or kitty litter)
- sharps container
- chemical waste container (from Queen's Environmental Health and Safety)

3. Procedures:

- **Procurement:**
 - The procurement and the use of controlled substances are under legislation and must follow all regulations.
 - Each and every Principal Investigator with a controlled substance listed on their AUP must have a valid exemption in place (for each and every compound).
 - <http://www.hc-sc.gc.ca/hc-ps/substancontrol/exemptions/applic-scieng-eng.php>
 - Individual PIs are responsible for submitting a drug exemption request to Health Canada; and for the acquisition, storing and disposal of controlled substances.
 - The application approval process for an exemption permit can take 6+ weeks; this time point must be taken into consideration in advance of study commencement.
 - Sharing of controlled substances is absolutely forbidden.
 - Animal Care Services cannot distribute controlled substances.
 - A checkbox has been added to CIHR grant applications for the indication of whether controlled substances will be required. CIHR is in contact with Health Canada to ensure that a valid exemption is on file.



University Animal Care Committee Standard Operating Procedure		
Document No: 14.1	Subject: Management of Controlled Substances	
Date Issued: March 29, 2016	Revision: 2	Page No: 2

- **Storage:**

*** 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) <http://www.hc-sc.gc.ca/hc-ps/substancontrol/substan/securit-eng.php> and is dependent upon the security level/classification assigned the drug. ***

- It is the lab's responsibility to know the security level of the substances in use and abide by all storage requirements.
- For Level 1 security, a cupboard, refrigerator, a drawer in a steel cabinet, or an equivalent may be used for level 1 security provided it is located in a locked room and fastened to the room's floor or wall. The device used to store the researcher's inventory is to be secured with an approved padlock or its equivalent.
- For Level 2 security, an alarm system is required. It must at least activate a local electric horn or bell when an unauthorized access is attempted. Storage requirements include a steel cabinet, refrigerator or equivalent is acceptable provided it is located in a locked room and fastened to a wall or floor in such a manner that it is not moveable. The cabinet or refrigerator must be locked with an approved padlock. The approved security device must be located in an area to which the public does not have access. Records of the issuing of combinations and keys, under the authorization of an officer in the institution, shall be maintained and be available to TPP inspectors.

- **Use:**

*** See log book example appended to this SOP. ***

- For all controlled substances, a log book must be maintained. This will include the volumes withdrawn directly from the source, but must also record the volume injected in to the animal (the volume recorded on the back of the cage card). These record should be kept in the same log book, but documented separately.
- The use of expired drugs is forbidden.
- Each and every injection requires a new sterile syringe and needle.
- Bottles in use should have the rubber stopper wiped with an alcohol swab between uses to maintain sterility.
- The UACC requires that all secondary substance containers (aliquots) are labelled appropriately. If secondary containers are used, they must be glass (vacutainers are ideal for this purpose). The containers must be labelled with the name of the product as well as the concentration, and the expiry date from the initial source(s).
- Drug cocktails (combination of drugs and/or diluent) can only be used for two weeks after mixing. This date must also be identified on the label.

- **Disposal:**

- Once controlled substances reach their expiry date or are no longer in use, they must be disposed of appropriately.
 - The destruction of controlled substances must be witnessed by a member of the lab.
-



University Animal Care Committee Standard Operating Procedure		
Document No: 14.1	Subject: Management of Controlled Substances	
Date Issued: March 29, 2016	Revision: 2	Page No: 3

- Immediately following the destruction, the witness and Principal Investigator are required to sign and print their names in the controlled substance log book, corroborating the substance has been altered or denatured to such an extent that its consumption has been rendered impossible or improbable.
- Withdraw the remainder of the drug from the bottle using a needle and syringe. The volume should reflect the “Balance in Bottle” recorded in your controlled substances log book.
- Denature the compound (that which you have drained from the bottle into the syringe). This is achieved by bulking the drug into bleach – transferring from the syringe into ~2.5 cm of bleach in a glass beaker (ideally within a hood).
- Transfer this waste (bleach and denatured drug) into a chemical waste/solvent waste container. These are available through [Queen’s Environmental Health and Safety \(EH&S\)](#).
- An EH&S form must also at this point be filled out (attached), a copy maintained in the lab, and a copy forwarded to EH&S.
(<http://live.wp2.queensu.ca/ehswww/chemical/regulations>)
- Deface the original empty bottle and any secondary containers (remove label, scratch out or Sharpie over the name). Dispose of this bottle in your lab glass disposal or an approved sharps container.
- When the lab calls for [chemical waste pick up](#) (full containers, or on-schedule), only the substance used to denature the drug needs to be identified, i.e. the bleach.

Note that disposal of the substance onto absorbent pads or kitty litter is also acceptable, (the pad/litter thereafter treated as biological waste), however EH&S’s preferred method is the denaturing of the compound in bleach. Steps other than the expulsion of the drug onto the pad/litter remain the same.

Revised: April 26, 2018 / March 28, 2019



Queen's
UNIVERSITY

DEPARTMENT OF ENVIRONMENTAL
HEALTH AND SAFETY

Rideau Building, 207 Stuart Street
Kingston, Ontario, Canada K7L 3N6
Tel 613 533-2999
Fax 613 533-3078

Certificate of Destruction of Controlled Substances

Generator(s) 1 _____ Health Canada file # _____
 2 _____
 3 _____

Inventory of controlled substance(s)

Name of Controlled Substance	Volume (kg/L)
1	
2	
3	
4	
5	
6	
7	

This certificate is to confirm that the product(s) listed above have been completely destroyed on this date, safely and without incident.

Signature of Principal Investigator

Date

Signature of Witness (Pharmacist or colleague)

Date

Signature of Disposal Representative

Date

Contact Information for the Acquisition of Controlled Substances

McGill University:

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
Fax : (514) 398-7283
DRSS@mcgill.ca

Health Canada requires the dispensary at McGill University to have an original signature, therefore Drug and Material requisitions (attached) must be mailed to:

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

CDMV:

CDMV is a Canada-wide distributor of products and services dedicated to veterinarians across Canada. They provide veterinary establishments with pharmaceuticals, biologicals (vaccines, serums), additives (vitamins, food supplements), pet food as well as consumable medical supplies and instruments.

<https://www.cdmv.com/en/index.sn>

<https://www.cdmv.com/en/sales-team-west-ontario.sn?region=3#regions>

1. ORDER FORM

McGill University

This form must be completed and signed by an individual legally empowered to take custody of these products.

Send all correspondence to:
McGill University, CMARC
3655 Pr. Sir-William-Osler
Montréal, QC H3G 1Y6
Att: Rosanna RM 1440

2. **Signature:**

3. **Print name:**

4. **Date:**

Exemption under Section 56
List your Authorization #

EDR
Emergency Drug Release
List your EDR #

DVM Licence (cannot be used for purchase of Pentobarbital 54.7 mg/ml or Buprenorphine 0.3 mg/ml).
For lab animal research only.

PAYMENT OPTIONS		
	our Credit Card information will be requested separately when your order is ready to be sent.	Card holder name:
	<input type="checkbox"/> MasterCard <input type="checkbox"/> Visa	Telephone: E-Mail:
	I purchase order I please send a copy of the Purchase Order with this order form. I purchase order must contain billing and shipping information.	PO#:
	I OAPAL (Internal McGill/MUHC only)	FOAPAL#: Department:

SHIPPING METHOD	
<input type="checkbox"/> Pick-up (Please note, if you pick-up you may pay with credit card in person)	5. SHIP TO [Company Name] [Street Address] "[City, ST Postal Code]" "[Contact person for shipping]" [e-mail] [Phone]
<input type="checkbox"/> Ship (Please provide shipping information) → <u>For Exemption 56 Authorization, drug orders will be shipped to the address listed on your authorization letters. Please give Contact, e-mail and telephone #.</u>	

QTY	DESCRIPTION	SIZE
	Buprenorphine 0.3 mg/ml	1 ml vial
	Pentobarbital 54.7 mg/ml	100 ml bottle
	Ketamine 100 mg/ml	10 ml vial
	Euthanyl 240 mg/ml	250 ml bottle
	Euthansol 340 mg/ml	250 ml bottle
Subtotal to be billed or charged, amount before shipping, handling and applicable taxes		\$

For office use only

SHIPPING	DELIVERY DATE	SALES ORDER REFERENCE #	CREDIT CARD AUTHORIZATION #