PURPOSE: To outline the steps required for a Principal Investigator (PI) to apply for an exemption permit to obtain, store and use controlled substances for scientific purposes according to the regulations set down by Health Canada’s Office of Controlled Substances (Controlled Drugs and Substances Act, S.C. 1996, c. 19 and the Directive on Physical Security Requirements of controlled substances).

EQUIPMENT AND MATERIALS REQUIRED:
- Valid Animal Use Protocol (AUP)
- Exemption application form
- Letter from applicable campus or division representative (required for exemption applications for drugs that are both controlled and restricted)
- Secure location for storage (refer to the “Directive On Physical Security Requirements for Controlled Substances” for specific requirements for secure storage of different substances)

PROCEDURE:
1. Once the Principal Investigator (PI) has a valid AUP which includes the use of a controlled substance, they may apply to Health Canada for an annual exemption to use this controlled substance for scientific purposes. The application form may be found at: http://www.hc-sc.gc.ca/hc-ps/substancontrol/exemptions/applic-scieng.php. The approved AUP must accompany the application to Health Canada.

2. A list of controlled substances can be found in the “Controlled Drugs and Substances Act” and can be viewed at: http://laws-lois.justice.gc.ca/eng/acts/C-38.8/page-24.html#docCont. Contact veterinary staff or consult the attached appendix for commonly used controlled anesthetics and analgesics.

3. Restricted drugs: Some controlled substances are also classified as restricted. A list of restricted drugs can be found in section J of “Food and Drug Regulations”. Restricted drugs include heroin, cocaine and any other drugs listed on the schedule viewable at http://laws-lois.justice.gc.ca/eng/regulations/C.R.C., c. 870/page-366.html#h-368. Researchers using a restricted drug in their study must also complete the following three steps:
a. Submit a letter signed by their applicable campus or division representative (i.e. Principal/ Vice-Principal Research or Dean/Vice-Dean Research) with their exemption application. Please refer to the attached Appendix 2 – “Template letter to Health Canada” for an example of the required letter.

b. Submit a copy of the above letter and their completed exemption application form to acc.coordinator@utoronto.ca

c. When the exemption application is approved, submit a copy of the Health Canada permit to acc.coordinator@utoronto.ca

4. The PI must ensure that they have appropriate secure storage designated when applying for the exemption permit in accordance with Health Canada’s Directives on Physical Security Requirements of controlled substances, found at: http://www.hc-sc.gc.ca/hc-ps/pubs/precurs/dealers-distrib/phys_securit_directive/index-eng.php Note that security requirements vary depending on the particular controlled substance in use as well as the amount stored.

5. Once the exemption application is approved, Health Canada will issue an authorization permit number which the researcher may use to order and begin work with the controlled substance. Researchers using restricted drugs must submit a copy of their permit to acc.coordinator@utoronto.ca

6. Diligence is required for appropriate storage and documentation of ongoing use of controlled substances in accordance with the Act. Both are subject to audit by Health Canada inspectors enforcing the Act.

SUPPLIER OPTION: DIVISION OF COMPARATIVE MEDICINE

PIs using their animals in facilities administered by the Division of Comparative Medicine (DCM) wishing to use commonly administered controlled substances can indicate the University of Toronto dispensary as the supplier of their controlled substance. The dispensary is administered by DCM veterinary staff, designated as Qualified Persons in Charge (A/QPIC) by Health Canada, permitting dispensing of controlled substances to authorized exemption permit holders in accordance with the Act. In this instance, DCM veterinary staff may dispense the substance to the researcher, with proof of authorized exemption permit, as needed for their work, subject to availability. The University of Toronto dispensary must be indicated as the supplier of the controlled substance on both the exemption application and exemption authorization if researchers choose to avail themselves of this option.

NOTES:

• Storage: The storage and use of controlled substances for scientific purposes is subject to audit by Health Canada inspectors enforcing the Controlled Drugs and Substances Act.

• Exemption renewals: Each annual exemption allows the researcher to possess and use that controlled drug for that year only. If the protocol work continues
beyond that year, the researcher must apply for a new exemption to possess and use that substance for the next year. Health Canada must be notified of any remaining substance at the end of the exemption period whether the work continues or not or if the drug will be transferred to another protocol (as stated in the exemption documentation sent to the Researcher upon approval from Health Canada).

- **Exemption or substance expiry:** If substances are expired or the exemption is expired and not renewed, the substance must be destroyed in accordance with Health Canada’s regulations. Once Health Canada has been notified and the suitable documentation of destruction has been signed and witnessed, the researcher may denature (or render the substance unusable) personally, or they may contact Rob Provost from Environmental Health and Safety (rob.provost@utoronto.ca) who will have the substance incinerated and a certificate provided by Stericycle.
### Appendix 1 - Commonly Used Controlled Drugs in Research for Anesthesia and Analgesia

<table>
<thead>
<tr>
<th>Drug</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Buprenorphine</td>
<td>(opioid analgesic, may be used as part of balanced anesthesia)</td>
</tr>
<tr>
<td>Ketamine</td>
<td>(may be used as part of balanced anesthesia or as injectable anesthetic most often paired with (\alpha)-adrenergic agonists for acute procedures)</td>
</tr>
<tr>
<td>Pentobarbital (Sodium)</td>
<td>(injectable anesthetic for acute procedures)</td>
</tr>
<tr>
<td>Diazepam</td>
<td>(may be used as part of balanced anesthesia or anti-seizure medication)</td>
</tr>
<tr>
<td>Morphine</td>
<td>(opioid analgesic, may be used as part of balanced anesthesia)</td>
</tr>
<tr>
<td>Fentanyl</td>
<td>(opioid analgesic, may be used as part of balanced anesthesia)</td>
</tr>
</tbody>
</table>
Appendix 2 – Template letter to Health Canada (only needed for controlled substances that are also classified as restricted drugs as listed in Food and Drug Regulations, Section J)

DATE

Michael D. Tran
National Compliance and Exemption Division
Office of Controlled Substances
Health Canada
150 Tunney’s Pasture Driveway
Ottawa, K1A 0K9

Dear Mr. Tran,

This letter requests authorization from Health Canada on behalf of Professor NAME OF THE PI, PI’s department, who has applied for an Exemption to Use a Controlled Substance (NAME OF THE RESTRICTED SUBSTANCE) for Scientific Purposes.

This will also confirm that the Primary Investigator of the project is Professor NAME OF THE PI, who is submitting an application for an exemption to use a controlled substance for scientific purposes.

Signed,

Professor NAME OF PRINCIPAL/VICE-PRINCIPAL-RESEARCH/DEAN/VICE-DEAN RESEARCH
Title
Faculty of _______________; or Campus:__________________
University of Toronto