

Change in the Process of Management and Use of Controlled Drugs for Research Animals

Background:

In the past, researchers have been able to obtain controlled drugs (e.g. ketamine, sodium pentobarbital, buprenorphine, etc.) from Animal Care Services personnel by completing standardized documentation to account for the use of the drug. Drugs were ordered and maintained through the Veterinary Director, using her Veterinary License.

At the last Canadian Council on Animal Care (CCAC) Assessment Visit in December 2014, UVic was informed that our current practice is not in compliance with the Controlled Drugs and Substances Act: [CDS ACT](#)) and the Health Canada Directive on Physical Security Requirements for Controlled Substances [HC DIRECTIVE](#)).

In their report, the CCAC made a Regular Recommendation requiring the University to comply with Health Canada's Controlled Drug and Substances Act. This is consistent with all other research institutions in Canada. The Animal Care Committee, the Senior Operations Advisory Committee, and the Animal Care Users Committee have been made aware of this recommendation within the assessment report.

The Office of Research Services (ORS) is working closely with Facilities Management, Campus Security, Health Canada and the research community to educate, assist and support researchers with this change.

Q: What does this change mean for researchers?

A: In order to gain compliance with the Act, researchers must now obtain and use their own supplies of controlled substances. Supplies cannot be shared between Principal Investigators. Researchers using controlled drugs must maintain detailed records for procurement and use, and the responsible Principal Investigator must regularly monitor supplies.

Q. What is the new process?

A: Researchers must first obtain an exemption from Health Canada to use controlled substances with their research animals. The application form is found here: [Scientific Exemption Application](#).

An approved protocol must be in place before an exemption will be issued. A copy of your approved, signed protocol must be sent with your exemption application.

Once an exemption has been granted, controlled substances must be ordered by, shipped to, and stored by the researcher. **Animal Care Services cannot store or aliquot controlled substances to researchers from a stock inventory.** Detailed records of controlled substance use must be kept by the researcher(s) using the substances.

A [PowerPoint presentation](#) and [flow chart](#) are now available on the website to walk researchers through the completion of the application process.

Q: When is this change taking place?

A: Currently, the plan is to require new and renewing protocols to be in compliance with the Act and Directive beginning **January 1, 2016**. As protocols approach their renewal dates, researchers with these

substances listed on their protocols will be reminded to initiate the process for completing their exemption application. Support through the Office of Research Services will be available to assist with the process.

Researchers are encouraged to begin this process well in advance of protocol expiry to ensure minimal disruption of their programs.

A [PowerPoint presentation](#) and [flow chart](#) are now available on the website to walk researchers through the completion of the application process.

Q. What should I do if there is a delay in approval?

There may be a period of time during which researchers are awaiting their exemption approval and controlled drugs are needed for their research animals. Animal Care Services will work with the researchers to ensure that animals are receiving the medications they require during this waiting period.

Q: What are the most common controlled substances used for research at UVic?

A: Currently, the following controlled drugs are most commonly used for research at UVic:

Drug Name	Common Trade Names	Used For?
Sodium Pentobarbital	Euthanyl, Euthansol	Euthanasia
Buprenorphine	Buprenex, Subutex	Pain control
Butorphanol	Torbugesic	Sedation
Ketamine	Ketaset, Vetalar, Ketalar	Anaesthesia

Q: How will I order these substances in the future?

A: Currently, McGill University is a licensed distributor who can sell these substances to researchers with a valid Scientific Exemption. A Purchasing Agreement (AGR) has been established with McGill to purchase controlled substances. Researchers with controlled substances on their Animal Use Protocols as of January 1 2016 are eligible to use this AGR to purchase controlled substances. New researchers, researchers wishing to be eligible, and researchers wishing to check their eligibility should contact the Animal Ethics Liaison (acsc@uvic.ca).

A partially completed template form, including the AGR information, is [available on the website](#). The template includes highlighted areas that must be completed by the submitting Principal Investigator. **The order form MUST be mailed.** It cannot be faxed or emailed, as the supplier requires an original signature.

Q: What process should I follow to receive & unpack controlled drugs?

A: Best practices would be as follows:

- Notify Science Stores that a package is expected from McGill once your order has been placed.
- When received, have 2 people go to Science Stores to pick it up.
- Animal Care Services can be the “second person” if your lab is short-staffed (contact acsah@uvic.ca; x3692 for assistance).

- Have 2 people involved in the unpacking and initial inventorying of the drugs (one to perform, one to witness). Have both people initial/sign the inventory form.

Q: How am I going to store these substances in my office or laboratory?

A: Installations of approved storage cabinets/safes was undertaken for existing researchers using controlled substances for their research in early 2016. New researchers or researchers wishing to start using controlled drugs for their research must work with their departments to arrange installation of approved storage.

Department Administrators are responsible for maintaining lists of key/combination holders for each department member storing controlled substances.

New researchers wishing to store controlled substances must work with their departments to install appropriate cabinets. Departments will be responsible for covering these expenses.

Q: Can I just remove the controlled substances from my protocol, and avoid this process?

A: If the experimental procedures you are undertaking require the use of controlled substances (e.g. procedures are painful and require the use of opioids, or ketamine is required as an anaesthetic), it may not be appropriate to take this approach.

If there are suitable alternatives to controlled substances with equivalent or better efficacy for the authorized procedures, you are encouraged to amend your protocol to reflect this, and include the scientific justification for the amendment. The Animal Care Committee must approve any amendments.

You are encouraged to contact the Veterinary Director (acsvet@uvic.ca) to discuss your protocol.

Q: The only controlled substance I use is sodium pentobarbital (“Euthanyl”) to euthanize animals. Is this included in the new rules?

A: Yes, sodium pentobarbital is a controlled drug.

Up to \$5000 (street value) of controlled substances may be stored by researchers in the designated space. This means that at least one 250ml bottle of sodium pentobarbital (street value \$1500) could be stored in each researcher’s designated space.

Q: What else can I use besides sodium pentobarbital to euthanize my research animals?

A: The CCAC guidelines on Euthanasia of Animals Used in Science (2010) are found here: <http://www.ccac.ca/Documents/Standards/Guidelines/Euthanasia.pdf>

The Frequently Asked Questions page is also helpful: [FAQ](#)

Q: Is Metacam (meloxicam) a controlled substance?

A: No. Metacam (meloxicam) is not a controlled substance.

Q: Is Xylazine a controlled substance?

A: No. Xylazine is not a controlled substance.

Q: Is Dexmedetomidine a controlled substance?

A: No. Dexmedetomidine is not a controlled substance.

Q: Is Atipamazole a controlled substance?

A: No. Atipamazole is not a controlled substance.

Q: Is Lidocaine a controlled substance?

A: No. Lidocaine is not a controlled substance.

Q: We have been using sustained release (SR) buprenorphine for pain control. It looks like McGill does not sell that. What should I do?

A: Health Canada does not approve of the use of compounded SR buprenorphine; therefore it must be removed from your protocol. Only regular buprenorphine can be used under an experimental license. [An expedited amendment](#) can be used to remove SR buprenorphine from your protocol – this must be done prior to submission of your application.

Q: What record keeping do I have to undertake? What does the record need to look like?

A: Record keeping requirements for controlled drugs are stringent. Records must contain the following:

- 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 a separate record sheet prepared for the dilution or mixture.

Several protocols may be included in a single exemption; however documentation must clearly establish under which protocol the drug volume is being used.

Should the University of Victoria be audited by Health Canada, inspectors will review researchers' documentation and storage to ensure compliance with the Act. If there is non-compliance, individuals may be subject to penalties under the Act ([Penalties](#); section 46).

The Animal Care Committee may request a review of Controlled Substances records when your protocol is renewed or amended.

Please note that Health Canada generally does not accept electronic logs for controlled substances, unless each entry is password protected and assigned to a unique user [as with many commercial pharmacy software programs]. If you wish to establish whether your electronic record keeping system would be acceptable, please contact Health Canada to review your proposal.

Several templates are available [on the website](#) (under 'References and Forms') for researchers to use. They can be customized for use in each researcher's laboratory.

Occupational Health, Safety and Environment (OHSE) is presently developing an update for their chemical storage database to include controlled drugs. In future, researchers will be able to include their inventory of controlled substances in this database.

Q: Can I share storage space with another researcher?

A: Health Canada advises:

"It is possible for researchers exempted under section 56 for scientific purposes to share storage. When storage is shared by more than one researcher it is the total illicit value of the controlled substances stored in that location which must be less than \$5000. If a researcher is sharing storage with another researcher, it must be explicitly indicated in the application.

However, sharing storage could cause a delay in the issuance of a section 56 exemption. As part of the review, the Exemption Officer reviewing the application would require a list of researchers sharing the same storage. The Exemption Officer would then have to evaluate the total illicit value for all the researchers sharing the storage. To do so, the Exemption Officer may have to retrieve those researcher's files from the central registry. Because of this, I would advise that the researchers maintain their own distinct storage to facilitate an efficient review."

Q: When will the next update on the Change in the Process of Management and Use of Controlled Drugs for Research Animals be provided?

A: If there is new information to be provided, an update will be communicated to researchers.

Q: Whom should I contact if I have questions or concerns?

A: Please contact the Animal Ethics Liaison (acsc@uvic.ca) if you have questions or concerns.