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.


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 (http://www.hc-sc.gc.ca/hc-ps/substancontrol/exemptions/applic-scien-eng.php).

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.

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.

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:

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Common Trade Names</th>
<th>Used For?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium Pentobarbital</td>
<td>Euthanyl, Euthansol</td>
<td>Euthanasia</td>
</tr>
<tr>
<td>Buprenorphine</td>
<td>Buprenex, Subutex</td>
<td>Pain control</td>
</tr>
<tr>
<td>Butorphanol</td>
<td>Torbugesic</td>
<td>Sedation</td>
</tr>
<tr>
<td>Ketamine</td>
<td>Ketaset, Vetalar,</td>
<td>Anaesthesia</td>
</tr>
</tbody>
</table>

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. At this time, a credit card will be required. If you wish to use your PCard to purchase controlled drugs, you must obtain specific authorization to do this, as normally these substances are restricted from purchase using PCards. Please contact UVic Purchasing for more information: purchasing@uvic.ca.

The Office of Research Services is working towards establishing a Purchasing Agreement with McGill University, to facilitate the ordering of controlled drugs from McGill.

Order form templates will be available on the website in the future. Until that time, please contact the Animal Health Technician Coordinator (acsaht@uvic.ca) to obtain a form, once you have obtained your Scientific Exemption.

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

A: ORS is working with Facilities Management, Campus Security and Health Canada to establish acceptable, standardized means to store these substances within a designated, laboratory-associated space (e.g. Principal Investigator's office), based on current approved use of controlled substances by researchers on campus. ORS will be working with individual researchers to ensure that the identified storage unit and
space will be functional for the designated lab-associated space. We are in the process of determining the costs associated with the purchase and installation of the storage and will be applying for central support as a special one-time request.

**28 September 2015 Update:** There are two options for storage. Researchers may choose either a wall-mounted “mailbox” type unit, which will have a digital lock upgrade (Part #1600-2), or they may choose a floor-mounted media safe (EDS -020). Details of these units are included in the appendix to this document. In either case, Facilities Management will be installing these units in the appropriate space following Health Canada specifications. Departmental Administrative Officers will be working with individual researchers to define their choices, location for installation, and installation date with Facilities Management.

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.

Because commercial supplies of sodium pentobarbital are only available in 250ml volumes, additional security requirements may be needed to store this drug. ORS and Animal Care Services are working with Health Canada to establish what volume can be stored in laboratory-designated space.

If Health Canada advises that security requirements to hold this volume of sodium pentobarbital cannot be met in the laboratory-designated space, the ORS, the Animal Care Committee and Animal Care Services will work with researchers to establish alternative procedures to use when euthanizing animals in order to meet CCAC guidelines for humane euthanasia.

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


The Frequently Asked Questions page is also helpful: FAQ (http://www.ccac.ca/en_/standards/guidelines/additional/faq-euthanasia)

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: 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.

Each protocol must have a separate Scientific Exemption – it is possible that one Principal Investigator will have more than one Scientific Exemption if they have more than one protocol where controlled drugs are 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 http://laws-lois.justice.gc.ca/eng/acts/c-38.8/page-19.html; section 46).

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

The ORS and Animal Care Services are developing templates that, if filled completely, will meet compliance standards. These templates will be available on the Animal Care Services Website in the next few months.

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: In September 2015, the next update will be provided.

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.
Collection boxes

#1 MAILBOX CHOICE NATIONWIDE

Model 1600-1 & 1600-2

- Extruded aluminum door 5/32" (4) thick with aluminum frame and heavy gauge metal compartment.
- Locks are 5-pin cylinder cam type, 2 keys each, 1000 changes.
- Prepared for Postal service lock if so required.
- Available in recessed and surface mount.
- Each unit individually boxed can be shipped by Parcel Post.

**SURFACE MOUNT SHOWN**

1600-1

1600-2

**Note:** 1600-1 and 1600-2 are always shipped with cam locks.

**OPTIONS**

- Engraved "LETTERS" 1/2" (13) high.
- Hood over slot.
- Gold Finish

*charges apply

**Dimensions**

<table>
<thead>
<tr>
<th>MODEL</th>
<th>HEIGHT</th>
<th>WIDTH</th>
<th>DEPTH</th>
<th>HEIGHT</th>
<th>WIDTH</th>
</tr>
</thead>
<tbody>
<tr>
<td>1600-1</td>
<td>19 1/8&quot; (486)</td>
<td>8 3/4&quot; (222)</td>
<td>7&quot; (178)</td>
<td>17 3/4&quot; (451)</td>
<td>7 1/4&quot; (184)</td>
</tr>
<tr>
<td>1600-2</td>
<td>19 1/8&quot; (486)</td>
<td>15 1/4&quot; (387)</td>
<td>7&quot; (178)</td>
<td>17 3/4&quot; (451)</td>
<td>13 3/4&quot; (349)</td>
</tr>
</tbody>
</table>

**Size of the Slots:**
- 1600-1 3/4" (20) H x 5 5/8" (144) W
- 1600-2 3/4" (20) H x 10" (254) W

**Model 1600 DD (Double door)**

- Doors are .080" (2) thick aluminum.
- Outside shroud is .080" (2) brushed clear anodized aluminum.
- Extruded aluminum frame and trim.
- Factory punched 4 key-hole slots 3/16" (5) for easy installation.
- Piano hinged doors prepared for Canada Post Lock.
- Also available in stainless steel. Contact customer service.
- Available with or without slot.
- Locks are 5-pin cylinder cam type, 2 keys each, 1000 changes.
- Each unit individually boxed can be shipped by Parcel Post.

**NOTE:** Top of unit extends out by 2 1/2" (90)

**Dimensions**

<table>
<thead>
<tr>
<th>HEIGHT</th>
<th>WIDTH</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frame</td>
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<tr>
<td>18 3/4&quot; (476)</td>
<td>18 3/4&quot; (476)</td>
</tr>
<tr>
<td>Compartment</td>
<td>16 1/2&quot; (419)</td>
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<tr>
<td>16 1/2&quot; (419)</td>
<td>16 1/2&quot; (419)</td>
</tr>
<tr>
<td>Postman's door</td>
<td>5 1/2&quot; (140)</td>
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<tr>
<td>16 1/2&quot; (419)</td>
<td>16 1/2&quot; (419)</td>
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<tr>
<td>Tenant's door</td>
<td>11&quot; (279)</td>
</tr>
<tr>
<td>Slot size</td>
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<tr>
<td>11&quot; (279)</td>
<td>11&quot; (279)</td>
</tr>
<tr>
<td>Weight</td>
<td>11 lbs - 5 kgs</td>
</tr>
</tbody>
</table>

*All measurements in brackets are in millimeters.

**Model 234 Nordic**

(Commercial exterior mailbox)

- Painted steel outside housing with aluminum front.
- Medium capacity lackable compartment.
- 5 pin cam lock with 2 keys as a standard.
- Outside housing painted black.

**DIMENSIONS**

**Box Size:** 15" x 10" x 5" (375 x 254 x 125)

**Door Size:** 10" x 10" (254 x 254)

**Slot size:** 1" x 9" (25 x 229)
**FIRE PROOF MEDIA AND DATA SAFES**

Designed to protect sensitive magnetic storage media (CD, computer media, magnetic tapes etc.) from fire, humidity - equipped with Multi-layer inner box of special anti-thermal materials.

Features:
- 1 hour or 2 hours fire protection certified by UL Class 350 1 hr, KS 1 hour
- Data certificate - 60Diskette, 90Data
- Three-way main bolt work with independent relocking device
- 2 to 3 stationary locking bolts on hinge to deter prying attack on hinges
- Extra liner provides superior protection for heat and moisture sensitive computer media

<table>
<thead>
<tr>
<th>MODELS</th>
<th>FIRE PROOF MEDIA AND DATA SAFES</th>
<th>UNIT COST</th>
</tr>
</thead>
<tbody>
<tr>
<td>EDS-020</td>
<td>• Outside - 14&quot;H x 19&quot; W x 15-1/3&quot;D</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Inside - 5-7/8&quot;H x 11-1/4&quot;W x 7-1/2&quot;D</td>
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<tr>
<td></td>
<td>• Weight - 106 lbs</td>
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