



ONTARIO VETERINARY COLLEGE  
Office of the Dean

## Communication to CVO Licensed Researchers

Based on interpretation of the regulatory requirements and previous regulatory feedback, U of G has previously required a section 56 Exemption for controlled substances used in research only for principal investigators who did **not** hold a veterinary license or when the purpose of the study was focused on the substance itself.

Recent clarification from Health Canada has contraindicated this interpretation. To ensure compliance with the Controlled Drugs and Substances Act, Principal Investigators (including licensed veterinarians) must obtain approval through the Section 56 exemption process for use of any controlled substance that is a part of the research protocol (as outlined in the AUP). Application for the exemption must also be indicated on the OR5. Further information about Health Canada exemptions can be found at the following links:

<http://www.hc-sc.gc.ca/hc-ps/substancontrol/exemptions/index-eng.php>

<https://www.ucalgary.ca/animalhealth/exemptions/faq>

[http://umanitoba.ca/research/orec/media/Info\\_package\\_for\\_filling\\_exemption\\_November\\_2011.pdf](http://umanitoba.ca/research/orec/media/Info_package_for_filling_exemption_November_2011.pdf)

Controlled Drugs that are commonly requested for research:

<http://www.ovc.uoguelph.ca/research/en/researchresources/resources/ControlledDrugsthatareCommonlyRequestedforResearch.pdf>

The exception to this occurs when an animal that is part of a research project requires unanticipated medical treatment. In this situation a licensed veterinarian can prescribe to an individual animal a controlled substance as part of a veterinarian-patient relationship.

For example, if every animal in the study will be receiving hydromorphone for pain control after a procedure that is part of the study, a veterinarian requires an exemption (i.e. Health Canada approval) to receive, administer, and store the drug.

If one animal involved in the study breaks its leg while participating in the study, a veterinarian does not require an exemption to receive and administer hydromorphone.

This change is currently being communicated to all relevant parties across campus. For studies currently underway, there will be an allowed transition period to ensure there is minimal interruption. The OVC HSC Pharmacy will be contacting all researchers that have ordered controlled substances in the past 12 months informing them they will need to apply for the exemption as soon as possible if they anticipate needing to order prior to the completion of the study.

The exemption application form can be found at:

[http://www.hc-sc.gc.ca/hc-ps/alt\\_formats/hecs-sesc/pdf/substancontrol/exemptions/scientific-eng.pdf](http://www.hc-sc.gc.ca/hc-ps/alt_formats/hecs-sesc/pdf/substancontrol/exemptions/scientific-eng.pdf)

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