Controlled Drugs and Substances and Veterinary Biologics Used in Scholarly Activities

Office of Administrative Responsibility: Research Services Office, Research Risk

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PURPOSE

To promote compliance with prescribed requirements for controlled drugs and substances with respect to the research, and teaching activities of the University of Guelph, and to communicate the University requirements for operational due diligence.

SCOPE

This guideline applies to all individuals conducting research, teaching or analytical service activities involving the use of controlled drugs or substances at the University of Guelph. It does not apply to human or animal clinical operations at the University.

GUIDELINE

1. Responsibilities

1.1 Vice President

i. Authorize any applications made to Health Canada for *licenses* issued under the Narcotic Control Regulations required for the conduct of a specific research program.

ii. Convene an ad hoc peer review committee to advise about extraordinary issues related to the management and use of controlled drugs and substances as recommended through the committee.

1.2 Pharmacy Manager

iii. Order, receive from licensed dealers, store, dispense to authorized persons, receive and dispose of controlled drugs and substances, and veterinary biologics used in University teaching and research programs

iv. Maintain prescribed records concerning the receipt of controlled drugs and substances and veterinary biologics from licensed dealers providing such substances to the University for sanctioned teaching, and research purposes

v. Appropriately label and issue controlled drugs and substances and veterinary biologics for sanctioned teaching, and research purposes

vi. Stipulate requirements for responsible care and secure custody of controlled drugs and substances and veterinary biologics and require that all unused product be returned to the HSC Pharmacy for disposition

vii. Determine whether Drug Use Applications must be submitted to Health Canada and liaise with federal authorities on behalf of University personnel; e.g., **Application for an Exemption to Use a Controlled Substance for Scientific Purposes** submitted to the Office of Controlled Substances, Health Canada; **Application for an Experimental Studies Certificate for a Veterinary Drug** submitted to the Veterinary Drugs Directorate, Health Canada;

viii. Take reasonable precautions (e.g., verifications of identification and signatures, confirming licensure with the College of Veterinarians of Ontario) to determine that persons are authorized under prescribed regulations to possess controlled drugs and substances, and veterinary biologics as applicable

ix. Maintain prescribed records concerning controlled drugs and substances, and veterinary biologics dispensed to authorized persons from the HSC Pharmacy

x. Take all reasonable steps to protect and secure all controlled drugs and substances, veterinary biologics and discretionary veterinary health products under his/her care and custody against spill, loss or theft;
xi. Report any known loss or theft of controlled drugs and substances and veterinary biologics to the Office of Controlled Substances, Health Canada, as prescribed within 10 days of the discovery thereof;
xii. Advise the Vice-President Research and Campus Community Police about any known extra-ordinary drug-related situation concerning safety, security or regulatory noncompliance as applicable;
xiii. Prepare a report annually for the Vice-President Research concerning the use of controlled drugs and substances and veterinary biologics at the University, which summarizes noteworthy compliance issues and corrective actions.

1.3 Campus Community Police

xiv. Consult with stakeholders including Pharmacy Manager and Principal Investigators as required regarding appropriate security provisions to be implemented, particularly if alarms, surveillance systems or renovations are considered.
xv. Investigate any losses/thefts of controlled drugs, substances or veterinary biologics.
xvi. Liaise with law enforcement agencies as required.

1.4 Manager, Research Risk

xvii. Maintain listing of current Departmental Appointees and provide to Pharmacy Manager as required.
xviii. Coordinate meetings of Drug Control Committee as required

1.5 Departmental Appointee

xix. Participate in the Drug Control Committee

xx. Provide their department with guidance and information regarding University requirements with respect to controlled drugs, substances, and veterinary biologics

xxi. Liaise with the Pharmacy Manager on drug control matters and communicate any changes or current issues with the department.

xxii. Co-sign completed Requests for Issue of Drugs for Use in Academic and Research Programs with Principal Investigators

xxiii. Take reasonable precautions to ensure that storage and record keeping requirements of controlled drugs, substances and veterinary biologics within the department meets the required standards. This is accomplished by ensuring that:

1. Drug requests are completed appropriately
2. Principal Investigator Self-Assessment forms are completed appropriately
3. Related incidents are reported accordingly

xxiv. Accommodate external audits as applicable.

Principal Investigator

i. Follow prescribed procedures, for requests of controlled substances, drugs and veterinary biologics
ii. Consult with the Pharmacy Manager and complete as necessary the following forms for Health Canada: **Application Form for an Exemption to Use a Controlled Substance for Scientific Purposes**; **Application for an Experimental Studies Certificate for a Veterinary Drug**. (Additional information herein provides guidance about prescribed requirements for these Applications.)
iii. Provide copies of Health Canada issued exemptions and/or experimental studies certificates to the Pharmacy Manager with associated drug requests
iv. Maintain records of controlled drugs, substances and veterinary biologics as prescribed by regulations
v. Take adequate steps to contain, protect and secure all controlled drugs, substances and veterinary biologics and discretionary veterinary health products, against spill, loss or theft in accordance with instructions from the Pharmacy Manager (e.g., store in a locked safe, drawer, cabinet or lockable refrigerator set between 2 and 8 degrees Celsius)
vi. Notify the Pharmacy Manager of relocation of the secure storage of controlled drugs, substances and veterinary biologics from any location previously identified and approved
vii. Notify the Pharmacy Manager of his/her extended absence from the University and make alternate arrangements for possession and safekeeping of his/her controlled substances
viii. Report any spill, loss or theft of a controlled drug or substance to the Departmental Appointee and to the Pharmacy Manager immediately after

the discovery of the spill, loss or theft. Report thefts to Campus Community Police

ix. Submit annually an inventory of controlled drugs and substances and veterinary biologics under his/her care and custody (e.g., names of controlled substances, balances, secure locations) to the Pharmacy Manager

x. Permit the Pharmacy Manager (or designate), Departmental Appointee, or Inspector to audit all records and stocks of controlled drugs and substances and veterinary biologics under the practitioner's or principal investigator's care and custody and facilitate any such inspections

xi. Consult with the Pharmacy Manager, University Veterinary Director and/or the Manager, Research Risk as appropriate about proposed work with novel veterinary biologics, new substances to be used in investigational veterinary drugs or new human drugs, and about new substance notifications and permit applications to federal agencies

xii. Return all unused controlled drugs and substances to the HSC Pharmacy for authorized disposition or destruction upon completion of a teaching or research program

2. Controlled Drugs and Substances

1.2 Only those persons authorized or exempted pursuant to the Controlled Drugs and Substances Act (CDSA) shall have possession, care and custody of controlled drugs and substances, namely:

- HSC pharmacist(s)
- practitioners who require controlled drugs for patient treatment
- employees of the HSC, designated by the Director (or equivalent) of the OVC – Health Sciences Centre, who perform duties under the authority of a practitioner
- University Campus Community Police constables acting in an enforcement capacity;

- persons authorized through the Office of Controlled Substances via:
    - CDSA Section 56 Exemptions for Scientific Purposes and/or Experimental (Clinical) Studies based upon applications endorsed by the HSC Pharmacy Administrator (e.g., veterinarians and/or investigators needing controlled substances for field or laboratory work; clinical trials of drugs and/or new drugs in animals).
    - Dealer's License (Section 9 of Narcotic Control Regulations) based on applications endorsed by the Vice President, Research in support of research programs

1.3 Except as authorized under the Controlled Drugs and Substances Act, no person shall import into Canada or export from Canada a substance included in Schedule I, II, III, IV, V or VI.

1.4 Except as authorized, no person shall produce a substance included in Schedule I, II, III, or IV of the Controlled Drugs and Substances Act.

1.5 Requests for drugs are to be submitted to the Pharmacist via the Request for Issue of Drugs for Use in Academic and Research Programs. Times required to process drug requests will be established by the HSC Pharmacy.

3. Records

Usage and transfer records must be maintained in a bound book and include the following information:

- date received
- name of substance
- quantity of substance (number of containers and quantity per container)
- name and address of the person from whom the drug was received (normally the HSC Pharmacy Manager and HSC Pharmacy)

- particulars of use including description of use, patient identifier and/or project identifier as applicable
- amount used
- amount remaining
- identity of the person using the controlled drug/substance (legibly printed name and signature)

Appendix B contains an example of a suitable usage record.

All records associated with Controlled Drugs and Substances referred to in this guideline are to be in a place, form, and manner that will permit an Inspector to readily examine them. Records must be maintained for at least seven years from the date of the making of the record. Records include but are not limited to:

- HSC Pharmacy records
- Request for Issue of Controlled Drugs for Use in Academic and Research Programs
- Log records/inventories (including receipt, transfers, usage, and disposal)
- Access records (i.e. issuance of keys, lock combinations)
- Reports of theft/loss

4. Additional Information and References

The Health Products and Food Branch (HPFB) Inspectorate of Health Canada is responsible for compliance and enforcement activities pursuant to the Controlled Drugs and Substances Act (CDSA) and the Food and Drugs Act. The possession, import, export, production, distribution and sale of narcotics, controlled drugs, targeted substances and precursor chemicals are all subject to legislated controls for public health and safety.

Canada's Drug Strategy and Controlled Substances Program falls within the Healthy Environments and Consumer Safety Branch (HECSB) of Health Canada.

The Office of Controlled Substances (OCS) oversees the national compliance and enforcement program for all products under the HPFB mandate (excluding food products regulated by the Canadian Food Inspection Agency, CFIA). It is also responsible for administering the exemption

process that allows possession of controlled drugs and substances for scientific and medical research.

The Veterinary Drugs Directorate (VDD) in HFPB ensures that veterinary drugs are safe and that food-source and companion animals treated with veterinary drugs are not endangered by use of the product.

Health Canada's Drug Product Database (DPD) contains specific information on all drugs approved for use in Canada. The DPD includes human pharmaceutical and biological drugs, veterinary drugs and disinfectant products.

4.1 Exemptions under Section 56 of CDSA for Scientific Purposes

Researchers (e.g. university principal investigators) who require controlled drugs and substances for scientific research purposes (i.e., for non-treatment purposes in laboratory or wild animals, for in vitro utilization, for human or animal clinical trials) must obtain an exemption under Section 56 of the Controlled Drugs and Substances Act. Exemptions to certain provisions of CDSA, which must be applied for and are subject to prescribed terms and conditions, allow researchers to legally possess specified quantities of controlled substances for specified research purposes. Exemptions, if issued, are valid for no longer than one year.

Licensed veterinarians (as researchers) are not required to hold an exemption issued under section 56 of the *Controlled Drugs and Substances Act (CDSA)* for controlled substances being administered to research animals by a licensed veterinarian, provided that:

- the substance will be administered by or under the direct, on-site, supervision of a licensed veterinarian;
- the animal is a patient of the veterinarian under their professional treatment AND
- the controlled substance is required for the condition for which the animal is treated. This could include treatment for pain and/or sedation.

If the controlled substance is the subject of the research, a Section 56 exemption is required, even if the Principal Investigator is a veterinarian.

Principal investigators should consult with the HSC Pharmacy Manager about their Applications to OCS. Exemption applications should be submitted to OCS a minimum of 8 weeks prior to the anticipated start date of the project.

4.2 Investigational New Drugs – Experimental Studies Certificates

The Veterinary Drugs Directorate issues Experimental Studies Certificates to researchers who undertake clinical evaluations of new drugs. Principal investigators must apply to the VDD. The HSC Pharmacy Manager should be consulted about any Application to VDD for an Experimental Studies Certificate for a Veterinary Drug. Certificate applications should be submitted to the VDD a minimum of 8 weeks prior to the anticipated start date of the project.

4.3 Extra-Label Drug Use

Numerous risk issues are associated with extra-label drug use in animals. More information can be found on the Health Canada website.

4.4 Reporting Adverse Reactions

The following are available resources related to adverse reactions:

- Health Canada's guidelines concerning adverse reaction reporting.
- Health Canada's pharmacovigilance program

Suspected adverse reactions to veterinary drugs should be reported to the VDD via the drug adverse reaction notification form. For adverse effects reporting related to veterinary pesticides, see the Health Canada website.

4.5 Veterinary Biologics

Veterinary biologics, which include vaccines, immunoglobulin products and diagnostic test kits for the diagnosis, prevention or treatment of animal diseases, are regulated by the Veterinary Biologics Section (VBS) of Canadian Food Inspection Agency (CFIA).

Veterinary biologics approved for sale in Canada listed on the CFIA website. Suspected adverse reactions to veterinary biologics must be reported to VBS in accordance with Guideline for Reporting Suspected Adverse Events Related to Veterinary Biologics via the CFIA adverse event report form. Information regarding the regulation of veterinary biologics produced by biotechnology can be found in the Guideline for Regulation of Biotechnology-Derived Veterinary Biologics.

4.6 Natural Health Products

Natural health products are regulated by the Natural Health Products Regulations pursuant to the Food and Drugs Act. The regulations apply only to human products; they include

substances or medicinal ingredient substances set out in Schedule 1 of the Regulations, but not substances set out in Schedule 2. Natural health products are identified with a natural products number (NPN) or a DIN-HM number which designates the product as a Homeopathic Medicine approved by Health Canada. The University's Research Ethics Board must approve research involving natural health products and human subjects.

4.7 Disposal

Unwanted controlled drugs and substances (as liquid, powder, tablet or injectable preparations) must be returned to the HSC Pharmacy for proper disposal. Logbook inventory records shall be annotated.

Unwanted biologics are to be disposed of as hazardous waste through services provided by Environmental Health and Safety (EHS). Empty bottles, vials, syringes and sharps must be collected in University standard (red or yellow) sharps collectors which are also disposed via the EHS service.

DEFINITIONS

controlled drug –

a drug set out in the Schedule to the Food and Drug Regulations, Part G.

controlled substance –

a substance included in Schedule I, II, III, IV, or V of the Controlled Drugs and Substances Act; includes any substance that contains a controlled substance (natural or synthetic).

DIN drug identification number –

An eight-digit numerical code assigned to each drug product marketed under or in accordance with the Food and Drugs Act and Food and Drug Regulations. Human and veterinary drugs must have a valid DIN to be sold in Canada.

departmental appointee –

a faculty member appointed by a Department Chair/Head to implement local procedures for drug control. If not the primary departmental appointee, the

Department Chair is appointed as the alternate departmental appointee. Identities of Departmental Appointees are available by contacting the HSC Pharmacy or the Manager, Research Risk.

drug –

any substance or mixture of substances manufactured, sold or presented for use in:

a. the diagnosis, treatment, mitigation or prevention of disease, disorder, or abnormal physical state, or its symptoms, in human beings or animals;

b. restoring, correcting or modifying organic functions in human beings or animals;

c. disinfection in premises where food is manufactured, prepared or kept.

extra-label drug use –

the use of a drug product in a manner that is not consistent with what is indicated on the label or package insert of any drug product approved by Health Canada.

inspector –

a person designated as an Inspector pursuant to Section 30 of the Controlled Drugs and Substances Act (e.g., peace officer).

narcotic –

any substance set out in the Schedule to the Narcotic Control Regulations or anything that contains any substance set out in the Schedule.

new drug –

a drug, or combination of drugs, for which the safety and effectiveness of use has not been established by Health Canada.

pharmacist –

a person who is registered and entitled under the laws of a province to practise pharmacy and to operate a pharmacy or dispensary.

Pharmacy Manager –

a person who shall be licensed to practice pharmacy in the Province of Ontario and who shall oversee the operations of the OVC -Health Sciences Centre (HSC) Pharmacy.

practitioner –

a person who is registered and entitled under the laws of a province to practise in that province the profession of medicine, dentistry or veterinary medicine, and includes any other person or class of persons prescribed as a practitioner; pursuant to Food and Drug Regulations, Part G, Division 4, practitioners may administer controlled drugs to patients under their professional treatments.

precursor –

a substance included in Schedule VI of the Controlled Drugs and Substances Act.

Schedule –

a listing of controlled drugs and substances pursuant to specific federal legislation.

veterinary biologics –

substances used for restoring, correcting or modifying organic functions in animals or for use in the diagnosis, treatment, mitigation or prevention of diseases, disorders, abnormal physical states, or the symptoms thereof, in animals. Veterinary biologics, which must be licensed by the Canadian Food Inspection Agency (CFIA) for use in Canada, include vaccines, bacterins, bacterin-toxoids, immunoglobulin products, diagnostic kits, and similar such substances derived through biotechnology.

RELATED EXTERNAL LEGISLATION OR POLICY

- *Controlled Drugs and Substances Act*
  - *Narcotic Control Regulations*
- *Food and Drugs Act*
  - *Food and Drug Regulations*
  - *Natural Health Products Regulations*
- *Health of Animals Act*
  - *Health of Animals Regulations*

LOCATION OF RESEARCH GUIDELINE

This guideline is published at: www.uoguelph.ca/research

REVIEW FREQUENCY

It is the responsibility of the Office of Administrative Responsibility to initiate review of this policy. This guideline is to be reviewed every 5 years.

APPENDIX

Appendix A: Changes from Previous Version

- Change of format to standard template
- Updating of website links
- Update to reflect Jan 2017 Health Canada policy eliminating need for licensed veterinarians to obtain an Exemption for Scientific Purposes for use of controlled substances within research projects except if the drug is the topic of study
- Update to remove provisions for research with cannabis following its removal as a controlled substance and legalization Oct 17, 2018

Appendix B: Example of a suitable usage and transfer record

Note that usage logs must be maintained in a bound book.

CONTROLLED DRUGS/SUBSTANCES USAGE LOG

Principal Investigator Name:

Name of Controlled Substance:

Quantity Received (number of containers and quantity per container):

Lot number/Serial number of container(s):

Date Received:

Received from (name and location):

Date	Lot number	Description of Use	Patient or project identifier	Quantity Used	Quantity Remaining	Used by (printed name)	Used by (signature)