Controlled Drugs and Substances and Veterinary Biologics Used in Scholarly Activities

Effective Date: April 2007

Revision History: July 2014
September 2008

Applicable Legislation:

- 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
- Canadian Environmental Protection Act
  - New Substances Notification Regulations (chemicals and polymers)

Intent:

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.

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.

experimental study –

a limited test of a new drug in animals carried out by an investigator.
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.

hospital –

a facility that is licensed, approved or designated by a province in accordance with the laws of the province to provide care or treatment to persons or animals suffering from any form of disease or illness.

inspector –

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

lot number –

any combination of letters or figures by which a product may be traced in manufacture and identified in distribution.

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. The Pharmacy Manager shall report to the Vice-President Research concerning the use of controlled drugs and substances in University teaching and research programs.

**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.

**provide** –

to give, transfer or otherwise make available, directly or indirectly.

**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.
Responsibilities

Vice President, Research

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

Pharmacy Manager

- 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.
- Maintain prescribed records concerning the receipt of controlled drugs and substances and veterinary biologics from all licensed dealers providing such substances to the University for sanctioned teaching, and research purposes.
- Appropriately label and issue controlled drugs and substances and veterinary biologics for sanctioned teaching, and research purposes.
- 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.
- 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;

- 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

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

- 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;

- 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;

- Advise the Vice-President Research and the Director, Campus Community Police about any known extra-ordinary drug-related situation concerning safety, security or regulatory noncompliance;

- 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.

The Pharmacy Manager does not hold responsibility over aspects involving research programs involved with growth of marihuana including but not limited to receipt, storage, and destruction of seed or plant material nor documentation requirements.
Campus Community Police

- 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.

- Investigate any losses/thefts of controlled drugs, substances or veterinary biologics.

- Liaise with law enforcement agencies as required.

Manager, Research Risk

- Consult with stakeholders including Principal Investigators as required regarding appropriate security provisions, operational procedures and license applications/exemptions associated with research programs involving growth of marihuana.

- Liaise with Health Canada regarding license applications, amendments, and exemptions associated with research programs involving growth of marihuana.

- Maintain listing of current Departmental Appointees and provide to Pharmacy Manager as required.

- Coordinate meetings of Drug Control Committee at least annually

Departmental Appointee

- Participate in the Drug Control Committee

- Provide his/her department with guidance and information regarding University requirements with respect to controlled drugs, substances, and veterinary biologics

- Liaise with the Pharmacy Manager on drug control matters and communicate any changes or current issues with the department.
• Co-sign completed Requests for Issue of Drugs for Use in Academic and Research Programs with Principal Investigators

• 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:
  
  o Drug requests are completed appropriately
  
  o Principal Investigator Self-Assessment forms are completed appropriately
  
  o Related incidents are reported accordingly

• Accommodate external audits as applicable.

**Principal Investigator**

**Controlled drugs and substances (excluding research activities involving cultivation of marihuana) and veterinary biologics**

• Follow prescribed procedures, for requests of controlled substances, drugs and veterinary biologics

• 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.)

• Provide copies of Health Canada issued exemptions and/or experimental studies certificates to the Pharmacy Manager with associated drug requests

• Maintain records of controlled drugs, substances and veterinary biologics as prescribed by regulations
• 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)

• Notify the Pharmacy Manager of relocation of the secure storage of controlled drugs, substances and veterinary biologics from any location previously identified and approved

• 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

• 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

• 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

• 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

• Consult with the Pharmacy Manager, University Veterinary Director and 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

• Return all unused controlled drugs and substances to the HSC Pharmacy for authorized disposition or destruction upon completion of a teaching or research program
Research activities involving cultivation of marihuana

- Consult with the Manager, Research Risk regarding proposed research projects involving cultivation of marihuana and complete, as necessary, the appropriate license applications for Health Canada
- In accordance with the provisions indicated on Health Canada issued licenses:
  - maintain records of controlled material including seeds and plant materials as prescribed
  - take adequate steps to contain, protect and secure the marihuana against spill, loss or theft in accordance as indicated within the license
  - restrict access to the controlled material to those indicated on license
  - adhere to any other terms and conditions of licenses granted under Health Canada;
- In the event of an extended absence from the University, make alternate arrangements for possession and safekeeping of his/her controlled substances including notification of Manager, Research Risk and license amendment as required
- Report any spill, loss or theft of a controlled drug or substance to the Departmental Appointee and to the Manager, Research Risk immediately after the discovery of the spill, loss or theft. Report thefts to Campus Community Police;
- Renew licenses as applicable
- Permit the Departmental Appointee, Manager, Research Risk, or Inspector to audit all records and stocks of controlled drugs and substances and veterinary biologics
- Destroy all unused seed and/or plant material through authorized disposition or destruction methods outlined in licence immediately upon completion of associated research

Controlled Drugs and Substances

1. 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:
  o 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).
  o Licence to Cultivate Marihuana for Scientific Purposes (Section 67 of Narcotic Control Regulations) based on applications endorsed by the Vice President, Research.
  o Dealer’s License (Section 9 of Narcotic Control Regulations) based on applications endorsed by the Vice President, Research in support of research programs

2. 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. No person shall possess a substance included in these Schedules for the purpose of exporting it.

3. Except as authorized, no person shall produce a substance included in Schedule I, II, III, or IV of the Controlled Drugs and Substances Act. Note that extraction or isolation of cannabinoids from cannabis plants (marihuana) is considered production under the regulations.

4. The person in charge of a place entered by an Inspector or peace officer and every person there shall give the Inspector or peace officer all reasonable assistance in the power of that person and shall furnish the Inspector or peace officer with such information as may reasonably be required.
5. No person shall knowingly make any false or misleading statement verbally or in writing to an Inspector. No person shall obstruct an Inspector or peace officer who is engaged in the performance of his/her prescribed duties.

6. No person shall knowingly make, or participate in, or assent to or acquiesce in the making of a false or misleading statement in any book, record, return or other prescribed document however recorded.

7. 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.

**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

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. The Canadian Council on Animal Care (CCAC) Guide
to the Care and Use of Experimental Animals, chapters X, XI and XII, addresses the subjects of pain control in animals, anesthesia and euthanasia.

**Exemptions under Section 56 of CDSA**

Researchers (e.g., physicians, veterinarians and university principal investigators) who require controlled drugs and substances for medical or 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.

The Evaluation and Authorization Division of the Office of Controlled Substances (OCS) manages the exemption process.

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.

**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.

**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.
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.

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.

Assistance will be provided concerning compliance with the aforementioned CFIA guidelines, laboratory and/or agricultural animal containment, operational biosecurity and environmental protection protocols, prescribed research stage notifications to the VBS, and with animal care and welfare issues.

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.

**Growth and Cultivation of Marihuana**

Under Section 67 of the Narcotic Control Regulations application may be made to Health Canada for a license to cultivate, gather or produce marihuana for scientific purposes. Requirements of these license applications include but are not limited to:

- Criminal background check and absence of convictions of any drug-related offences in the past 10 years for all personnel involved in the research
- Provisions to maintain the physical security of the cannabis, and its seeds according to the Directive on Physical Security Requirements for Controlled substances.
- Letters from both the Municipality and Police Services that they are aware of the proposed research.
- Provisions to ensure the destruction of unwanted controlled material.

While Licences under 67 of the Narcotic Control Regulations allow for growth of cannabis, any transfer of plant material, seeds or derivatives and/or extraction/isolation of cannabinoids require a Dealer’s licence.

Licences are valid for no longer than 1 year.

Proposed research involving cultivation of marihuana should be discussed with the Manager, Research Risk. License applications and further information are available by request from the Manager, Research Risk.
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.

The Pharmacy is not able to accept marihuana seed or plant material for disposal and as such the Principal Investigator must ensure appropriate destruction.

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.
Appendix A: Changes from the Previous Version

Changes from the previous version (2008) include:

- Minor changes and clarification throughout
- Updating of website links, resources, names and titles of positions
- Reorganization of guideline to clarify and emphasize roles and responsibilities
- Clarification of the responsibilities of departmental appointees
- Addition of department chair as alternate to departmental appointee
- Addition of information relating to research involving the growth of marihuana
- Removal of listing of departmental appointees
- Addition of section regarding record keeping including an example of an appropriate usage log
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):

<table>
<thead>
<tr>
<th>Date</th>
<th>Lot number</th>
<th>Description of Use</th>
<th>Patient or project identifier</th>
<th>Quantity Used</th>
<th>Quantity Remaining</th>
<th>Used by (printed name)</th>
<th>Used by (signature)</th>
</tr>
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