

Environmental Health and Safety	 Controlled Substances 	Issue Date: 09 MAR 2022
SOP# 401.01		Effective Date: 09 MAR 2022

SOP Revision History

Revision No. 01	Revision Date. 09 MAR 2022	Summary of Changes: Sec. 2.3.3. Link to Directive on Physical Security. Sec. 4.1.5. Synthetic cannabinoids. Sec. 4.2. Link to CDSA for list of controlled substances. Sec. 5.1.5. Exemption validity extended to two years as per Health Canada.
Supersedes: 401		

1. PURPOSE AND OBJECTIVES

The Controlled Drugs and Substances Act (“CDSA”) prohibits activities related to controlled substances. Researchers requiring a controlled substance for research purposes must apply for and obtain a Controlled Substance Exemption under subsection 56(1) of the CDSA. This exemption is issued by Health Canada and authorizes researchers to purchase, if applicable, possess and use a specific controlled substance in specific quantities for a specific research purpose.

This Standard Operating Procedure (“SOP”) outlines the manner in which researchers requiring a controlled substance for scientific research purposes at McGill University, in the context of sponsored and unsponsored research, must apply for a Controlled Substance Exemption under subsection 56(1) of the CDSA, and purchase, store, use and dispose of the controlled substance.

To that effect, this SOP aims to ensure the health and safety of the McGill University community, to support researchers and to facilitate researchers’ compliance with the CDSA and the Health Canada requirements and conditions for a Controlled Substances Exemption under subsection 56(1) of the CDSA, including Health Canada’s Directive on Physical Security Requirements for Controlled Substances. This SOP does not apply to McGill University-affiliated hospitals or institutions, or to McGill University-affiliated research institutes and centres. For questions on applicability, please contact Environment Health and Safety.

2. GENERAL ROLES AND RESPONSIBILITIES

2.1. ENVIRONMENTAL HEALTH AND SAFETY (“EHS”)

- 2.1.1. EHS is responsible for the enforcement, oversight and administration of this SOP and the process and procedures described in this SOP, and must consult, whenever necessary, all relevant stakeholders, including any offices, units or committees, on the development, review and revision of new or existing processes and procedures to apply for a Controlled Substance Exemption, and for the purchase, storage, use and disposal of controlled substances.
- 2.1.2. EHS must provide ongoing advice and consultation to researchers and other concerned members of the research community at McGill University on the process and procedures described in this SOP and the Health Canada requirements and conditions for a Controlled Substance Exemption, including Health Canada’s Directive on Physical Security Requirements for Controlled Substances.
- 2.1.3. EHS must serve as the University’s central liaison between Health Canada and individual researchers.
- 2.1.4. EHS is hereby authorized to monitor, remotely and without notice or limitation, a researcher’s controlled substance inventory and related activities as captured and logged in McGill University’s MyLab system.

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- 2.1.5. EHS shall notify OSR should it become aware of Controlled Substance misuse, faulty administration by a researcher or any other issue that might affect an active Exemption vis-à-vis Health Canada or research funding agencies so that OSR can take relevant steps on use of funds.

2.2. OFFICE OF SPONSORED RESEARCH (“OSR”)

- 2.2.1. OSR receives and reviews all OSR Checklists for research projects in the context of externally-funded grants and project agreements, noting, among other things, any projects that may require a Controlled Substance Exemption.
- 2.2.2. Until such time as OSR receives confirmation from EHS that a researcher conducting sponsored research requiring the use of a controlled substance has received a Controlled Substance Exemption and the appropriate training and orientation, OSR may at its discretion grant a six-month temporary release of research funds. Such release can be renewable until the Exemption is granted to allow the researcher to undertake research activities that do not require a valid Exemption to be in place.
- 2.2.3. Upon receiving confirmation from EHS that a researcher conducting sponsored research requiring the use of a controlled substance has received a Controlled Substance Exemption and the appropriate training and orientation, OSR shall provide the researcher with full access to the awarded research funds for the period indicated in the Health Canada Controlled Substance Exemption. If the Exemption expires before the end of the research project, at expiration date, OSR will check the status of the Exemption with researcher and EHS (i.e. extension of Exemption, end of use of Controlled Substance, etc.) to assess required action on use of funds by the researcher beyond the Exemption expiry date.

2.3. RESEARCHER

- 2.3.1. For the purposes of this SOP, a researcher is a principal investigator (PI) or person responsible for a research project, with a minimum of a bachelor’s degree in science (B.Sc.), including a McGill University veterinarian, requiring a controlled substance for research purposes on McGill University campuses.

A McGill veterinarian who otherwise requires a controlled substance for non-research purposes at McGill, that is, for purposes related to animal care and the provision of veterinary services, either as part of or outside the context of a research project, their own or another’s, are not “researchers” for the purposes of this SOP. In such case, a McGill veterinarian is not required to apply for or obtain a Controlled Substance Exemption to purchase, possess or use the controlled substance. However, in order to ensure consistency and standardization, the McGill veterinarian must nonetheless maintain adequate recordkeeping, both in writing, using the appropriate records appended to this SOP, and in MyLab, for the purchase, location and relocation, administration and disposal of the controlled substance.

- 2.3.2. A researcher requiring a controlled substance for research purposes at McGill University must, whenever necessary, such as in the context of sponsored research, notify OSR by means of the OSR Checklist, and must always contact and consult EHS to apply for, obtain, maintain and renew a Controlled Substance Exemption.

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2.3.3. A researcher must ensure that they and all other individuals participating in the same research project, under the researcher’s direction and control, are familiar with the legislative and external regulations governing controlled drugs and substances, and that they and these individuals are in compliance with this SOP, the process and procedures described in this SOP, and the Health Canada requirements and conditions for a Controlled Substance Exemption. Including Health Canada’s Directive on Physical Security Requirements for Controlled Substances. [Directive on Physical Security Requirements for Controlled Substances and Drugs Containing Cannabis - Canada.ca](https://www.hc-sc.gc.ca/ahc-ahs/alt_formats/hccccc/eng/legislation/directive/directive.html)

To that effect, researchers must ensure that they and any individuals participating in the same project, under the researcher’s direction and control, have received the appropriate training and orientation.

2.3.4. Researchers must maintain adequate recordkeeping for the purchase, if applicable, the administration, relocation and disposal of controlled substances, both in writing, using the appropriate records appended to this SOP, and in MyLab, with the understanding that they may, upon request, be required to make written records available to Health Canada, EHS, and in the context of research involving animals, to the Facility Animal Care Committee (FACC), Quality Assistance Advisor or Veterinary staff.

Researchers must ensure that the written records referred to in the preceding paragraph are maintained for a period of 5 years.

2.4. COMPARATIVE MEDICINE AND ANIMAL RESOURCES CENTRE (“CMARC”)

2.4.1. CMARC is a McGill University resources centre and a provider of animal care and veterinary services to the McGill University community. In addition, CMARC is also a licensed distributor of certain controlled substances. This SOP and the process and procedures described in this SOP apply, where applicable, to CMARC and any members and support staff involved on its behalf in the purchase and storage of controlled substances and distribution of controlled substances to external clients and internally to McGill University researchers including veterinarians.

2.4.2. Any CMARC members or support staff involved on CMARC’s behalf and for its purposes in the purchase, storage and distribution of controlled substances must ensure that they are familiar with legislative and external regulations governing controlled drugs and substances, and that they are in compliance with this SOP, the process and procedures described in this SOP, and the Health Canada requirements and conditions for a Controlled Substance Exemption, including Health Canada’s Directive on Physical Security Requirements for Controlled Substances.

To that effect, CMARC members or support staff involved on CMARC’s behalf and for its purposes in the purchase, storage and distribution of controlled substances must ensure that they have received the appropriate training and orientation as a prior to participation in any duly approved controlled substance activity.

2.4.3. For the purposes of this SOP, CMARC must maintain adequate recordkeeping for the purchase, storage and distribution of controlled substances using MyLab, with the understanding that EHS may monitor, remotely and without notice or limitation, the centre’s controlled substance inventory and related activities as captured and logged in the MyLab system.

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3. EXCEPTION

3.1.1. Researchers, including McGill University veterinarians, do not require a Controlled Substance Exemption for a substance being administered to research animals provided all of the following conditions are met:

- (i) The substances will be administered to animals solely by an appropriately licensed veterinarian;
- (ii) The animal is a patient of the veterinarian under their professional treatment; and,
- (iii) The controlled substance is required for the condition for which the animal is being treated

4. DEFINITIONS

4.1. Controlled substances are drugs that have significant abuse risk. These include, but are not limited to:

4.1.1. Opioids:

- 4.1.1.1. Morphine
- 4.1.1.2. Hydromorphone
- 4.1.1.3. Fentanyl
- 4.1.1.4. Buprenorphine
- 4.1.1.5. Butorphanol

4.1.2. Barbiturates:

- 4.1.2.1. Pentobarbital
- 4.1.2.2. Pentothal
- 4.1.2.3. EUTHANYL® (pentobarbital)

4.1.3. Benzodiazepines:

- 4.1.3.1. Diazepam
- 4.1.3.2. Midazolam

4.1.4. Dissociative anesthetics:

- 4.1.4.1. Ketamine
- 4.1.4.2. TELAZOL® (tiletamine/zolazepam)

4.1.5. Synthetic cannabinoids:

- 4.1.5.3. HU-210
- 4.1.5.4. WIN-55,212-2
- 4.1.5.5. CP 55,940

4.2. For a complete list of controlled substances, refer to the Schedules in Parts G and J of Health Canada's Food and Drug Regulations, [C.R.C., c. 870](#) . And the Controlled Drugs and Substance Act, [Controlled Drugs and Substances Act \(justice.gc.ca\)](#)

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5. PROCEDURES

5.1. APPLICATION FOR A CONTROLLED SUBSTANCE EXEMPTION

- 5.1.1. A researcher requiring a controlled substance for research purposes at the University must, whenever necessary, such as in the context of sponsored research, notify OSR through the OSR Checklist, and must always contact and consult EHS to apply for, obtain, maintain and renew a Controlled Substance Exemption.

The application form for a CONTROLLED SUBSTANCE EXEMPTION is available on the EHS [website](#). [Cannabis and Controlled Substance Compliance Program \(CCSCP\) | Environmental Health and Safety - McGill University](#)

- 5.1.2. There are 6 application types:

- i. New exemption
- ii. Extension of valid exemption (no additional quantities)
- iii. Extension of valid exemption (additional quantities)
- iv. Amendment of a valid exemption
- v. Cancellation of a valid exemption
- vi. Transfer of controlled substances from one researcher to another within an institution

In completing the application form, the researcher will be asked to provide, among other information:

- i. License number issued by provincial licensing body (if applicable)
- ii. Project or Study Description
- iii. Details of Administration
- iv. The current year's approval of the protocol from the local Animal Care Committee (if applicable)
- v. Supplier of Controlled Substances
- vi. Description of Storage and Security

Researchers are advised to contact EHS with inquiries or for any assistance in completing this form.

- 5.1.3. Once completed, EHS must submit the application form to Health Canada on behalf of the researcher.
- 5.1.4. Upon receipt of approval of the researcher's exemption application, EHS must inform the researcher, copying OSR, in the context of sponsored research, and other interested parties as the case may be.

In addition, EHS must:

- provide the appropriate training and orientation to the researcher and, at the request of the researcher, to individuals participating in the same project, under the researcher's direction and control, including but not limited to colleagues, assistants and technicians; and
- create or update the researcher's user profiles on MyLab and McGill Market Place ("MMP").

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5.1.5. A Controlled Substance Exemption is valid for two years from the issuance date. Two months prior to the expiration of the exemption, EHS must send the researcher a written reminder of the expiration date, with information regarding potential next steps such as the possibility of applying for exemption extension.

5.2. PURCHASE:

- 5.2.1. The researcher, or in certain circumstances their authorized person, must, in accordance with the terms and conditions of a valid Controlled Substance Exemption, purchase a controlled substance only either through MMP or directly from CMARC where the controlled substance is Buprenorphine, Ketamine and Pentobarbital. For any inquiries or requests for an exception, the researcher must contact EHS in writing.
- 5.2.2. The controlled substances purchased by and in the researcher’s possession at any given time must not exceed the total quantity of controlled substances indicated in their Controlled Substance Exemption.
- 5.2.3. The controlled substance must be delivered from the supplier directly to the researcher or designated receiving person. The researcher is responsible for examining the contents and ensuring that the items match the items ordered and that any seals are intact. The researcher, or designated recipient, as the case may be, must sign to acknowledge receipt of the package.
- 5.2.4. The researcher must complete the “Controlled Substance Ordering/Receiving Record” appended to this SOP for each order placed and received. In addition, the researcher must ensure that their MyLab profile is updated accordingly. Receipt documentation in writing and using MyLab must include the date of receipt, name, address and registration number of supplier, type, and quantity of drug received.
- 5.2.5. EHS may follow-up with individual researchers on a case-by-case basis to ensure that the controlled substance ordered and received as per the information contained in MyLab has arrived at its destination.
- 5.2.6. The researcher must ensure that each item and unit (ex. bottle, vial, patch, etc.) received on a given date is assigned and identified with a unique tracking number. The tracking number must be composed of two parts as illustrated below: the receiving date and a sequential number for each item received on that date:

Example:

DRUG	RECEIVING DATE (yy-mm-dd)	TRACKING NUMBER
Ketamine 100 mg/ml 4 x 50ml bottles	14-01-24	140124-1 to 140124-4
Buprenorphine 0.03 mg/ml 10 x 1ml vials (2 boxes of 5 vials)	14-01-24	140124-5 and 140124-6
Diazepam 5 mg/ml 1 x 2ml vial	14-02-26	140226-1

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5.3. STORAGE & SECURITY REQUIREMENTS:

- 5.3.1. The storage conditions and physical security requirements for controlled substances are dependent on the security level and classification assigned to the drug by Health Canada. The researcher must ensure that the storage conditions and physical security for controlled substances, including mixtures and dilutions, duly in their possession satisfies the requirements of Health Canada's Directive on Physical Security Requirements for Controlled Substances, which is available on the Health Canada [website](#).
- 5.3.2. Security Levels 1 and 2, and in certain circumstances, at the discretion of Health Canada, Security Level 3, apply at McGill University. The security requirements for each level are summarized below.

Security Requirements for Level 1

For Level 1, a cupboard, refrigerator, a drawer in a steel cabinet, or an equivalent may be used to contain controlled substances provided that the storage units are located in locked rooms and fastened to the room's floor or wall. The storage unit must be secured with an approved padlock or equivalent locking mechanism. Records of the issuing of combinations and keys, under the authorization of a departmental designate must be maintained and made available to Health Canada inspectors upon request.

Security Requirements for Level 2

For Level 2, an alarm system is required and must at least activate a local electric horn or bell when an unauthorized access is attempted. Storage requirements for Level 2 include a steel cabinet, refrigerator or equivalent locked in a room and fastened to a wall or floor in such a manner that it is not moveable. The cabinet or refrigerator must be locked with an approved padlock. The approved security device must be located in an area to which the public does not have access. Records of the issuing of combinations and keys must be maintained and be available to Health Canada inspectors upon request.

Security Requirements for Level 3

For Level 3, an alarm system will be required and must activate at minimum a local electric horn or bell when an unauthorized access is attempted. The controlled substances must be located in a locked vault or safe with requirements for each listed below. Records of the issuing of combinations and keys must be maintained and made available to Health Canada inspectors upon request.

Requirements for Vault (Level 3)

- *Wall/floor/ceiling*
 - Constructed of 10 cm (4") cement block minimum or equivalent.
 - Structural floor to structural ceiling construction (i.e. no false floors or ceilings).
 - Unsecured openings must have one dimension less than 15 cm (6") and not to exceed 619 cm² (96in²). Acceptable grill work for secured opening will consist of 3.5 mm (10 gauge) metal mesh screen or equivalent.
- *Door*
 - Solid core wooden door or hollow metal.

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- Locking device must penetrate the door frame at least 1.25 cm or be of a vertical throw type lock. Locking device cannot be on a master key system.
- Metal frame grouted in the area of the strike plate. Wood frame blocked in the area of the strike plate complete with a high security strike.
- One and one half pair butt hinges (3 hinges (no removable pins if the door has an outswing)).
- Windows in door are not permitted.

Records of the issuing of combinations and keys must be maintained and be available to Health Canada inspectors.

Requirements for Safe (Level 3)

A records safe may be used for this security level providing it is not rated lower than U.L.C. (Underwriters Laboratories of Canada) type "D" (350 - 1 new rating). The safe must be anchored to the floor.

The safe must be located in a locked cupboard or room. No window may be located within 4.5 metres (15') from the grade level or roof deck unless it is locked. There are no size restrictions on the windows. Windows are not permitted within 1 metre (3') of the door. Windows fixed or openable with a lock must have a grill or screen of 3.5 mm (10 gauge) expanded metal mesh or equivalent installed in a manner that it is removable from the inside only. An acceptable alternative to the window requirements stated above is if the windows are polycarbonate glazed and mounted in a heavy duty frame.

If the safe is located in a metal cage, in lieu of a locked room or cupboard, the cage must meet the requirements outlined in Appendix D of the Health Canada Directive on Physical Security Requirements for Controlled Substances.

- 5.3.3. The following is a list of some of the padlocks available which meet or exceed Health Canada's requirements. Alternative locking mechanisms with the equivalent or higher safety rating will be considered.

Manufacturer clearance	Model	Shackle diameter (mm)	Shackle (mm)
Abloy	3071	11	25
American	570 (with dead locking)	10	28
Best	27b462 (with security sheath)	12	32
Master	15	11	25
Medeco	50-600	10	25
Papaiz	Cr60	10	35
Viro	304/60 mm	10	35

- 5.3.4. Researchers must store their controlled substances separately from the inventory of other researchers.
- 5.3.5. Only the researcher and authorized individuals may have access to the controlled substance storage unit.
- 5.3.6. The researcher must ensure that the issuing of combinations and keys are maintained and shared with EHS and made available, upon request, to inspectors from Health Canada.

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5.3.7. The researcher must identify the controlled substance's storage unit and its location on the "Ordering/ Receiving Record" appended to this SOP and in MyLab.

5.4. TRANSFER AND RELOCATION OF CONTROLLED DRUGS:

5.4.1. The researcher cannot transfer any quantity of Controlled Substances in inventory to other researchers without the prior authorization from Health Canada. For more information the application process for an intra-University transfer of controlled substances, researchers are advised to contact EHS.

5.4.2. Controlled substances may be relocated to another storage unit and/or at another location provided that the storage unit and location are indicated in same Controlled Substance Exemption and satisfy the storage conditions and physical security requirements of Health Canada's Directive on Physical Security Requirements for Controlled Substances.

5.4.3. The researcher must ensure that the "Relocation Record" appended to this SOP is complete each time a controlled substance, or mixture or dilution thereof, is moved from one unit and/or location to another.

5.5. ADMINISTRATION:

5.5.1. The researcher may appoint authorized persons to administer substances. The names and signatures of the authorized persons, and storage units and locations to which they have access must be documented on the "Controlled Substance Authorized Persons Record" appended to this SOP and in MyLab as applicable by the researcher.

5.5.2. Authorized individuals must follow the procedures outlined in this SOP, and are obligated to immediately report any suspected loss or diversion of controlled substances to the licensee.

5.5.3. Only the researcher or authorized persons may access and administer controlled substances and must ensure to complete the "Administration Record" appended to this SOP and update MyLab accordingly: recording the date, time, species/ID#, if applicable, user identification, dose, resulting balance (must keep a "running inventory" – starting with the total amount, record and subtract the amount used every time), and a signature of the individual administering the dose.

5.5.4. Controlled substances must never be used after their expiration date.

5.5.5. The researcher must ensure that the "Administration Record" is completed each time a controlled substance, or a dilution or mixture thereof, is administered by them or an authorized person.

5.5.6. When preparing a dilution and mixture of controlled drugs, the researcher must ensure that:

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- the dilution or mixture is assigned a tracking number composed of the original tracking number with an added sequential letter, e.g., 131219-1A, 131219-1B
- each dilution or mixture is separately and individually recorded
- an “Administration Record” is prepared for the dilution or mixture using the new tracking number
- the tube or vial of dilution/mixture is identified with the new tracking number
- all dilutions or mixtures containing a controlled drug are stored as described in accordance with the conditions and requirements of Health Canada’s Directive on Physical Security Requirements for Controlled Substances.

5.6. DESTRUCTION AND DISPOSAL:

- 5.6.1. The researcher is responsible for the destruction of any unused or expired controlled substance duly in their possession.
- 5.6.2. The destruction of a controlled substance must be witnessed by an individual participating in the same project, under their direction or control, and by a representative of EHS who must facilitate that the method of destruction alters or denatures the controlled substance in such a way as to make it non-recoverable and its consumption improbably or impossible.
- 5.6.3. The researcher, or other authorized person, and the witness, including the EHS representative, must sign and print their names on a joint statement indicating that they witnessed the destruction and that the controlled substance destroyed has been altered or denatured to such an extent that its consumption has been rendered impossible or improbable.
- 5.6.4. The researcher must ensure that a commercially available pharmaceutical disposal system for controlled substances is used, that all controlled substances contained in each disposal container are logged, and that the disposal containers are stored until full in a storage unit and at a location as per Health Canada’s Directive on Physical Security Requirements for Controlled Substances.
- 5.6.5. Controlled substances, destroyed or otherwise, must never be flushed or poured down a drain.
- 5.6.6. The researcher must contact EHS for disposal of full disposal containers.
- 5.6.7. The researcher must ensure that the amount discarded, the date of destruction and the reason for destruction are logged on the “Administration Record” and that MyLab is updated accordingly.
- 5.6.8. Any theft or loss must be reported to McGill Security and EHS immediately, and within 10 days of its discovery to Health Canada at the address below:

Office of Controlled Substances
Address Locator #3502A
Ottawa, Ontario

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Telephone: 613-952-2219
Fax Number: 613-941-5360

5.7. REVIEW

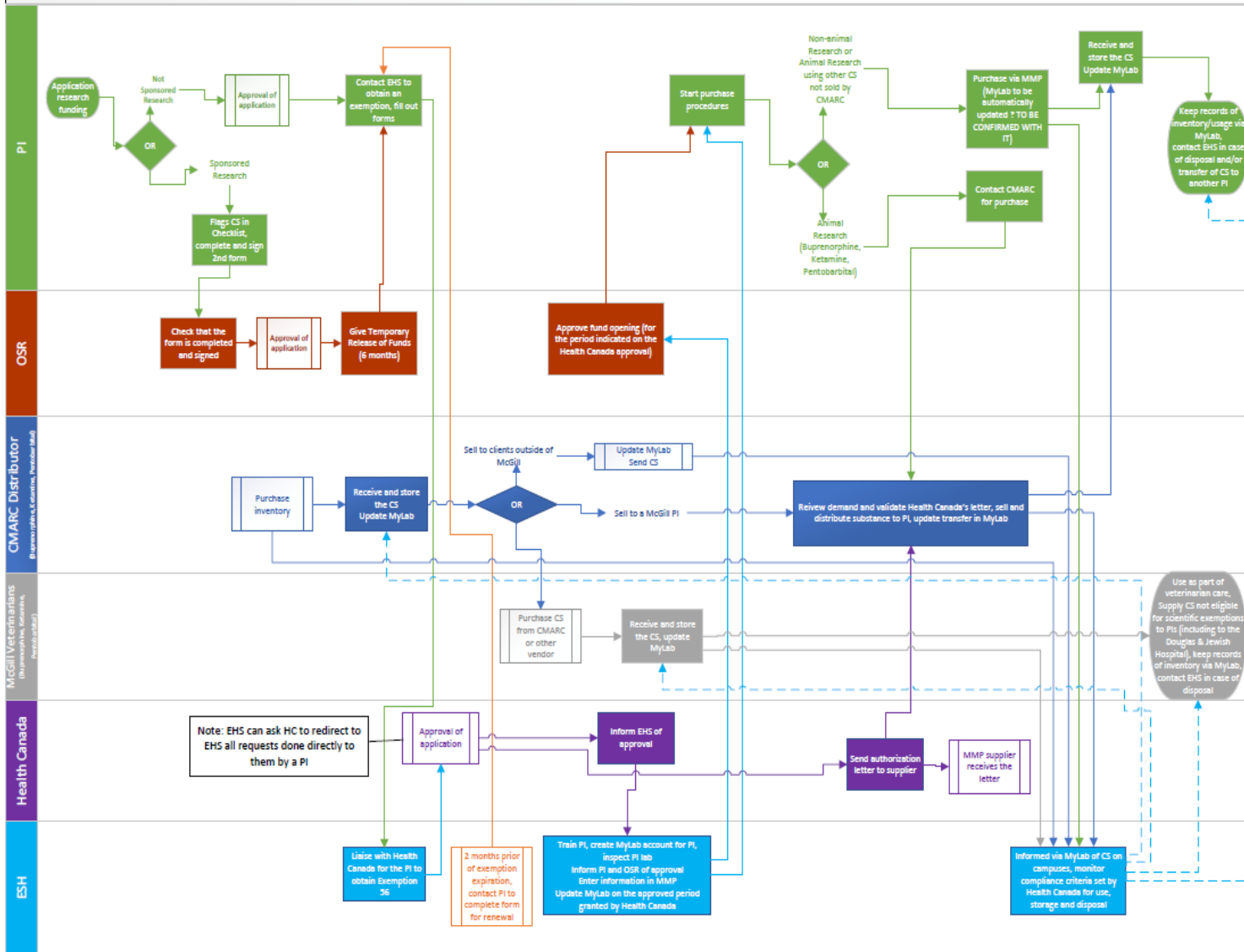
- 5.7.1. Further to section 2.1.1, EHS is responsible for coordinating the periodic review of this SOP at least every three years, or as needed, to ensure, among other things, that the SOP continues to align with CDSA and the Health Canada requirements and conditions for a Controlled Substances Exemption under subsection 56(1) of the CDSA, including Health Canada's Directive on Physical Security Requirements for Controlled Substances.

5.8. DISCREPANCIES

- 5.8.1. This SOP is not a substitute for the CDSA or the Health Canada requirements and conditions for a Controlled Substances Exemption under subsection 56(1) of the CDSA, including Health Canada's Directive on Physical Security Requirements for Controlled Substances. Although every reasonable effort is taken to ensure that this SOP aligns with all relevant external legislation, regulations and directives, discrepancies between them may arise. In the event of a perceived or actual discrepancy, the CDSA and the Health Canada requirements and conditions for a Controlled Substances Exemption, including the Health Canada Directive on Physical Security Requirements for Controlled Substances, prevail over this SOP until such time as after EHS investigates and, if necessary, resolves said discrepancy.
- 5.8.2. Any alleged discrepancy between this SOP and relevant external legislation, regulations and directives must be promptly reported to EHS so that EHS may investigate and, if necessary, resolve it.



Proposed Controlled Substances Process (Excluding Cannabis)





CONTROLLED SUBSTANCE AUTHORIZED PERSONS RECORD

Licensee		
License #	Issue date	Expiration date

Name		Drug box(es) #	Authorized by		
PRINT	SIGNATURE		PRINT NAME	SIGNATURE	Date

DO NOT CONTINUE, USE ADDITIONAL SHEET



CONTROLLED SUBSTANCE ORDERING/RECEIVING RECORD

Order Date	Invoice #	Drug & concentration	Qty	Source	Received Date	Storage (Drug Box #)	Tracking # ¹	Received by PRINT	Received by SIGN
Page#	Reviewed by: PRINT _____ SIGNATURE _____								

¹ Tracking number is composed of the date followed by a sequential number reset daily: yymmdd-1, 2, 3, n, Ex: If three bottles are received on Dec.21, 2013, tracking numbers will be: 131221-1, 131221-2, and 131221-3.



CONTROLLED SUBSTANCE ADMINISTRATION RECORD

Item	Concentration	Amount/Unit
Box#	# units	Date
Tracking # (only 1 tracking #/record)		

Date	Time	Species/ ID# or new tracking # ¹	Prescribed by (PRINT)	Administered by		Amount Dispensed	Balance
				Signature	PRINT Last Name		
	:	A					
	:	P					
	:	A					
	:	P					
	:	A					
	:	P					
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DO NOT CONTINUE, USE ADDITIONAL SHEET

¹When using a controlled drug to prepare a dilution or drug mixture, assign a new tracking number, composed of original tracking with added sequential letter. Ex. 131219-1A, 131219-1B. Use a separate Administration Record with the new tracking number.

Page#: ___ of ___	Reviewed by: PRINT _____	SIGNATURE _____
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