STANDARD OPERATING PROCEDURE #401

CONTROLLED SUBSTANCES

1. PURPOSE

This Standard Operating Procedure (SOP) describes procedures for acquiring, storing, using and discarding controlled substances.

2. RESPONSIBILITY

2.1. The Rules and Regulations on Controlled Substances require safeguarding for all controlled substances procured pursuant to a practitioner/researcher's registration (the licensee).

2.2. Typically, the licensee is the Principal Investigator of a research protocol. The licensee is responsible for obtaining and renewing the Exemption to Use a Controlled Substance for Scientific Purposes and for ensuring that all acquisition, storage, security, inventory, disposal and record-keeping requirements are met.

2.3. Such a responsibility shall not be delegated to another individual.

2.4. The regulations require licensees to maintain adequate recordkeeping for the purchase, administration and disposal of all controlled substances. Records must be maintained for a period of two years. The researcher must make these records available to the Minister or an inspector upon request.

2.5. The licensee may appoint authorized persons to administer substances to animals under their care. Names, signatures and access to storage locations for each authorized person must be documented on the Controlled Substance Authorized Persons Record by the licensee.

2.6. 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.

3. DEFINITIONS

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

- 3.1.1. Opioids:
  - 3.1.1.1. Morphine
  - 3.1.1.2. Hydromorphone
  - 3.1.1.3. Fentanyl
  - 3.1.1.4. Buprenorphine
  - 3.1.1.5. Butorphanol
- 3.1.2. Barbiturates:
  - 3.1.2.1. Pentobarbital
  - 3.1.2.2. Pentothal
  - 3.1.2.3. EUTHANYL® (pentobarbital)
- 3.1.3. Benzodiazepines:
  - 3.1.3.1. Diazepam
  - 3.1.3.2. Midazolam
- 3.1.4. Dissociative anesthetics:
  - 3.1.4.1. Ketamine
  - 3.1.4.2. TELAZOL® (tiletamine/zolazepam)

4. PROCEDURES

4.1. Acquisition:

4.1.1. Researchers wishing to use controlled drugs must submit to the Health Canada Office of Controlled Substances (OCS) a completed “Application Form for an Exemption to use a Controlled Substance for Scientific Purposes”.

4.1.2. A valid practice or research license is mandatory in order to purchase and use and possess controlled drugs.

4.1.3. Download form at: http://www.hc-sc.gc.ca/hc-ps/substancontrol/exemptions/applic-scien-eng.php

4.1.4. Exemptions are only valid for a one year period. Notifications of expiry are not sent. Exemption holders are responsible for keeping track of the expiry date and resubmitting forms. It is advisable to reapply well in advance of the exemption expiry date.

4.1.5. The licensee (or authorized designee) procures controlled substances from a licensed manufacturer or distributor using his/her registration.

4.1.6. Limit the quantities ordered as to avoid the risk of exceeding expiry date.

4.1.7. Complete the Ordering/Receiving Record each time an order is placed and received. Initial receipt documentation must include the date of receipt, name, address and registration number of vendor, type, and quantity of drug received.

4.1.8. Assign a tracking number composed of 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

4.1.9. Identify each unit (ex. bottle, vial, patch, etc.) with a unique tracking number.

4.2. Storage of controlled drugs:

4.2.1. The storage conditions and physical security for the controlled substance must provide for effective prevention of theft and must meet the requirements of the "Directive on Physical Security Requirements for Controlled Substances", available on the Health Canada website: http://www.hc-sc.gc.ca/hc-ps/substancontrol/substan/securit-eng.php

4.2.2. The licensee is responsible for ensuring adequate storage and security of all controlled substances acquired under his exemption.

4.2.3. Each licensee must have his or her own storage.

4.2.4. For scientific exemptions, the required security level is Security Level - 1 and the maximum licensee holdings is $5000.

4.2.5. A cupboard, refrigerator, a drawer in a steel cabinet, or an equivalent may be used provided it is located in a locked room and fastened to the room's floor or wall.

4.2.6. The device used to store the researcher's inventory is to be secured with an approved padlock (see below) or its equivalent:

MANUFACTURER	MODEL	SHACKLE DIAMETER	SHACKLE CLEARANCE
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	304/60mm	10	35

4.2.7. The approved security device described in section 4.2.5 must be located in an area to which the public does not have access.

4.2.8. All controlled substances, including mixtures and dilutions, must be adequately stored.

4.2.9. Only the licensee and authorized individuals should have access to the controlled substance storage. Records of the issuing of combinations and keys shall be maintained and be available to inspectors.

4.2.10. Identify the storage box and location on the Ordering/Receiving Record.

4.3. Transfer and relocation of controlled drugs:

4.3.1. Controlled substances are not transferable. They must remain under the responsibility of the licensee.

4.3.2. Controlled substances can be relocated to another storage location covered under the same registration.

4.3.3. Complete the Relocation Record each time an amount of drug is moved from one storage location to another.

4.4. Preparing dilutions and mixtures of controlled drugs:

4.4.1. When preparing a dilution or a mixture containing a controlled drug, assign a new tracking number composed of the original tracking number with an added sequential letter, e.g., 131219-1A, 131219-1B.

4.4.2. Prepare an Administration Record for the dilution/mixture using the new tracking number.

4.4.3. Identify the tube or vial of dilution/mixture with the new tracking number.

4.4.4. Store all dilutions/mixtures containing a controlled drug as described in section 4.2.

4.5. Administration:

4.5.1. Only authorized persons can access and administer controlled substances.

4.5.2. Complete the Administration Record: Record the date, time, species/ID#, 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.

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

4.5.4. Return the completed Administration Record to the licensee for review and filing.

4.6. Discarding or loss of controlled substances:

4.6.1. The researcher is responsible for the destruction of any unused or expired controlled substances.

4.6.2. The destruction must be witnessed by a member of his/her research staff who is working on the same research project as specified in the exemption, and who works under the researcher’s direction and control.

4.6.3. The method of destruction used must alter or denature the controlled substance in such a way as to make it non-recoverable and thus make their consumption improbable or impossible.

4.6.3.1. Liquids can be poured onto a piece of absorbent paper. The absorbent paper is then placed in a closed container, i.e., a sharps container, to be destroyed by incineration. Alternatively, liquids can be poured into an absorbent substrate such as cage bedding, cat litter or a commercially available liquid waste solidifier. The absorbent substrate is then discarded as regular waste.

4.6.3.2. Add water to powders and destroy as described in section 4.6.3.1.

4.6.3.3. Crush tablets into powder, add water and destroy as described in section 4.6.3.1.

4.6.3.4. Never flush or pour controlled substances down the drain.

4.6.4. Log the amount discarded, the date of destruction and the reason for destruction on the Administration Record.

4.6.5. The authorized person and the witness 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.

4.6.6. The licensee shall make records available to the Minister or an inspector upon request.

4.6.7. Report significant loss of controlled substance to the licensee. The licensee must notify the Minister of Health and Welfare Canada within a period of 10 days at the address below:

Office of Controlled Substances
Address Locator #3502A
Ottawa, Ontario
K1A 1B9
Telephone: 613-952-2219
Fax Number: 613-941-5360

4.7. Recordkeeping:

4.7.1. Records must be kept for the purchase, relocation, administration and disposal of all controlled substances.

4.7.2. Records must be maintained for a period of two years.

4.7.3. Records must include details from the date of order/purchase throughout the controlled substance's life cycle, i.e., until containers are empty or disposed of.

4.7.4. The researcher must make these records available to the Minister, an inspector, the Facility Animal Care Committee (FACC), Quality Assistance Advisor or Veterinary staff upon request.

4.7.5. Controlled Substances Authorized Persons Record:

4.7.5.1. Document names, signatures and access to storage locations for each authorized person, as appointed by the licensee,

4.7.6. Controlled Substances Ordering/Receiving Record:

4.7.6.1. Used to document each time an order is placed and received.

4.7.6.2. The tracking number is assigned and documented on this form.

4.7.7. Controlled Substances Relocation Record:

4.7.7.1. To be completed each time an amount of drug is moved from one storage location to another.

4.7.8. Controlled Substances Administration Record:

4.7.8.1. To be completed each time a controlled substance is administered.

4.7.8.2. Used to keep a running inventory of the amount of controlled drug that remains in a given container.

4.7.9. Monitoring:

4.7.10. Facility Animal Care Committee (FACC), Quality Assistance Advisor or Veterinary staff may verify controlled substances logs and storage during their regular rounds in animal facilities or research laboratories.

McGill

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

Page#: ___ of ___

McGill

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.

McGill

CONTROLLED SUBSTANCE RELOCATION RECORD

Date	Tracking #[2]	Drug & concentration	Qty	Origin (Drug Box #)	Destination (Drug Box #)	Relocated by PRINT	Relocated by SIGN	Received by PRINT	Received by SIGN

Page#

Reviewed by: **PRINT** ______________________ **SIGNATURE** ____

---

[2] 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						
	: A P						
	: A P						
	: A P						
	: A P						
	: A P						
	: A P						
	: A P						
	: A P						
	: A P						
	: A P						
	: A P						
	: A P						
	: A P						
	: A P						
	: A P						
	: A P						
	: A P						
	: A P						
	: A P						
	: A P						

DO NOT CONTINUE, USE ADDITIONAL SHEET

[1] When 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. 131219-1**A**, 131219-1**B**. Use a separate Administration Record with the new tracking number.

Page#:___ **of** ___	**Reviewed by:** **PRINT** _____________________ **SIGNATURE** ___________________________