PURPOSE:

The purpose of this Standard Operating Procedure (SOP) is to detail the procedures by which the Montreal Neurological Institute (MNI) monitors and ensures compliance with the procedures described in animal use protocols (AUPs) previously approved by the Animal Care Committee (ACC). It also describes the procedures for addressing any breaches with approved AUPs and SOPs, and defines the roles and responsibilities of the members of the Animal Care and Use Program (ACUP) in the monitoring process.

SCOPE:

Post-Approval Monitoring (PAM) is mandated by the Canadian Council on Animal Care (CCAC) to ensure that animals for teaching and research purposes are well cared for and used appropriately according to the parameters set by approved protocols.

In animal users PAM may raise the feelings of mistrust or a sentiment of counterproductive administrative burden. As such, compliance monitoring must involve two-way communication with an opportunity for user feedback and a support system.
The overall goal of the Compliance Officer (CO) is to promote self correction at the research level by providing animal users with compliance related information and help in following the rules.

**RESPONSIBILITY:**

**Investigators and their laboratory team**

are responsible for working with the CO in implementing PAM procedures by providing any documentation that may be required and implementing any recommendations that may be given.

**Compliance Officer**

is responsible for working with the investigators and their laboratory team by observing animal use activity, preparing accurate reports and providing recommendations for maintaining compliance.

maintains a working relationship with the McGill University Animal Compliance Office (ACO), by being a member of the McGill Quality Assistance Program Subcommittee.

**Animal Care Facility (ACF) Staff**

are responsible for collaborating with the CO in implementing PAM procedures. This includes answering all of the CO’s questions to the best of their ability and providing any documentation that may be required as well as providing training support to animal users as necessary to ensure compliance.

**The MNI Clinical Veterinarian or Designated Representative**

is responsible for working with the CO in an advisory capacity. This includes attending PAM observation visits with the CO to provide his/her technical expertise and comments for the detailed written report.

**Animal Care Committee Chair**

is responsible for providing operational supervision of the CO and his/her execution of the PAM program, ensuring that the MNI ACC receives PAM reports and that all ACC members have an opportunity to discuss these reports.

**Montreal Neurological Institute’s Animal Care Committee members**

are responsible for providing recommendations for maintaining compliance.

**POLICY:**

1. **Selection of procedures and documents for review:**
   
i. All active AUPs, corresponding SOPs, and approved amendments, regardless of the category of invasiveness will be reviewed at regular intervals (see page 6: Procedures)
   
ii. Cases selected at the discretion of the clinical veterinarian, senior ACF staff and/or the MNI ACC will be reviewed promptly.
iii. Suspected cases of abuse and allegations of non-compliance will be reviewed with high priority.
iv. All active MNI ACF SOPs and animal care activities will be regularly reviewed.

2. Aspects of research that will be reviewed:

Protocol compliance, including:
1. Procedures
2. Anesthesia
3. Analgesia
4. Surgery
5. Post-surgical/procedural monitoring and care
6. Euthanasia
7. Breeding
8. Record keeping
9. Laboratory practices related to animal use
10. Pain management
11. Potential Hazards to personnel and animals
12. Regulatory requirements (i.e. appropriate use of personal protective equipment, storage of controlled drugs, etc.)

3. Types of visits performed:

Three forms of PAM will be used:

1. Regular visits: the CO will choose a lab to visit at random.
2. Follow up visits: will be carried out to confirm implementation of recommended corrections
3. “For cause” visits: a CO visit to a specific lab will be triggered by suspected or known problems uncovered during lab visit or veterinarian rounds, or reported by Animal Care Staff or any other concerned person.

4. Post-Approval Monitoring Process:

- The CO will provide all necessary PAM documentation to the PI and lab manager in advance of the proposed PAM visit.
- All necessary documentation for the PAM visit will be provided to the CO by the PI, lab staff, and ACF staff by a specified due date. The CO will be able to visit all areas of the MNI being used for animal procedures, including surgical, procedural, recovery areas, and any other relevant facilities within or outside the MNI.
- The CO will wear the appropriate personal protective equipment (PPE) indicated for the specific activity or laboratory.
- All persons directly associated with the procedures listed in the protocol must be present during the PAM visit and the PI. If the PI is not directly involved, he/she has the option to be present or not.
- If there are procedures that are common to more than one AUP by the same PI, the CO will need to observe these common procedures only once during a PAM visit.
• The MNI Clinical Veterinarian or Designated Representative will be present on the observation visits to provide his/her technical expertise. If at any time during the visit the CO observes conditions or situations that indicate animal welfare concerns or violations, the CO will document them and inform the PI, and without delay provide the information to the ACC Chair. In the case where the MNI Clinical Veterinarian is observing and a major deficiency is found, according to the MNI ACC Terms of Reference (Jan 2009), “The MNI ACC ... delegates to the MNI veterinarian the authority to treat, remove from a study or euthanize, if necessary, an animal according to the Veterinarian's professional judgment.”

• The CO will meet with the lab staff and PI (if present) immediately after the PAM visit to discuss the results and the MNI Clinical Veterinarian or Designated Representative may also remain for this discussion.

• The CO does not have the authority to approve or disapprove any corrective action. This is the role of the ACC Chair or full ACC, depending on the seriousness of the compliance issue.

• In case the ACC Chair is the PI whose AUP is being reviewed, an Acting Chair will be elected by the ACC to review this specific case.

• In case an ACC member’s AUP is being reviewed, he/she has to remove himself/herself from any decision making.

5. Written Reports:

Two types of reports will be prepared:

• **Summary report:** to be presented at the next ACC meeting following the PAM visit. Includes: the protocols and documentation reviewed, deficiencies observed if any, and where appropriate corrective actions are needed.

• **Detailed report:** will list major, significant and minor deficiencies of a lab, an action plan to correct the deficiencies, and a due date.
  - Major deficiency is defined as, a finding that would or has the potential to put a real danger or threat to animal welfare and well-being or to the safety of personnel and requires immediate action due to its severity.
  - Significant deficiency is defined as, a finding that could put a threat to animal welfare and well-being or to the safety of personnel if not corrected in an expeditious manner.
  - Minor deficiency is defined as, a finding that has no real or potential threat to animals and humans.

A Full Compliance Letter will be sent without delay to inform the PI when no compliance issues are found.

• Both reports are written by the CO.

• Typically, the detailed report will be written in consultation with the ACC Chair, Veterinarian, and ACF manager (when possible).

• The CO will send a draft detailed report to the PI and lab manager within 10 days after the PAM visit.
• The PI will need to respond to the draft of the detailed report by a specific due date and propose corrective action for non compliance issues found.
• A final detailed report will be sent to the PI, lab manager, and a copy to the ACC Chair. The detailed report will specify specific due dates to implement corrective actions for non compliance issues.
• The CO will follow up with the PI and lab manager to ensure corrective actions have been implemented.

An MNI PAM report including a summary of PAM findings will be sent at regular intervals to the McGill Quality Assistance Subcommittee.

6. ACC Meeting

The CO will introduce the PAM summary report at the next ACC meeting. The PAM detailed report will only be provided to ACC members if there is a need to discuss major or significant recommendations for corrective action. Recommendations agreed upon at ACC meetings will be documented and added to the detailed report and then sent to the PI.

PAM discussions will be minuted.

7. Follow-up

A follow-up visit or communication will be necessary:

• If the CO needs to visit the PI’s lab to verify if a corrective action documented in the detailed report was implemented.
• If additional monitoring sessions are deemed necessary.

8. Violation of the PAM Process

All cases of non-compliance discovered by the PAM program and not corrected by the PI will be sent to the MNI ACC Chair, who will evaluate the situation and if necessary will forward the case to the MNI Director for final resolution.

9. Appeal process

In the event that an investigator disagrees with the PAM results and/or suggestions made by the CO and/or corrective actions recommended by the ACC, the investigator may appeal in writing within 30 days of receipt of the final detailed report to the Director of the MNI.

10. Record Keeping and Confidentiality

All documentation generated during the PAM process, including email correspondence, will be kept in strict confidence, on file in the CO’s office.
PAM documents will be kept in a locked filing cabinet and will only be accessible to the 
CO and ACC Chair. As well, the CO’s office will be red-dotted. A red dot is placed on 
office doors to indicate that only authorized people have access.

Any information regarding non-compliance from concerned persons will be treated in 
strict confidentiality, and such persons are protected by the appropriate University policy.

11. AUPs Involving Two or More Institutions

An Investigator whose home institution is not the MNI and who wishes to carry out 
animal-based work within the MNI’s facilities must first submit an approved AUP to the 
MNI’s ACC.

All animal-based work at the MNI will be subject to the MNI PAM program and a copy of 
the final detailed report will be sent to the PI.

PROCEDURE:

I. Selecting AUPs for PAM program

a. The CO selects AUPs, corresponding SOPs, and approved amendments, typically at 
   least 6 months after the experiments have started and the procedures have been 
established.

b. The CO selects at random, but giving priority to higher level AUPs.

c. Generally the CO will monitor D level AUPs annually, and for C and B level AUPs 
   the CO monitors them less frequently, but at least every second year. The CO can visit 
   more than once a year if a “for cause” visit is required.

II. Notifying the PI and lab team of a PAM visit

a. For regular PAM visits the CO sends a PAM introductory letter and PAM Audit 
   Checklist to the PI, lab manager, and/or administrative assistant, by e-mail and 
through internal mail one month in advance of the PAM visit.

b. One week after the CO has sent the documents, the CO contacts the PI, lab manager, 
or administrative assistant by phone to schedule the PAM visit, at a mutually 
   convenient time.

c. In “for cause” PAM visits the CO notifies the PI, lab manager, and/or administrative 
   assistant 1 week in advance of the PAM visit date.

III. Pre-review of the AUP and related documents by CO

a. Two weeks before the PAM visit the CO contacts the PI, lab manager, and appropriate 
   ACF staff to obtain any necessary documentation (i.e. breeding records, log books, 
etc.) that will assist in the PAM visit.

b. Typically, the CO meets with the Veterinarian and/or ACF staff(if possible) to 
discuss any animal care issues related to the AUP and documents them for the PAM 
   visit.
c. The CO reviews the selected AUP, any corresponding SOPs and amendments, communications, and other relevant documents, using the PAM Audit Checklist and PAM plan as a guide.

d. The CO writes in Section 3d of the PAM plan any procedures that are also found in other AUPs of the same PI.

IV. Conducting a PAM visit

The CO conducts the PAM visit in two parts.

AUP Review Meeting:

a. The CO first discusses the goal of the meeting to confirm that the written AUP and the work being done correspond. Additionally, the CO takes the time to answer any questions the PI or lab staff might have about the animal care and use program.

b. The CO uses the PAM Audit Checklist and PAM plan to ask the PI and lab staff all questions at that point in time, related to the specific protocol under review. The CO also asks to see all records associated to the AUP under review, such as: blood collection records, animal inventories, etc...

c. The CO documents all comments to questions, records reviewed and any deficiencies noted, on the PAM Audit Checklist.

Observation Visit:

a. The CO and the MNI Clinical Veterinarian or Designated Representative visits the laboratory and inspects all areas where animal procedures and surgeries are performed, as mentioned in the AUP(s) under review, and wears any PPE required.

b. The CO uses the PAM Audit Checklist and PAM plan as a guide to what procedures need to be examined, i.e. surgical procedures, euthanizing procedures, etc...

c. The CO writes in the Study Procedures section of the PAM Audit checklist all procedures observed that are common in other AUPs of the PI.

d. The CO documents all comments to questions, observations of procedures, and any deficiencies noted, on the PAM Audit Checklist.

After the observation visit, the CO discusses the results of the visit with the PI and lab staff to confirm the CO’s and if appropriate, the MNI Clinical Veterinarian or Designated Representative’s observations. The PI and lab staff has an opportunity to ask any questions about the PAM visit or observations made. The CO informs the PI that a draft of the detailed report or Full Compliance letter ill be sent to them within 10 days and then they will have an opportunity to comment on the results of the report.

V. Writing PAM reports

The CO writes three reports.
**Note:** If the CO finds no deficiencies after a PAM visit, the CO sends a Full Compliance Letter to the PI and lab manager, with a copy to the ACC Chair.

**Summary report:**

a. The CO writes a summary report for the ACC meeting that follows PAM visits. The summary report includes information on the protocols and documentation reviewed during PAM visits, deficiencies observed if any, and corrective actions needed.

**Detailed report:**

a. The CO writes a detailed report after the PAM visit, which includes all deficiencies.

b. The CO uses the completed PAM Audit Checklist, notes from the PAM plan, and consults with the ACC Chair, Veterinarian, and ACF manager to help complete the detailed report.

c. The CO sends a draft of the detailed report to the PI and lab manager within 10 working days of the PAM visit. The PI reviews the draft report and has up to the specified due date to provide feedback and propose corrective actions.

d. The CO discusses any feedback provided by the PI with the ACC Chair, Veterinarian, and ACF manager, in order to finalize the report.

e. The CO sends the final detailed report to the PI and lab manager, and sends a copy of the report to the ACC Chair.

f. If deficiencies have been found the CO contacts the PI and lab manager by the due date specified in the report to ensure that all corrective actions are put into place.

**MNI PAM Report:**

a. The CO writes a MNI PAM report for the McGill Quality Assistance subcommittee that includes a summary of PAM findings over a specified period.

**VI. Tracking PAM results**

a. The CO keeps a hardcopy of the PAM detailed report in the respective protocol file and the PAM summary reports in the PAM binder. The CO saves all electronic copies of reports on the ACC office computer in the PAM folder. The CO files all PAM documents in a locked cabinet, in the ACC office which is red dotted.

b. The CO enters all PAM information into a database that is password protected so that any institutional trending or follow up can be done.