Institut-Hôpital neurologique de Montréal
Montreal Neurological Institute-Hospital

Montreal Neurological Institute Animal Care Committee

STANDARD OPERATING PROCEDURE

No: PAM001.04	**Effective Date: May 1, 2009**
Section: Compliance	**Date Reviewed: March 11, 2009**
Subject: SOP **Post-Approval-Monitoring**	**Date Revised: June 26, 2023**
Prepared by: MNI Compliance Officer	**Approved by: MNI ACC**

PURPOSE:

The purpose of this Standard Operating Procedure (SOP) is to detail the methods by which the Neuro – Montreal Neurological Hospital and Institute (MNI) monitors and ensures compliance with the procedures described in animal use protocols (AUPs) previously approved by the Neuro Animal Care Committee (ACC). It also describes the procedures for addressing any breaches with approved AUPs and SOPs and defines the role and responsibilities of the members of the MN 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.

The overall goal of the PAM process is to promote self-correction at the research level by providing animal users with compliance related information and help in interpreting and applying industry standards. As such, compliance monitoring must involve a two-way communication with an opportunity for user feedback and a support system.

The process requires the involvement of key members of the MNI ACUP.

MEMBERS:

Principal Investigators (PI) and their laboratory team

are expected to work with the Compliance Officer in implementing PAM procedures by providing any documentation that may be required and implementing any recommendations that may be given.

Compliance Officer (CO)

works with the investigators and their laboratory team by observing animal use activity, preparing accurate reports, and providing recommendations for maintaining compliance and to favor improvement of procedures when possible.

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

Centre for Neurological Disease Models (CNDM) Staff

collaborates 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 if necessary to ensure compliance.

The MNI Institute Veterinarian or Designated Representative

works with the CO in an advisory capacity. This includes attending PAM observation visits, if requested by the CO, to provide their technical expertise and comments for the detailed written report.

Animal Care Committee Chair

provides operational supervision of the CO and their execution of the PAM program, ensuring that the Neuro ACC receives a summary of PAM reports and that all ACC members have an opportunity to discuss these reports.

The Neuro's Animal Care Committee members

provide recommendations for maintaining compliance.

POLICY AND PROCEDURE:

1. a. Selecting AUPs for PAM review

i. The CO selects active AUPs, corresponding SOPs, and approved amendments, typically **at least 6 months** after the experiments have started and the procedures have been established.
ii. The CO selects at random but giving priority to AUPs with procedures of higher level of invasiveness.
iii. All approved AUPs are reviewed every two years as part of the Biennial Review. Still, the CO can visit more often if a "for cause" or "follow-up" visit is required.

b. Other procedures and documents for PAM review:

i. Cases selected at the discretion of the Institute Veterinarian, senior CNDM staff and/or the Neuro ACC will be reviewed promptly.
ii. Suspected cases of abuse and allegations of non-compliance reported to the Neuro ACC will be reviewed with high priority.
iii. All active MNI CNDM SOPs and animal care activities will be regularly reviewed.

2. Types of visits performed:

a. Regular visits: the CO will choose a lab to visit at random.
b. Follow up visits: will be carried out to confirm implementation of recommended corrections in cases of significant and major non-compliance and if additional monitoring sessions are deemed necessary.
c. "For cause" visits: Occur when issues are discovered or reported by any concerned person.

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

a. For regular PAM visits, the CO sends a PAM introductory letter (Appendix A), a PAM visitation letter for biennial review (Appendix B) and a printout of the PAM Audit Checklist (Appendix C) to the PI.
b. Within two weeks following the documentation sent by the CO, the PI confirms by e-mail which date is convenient from the dates provided in the PAM visitation letter.
c. In the case of "follow-up" PAM visits, the CO notifies the PI and lab manager, one week in advance of the PAM visit date**.**
d. "For cause" visits can occur with or without prior notification of the PI based on the urgency for implementation of corrective actions.

4. Preparation for a PAM visit: Pre-review of the AUP and related documents by CO

a. Before the PAM visit, the CO reviews the selected AUP, any corresponding SOPs and amendments, communications, and other relevant documents. They note any procedures that are common in other AUPs of the same PI. All the information is entered into the PAM database, specifically, on the profile page (Appendix C) of the PAM Audit Checklist.

b. One week before the PAM visit, the CO contacts the appropriate CNDM staff to obtain any necessary documentation (i.e., breeding records, logbooks, etc.) that will assist in the PAM visit. Other AUP related documentation is provided to the CO by the PI or researcher the day of the PAM visit.

c. Typically, the CO meets with the Veterinarian and/or CNDM staff (if possible) to discuss any animal care issues related to the AUP and documents them for the PAM visit.

5. Conducting a PAM visit

a. Aspects of research that will be reviewed:

Compliance to all information and procedures described in the AUP is subject to review by the CO**.**

b. The CO conducts at least two types of PAM visits:

i. AUP Assessment meeting: All persons directly associated with the procedures listed in the protocol should be present during this meeting including the PI.

The CO:

1. 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 ACUP.
2. uses the PAM Audit Checklist to ask the PI and lab staff all questions related to the specific protocol(s) under review. The CO also asks to see all records associated to the AUP under review, such as: blood collection records, animal procedure log, controlled drug log, etc.
3. documents all comments to questions, records reviewed, and any deficiencies noted, on the PAM Audit Checklist in the PAM database.

ii. Observation Visit(s): CO will visit areas of the MNI being used for animal procedures, including surgical, procedural, recovery areas, and any other relevant

facilities within or outside the MNI. If all procedures listed in the protocol cannot be observed at one time, multiple visits will be scheduled.

If the PI is not participating in the procedure, they have the option of not being present at the observation visit.

The CO:

1. visits the laboratory and inspects all areas where animal procedures are performed. Upon request by the CO, the MNI Institute Veterinarian or Designated Representative may join the CO for the observation visit if additional technical expertise is needed. If at any time during the visit the CO observes conditions or situations that indicate animal welfare concerns or violations, they will document them and inform the PI, and without delay provide the information to the ACC Chair. If the CO observes deviations to the AUP that affect animal welfare and requires urgent attention, they will consult with the Institute Veterinarian. The Institute Veterinarian has the authority to treat, remove from a study or euthanize, if necessary, an animal according to their professional judgment, as per the Neuro ACC Terms of Reference (April 2023).
2. completes the appropriate questions of the PAM Audit Checklist, depending on what procedure(s) is being performed.
3. at every visit, documents all comments to questions, observations of procedures, and records any noted deficiencies on the PAM Audit Checklist in the PAM database. The CO may take photos or videos when useful, but these must be kept confidential at all times. If there is a procedure that is the same in more than one AUP, the CO will observe it only once.

After each observation visit, the CO discusses their findings with the PI and lab staff. The PI and lab staff have an opportunity to ask any questions about the PAM visits or observations made. Within 10 days of the PAM visit, the CO sends the PI the detailed report (Appendix D), attached with a Full Compliance letter (Appendix E), a Minor Non-Compliance letter (Appendix F), or a Non-Compliance letter (Appendix G), at which time they will have an opportunity to comment on the results of the report.

c. AUPs Involving Two or More Institutions

A PI whose home institution is not the MNI and who wishes to carry out animal-based work within the MNI's CNDM facilities must first provide the Neuro ACC with their approved AUP from their home institution or submit for approval a new AUP to the Neuro ACC. This does not apply to cases when technological services are provided to outside MNI investigators if housing is not included.

All animal-based work at the MNI will be subject to the MNI PAM program and a copy of the detailed report will be sent to the PI and their home institution's ACC Chair.

6. Writing PAM reports

The CO writes three reports.

Note: If the CO finds no deficiencies during a PAM visit, a Full Compliance Letter is sent to the PI without delay, with a copy to the ACC Chair.

a. Summary report:

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

If additional recommendations are made with respect to the PAM findings when presented at ACC meetings, this will be documented and added to the detailed report and then sent to the PI.

PAM discussions will be minuted.

b. Detailed report:

This report lists major, significant, and minor deficiencies observed during PAM visits, an action plan to correct the non-compliance findings, and a due date.

The non-compliance findings are categorized into the following:

- Major deficiency is defined as, a finding that 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.

The CO:

i. completes the detailed report form in the PAM database, including all compliance and non-compliance findings.

ii. uses the completed PAM Audit Checklist and notes from the PAM visits, and consults with the ACC Chair, Veterinarian, and CNDM Associate Director (if necessary) to help complete the detailed report.

iii. prepares a PDF of the completed detailed report from the PAM database and attaches a Non-Compliance letter, specifying the level of deficiencies noted.
Sends the documents to the PI within *10 working days* of the PAM visit. A copy of the report is sent to the ACC Chair. The PI reviews the report and has up to the specified due date to agree to the proposed corrective action(s) suggested in the report or provide other corrective actions with respective due dates for implementation. This information sent by the PI is entered into the PAM database report. In cases of non-compliance, the CO follows up with the PI and/or lab personnel to ensure that all corrective actions are put into place in accordance with the agreed deadlines.

c. MNI PAM Report:

At regular intervals, the CO prepares a MNI PAM report for the Neuro ACC that includes a summary of PAM findings over a specified period.

7. Violation of the PAM Process

All cases of non-compliance discovered by the PAM program and not corrected by the PI within the specified time period will be sent to the MNI ACC Chair, for evaluation of the situation and if necessary, will be forwarded to the MNI Director for final resolution.

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, the Vice-Chair will review this specific case.

In case an ACC member's AUP is being reviewed, they must remove themselves from discussions and decisions made by the Neuro ACC.

Appeal process

In the event that a PI disagrees with the PAM results and/or suggestions stated in the detailed report and/or corrective actions recommended by the ACC, the PI can contact the Neuro ACC Chair to discuss the findings. If the PI would like to formally appeal the conclusions of the PAM report, he/she should do so in writing, within 30 days of receipt of the final detailed report, to the Director of the MNI.

8. Record Keeping and Confidentiality

All documentation generated during the PAM process, including email correspondence, will be kept in strict confidence, on file in the ACC's office. Specifically, the CO keeps an electronic copy of the PAM detailed reports, PAM summary reports as well as PAM database information on a secured network drive. Corresponding emails and documentation are kept on a Compliance email account which is password-protected. Also, monthly, all PAM data will be backed up onto a USB key which is kept in a locked filing cabinet in the ACC office.

A red dot is placed on the ACC 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 University's Safe Disclosure (Whistle Blowing) Reporting policy.