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: **AUP Post-Approval-Monitoring**	**Date Revised:** **June 19, 2019**
Prepared by: **MNI Compliance Officer**	**Approved by:** **MNI ACC Chair**

PURPOSE:

The purpose of this Standard Operating Procedure (SOP) is to detail the methods 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 role 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.

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:

Investigators 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.

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

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 as 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 his/her technical expertise and comments for the detailed written report.

Animal Care Committee Chair

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

Montreal Neurological Institute'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 MNI ACC will be reviewed promptly.
ii. Suspected cases of abuse and allegations of non-compliance reported to the MNI 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) or a PAM visitation letter for biennial review (Appendix B) and a printout from the PAM database of the PAM Audit Checklist (Appendix C) to the PI.
b. One week after the CO has sent the documents, he/she contacts the PI and/or lab manager, by e-mail or phone to schedule the PAM visit**,** at a mutually convenient time. For the biennial review, 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 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. He/she notes 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, log books, 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 PAM visits:

i. AUP Review meeting: All persons directly associated with the procedures listed in the protocol must 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, he/she has 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, he/she 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, he/she 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 MNI ACC Terms of Reference (June 2019).

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.

   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 his/her 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. The CO informs the PI that a 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) will be sent to them, at which time they will have an opportunity to comment on the results of the report. Full compliance letters are sent immediately and non-compliance reports are sent within 10 days of the PAM visit.

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 MNI ACC with their approved AUP from their home institution or submit for approval a new AUP to the MNI 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.

In the event that 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 MNI ACC that includes a summary of PAM findings over a specified period. This report will also be presented verbally at the McGill Quality Assistance subcommittee.

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, he/she has to remove himself/herself from discussions and decisions made by the MNI 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 MNI 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, corresponding letters and documentation as well as the PAM summary reports on a secured network drive. PAM database information will be stored on a desktop with a secured username and password and once a month the data will be backed up onto a secured network drive.

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.

APPENDIX A

Montreal Neurological Institute
Animal Care Committee

[DATE]

[PI NAME]

[Academic Affiliations]

[Research groups]

SUBJECT: Post-Approval Monitoring of AUP [# of AUP]

Dear [PI NAME],

As mandated by the Canadian Council on Animal Care (CCAC), the Montreal Neurological Institute Animal Care Committee (MNI ACC) has developed a procedure for performing Post-Approval Monitoring (PAM) of all MNI animal care and use activities. PAM is intended to be collegial and supportive of animal based research at the MNI. To implement this program, X, has been appointed as the MNI Compliance Officer. It will be her responsibility to work with the investigators and their laboratory teams, by observing animal use procedure(s) and reviewing appropriate documentation to ensure compliance.

The PAM program will involve an AUP Assessment initial meeting with you and your team and subsequently of animal use procedure(s). At the conclusion of the PAM visit, the MNI Compliance Officer will summarize her initial findings with you and your staff to ensure their accuracy.

If no compliance issues are observed you will receive a Full Compliance Letter to that effect. If compliance issues are noted, you will receive within ten days after the PAM visit a detailed report requesting that you provide a plan for corrective action or agree to the proposed corrective plan by a specified due date. Once you send your plan of corrective action to MNI Compliance Officer, she will return a copy of the detailed report to you. MNI Compliance Officer will notify you if any follow up visit is required for additional monitoring or to ensure that corrective action has been implemented.

MNI Compliance Officer will work with you and your laboratory staff to help your team stay fully compliant with the requirements of the CCAC guidelines and the MNI animal care program. Please be assured **that while the MNI Compliance Officer may provide your laboratory staff with compliance related information and may suggest specific corrective action, it is you, the Principal Investigator (PI), who is responsible for ensuring that procedures in your laboratory are being done according to the approved protocol.**

The Compliance Officer is available for a PAM visit on the following: [DATES] and will send all the relevant documents by e-mail. Please reply by e-mail to compliance.mni@mcgill.ca by [DATES] stating the date of the PAM visit most convenient for you and your lab team involved with **AUP's #XXXX.**

The MNI ACC greatly appreciates your cooperation and partnership in ensuring the integrity of the MNI Animal and Care Use Program.

Sincerely,

Chair, MNI ACC

Encl: PAM Audit Checklist
cc: MNI Compliance Officer

APPENDIX B

Montreal Neurological Institute
Animal Care Committee

[PI INFORMATION] **[DATE]**

SUBJECT: Biennial Post-Approval Monitoring Review of AUP #[ ]

Dear [PI],

As part of the biennial Post-Approval Monitoring (PAM) program, the MNI Compliance Officer would like to re-visit your laboratory to review [AUP #].

1. AUP REVIEW MEETING
The Compliance Officer will:
•Meet with the PI and lab personnel to explain the PAM program and answers question about the Animal Care and Use Program (ACUP).
•Use the Audit Checklist to ask questions related to personnel, training, documentation and laboratory process.
•Report all comments, records reviewed and any non-compliance issues noted.

2. OBSERVATION VISIT
The Compliance Officer will schedule a separate visit with the lab personnel to do as follows:
•To observe all ongoing animal procedures associated with the AUP.
•Complete the appropriate questions on the Audit Checklist.
•Report comments, observations, and any non-compliance issues observed.

Within ten working days after PAM visit, the Compliance Officer will -
Send a PAM detailed report to the PI with the conclusion that details, if there are any, non-compliance issues found. If compliance issues are noted, you will receive within ten days after the PAM visit a PAM detailed report requesting that you provide a plan for corrective action or agree to the proposed corrective plan by a specified due date.

If deemed necessary, the MNI Compliance Officer may request a follow-up visit.

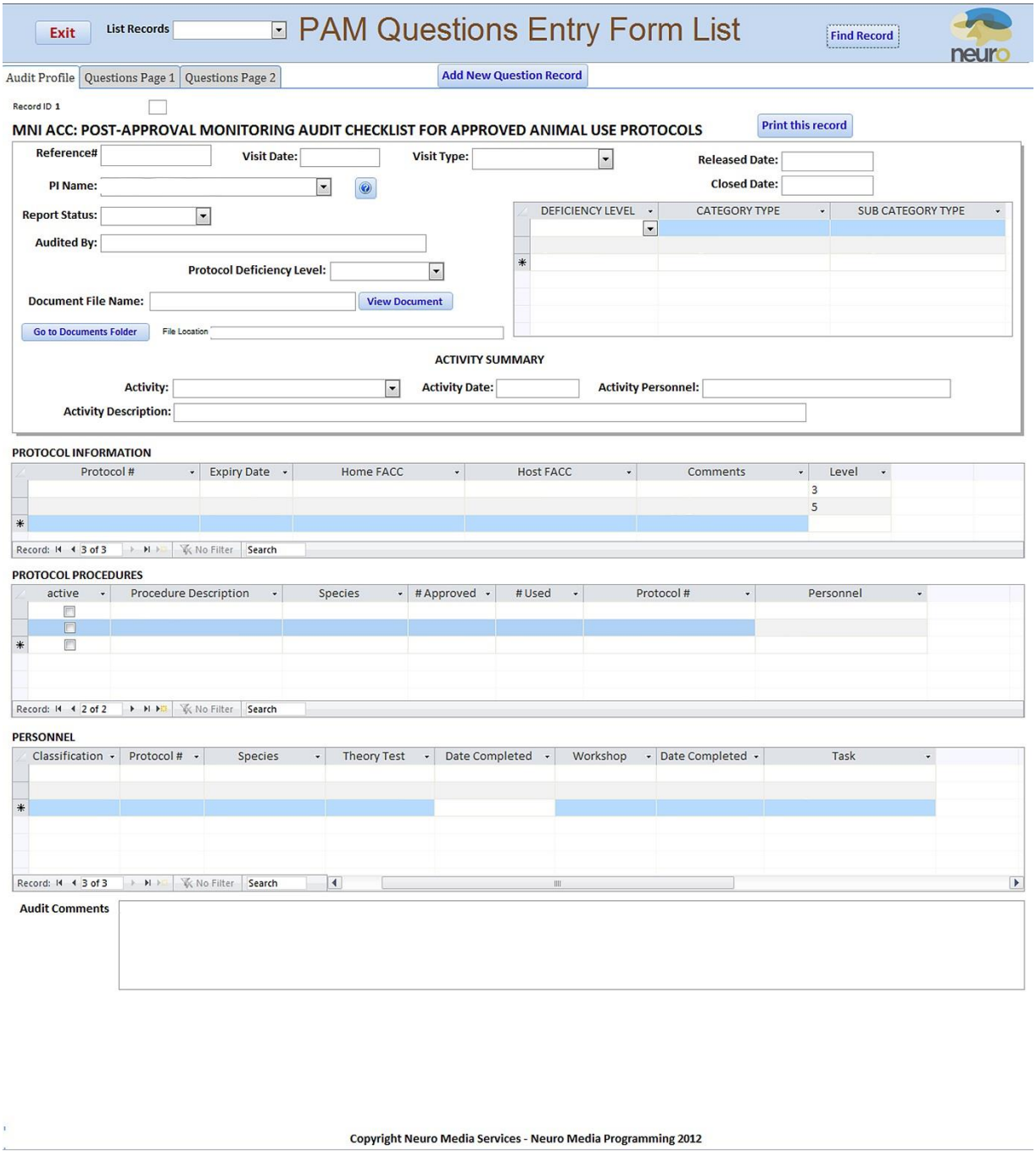
The Compliance Officer is available for a PAM Review Meeting on the following: **[2 or 3 DATEs].** Please e-mail compliance.mni@mcgill.ca by **[DATE]**, stating the date of the PAM visit most convenient for you and/or your lab team involved with AUP # **[…].**

The MNI ACC greatly appreciates your cooperation and partnership in ensuring the integrity of the MNI Animal Care and Use Program.

Sincerely,

MNI Compliance Officer **for**
MNI ACC Chair

APPENDIX C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PAM Questions Entry Form List
Find Record
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Audit Profile
Questions Page 1
Questions Page 2
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Record ID 1
MNI ACC: POST-APPROVAL MONITORING AUDIT CHECKLIST FOR APPROVED ANIMAL USE PROTOCOLS
Print this record
Reference#
Visit Date:
Visit Type:
Released Date:
PI Name:
Closed Date:
Report Status:
Audited By:
Protocol Deficiency Level:
Document File Name:
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CATEGORY TYPE
SUB CATEGORY TYPE
ACTIVITY SUMMARY
Activity:
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Activity Personnel:
Activity Description:
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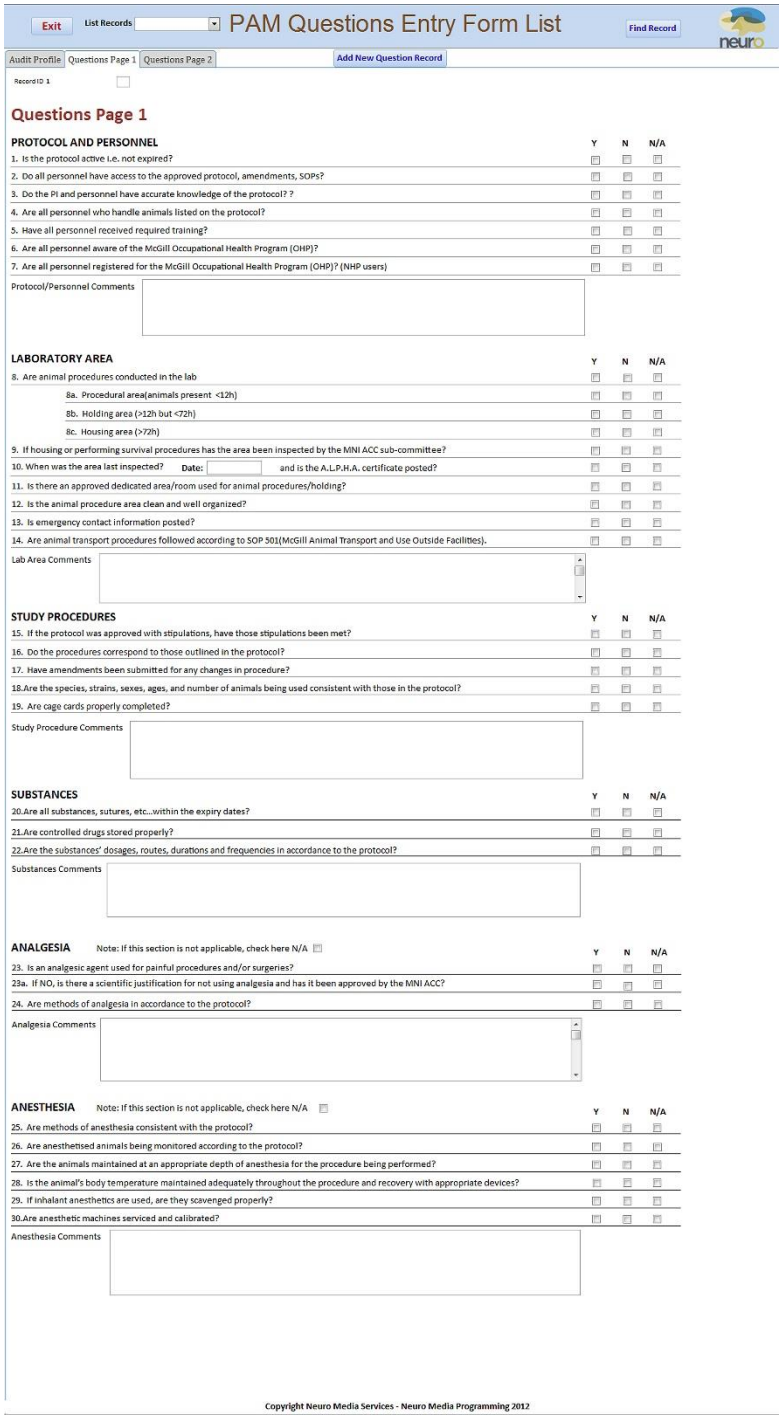

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Audit Profile | Questions Page 1 | Questions Page 2 | Add New Question Record

RecordID 1

Questions Page 1

PROTOCOL AND PERSONNEL	Y	N	N/A
1. Is the protocol active i.e. not expired?			
2. Do all personnel have access to the approved protocol, amendments, SOPs?			
3. Do the PI and personnel have accurate knowledge of the protocol? ?			
4. Are all personnel who handle animals listed on the protocol?			
5. Have all personnel received required training?			
6. Are all personnel aware of the McGill Occupational Health Program (OHP)?			
7. Are all personnel registered for the McGill Occupational Health Program (OHP)? (NHP users)			

Protocol/Personnel Comments

LABORATORY AREA	Y	N	N/A
8. Are animal procedures conducted in the lab			
8a. Procedural area(animals present <12h)			
8b. Holding area (>12h but <72h)			
8c. Housing area (>72h)			
9. If housing or performing survival procedures has the area been inspected by the MNI ACC sub-committee?			
10. When was the area last inspected? Date: and is the A.L.P.H.A. certificate posted?			
11. Is there an approved dedicated area/room used for animal procedures/holding?			
12. Is the animal procedure area clean and well organized?			
13. Is emergency contact information posted?			
14. Are animal transport procedures followed according to SOP 501(McGill Animal Transport and Use Outside Facilities).			

Lab Area Comments

STUDY PROCEDURES	Y	N	N/A
15. If the protocol was approved with stipulations, have those stipulations been met?			
16. Do the procedures correspond to those outlined in the protocol?			
17. Have amendments been submitted for any changes in procedure?			
18.Are the species, strains, sexes, ages, and number of animals being used consistent with those in the protocol?			
19. Are cage cards properly completed?			

Study Procedure Comments

SUBSTANCES	Y	N	N/A
20.Are all substances, sutures, etc...within the expiry dates?			
21.Are controlled drugs stored properly?			
22.Are the substances' dosages, routes, durations and frequencies in accordance to the protocol?			

Substances Comments

ANALGESIA Note: If this section is not applicable, check here N/A	Y	N	N/A
23. Is an analgesic agent used for painful procedures and/or surgeries?			
23a. If NO, is there a scientific justification for not using analgesia and has it been approved by the MNI ACC?			
24. Are methods of analgesia in accordance to the protocol?			

Analgesia Comments

ANESTHESIA Note: If this section is not applicable, check here N/A	Y	N	N/A
25. Are methods of anesthesia consistent with the protocol?			
26. Are anesthetised animals being monitored according to the protocol?			
27. Are the animals maintained at an appropriate depth of anesthesia for the procedure being performed?			
28. Is the animal's body temperature maintained adequately throughout the procedure and recovery with appropriate devices?			
29. If inhalant anesthetics are used, are they scavenged properly?			
30.Are anesthetic machines serviced and calibrated?			

Anesthesia Comments

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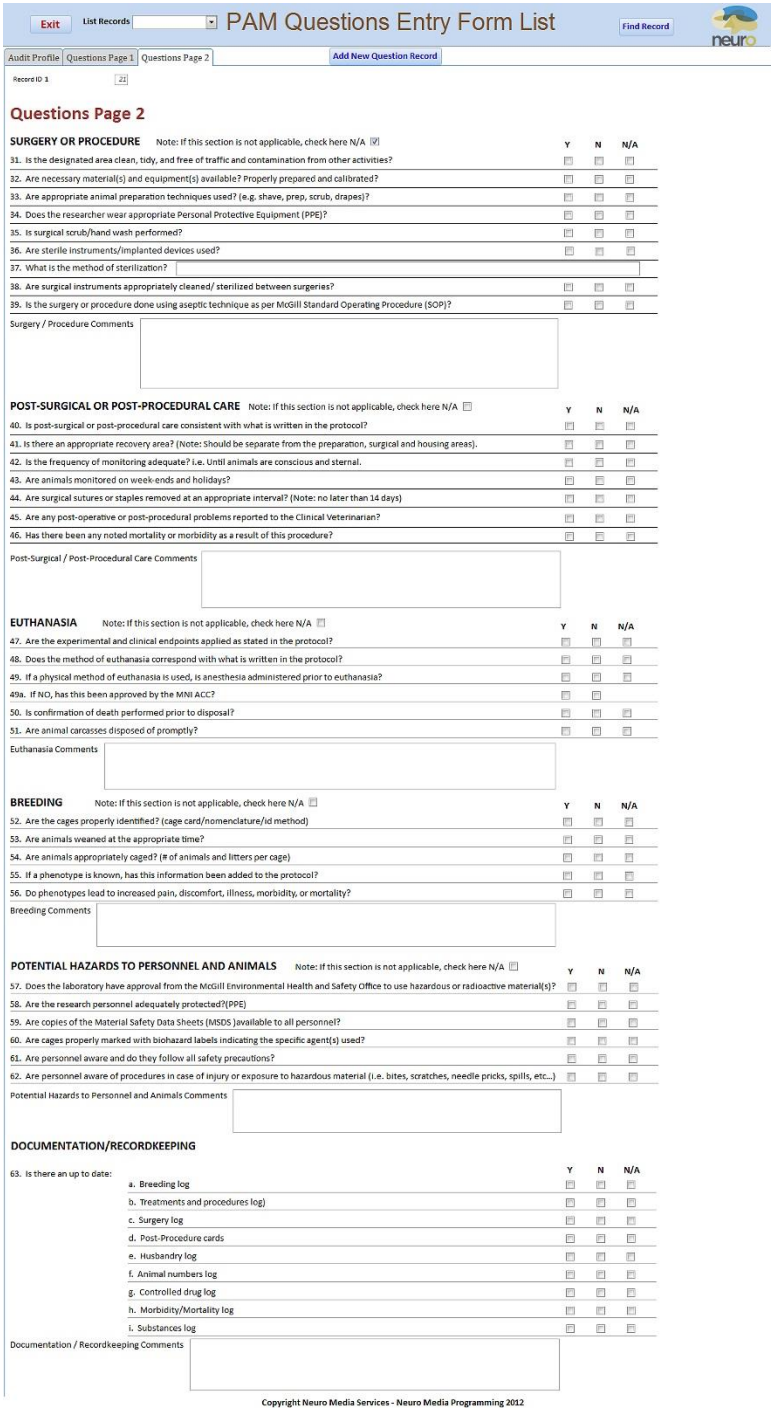

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Audit Profile | Questions Page 1 | Questions Page 2 | Add New Question Record

Record ID 1 | 21

Questions Page 2

SURGERY OR PROCEDURE Note: If this section is not applicable, check here N/A ☑

	Y	N	N/A
31. Is the designated area clean, tidy, and free of traffic and contamination from other activities?	☐	☐	☐
32. Are necessary material(s) and equipment(s) available? Properly prepared and calibrated?	☐	☐	☐
33. Are appropriate animal preparation techniques used? (e.g. shave, prep, scrub, drapes)?	☐	☐	☐
34. Does the researcher wear appropriate Personal Protective Equipment (PPE)?	☐	☐	☐
35. Is surgical scrub/hand wash performed?	☐	☐	☐
36. Are sterile instruments/implanted devices used?	☐	☐	☐
37. What is the method of sterilization?			
38. Are surgical instruments appropriately cleaned/ sterilized between surgeries?	☐	☐	☐
39. Is the surgery or procedure done using aseptic technique as per McGill Standard Operating Procedure (SOP)?	☐	☐	☐

Surgery / Procedure Comments

POST-SURGICAL OR POST-PROCEDURAL CARE Note: If this section is not applicable, check here N/A ☐

	Y	N	N/A
40. Is post-surgical or post-procedural care consistent with what is written in the protocol?	☐	☐	☐
41. Is there an appropriate recovery area? (Note: Should be separate from the preparation, surgical and housing areas).	☐	☐	☐
42. Is the frequency of monitoring adequate? i.e. Until animals are conscious and sternal.	☐	☐	☐
43. Are animals monitored on week-ends and holidays?	☐	☐	☐
44. Are surgical sutures or staples removed at an appropriate interval? (Note: no later than 14 days)	☐	☐	☐
45. Are any post-operative or post-procedural problems reported to the Clinical Veterinarian?	☐	☐	☐
46. Has there been any noted mortality or morbidity as a result of this procedure?	☐	☐	☐

Post-Surgical / Post-Procedural Care Comments

EUTHANASIA Note: If this section is not applicable, check here N/A ☐

	Y	N	N/A
47. Are the experimental and clinical endpoints applied as stated in the protocol?	☐	☐	☐
48. Does the method of euthanasia correspond with what is written in the protocol?	☐	☐	☐
49. If a physical method of euthanasia is used, is anesthesia administered prior to euthanasia?	☐	☐	☐
49a. If NO, has this been approved by the MNI ACC?	☐	☐	
50. Is confirmation of death performed prior to disposal?	☐	☐	☐
51. Are animal carcasses disposed of promptly?	☐	☐	☐

Euthanasia Comments

BREEDING Note: If this section is not applicable, check here N/A ☐

	Y	N	N/A
52. Are the cages properly identified? (cage card/nomenclature/id method)	☐	☐	☐
53. Are animals weaned at the appropriate time?	☐	☐	☐
54. Are animals appropriately caged? (# of animals and litters per cage)	☐	☐	☐
55. If a phenotype is known, has this information been added to the protocol?	☐	☐	☐
56. Do phenotypes lead to increased pain, discomfort, illness, morbidity, or mortality?	☐	☐	☐

Breeding Comments

POTENTIAL HAZARDS TO PERSONNEL AND ANIMALS Note: If this section is not applicable, check here N/A ☐

	Y	N	N/A
57. Does the laboratory have approval from the McGill Environmental Health and Safety Office to use hazardous or radioactive material(s)?	☐	☐	☐
58. Are the research personnel adequately protected?(PPE)	☐	☐	☐
59. Are copies of the Material Safety Data Sheets (MSDS) available to all personnel?	☐	☐	☐
60. Are cages properly marked with biohazard labels indicating the specific agent(s) used?	☐	☐	☐
61. Are personnel aware and do they follow all safety precautions?	☐	☐	☐
62. Are personnel aware of procedures in case of injury or exposure to hazardous material (i.e. bites, scratches, needle pricks, spills, etc...)	☐	☐	☐

Potential Hazards to Personnel and Animals Comments

DOCUMENTATION/RECORDKEEPING

63. Is there an up to date:	Y	N	N/A
a. Breeding log	☐	☐	☐
b. Treatments and procedures log)	☐	☐	☐
c. Surgery log	☐	☐	☐
d. Post-Procedure cards	☐	☐	☐
e. Husbandry log	☐	☐	☐
f. Animal numbers log	☐	☐	☐
g. Controlled drug log	☐	☐	☐
h. Morbidity/Mortality log	☐	☐	☐
i. Substances log	☐	☐	☐

Documentation / Recordkeeping Comments

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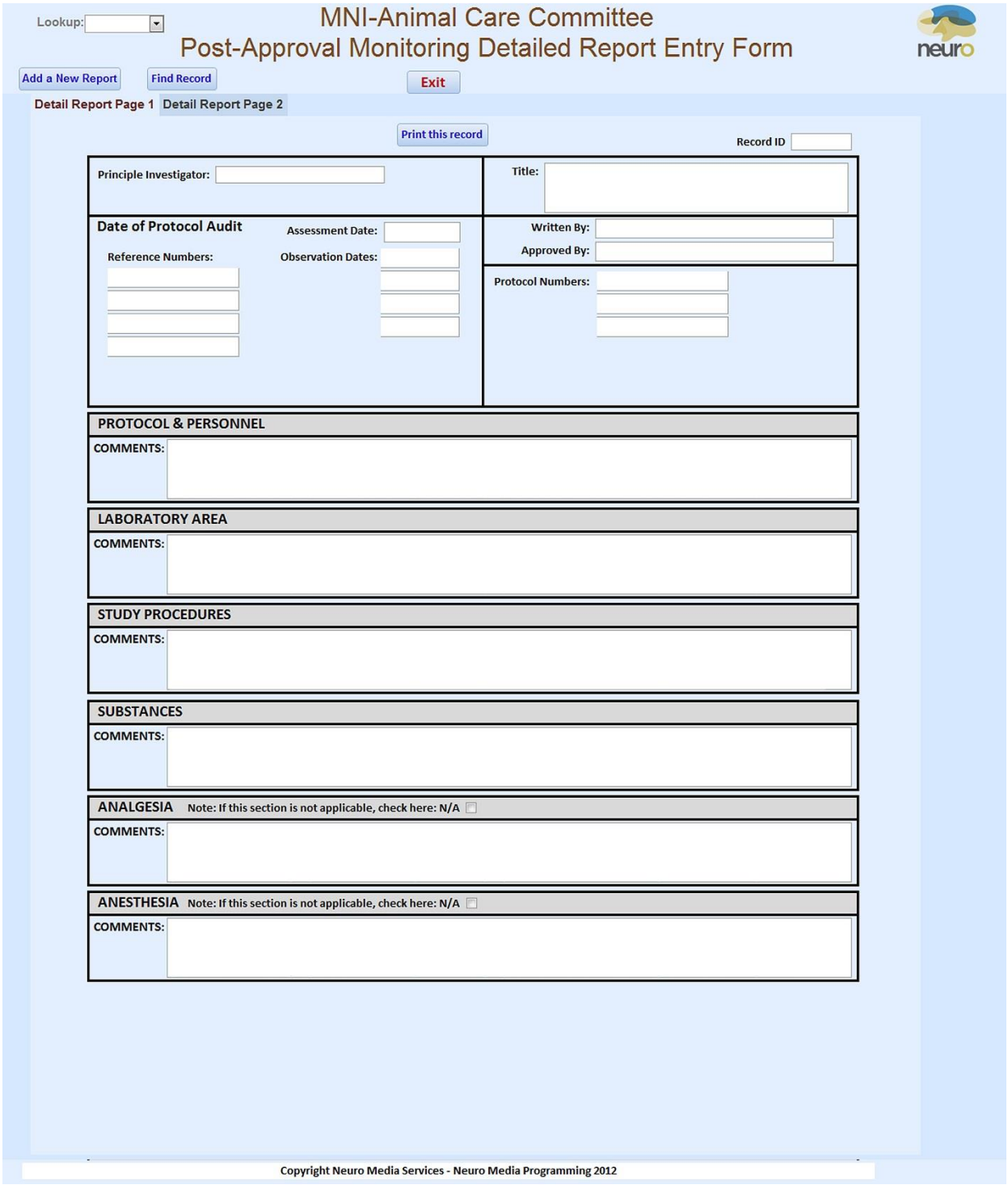
APPENDIX D


Lookup:
MNI-Animal Care Committee
Post-Approval Monitoring Detailed Report Entry Form
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Add a New Report
Find Record
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Detail Report Page 1
Detail Report Page 2
Print this record
Record ID
Principle Investigator:
Title:
Date of Protocol Audit
Assessment Date:
Written By:
Approved By:
Reference Numbers:
Observation Dates:
Protocol Numbers:
PROTOCOL & PERSONNEL
COMMENTS:
LABORATORY AREA
COMMENTS:
STUDY PROCEDURES
COMMENTS:
SUBSTANCES
COMMENTS:
ANALGESIA
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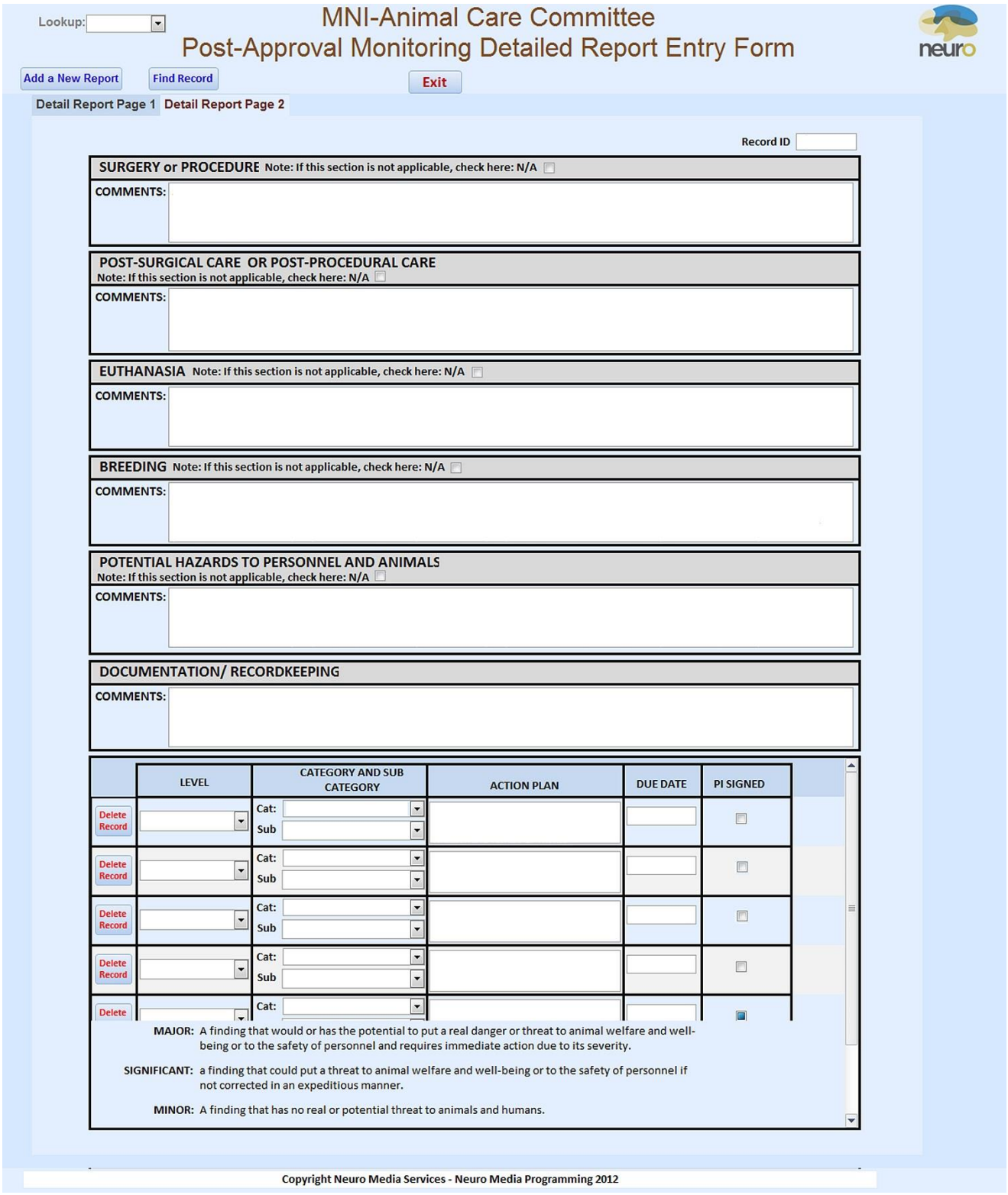

Lookup:

MNI-Animal Care Committee
Post-Approval Monitoring Detailed Report Entry Form

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Add a New Report | Find Record | Exit

Detail Report Page 1 | Detail Report Page 2

Record ID

SURGERY or PROCEDURE Note: If this section is not applicable, check here: N/A

COMMENTS:

POST-SURGICAL CARE OR POST-PROCEDURAL CARE
Note: If this section is not applicable, check here: N/A

COMMENTS:

EUTHANASIA Note: If this section is not applicable, check here: N/A

COMMENTS:

BREEDING Note: If this section is not applicable, check here: N/A

COMMENTS:

POTENTIAL HAZARDS TO PERSONNEL AND ANIMALS
Note: If this section is not applicable, check here: N/A

COMMENTS:

DOCUMENTATION/ RECORDKEEPING

COMMENTS:

	LEVEL	CATEGORY AND SUB CATEGORY	ACTION PLAN	DUE DATE	PI SIGNED
Delete Record		Cat: Sub			
Delete Record		Cat: Sub			
Delete Record		Cat: Sub			
Delete Record		Cat: Sub			
Delete		Cat:			

MAJOR: 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: 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: A finding that has no real or potential threat to animals and humans.

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APPENDIX E

Montreal Neurological Institute
Animal Care Committee

[PI NAME] **[DATE]**
[Academic Affiliations and Research Groups]

SUBJECT: Letter of Full Compliance for Animal Use Protocol [# of AUP]

Dear [PI NAME]

On [DATE], a routine Post-Approval Monitoring visit to observe the activities approved under the Animal Use Protocol (AUP) identified above, was conducted by, the MNI Compliance Officer, on behalf of the MNI Animal Care Committee (ACC).

Based on the information gathered during the Animal Use Protocol (AUP) review meeting and the procedures observed: [list procedures], it has been determined that all activities associated with this protocol are being performed as approved.

Please sign and date the last page of the report to confirm that it has been reviewed and that you agree with all the observations and comments.
The signed document must be returned no later than **[DATE]** to compliance.mni@mcgill.ca
You and your staff are to be commended for the attention to detail, the professional manner in which the animal procedures were conducted, and the humane way in which the animals were handled.

Successful PAM visits such as this provide clear evidence that the MNI research community is following the regulations set by the Canadian Council on Animal Care (CCAC), the MNI, and McGill University. I would like to thank you and your staff for your support of the MNI's commitment to quality animal care and progressive research.

Congratulations on a job well done! Please show this letter to all concerned.

Sincerely,

Chair, MNI ACC
Encl.: Copy of the PAM Detailed Report
cc: MNI Compliance Officer

APPENDIX F

Montreal Neurological Institute
Animal Care Committee

[PI NAME] **[DATE]**
[Academic Affiliations and Research Groups]

SUBJECT: Letter of Minor Non-Compliance for Animal Use Protocol [# of AUP]

Dear [PI NAME]

On [DATE], a routine Post-Approval Monitoring visit to observe the activities approved under the **Animal Use Protocol** (AUP) identified above, was conducted by the MNI Compliance Officer on behalf of the MNI Animal Care Committee (ACC).

Based on the information gathered during the Animal Use Protocol (AUP) review meeting and the procedures observed: [list procedures], it has been determined that the majority of procedures associated with this protocol are being performed as approved, however there is **XXX compliance** issue(s) with respect to the following activity:
Deficiency Level:
Category Type:
There are also, XXXX **PAM recommendation(s)** that have been reported.

Please sign and date the last page of the report to confirm that it has been reviewed and that you agree with all the comments and recommendations.
The signed document must be returned no later than **[DATE]** to compliance.mni@mcgill.ca

You and your staff are to be commended for the attention to detail, the professional manner in which the animal activities were conducted, and the humane way in which the animals were handled.

Successful PAM visits such as this provide clear evidence that the MNI research community is following the regulations set by the Canadian Council on Animal Care (CCAC), the MNI, and McGill University. I would like to thank you and your staff for your support of the MNI's commitment to quality animal care and progressive research.

Congratulations on a job well done! Please show this letter to all concerned.

Sincerely,

Chair, MNI ACC
Encl.: Copy of the PAM Detailed Report
cc: MNI Compliance Officer

APPENDIX G

Montreal Neurological Institute
Animal Care Committee

[PI NAME] **[DATE]**
[Academic Affiliations and Research Groups]

SUBJECT: Letter of Non-Compliance for AUP [# of AUP]

Dear [PI NAME],

On [DATE], a routine Post-Approval Monitoring visit to observe the activities approved under the protocol identified above, was conducted by the, MNI Compliance Officer, and [NAME], MNI Institute Veterinarian or Designated Representative on behalf of the MNI Animal Care Committee (ACC).

Based on the information gathered during the Animal Use Protocol (AUP) review meeting and the procedures observed: [list procedures], it has been determined that there are certain compliance issues with respect to the following activities [list findings].

The attached Post-Approval Monitoring (PAM) Detailed Report provides a more comprehensive explanation of the activities observed and issues identified. We realize that certain observations may not be entirely accurate, and we encourage responses which provide clarifying information obtained during the PAM visit. For the observations that are accurate Please provide a response to these observations in the table on the last page of the attached detailed report and return the report to room 658 by [DATE].

We also realize that on occasion, research may drift from the original protocol-indeed the very nature of research requires original and creative thought-and may become unintentionally divergent from the original protocol. When non-compliant activities are identified, the lab personnel must either return immediately to the original protocol or suspend the change and submit an amendment to the MNI ACC for their approval.

Thank you for your consideration, clarification, and response to these items. The PAM visit is intended to be a collegial review of approved activities and an opportunity for education and information sharing of the MNI animal care and use process. The ACC appreciates your adherence to the procedures in the approved protocol until any proposed amendments are reviewed and approved.

Sincerely,

MNI Compliance Officer **for:**
Chair, MNI ACC
Encl.: Copy of the PAM Detailed Report
cc: Chair, MNI ACC

APPENDIX H

MNI ANIMAL CARE COMMITTEE:
POST-APPROVAL MONITORING SUMMARY REPORT

TO: MNI ACC

DATE:

SUBMITTED BY: [NAME]

PERIOD COVERED: [DATE] to [DATE]

Post-approval monitoring visits were conducted from [DATE] to [DATE] by the MNI Compliance Officer, [NAME] and The MNI Institute Veterinarian or Designated Representative, [NAME]. The purpose of the post-approval monitoring visits was to assess compliance of study activities with those approved in the protocol. Documentation (in vivo data, records) provided by the Principal Investigators, Lab teams, and Animal Care staff was reviewed to confirm that the approved protocol was followed.

[# of AUPs] Animal Use Protocols were selected and reviewed during the month of [MONTH]:

PROTOCOL#	TITLE

The Compliance Officer obtained relevant study data from the Principal Investigator or lab personnel for each study. The following documentation was reviewed against the approved protocol.

PROTOCOL#	TYPE OF DOCUMENTATION REVIEWED	SUBMITTED BY

The Principal Investigators and Lab personnel were courteous and helpful, taking time to meet and discuss the content of the data/records.

The following observations were made upon comparison of the approved protocols with the selected study documentation during the PAM visits.

PROTOCOL#	LEVEL OF DEFICIENCY	TYPE OF DEFICIENCY	ACTION PLAN	DUE DATE

MAJOR: 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: 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: A finding that has no real or potential threat to animals and humans.

The next PAM summary report will be submitted at the [DATE] ACC meeting.