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 following the rules. 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.

**Animal Care Facility (ACF) 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 Clinical Veterinarian or Designated Representative**

works 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**

provides 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**

provide recommendations for maintaining compliance.
POLICY AND PROCEDURE:

1. a. Selecting AUPs for PAM program
   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 clinical veterinarian, senior ACF 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 ACF SOPs and animal care activities will be regularly reviewed.

2. Types of visits performed:

   Three forms of PAM will be used:
   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: 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.

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 “for cause” and “follow-up” PAM visits the CO notifies the PI and lab manager, one week in advance of the PAM visit date.
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, in the profile page (Appendix C) of the PAM Audit Checklist.

b. One week before the PAM visit the CO contacts the appropriate ACF 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 ACF 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:**

   **Protocol compliance, including:**
   Procedures, Anesthesia, Analgesia, Surgery, Post-surgical/procedural monitoring and care, Euthanasia, Breeding, Documentation/Recordkeeping, Laboratory practices related to animal use, Pain management, Potential Hazards to personnel and animals, and Regulatory requirements (i.e. appropriate use of personal protective equipment, storage of controlled drugs, approval of animal use areas outside ACF, etc.)

b. **The CO conducts two PAM visits or more:**

   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 AUP.
   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 Visits:** 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 have to take place.
If the PI is not directly involved, he/she has the option of not being present at the observation visit.

The CO:

1. and the MNI Clinical Veterinarian or Designated Representative visit the laboratory and inspect all areas where animal procedures and surgeries are performed, as mentioned in the AUP(s) under review. They wear the appropriate personal protective equipment (PPE) indicated for the specific activity or laboratory. The MNI Clinical Veterinarian or Designated Representative is 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, he/she 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 an animal welfare issue is found, he/she has the authority to treat, remove from a study or euthanize, if necessary, an animal according to the Veterinarian's professional judgment, as per the MNI ACC Terms of Reference (Aug 2012).

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 the results of the visit with the PI and lab staff to confirm his/her and if appropriate, the MNI Clinical Veterinarian’s or Designated Representative’s observations. 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 and then 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**

An Investigator whose home institution is not the MNI and who wishes to carry out animal-based work within the MNI’s ACF 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, deficiencies observed if any, and corrective actions suggested.

   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 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.

   The CO:
   i. completes the detailed report form in the PAM database, which includes 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 ACF manager (if necessary) to help complete the detailed report.
iii. prints a copy 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. The PI will also need to specify specific due dates to implement corrective action(s). 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 and McGill Quality Assistance subcommittee 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, he/she has to remove himself/herself from any decision making.

Appeal process
In the event that an investigator disagrees with the PAM results and/or suggestions stated in the detailed report 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.

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 a
pdf copy of the PAM detailed reports, corresponding letters and documentation in the PAM PI Report binder and the PAM summary reports in the PAM ACC Report binder.

PAM documents are kept in a locked filing cabinet and will only be accessible to ACC staff. As well, the ACC office is red-dotted. A red dot is placed on office doors to indicate that only authorized people have access.

PAM database information will be stored on a laptop with a secured username and password and the data will be backed up onto a secured network drive.

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

Montreal Neurological Institute
Animal Care Committee

[DATE]

[PI NAME]

[OFFICE LOCATION]

SUBJECT:    Post-Approval Monitoring of AUP [# of AUP], Title 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 review meeting with yourself and your team and subsequently a laboratory observation visit with MNI Compliance Officer and the [NAME], MNI Clinical Veterinarian or Designated Representative. 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 PAM 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 detail 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 Principle Investigator (PI), who is responsible for ensuring that your procedures in your laboratory are being done according to the approved protocol.

The MNI Compliance Officer will be getting in touch with you by [DATE] to arrange the first PAM visit to your laboratory and will send all the relevant documents by e-mail.

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 #[], [TITLE].

Dear [PI],

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

To remind you, the PAM program includes:

- Review meeting of the PAM Audit Checklist and records associated with the AUP, and to answer any questions of the lab personnel.
- Observation of procedures in the AUP.
- Discussion of observations with lab team.

If compliance issues are noted, the following process is followed:

- Within ten days after the visit, a PAM report is sent to the PI.
- The report details the non-compliance issues found and suggests corrective action.
- PI is requested to provide information as to what plan for corrective action will be implemented and to specify due date.
- If deemed necessary, the MNI Compliance Officer may request a follow up visit.

The Compliance Officer and the Clinical Veterinarian are available for a PAM visit 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

MNI ACC: POST-APPROVAL MONITORING AUDIT CHECKLIST FOR APPROVED ANIMAL USE PROTOCOLS

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<th>Host FACC</th>
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PROTOCOL PROCEDURES

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PERSONNEL

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Audit Comments

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### Questions Page 1

**Protocol and Personnel**

1. Is the protocol active - i.e. not expired? [Y/N/R/A]
2. Are all personnel (including those who handled animals before the protocol) aware of the approved protocol, amendments, IACUC? [Y/N/R/A]
3. Do all personnel (including those who handled animals before the protocol) have a copy of the approved protocol? [Y/N/R/A]
4. Are all personnel who handle animals listed on the protocol? [Y/N/R/A]
5. Are all personnel required to receive training? [Y/N/R/A]
6. Are all personnel aware of the IACUC Occupational Health Program (OHP)? [Y/N/R/A]
7. Are all personnel registered for the IACUC Occupational Health Program (OHP)? [Y/N/R/A]

**Laboratory Area**

1. Are all animal procedures conducted in the lab? [Y/N/R/A]
2. Is the veterinary anesthetist present? [Y/N/R/A]
3. Is the laboratory area monitored? [Y/N/R/A]
4. Is the laboratory area clean and well-ventilated? [Y/N/R/A]
5. Is the laboratory area free of potential hazards? [Y/N/R/A]

**Study Procedures**

1. Are the procedures performed in accordance with the approved protocol? [Y/N/R/A]
2. Does the tissue from the protocol follow the approved protocol and use of animals? [Y/N/R/A]
3. Are the tissues collected in a manner to ensure the safety of the personnel? [Y/N/R/A]
4. Are the tissues collected in a manner to ensure the safety of the personnel? [Y/N/R/A]
5. Are the tissues collected in a manner to ensure the safety of the personnel? [Y/N/R/A]

**Substances**

1. Are all substances, toxins, etc., within the supply dates? [Y/N/R/A]
2. Are all chemicals properly stored? [Y/N/R/A]
3. Are the substances' actions, routes, effects, and frequency in accordance with the protocol? [Y/N/R/A]

**Anesthesia**

1. Are methods of anesthesia consistent with the protocol? [Y/N/R/A]
2. Are the animals maintained at an appropriate depth of anesthesia for the procedure being performed? [Y/N/R/A]
3. Was the depth of anesthesia maintained adequately throughout the procedure and recovery with appropriate devices? [Y/N/R/A]
4. Are the anesthetics used or used, as they were prescribed? [Y/N/R/A]

**Appendix C**
...continued Appendix C
APPENDIX D

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

**Lookup:**

**Date of Protocol Audit**
- Reference Numbers:
- Observation Dates:
- Protocol Numbers:

**PROTOCOL & PERSONNEL**

**LABORATORY AREA**

**STUDY PROCEDURES**

**SUBSTANCES**

**ANALGESIA**

**ANESTHESIA**

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

**COMMENTS:**

...continued Appendix D
APPENDIX E
Montreal Neurological Institute
Animal Care Committee

[PI NAME] [DATE]

[OFFICE LOCATION]

SUBJECT: Letter of Full Compliance for AUP [# of AUP], Title 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 Clinical 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 all activities associated with this protocol are being performed as approved. 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
SUBJECT: Letter of Minor Non-Compliance for AUP [# of AUP], Title 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 Clinical 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 the majority of procedures associated with this protocol are being performed as approved, however the following minor compliance issues have been observed: [list findings] **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 684 by [DATE].**

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]
[OFFICE LOCATION]

SUBJECT: Letter of Non-Compliance for AUP [# of AUP], Title 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 Clinical 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 684 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
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 Clinical Veterinarian or Designated Representative, [NAME]. The purpose of the post-approval monitoring visits was to assess compliance of study activities with those approved in 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]:

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<th>PROTOCOL#</th>
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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.

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<tr>
<th>PROTOCOL#</th>
<th>TYPE OF DOCUMENTATION REVIEWED</th>
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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.

<table>
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<tr>
<th>PROTOCOL#</th>
<th>LEVEL OF DEFICIENCY</th>
<th>TYPE OF DEFICIENCY</th>
<th>ACTION PLAN</th>
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**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.