

UNIVERSITY OF MANITOBA PROCEDURE

Procedure:	Animal Care and Use
Parent Policy:	Animal Care and Use Policy
Effective Date:	December 7 2011
Revised Date:	June 4 2019
Review Date:	December 7 2021
Approving Body:	Vice-President (Research and International) and Senate Committee on University Research
Authority:	Vice-President (Research and International) and Senate Committee on University Research
Responsible Executive Officer:	Vice-President (Research and International)
Delegate: (If applicable)	Associate Vice-President (Research)
Contact:	Animal Care Coordinator
Application:	Faculty/School Councils, Student and other trainees, External Parties, Employees [All employees who use animals in research, teaching and/or testing]

Part I Reason for Procedure

- 1.1 To enable the implementation of the Animal Care and Use Policy (the "Policy"), by establishing procedures relating to:
- (a) Responsibilities;
 - (b) Protocol Review and Approval;
 - (c) Collaboration;
 - (d) Education and Training;
 - (e) Post Approval Monitoring;

- (f) Peer Review;
- (g) Animal Acquisition, Housing and Disposal;
- (h) Authority to Terminate Animal Use;
- (i) Appeal of Protocol Review Decisions; and
- (j) Non-Compliance.

Part II Procedural Content

2.1 Definitions

The following terms have the defined meanings for the purpose of these Procedures:

2.1.1 Abbreviated Protocol for Minimal Animal Involvement means a document submitted by an Animal User for consideration by a subcommittee of the Animal Care Committee (ACC), and containing a brief description of the study which allows for confirmation of minimal Animal use.

2.1.2 Category of Invasiveness or COI means the categories defined by the Canadian Council on Animal Care (CCAC) describing the invasiveness of the procedures used on a live Animal. Invasiveness is based on the degree and duration of pain or physical distress associated with the procedure.

2.1.3 Collaborator and Collaborative Project means Animal Users who share expertise, facilities, equipment, or financial support in order to complete animal research, teaching, or testing as described in an approved Protocol.

2.1.4 Off-site Housing means locations (other than the Facilities) in which Animals for use are housed.

2.1.5 Research Personnel refers to personnel, other than the Principal Investigator (PI), identified on the Protocol. Such persons are normally co-investigators, collaborators, post doctoral fellows, research associates, technicians or students.

2.1.6 Any references in the singular form shall be deemed to include the plural form where the meaning of a section so requires.

2.2 Responsibilities

Implementing and adhering to Applicable Requirements concerning the proper care and use of Animals in research, teaching or testing is an institutional responsibility shared by: the University Administration, including central, faculty and departmental administration; specially appointed committees, including the Committee on Animal Care (CAC) and the ACCs; the Director, Animal Care and Use Program (DACUP), Veterinary Services Staff, Directors of Facilities, Animal Care Facilities Staff and Animal Users.

Notwithstanding this shared responsibility, the specific responsibilities of these individuals, groups/units, and committees are as follows:

2.2.1 The Associate Vice-President (Research) (AVPR) is responsible for the implementation of these Procedures.

2.2.2 The DACUP is responsible for providing overall direction to the University's Animal Care and Use Program.

2.2.3 Faculty/School Deans/Directors and Department Heads:

2.2.3.1 Faculty/School Deans/Directors and Department Heads have a general responsibility for the research, teaching or testing carried out in their Faculty/School or Department, and for encouraging and ensuring compliance with Applicable Requirements.

2.2.3.2 Deans/Directors of Faculties/Schools and Department Heads are responsible for the operations of the Facilities under their jurisdiction and for ensuring that they meet all Applicable Requirements. Deans/Directors of Faculties/Schools are responsible for ensuring funding to meet Applicable Requirements with respect to maintenance, upgrade, and long term planning of Facilities under their jurisdiction.

2.2.3.3. Where a unit (e.g., Research Centre/Institute) reports directly to a Vice-President, these responsibilities are vested in the appropriate Vice-President.

2.2.4 The CAC is responsible for ensuring University-wide understanding of, and compliance with, all Applicable Requirements. The specific composition and detailed terms of reference of the CAC are determined by the Senate Committee on University Research (SCUR) and must accord with the requirements of the CCAC.

2.2.5 The ACCs are responsible for the ethical review of Protocols and ensuring compliance with the approved Protocols. ACC Chairs have delegated authority for signature, on behalf of the University, of approved Protocols under their jurisdiction. ACC Chairs are responsible to the AVPR. The specific composition and detailed terms of reference of the ACCs are determined by the CAC and must accord with the requirements of the CCAC.

2.2.6 The Education Committee is responsible for the development and delivery of the education program as required by the CCAC. The specific composition and detailed terms of reference are determined by the CAC and must accord with the requirements of the CCAC.

2.2.7 The Infrastructure Planning Committee is responsible for advising on Facility infrastructure related matters. The specific composition and detailed terms of reference are determined by the CAC.

2.2.8 Local Animal Users Committees (the "LAUCs"), where established, are responsible for providing the respective Dean/Director with advice relevant to the Facility under their jurisdiction. The specific composition and detailed terms of reference of the LAUCs are determined by the Dean/Director.

2.2.9 Veterinary Services Staff are responsible for the provision of veterinary and Animal health care and ensuring that Animal welfare needs are addressed; supporting and facilitating the research program; promoting the education of Animal Users; and ensuring compliance with Applicable Requirements.

2.2.10 Animal Care Facilities Staff are responsible for the provision of animal husbandry, environmental enrichment, and monitoring animal welfare and health in accordance with institutional policy and standard operating procedures. This includes diligent observations of animals and the reporting of any abnormalities and ensuring that all research access to animals born in house is approved and accounted for.

2.2.11 Directors of Facilities are responsible for: the overall operations of the Facilities, in particular, for the acquisition, daily maintenance and care of Animals in the Facility; ensuring that an approved Protocol is in place before Animals are acquired; ensuring that the actual use does not exceed the number approved by the ACC; providing leadership and advice in the maintenance and planning of Facilities; developing a crisis management plan and ensuring facility staff are appropriately trained; acting as a resource person to Animal Users regarding new protocol development; and informing the Dean/Director/Vice-President of concerns that may arise in the discharge of his/her duties. Directors of Animal Facilities may vary in terms of reporting structure and title. Directors of Animal Facilities work closely with the DACUP and Veterinary Services to ensure that animal husbandry, animal health and welfare needs are addressed.

2.2.12 PIs are responsible for designing and carrying out their research, teaching or testing activities in accordance with the Applicable Requirements, which include: ensuring an approved Protocol is in place prior to initiation of work or acquisition of Animals; ensuring Protocols are adhered to; ensuring Research Personnel are appropriately trained; educating Research Personnel in the rationale for and implementation of Applicable Requirements; and ensuring that Research Personnel working under their supervision respect and observe Applicable Requirements.

2.2.13 Academic Staff Members with appropriate expertise are also expected to serve, as may be reasonably required, on the university's animal care and use committees including but not limited to the CAC, ACCs, LAUCs, and the Education Committee.

2.2.14 Research Personnel are responsible for carrying out the care and use of Animals in accordance with Applicable Requirements.

2.3 Protocol Review and Approval

2.3.1 All protocols are received and logged by the animal care coordinator and are distributed to the applicable ACC for review by the full committee at the monthly ACC meeting. "E" category of invasiveness (coi) protocols will be distributed to the applicable ACC only when scientific and ethical merit review is in place.

2.3.2 Following review, Protocols will be assigned a classification that either allows use to proceed or which requires additional input or modification prior to use proceeding. Protocols which allow use to proceed will be assigned one of the following classifications: approved; approved subject to; or provisional approval. Protocols which require additional input or modification prior to use proceeding will be assigned one of the following categories: conditional approval or hold. Protocols found to be ethically unacceptable, will be assigned a category of denied. See below for details on protocol classifications.

Approved: Full approval, no conditions, no requests from the committee/reviewers for clarification or additional information. The PI is issued a protocol number and allowed to begin the research.

Approved Subject to: Minor clarifications and/or additional information is required. The PI is given a protocol number and allowed to begin the project. The PI must respond to the request for minor clarifications/additional information by a specified date.

Provisional Approval: When a protocol is received that is urgent and cannot wait until the next committee meeting for review, it is sent out to the chair, the applicable veterinarian and two primary reviewers which will consist of one scientific member and one community representative. Once the primary reviewers, the chair and the veterinarian are satisfied with the protocol and responses (if applicable) from the PI, it is provisionally approved. The PI is issued a protocol number and is allowed to begin the research. Approval of the application remains provisional until the application is reviewed by the full committee at its next monthly meeting. If the committee is satisfied with the protocol, full approval is then granted. If the committee raises additional concerns or requires additional information, this request is forwarded to the PI who must comply by a specified date.

Conditional Approval: Additional information/clarification is required. The PI does not get a protocol number and may not begin the research. A letter is sent to the PI indicating the concerns of the reviewers/committee. The PI's response to the concerns

is forwarded to the primary reviewers, chair and applicable veterinarian for consideration. When “conditional approval” is granted, the PI’s comments do not need to go back to the full committee. Once all reviewers, the chair, and the veterinarian are satisfied with the PI’s response(s), full approval is granted.

Hold: There are numerous and major concerns with the protocol. The PI does not get a protocol number and may not begin the research. A letter outlining the concerns is sent to the PI. The PI’s response is reviewed by the full committee at the next monthly meeting. The protocol is not approved until the committee agrees that the PI has adequately addressed (in writing) all of the concerns raised by the reviewers/committee. Once all concerns have been adequately addressed, full approval is granted.

Denied: When the protocol is found to be ethically unacceptable or has failed to prove scientific merit. The PI does not get a protocol number and may not begin the research.

2.3.3 An approved Protocol is not to be modified without the written approval of a veterinarian and the Chair of the appropriate ACC. An amendment form must be completed by the Animal User when requesting a minor modification. Major changes would necessitate preparation and submission of a new protocol. Amendments must be approved before protocol changes can be implemented. See the U of M Guideline 002, “Submission of a New Protocol or an Amendment to an Existing Protocol”.

2.3.4 Protocol approvals are valid for one year from the date approved.

2.3.5. Where the Academic Staff Member receives products from Animals but does not dictate or participate in the use, the Academic Staff Member is required to complete an Abbreviated Protocol for Minimal Animal Involvement.

2.4 Collaboration

2.4.1 Where the Academic Staff Member enters into a collaborative project with researchers at another institution (the “host” institution”) and the housing, care and use of Animals occurs at the host institution, a copy of the host institution’s approval letter and approved protocol is forwarded to a sub-committee of the home U of M ACC (home institution) consisting of the chair, a veterinarian and a community representative. The sub-committee of the U of M ACC will then review the protocol to ensure that a comparable review has been conducted. If the home U of M ACC sub-committee has questions or concerns, they will be relayed to the PI and the host ACC chair. The PI will be required to respond to the questions/concerns accordingly. Once all concerns are addressed, the protocol will receive provisional approval pending review by the full U of M ACC at its next monthly meeting. Additional dialogue will occur with the PI and host ACC chair as necessary.

2.4.2 Once the protocol is approved, the U of M ACC will advise the PI and the host institution as follows:

“In the spirit of collaboration, we are accepting of the details provided and are willing to approve the collaboration. Please advise us if any adverse events or unexpected morbidity occurs.”

2.4.3 If there is no ACC or equivalent at the collaborating institution, a U of M ACC will consider the protocol for approval.

2.4.4 When multiple research partners are involved in a field study project, the ACC of the PI will normally take the lead in providing an ethical review of the protocol. Co-PIs are responsible for provision of the reviewed protocol to their home institution, indicating that approval has already been given by the lead ACC. Questions concerning the reviewed procedures from the home ACCs of the co-operators will be directed to the lead ACC for resolution. PIs must ensure that the procedures to be used are ethically acceptable and comply with all legislative and other applicable standards.

2.5 Education and Training

The Education Committee will develop an education program as required by the CCAC.

To ensure Animal Users are competent and thoroughly familiar with the Applicable Requirements, they must participate in the education and training stipulated and provided by the University.

2.5.1 PIs and Research Personnel are expected to complete the Animal User training course prior to initiating Animal use.

2.5.2 PIs and Research Personnel are expected to complete wet labs as required. Requirements are based on experience, the procedures being performed, and requirements of the appropriate ACC. Wet labs are to be completed prior to Animal use being initiated where possible and, in all cases, before unsupervised Animal use is initiated.

2.5.3 Animal Care Facilities Staff must complete the Animal User training course. For newly appointed personnel, a grace period will normally be provided but will not extend beyond 3 months.

2.5.4 Veterinary Services Staff must complete the Animal User training course. For newly appointed personnel, a grace period will normally be provided but will not extend beyond 3 months.

2.6 Post Approval Monitoring

The ACCs, Veterinary Services Staff, Animal Care Facilities Staff and Animal Users currently are responsible for post approval monitoring. The process currently in place is as follows:

2.6.1 Information Acquisition

2.6.1.1 Procedures as described in Protocols to be subjected to post approval monitoring are flagged by the ACC during the Protocol review process and/or by Veterinary Services Staff at any time.

2.6.1.2 Animal Users inform Veterinary Services Staff when procedures that have been flagged for post approval monitoring will be initiated.

2.6.1.3 Facilities are responsible for informing Veterinary Services Staff when Animals have been ordered or requested.

2.6.1.4 Animal Users are responsible for informing Veterinary Services Staff of unexpected signs of pain, distress or mortality of Animals which occur during the Animal use.

2.6.1.5 Veterinary Services Staff are responsible for informing the ACCs of the results of post approval monitoring activities.

2.6.2 Monitoring

2.6.2.1 Veterinary Services Staff monitor flagged or invasive procedures during rounds or in specially arranged meetings.

2.6.2.2 When Animal Care Facilities Staff observe the use of procedures which are not approved in the Protocol, a report is made to the Director of the Facility and/or Veterinary Services Staff for immediate action. The Director of the Facility or Veterinary Services Staff will inform the ACC in a timely manner, usually at the next ACC meeting.

2.6.2.3 Records, such as surgical/anesthesia records and mortality data, are monitored by Veterinary Services Staff on a routine basis for indications of unexpected pain, distress or mortality.

2.6.2.4 The ACCs scrutinize Protocol renewals for indications of unexpected pain, distress or mortality.

2.6.3 Problem Solving

2.6.3.1 Unexpected pain, distress or mortality

2.6.3.1.1 In cases where information from direct communications, records or protocol renewals indicate procedures may be causing higher than expected levels of pain, distress or mortality, a veterinarian (or designate) meets with the Animal User(s) to assess/rectify the problem.

2.6.3.2 Noncompliance

2.6.3.2.1 In the first instance of noncompliance, the ACC Chair or a veterinarian meets with the Animal User(s). Education and assistance is the focus of this discussion.

2.6.3.2.2 In cases of repeated noncompliance or serious non-compliance, 2.11 Non-Compliance, is followed.

2.7 Peer Review

2.7.1 To ensure that use of Animals is undertaken only in necessary and valid projects, all projects must be evaluated for scientific or instructional merit. The majority of projects undergo peer review for scientific merit by the sponsor, e.g., proposals to national granting councils/agencies. In cases where the sponsor does not use adequate peer review to assess the quality of the proposed research, the proposal must be independently peer-reviewed and recommended, with documentary evidence of that review submitted to the ACC.

2.7.2 The AVPR is responsible for establishing a mechanism for assessing the scientific/instructional merit of those projects that are not subject to recognized peer review by a sponsor, e.g., a national granting council/agency. The mechanism established must involve at least two persons capable of an independent and critical assessment of the proposed use. The mechanism must be approved by the CAC.

2.8 Animal Acquisition, Housing and Disposal

2.8.1 An approved Protocol is required before Animals may be purchased, bred or otherwise brought into Facilities or Off-site Housing or used in the field.

2.8.2 Arrangements for Animal acquisition and housing must be made in accordance with Facility requirements. The approval of a Protocol or the authorization of research funding is no guarantee that the University will be able to breed or acquire, house and care for the Animals specified. If, at the time the use is to be undertaken, the capacity of the Facilities is otherwise fully utilized, the use may have to be modified or rescheduled.

2.8.3 All Animals must be procured, transported and received according to CCAC Guidelines on: procurement of animals used in science. In order to comply with these guidelines, the following must be adhered to:

2.8.3.1 For Animals caught in the wild or donated to the University, the veterinarian must receive prior notification and approve receipt of the Animals. All Animals that are wild and are acquired by the University must be obtained and transported in compliance with all applicable wildlife, transport of exotic biota and endangered biota regulations in the jurisdiction of origin, as well as in Canada and Manitoba.

2.8.3.2 Animals to be acquired through suppliers who are either new suppliers to the University or with whom the University has had prior problems, must be inspected by a veterinarian or a designate preferably prior to shipping but before acceptance.

2.8.3.3 An Animal acquisition letter of agreement must accompany Animals upon arrival from sources which do not sell purpose bred Animals.

2.8.4 Animals must be housed in Facilities or at Off-site Housing which are inspected annually by an ACC and approved by the CAC and are in compliance with Applicable Requirements.

2.8.4.1 Off-site Housing is not normally allowed due to the difficulty of monitoring the health and welfare of Animals, husbandry practices, research procedures and Protocol adherence. Exceptions to this may be granted by the ACC if scientific justification is provided.

2.8.4.2 In cases where Off-site Housing has been approved, the Animal User must either: a) comply with requests from the ACC for information regarding the physical nature of the site, methods of Animal husbandry, handling and capture, housing and/or procedures and the Off-site Housing must agree to an inspection by the ACC when requested or; b) provide assurance that the site has a CCAC Good Animal Practice certificate or equivalent. If the Off-site Housing is outside of Canada, a description of the practices and or the name of the agency that assures Animal welfare may be required.

2.8.5 Wherever possible, all procedures on live Animals should be conducted in Facilities. The amount of time Animals are held in laboratories must be minimized and must not exceed 24 hours. Animals cannot be held outside Facilities without ACC approval. Laboratories in which live Animals are held must be inspected annually by the appropriate ACC.

2.8.6 All breeding colonies will normally be managed by the respective Animal Care Facilities Staff in order to manage breeding colony production, ensure transparency and maintain accurate Animal usage records.

2.8.6.1 The ACC may approve breeding colony management by an Animal User who provides adequate scientific justification. Normally, this would occur only when the breeding itself is an integral part of the research procedures.

2.8.7 Disposition of animals must follow the approved disposition as indicated in section 13D of the approved Protocol.

2.8.7.1. Disposition of animals to another institution for purposes other than research or teaching must be approved by the DACUP and an Animal Transfer Agreement must be completed prior to the transport of the animals. The DACUP will provide health documentation for the animals if requested by the receiving institution. The DACUP will notify the applicable ACC of the disposition of the animals.

2.8.7.2 It is regular practice that agricultural/food animals healthy at the end of a research or teaching program (accounting for drug withdrawal times) are sent for slaughter or sold through the regular channels and are processed for human consumption. Animals that have a market value, or where transfer to a new owner represents no threat to public or animal health or welfare or to the integrity of the University, may be sold at fair market value. Agricultural animals are allowed to move without a transfer agreement.

2.8.7.3. The practice of selling healthy agricultural / food animals to be used for meat or other products is not affected by this policy outlining the adoption of healthy research animals as companion pets.

2.8.7.4 Disposition of animals to individuals for adoption will follow the *U of M Procedure for Adoption of Animals Used in Research and Teaching*.

2.9 Authority to Terminate Animal Use

2.9.1 Veterinarians and the DACUP have the authority to: stop any objectionable procedure if it is considered that unnecessary distress or pain is being experienced by an Animal; stop immediately any use of Animals which deviates from the approved use, any non-approved procedure, or any procedure causing unforeseen pain or distress to Animals; and humanely kill an Animal if pain or distress caused to the Animal is not part of the approved Protocol and cannot be alleviated. veterinarians also have the authority to treat, remove from a study or euthanize an Animal, if necessary.

2.9.2 In addition, ACC chairs, or their designates, in consultation with a veterinarian or the DACUP, have the same authority as noted in 2.8.1.

2.10 Appeal of Protocol Review Decisions

2.10.1 An appeal of a decision to reject a Protocol shall be made to the DACUP.

2.10.2 The appellant and the ACC Chair will be invited to meet with the DACUP in order to either 1) resolve the outstanding issues or 2) clearly document the issues of disagreement between the ACC and the appellant.

2.10.3 If the ACC Chair and the appellant, in consultation with the DACUP, are unable to come to an acceptable resolution of the differences, the DACUP will refer the appeal, complete with the documented issues, to the CAC Chair, who with the advice and approval of the CAC, will establish a sub-committee of three members to hear the appeal and recommend to the CAC.

2.10.4 In such cases, both the appellant and the Chair of the applicable ACC shall be given an opportunity to appear before the appeal sub-committee.

2.10.5 The decision of the CAC shall be final and binding.

2.11 Non-Compliance

2.11.1 Instances of non-compliance with the Policy or these Procedures shall be brought to the attention of the Chair of the appropriate ACC and the DACUP for documentation and resolution.

2.11.2 If a resolution is not reached or the problem recurs, the DACUP shall advise the Chair of the CAC who shall attempt to obtain a satisfactory resolution through the appropriate Dean/Director.

2.11.3 Serious instances of noncompliance or repetitive breaches in Policy and Procedures shall be forwarded by the CAC Chair to the Vice-President (Academic) and Provost for disposition.

Part III Accountability

3.1 The Office of Legal Counsel is responsible for advising the Vice-President (Research and International) that a formal review of this Procedure is required.

3.2 The Associate Vice-President (Research) is responsible for the implementation, administration and review of this Procedure.

3.3 The Vice-President (Research and International) is/are responsible for complying with this Procedure.

Part IV Review

4.1 Governing Document reviews shall be conducted every ten (10) years. The next scheduled review date for this Procedure is June 2029.

4.2 In the interim, this Procedure may be revised or repealed if:

- (a) the Vice-President (Research and International), in consultation with the Senate Committee on University Research, or the Approving Body deems it necessary or desirable to do so;
- (b) the Procedure is no longer legislatively or statutorily compliant;
- (c) the Procedure is now in conflict with another Governing Document; and/or
- (d) the Parent Policy is revised or repealed.

Part V
Effect on Previous Statements

5.1 This Procedure supersedes all of the following:

- (a) Care and Use of Animals Procedure, revised July 2, 2013 (previous versions revised December 3, 2008 and June 2, 1999);
- (b) all previous Board of Governors/Senate Governing Documents on the subject matter contained herein; and
- (c) all previous Administration Governing Documents on the subject matter contained herein.

Part VI
Cross References

6.1 This Procedure should be cross referenced to the following relevant Governing Documents, legislation and/or forms:

- (a) Animal Care and Use Policy;
- (b) Animal Transfer Agreement;
- (c) Animal Use Protocol Form;
- (d) Composition and Terms of Reference for the Animal Care Committees
- (e) Composition and Terms of Reference for the Committee on Animal Care
- (f) Composition and Terms of Reference for the Education Committee
- (g) Composition and Terms of Reference for the Infrastructure Planning Committee
- (h) U of M Guideline 001, "Adoption of Animals Used in Research and Teaching"

- (i) U of M Guideline 002, "Submission of a New Protocol or an Amendment to an Existing Protocol".