**Application Guidelines**

Before you begin the application process to receive ethical clearance from the MacEwan University Animal Research Ethics Board (AREB), researchers are responsible for reading *MacEwan University Policy on Animal Research Ethics*, relevant AREB *Standard Operating Procedures* (SOPs), and all relevant *Canadian Council on Animal Care Policy Statements and Guidelines*.

# Types of Animal Use Projects Requiring AREB Approval

The use of sentient animals in teaching, training or research require approval from the AREB. Sentient animals are defined by the Canadian Council on Animal Care ([CCAC](http://www.ccac.ca/en_)) as cephalopods (e.g., octopus, squid, cuttlefish or nautilus) and vertebrates. Any and all work with these species requires AREB approval if the animal depends on an external food source for survival. This means that while research with fish requires approval (because fish are vertebrates), work with fish eggs does not require approval (because fish eggs do not require an external food source).

In cases where a researcher is employed at MacEwan University and uses animals housed at another location (e.g., another university), or studies wildlife in the field in collaboration with the primary investigator on the project, the primary ethics approval should be sought from the other institution or from an ethics committee that oversees the field station where wildlife is studied (if applicable). For more information about animal research collaboration procedures, please see *SOP 113 – Animal Based Research Collaboration*.

If you have any questions about whether your project will require approval, please contact areb@macewan.ca

## **Proposal Preparation: Time-frame & Pre-application Requirements**

There are several steps involved in obtaining ethical approval for animal use for research, teaching or testing at MacEwan University. Please note that no animals may be purchased, brought onto campus or bred for research or teaching purposes before a project is approved. It is **the responsibility of the investigator** to allow sufficient time for review in advance of the anticipated project start date. Time frame considerations include the following:

1. **Scientific or Pedagogical Merit Peer Review:** Before your application can be reviewed by the AREB, it must first undergo a merit review. If your project has not been reviewed by an external funding agency, it will need to be arranged through Research Services and generally takes between 2 and 4 weeks. For more information, please see *SOP RS 101 – Scientific Merit Peer Review Process* or *SOP RS 102 – Pedagogical Merit Peer Review Process*.
2. **Animal User Training Part I:** All researchers involved in an animal user protocol (including student researchers) must complete the MacEwan University AREB Animal User Training: Part I prior to beginning any animal research. The course can be accessed in Blackboard, under Self-Enroll Courses. Training is valid for a period of 5 years. Applications received by the AREB with involvement from animal users who have not completed the training will be not receive approval until the training is completed. Please expect completion of the course to take between 3-5 hours.
3. **Animal User Training Part II:** All researchers who will be handling animals must also complete Animal User Training: Part II. This hands-on training can be scheduled with the Animal Care Technician by emailing AREB@macewan.ca
4. **Submission Completeness:** Proposals that lack required items or that do not provide sufficient detail for review will be returned to the researcher for completion and resubmission. If additional information or updates are required, your application will be delayed until this information is received. When the additional information or updates are received, or if no additional information or updates are required, your application will be processed and scheduled to be reviewed at the next AREB meeting.
5. **Ethical Complexities:** Proposals involving ethical issues that necessitate further consideration may require time for consultation, revision and/or committee discussion at more than once scheduled meeting.

It is strongly recommended that researchers consult with the University Consulting Veterinarian when drafting new Standard Operating Procedures and before their protocol is submitted to the AREB. This consultation process should address any minor issues are before the application goes for ethical review, thus reducing possible time delays. This consultation can be arranged by emailing AREB@macewan.ca.

1. Application Preparation

Note that the initial application process and all subsequent management of your application is done using the ROMEO system.

New Projects:

* All new applications for animal **research** must be submitted using the
*Animal Use Protocol (AUP): Research Application Form.*
* All new applications for animal use in **teaching or display** must be submitted using the *Animal Use Protocol: Teaching/Display Application Form.*

**For all new research, teaching or display projects, please complete and attach the following:**

* An *Animal User Training: Part I certificate of completion* from Blackboard.
* An *Animal User Training: Part II - Evidence of Training Form* for all researchers (including students) listed on the protocol. This form is used to track local orientation to the project and research/teaching site for each investigator and should include details of the specific training related to the project that all lab and animal care personnel have received.
* *AREB Standard Operating Procedure Form (SOP) Form(s)*. This form should be used for each standard operating procedure that takes place within the project, as well as for all lab maintenance, cleaning, etc. More information about development and submission of SOPs can be found in *SOP 112 – Development and Submission of Project Specific SOPs*.
* If it can reasonably be expected that animals in the study might experience sickness, pain, distress, or suffering at any point during the research project, please also submit a copy of your *Endpoint Monitoring Checklist.*

Note that the checklist does not only have to apply to humane euthanasia, but can also be used to identify behaviours (ie. stress, aggression etc) that would lead to a study being stopped.

**Please ensure that you have attached all the required supporting materials and forms.**Your application will be returned to you for completion, if all the above criteria are not met.

**2. Review Process**

**Scientific or Pedagogical Merit Peer Review**

* If scientific or pedagogical merit peer review has not already been obtained through an external funding agency, it must undergo scientific or pedagogical merit peer review through the MacEwan University Research Office, as per CCAC requirements. Please see SOPs *RS 101 – Scientific Merit Peer Review Process* or *SOP RS 102 – Pedagogical Merit Peer Review Process* for details.

**AREB Review**

* Once the AREB has received confirmation of peer merit or pedagogical review from the Research Office and a preliminary review has been completed, your application will be reviewed at the next scheduled AREB meeting by the full committee.

For more information about the submission guidelines, please see *SOP 100 – Submission of Applications for Ethical Review.*

3. AREB Review of Proposals

For a detailed description of the process involved in AREB review of proposals, please see *SOP 103 – Ethical Review of Applications*

Following consideration of an application, the AREB will make one of the following decisions:

* Full Approval – the project is approved as submitted
* Conditional Approval – the project will be approved when AREB outlined conditions are met (e.g., clarifications, modifications)
* Deferral – the decision on the application will be deferred in cases where insufficient information is available to arrive at a decision or if the AREB recommends extensive revisions
* Rejection – the project is rejected due to not meeting the standards for ethical practices set out by the CCAC and/or University policies.

If your application has been approved, you will receive a signed and dated approval letter, indicating that you have been granted ethical approval for a period of one year (after which your project may be renewed).

If your application has been conditionally approved pending clarification of information, provision of further information, or requested changes, please submit the requested information and/or changes to the AREB within 30 days. In most cases, the Chair alone will approve the protocol following the outlined changes.

If your application has been rejected and you wish to appeal, please *see SOP RS 111: Appeals of AREB Decisions*.

4. Post-Approval Management of your Study

1. **Renewal of Previously Approved Projects**

AREB approval is valid for one year. To renew your research or teaching/display project, you must submit the corresponding Animal Use Protocol renewal form in ROMEO. Note that all projects may be renewed up to three times after approval of the original application. Projects continuing after 4 years will require the resubmission of a new application, including conducting scientific or pedagogical merit review.

1. **Modifications to Previously Approved Projects**

For previously approved projects requiring MINOR modifications, please submit the *Modification Form* (minor modifications defined as changes that do not have significant effects on the safety or well-being of animals or researchers. E.g., the addition of 1 or 2 trained animal users, the addition of less than 10% the total animals, or changing housing or procedure locations.

For previously approved projects requiring modifications not outlined above or in *SOP 105 – Animal Use Protocol (AUP) Modifications and Renewals*, please submit a new protocol application.

1. **Incident Reporting**

Following the approval of a project, it is important for animal users to continue to communicate with the AREB and the University Consulting Veterinarian. The AREB requires investigators to immediately report anything that may warrant protocol review including proposed amendments to protocols and unforeseen events that might affect animal welfare. For more information about incident reporting and resolution reporting, please see *SOP 303 – Incident Reporting and Resolution: Animal Welfare, Morbidity and Mortality.*

All animal related incidents and resolutions must be reported to the AREB Chair as soon as possible using the AREB Event Report and Resolution Form.

Additionally, the AREB requires, as a conditional of approval for each project, that investigators inform the AREB if the research project is discontinued before the expected date of completion.

1. **Post-Approval Monitoring (PAM)**

The AREB is responsible for monitoring all approved projects to ensure compliance with the guidelines and protocols set out in the Animal Use Protocol (AUP), and compliance with federal, provincial, and Canadian Council on Animal Care (CCAC) guidelines.

The AREB conducts minimally:

* One (1) site visit per year to animal facilities
* Two (2) veterinarian site visits per year to the animal facilities
* One (1) protocol audit per year, per protocol

For more information, see *SOP 106: Post Approval Monitoring – General*.

PAM: Site Visits

Site Visits will be scheduled in consultation with the researcher(s); however, a site visit may also occur unannounced at any time, particularly if a report of non-compliance with animal procedures has been received.

Site visits are conducted to inspect animal housing conditions, procedures, environmental conditions, animal care and management practices such as health monitoring, environmental enrichment, biosafety procedures and animal care and use record.

The Principle Investigator (PI) and all animal users and project personnel involved with the animal use protocol should be present for the visit.

Following the site visit, the PAM liaison will provide you with written feedback within eight (8) working days.

For more information, see *SOP 107 – Site Visits.*

PAM: Veterinarian Site Visits

The AREB veterinarian has unlimited access to animal facilities and makes a site visit minimally twice per year.  Veterinarian site visits will include a review of maintenance of appropriate environmental conditions, animal care and management practices such as health monitoring, environmental enrichment, biosafety procedures and animal care and use records.

Veterinarian site visits are typically unannounced.  In cases where the site visit has been arranged with the PI/animal user, the veterinarian will contact the PI/animal user directly and arrange the visit.

Following the veterinarian site visit, the veterinarian will provide the AREB Chair with a written report of visit recommendations, commendations and non-compliance issues.

For more information, see *SOP 107: Site Visits.*

PAM: Protocol Audits

All AREB approved protocols are subject to a minimum of one (1) protocol audit per year.  More frequent protocol audits may be done for protocols classified as CCAC Categories of Invasiveness C, D and E.  Initiation of a protocol audit may also occur at any time if a report of non-compliance with animal procedures has been received.

Protocol audits are conducted to review of the protocol and compare of the protocol content to what is observed in the animal housing/testing area(s), and are also conducted in the field, when possible. When a visit to a field site is not possible, researchers may be asked to attend and AREB meeting to demonstrate procedures or share pictures of their field set-up.

 For more information, see *SOP 108: Protocol Audits*.

PAM: Non-Compliance

All compliance concerns should be undertaken in a collaborative and collegial manner that is supportive of animal-based research while ensuring appropriate and timely issue resolution.  Communication must be professional and based on mutual respect and trust between individuals.

Compliance concerns will be addressed according to their classification (procedural or ethical).  See *SOP 109: Non-Compliance and Response*, for descriptions and specific response actions.

# 5. Animal Based Research Collaboration

If you are looking to collaborate with a researcher from another institution, and the research is taking place at another institution, the AREB requires you to complete a collaboration request form in ROMEO for AREB review. You must submit the approved AUP from the host institution that shows you have been added to the project, along with the approval letter and the contact details for the host Animal Care Committee.

The AREB will review the documentation to ensure that it meets the committee’s normal standards and does not contravene any institutional policies on animal care and use. The AREB can then approve the protocol, conditional to its approval by the host institution’s ACC.

**6. Ongoing Review**

After initial approval has been issued for the project, it is the researchers’ responsibility to ensure the AREB is kept up to date with any revisions to the project by submitting a modification for review BEFORE they are implemented.

Project renewals must also be submitted in a timely manner; regular renewals (projects in year 1 to year 3) should be submitted at least 6 weeks ahead of the project expiry date.

For full project renewals (year 4), a request for merit review should be submitted to Research Services 12 weeks ahead of the project expiry date, and a new protocol submission should be received 8 weeks in advance of the expiry date to ensure full board review and approval ahead of the expiry date.

For questions regarding the application process, training or consultations, please email AREB@macewan.ca.