

SOP:	103.8	Ethical Review of Applications
Version Date:	10-2024	
Review By:	10-2027	
Subject:	To describe the AREB review process for all animal research, testing, and teaching applications.	
Related Documents	SOPs RS 101; RS 102	

Depending on the nature of the request, a submission to the Animal Research Ethics Board (AREB) may take one of two pathways: full board review, or delegated subcommittee review.

Full Board Review

1. The AREB will review all new protocols, protocols that are subject to full review after three consecutive annual renewals, major modifications that significantly alter the approved protocol, and annual review of all ongoing protocols that are CCAC Category of Invasiveness “D” or “E”.
2. The AREB will consider a complete application at its next scheduled meeting if it is received by midnight on the submission closing date listed on the Office of Research Services website.
3. The application will be reviewed by a majority of the voting members, which must include minimally: the AREB Chair or Vice-Chair, the Consulting Veterinarian, one (1) community representative, and one (1) member with relevant expertise.
4. If the animal-based study group under review is not represented in AREB membership, the AREB will ensure representation of the group during protocol discussions. This may include, but is not limited to, inviting the Researcher to participate in the discussion portion of the review, or include an ad-hoc reviewer with expertise in the animal group in the review process.
5. If a member of the AREB is an investigator, co-investigator, supervisor, or has a relationship with the investigator resulting in a real or perceived conflict of interest, they must disclose this to the AREB Chair and may not participate or be present during the review of the application. If the AREB Chair is an investigator, co-investigator, supervisor, or has a relationship with the investigator resulting in a real or perceived conflict of interest, the Chair may not participate or be present during the review of the application, and the Vice-Chair will chair the review.
6. The AREB will assess each application in accordance with CCAC guidelines. The AREB must ensure that it is sufficiently informed on all aspects of the research protocol to make an ethical assessment.
7. The AREB must consider each section of the application and assess:

- a. Whether the project will achieve its aims;
 - b. Whether it is essential that animals be used for the project;
 - c. Whether the investigator has explored all animal alternatives (i.e., replacement, reduction, and refinement of animal use);
 - d. Whether the investigator has the skills to complete the project successfully as given evidence by proof of training and experience;
 - e. Whether the level of invasiveness, including housing and handling, of animals is appropriate;
 - f. Whether the endpoint(s) are appropriate.
8. The AREB will consider the views or opinions provided by peer merit reviews (see SOPs RS 101 and RS 102) in protocol reviews.
 9. The AREB may consider whether pre-authorizations, reviews, or applications have been received or submitted for protocols, e.g., hazardous materials, veterinary review, licenses and permits, etc.
 10. The AREB will seek to reach a decision concerning ethical acceptability of a proposal by consensus. If a consensus is not reached, the members will vote on a decision and the majority vote will be accepted. If the Consulting Veterinarian votes against the decision to pass the application because of animal health concerns, they will have the right to veto the consensus or the majority vote.
 11. AREB discussions and decisions, including any major concerns and considerations of all members, will be noted in the minutes, without identifying specifically the committee member whose concern it was, regardless of the AREB final decision.

Delegated Subcommittee Review

1. Annual review of ongoing protocols that are CCAC Category of Invasiveness “A”, “B” or “C” that are not proposing major changes to the protocol will be reviewed by a subcommittee of the AREB consisting minimally of the AREB Chair or Vice-Chair; the Consulting Veterinarian; one (1) community representative; and one (1) member with relevant expertise.
2. In exceptional circumstances, new protocols or fourth year renewals may undergo delegated subcommittee review consisting minimally of the AREB Chair or Vice-Chair; the Consulting Veterinarian; one (1) community representative; and one (1) member with relevant expertise. In these circumstances, this interim approval would require final approval by AREB review at the next scheduled meeting.

3. If the animal-based study group under review is not represented in AREB membership, the review subcommittee will ensure representation of the group by including an ad-hoc reviewer with expertise in the animal group in the review process.
4. Complete protocols for delegated subcommittee review will be sent to the protocol review subcommittee within five (5) business days of receipt.
5. If a member of the AREB is an investigator, co-investigator, supervisor, or has a relationship with the investigator resulting in a real or perceived conflict of interest, the member must disclose this to the Chair and may not participate in the review of the delegated application.
6. The AREB delegated subcommittee reviewers will provide Animal Care & Ethics Staff with electronic feedback on the application within five (5) business days of receipt.
7. The review process, including committee feedback and exchanges between the AREB and the protocol authors, will be documented in the online review platform, and assigned to the AREB Chair for review.

Review Decisions

Upon making its decision, the AREB will inform the applicant of its decision in writing within five (5) business days of the receipt of feedback, unless otherwise notified:

- a. Full Approval: The project is approved as submitted. Research may begin as soon as the AREB Approval Letter is received, provided that all other institutional requirements have been met. The period of approval will commence on the day the letter is sent and will expire within one (1) year of the approval date.
- b. Interim Approval: For delegated reviews of fourth year renewals or new protocols, the project may be approved by a subcommittee, pending final AREB approval at the next full board meeting. Research may begin as soon as the initial Letter of Approval is issued, provided that all other institutional requirements have been met. Following AREB approval at the next full board meeting, the final AREB Letter of Approval will be sent to the PI.
- c. Conditional Approval: The AREB may decide that an application be approved provided certain conditions are met or required changes are made. A written explanation of the conditions and/or modifications is sent electronically to the Principal Investigator (PI). Where appropriate, the communication will include written reasons for the required modifications. When the PI provides the AREB with evidence that the conditions have been met and the documents have been amended, the Chair (and any additional members deemed necessary at the time of review) confirms the revisions and the Letter of Approval will be sent. The period of approval will commence on the day the letter is sent and will expire within one (1) year of the approval date. If proof that the conditions have

been met and documents have been amended has not been received by the AREB within ninety (90) days, the application will be dismissed, and the applicant will be required to re-submit for review later.

- d. Deferral: The AREB may defer a decision on any submitted research application if it does not have sufficient information to arrive at a determination or if the AREB recommends extensive revisions to any part of the research. The application will be brought back before the full board for consideration after the initial information or revisions are received. If a revised application has not been received by the AREB within ninety (90) days, the application will be dismissed, and the applicant will be required to re-submit the application for review later.
 - e. Rejection: The AREB may reject any protocol that does not meet the standards for ethical practices set out by the CCAC guidelines and/or university policies and where revision is unlikely to enable the AREB to reach a determination. A researcher may request reconsideration of a decision made by the AREB and has the right to appeal the decision pursuant to the provisions in RS SOP 111 and MacEwan University Policy '*Animal Research Ethics*'.
12. The AREB will inform the applicant of its decision in writing within five (5) business days of the meeting at which the application was reviewed, unless otherwise notified.

Approval Letters

13. The AREB Approval Letters must include minimally the following:
- a. The AREB reference number;
 - b. The name of the applicant;
 - c. A statement indicating that the decision of the subcommittee is not final, and is pending AREB approval (for new protocols and fourth year renewals reviewed by delegated subcommittee review), if applicable;
 - d. The date of the meeting at which the application was reviewed, or, for delegated reviews, the date of the meeting at which the application will be reviewed;
 - e. The duration of the approval, or if approval has been deferred, when final approval may be granted;
 - f. Information about any required follow-up reporting requirements (e.g., incident reporting, project closure, etc.).

8. Notification of AREB rejection must include grounds for rejecting the project with reference to CCAC requirements or other relevant guidelines and/or legislation.

Previous Versions

SOP Number	Date Effective	Summary of Changes
103.0	03-2011	
103.1	12-2011	
103.2	05-2012	
103.3	01-2014	
103.4	11-2016	Administrative edits.
103.5	10-2019	Clarification to interim approvals.
103.6	08-2020	Requirements to ensure relevant animal groups are represented during protocol discussions and review
103.7	10-2021	Revisions to better streamline the document and reduce redundancies
103.8	10-2024	Vice-Chair position.