|  |  |  |
| --- | --- | --- |
| **SOP:** | **103.5** | **Ethical Review of Applications** |
| **Version Date:** | 10-2019 | |
| **Review By:** | 10-2022 | |
| **Subject:** | To describe the AREB review process for all animal research, testing, and teaching applications. | |
| **Related Documents** | SOPs RS 101; RS 102 | |

**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 Research Services website.
3. The application will be reviewed by a majority of the voting members, which must include: minimally, the AREB Chair or designate, the Consulting Veterinarian, one (1) community representative, and one (1) member with relevant expertise.
4. 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, he/she 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, he/she may not participate or be present during the review of the application, and another AREB member will be selected to chair the review.
5. 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 in order to make an ethical assessment.
6. The AREB must consider each section of the application form and assess:
   1. Whether the project will achieve its aims;
   2. Whether it is essential that animals be used for the project;
   3. Whether the investigator has explored all animal alternatives (i.e., replacement, reduction, and refinement of animal use);
   4. Whether the investigator has the skills to complete the project successfully as given evidence by proof of training and experience.;
   5. Whether the level of invasiveness, including housing and handling, of animals is appropriate;
   6. Whether the endpoint(s) are appropriate.
7. The AREB will take into account the views or opinions provided by peer reviews (see SOPs RS 101 and RS 102) in protocol reviews.
8. The AREB may take into account whether pre-authorizations, reviews, or applications have been received or submitted for protocols, e.g., hazardous materials, veterinary review, licenses and permits, etc.
9. 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, he/she will have the right to veto the consensus or the majority vote.
10. Following consideration of a proposal, the AREB will make one of the following decisions:
    1. 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.
    2. 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 at a later date.
    3. 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 at a later date.
    4. 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 C5053.
11. AREB discussions and decisions, including the 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.
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.
13. The AREB Approval Letter must include minimally the following:  
    1. The AREB reference number;
    2. The name of the applicant;
    3. The date of the meeting at which the application was reviewed;
    4. The duration of the approval;
    5. Information about any required follow-up reporting requirements (e.g., incident reporting, project closure, etc.).
14. Notification of AREB rejection must include grounds for rejecting the project with reference to CCAC requirements or other relevant guidelines and/or legislation.

**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 designate; 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 designate; 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. Complete protocols for delegated subcommittee review will be sent to the protocol review subcommittee within five (5) business days of receipt.
4. 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, he/she must disclose this to the Chair and may not participate in the review of the delegated application.
5. The AREB delegated subcommittee reviewers will provide the Research Ethics Officer with electronic feedback on the application within five (5) business days of receipt.
6. The Research Ethics Officer will document the review process, including all exchanges between the AREB and the protocol authors, compile the feedback and electronically send it to the AREB Chair for review.
7. After receiving the feedback from the AREB delegated subcommittee, the Chair will make one of the following determinations:
   1. Full Approval Pending Final AREB Review: The project is approved as submitted, pending final AREB approval at next full board meeting. Research may begin as soon as the AREB Letter of Approval Pending Final AREB Review is received, provided that all other institutional requirements have been met. Following final AREB approval, the final AREB Letter of Approval will be sent to the PI. The period of approval will commence on the day the Full Approval Pending Final AREB Review Letter is sent and will expire within one (1) year of the approval date.
   2. Conditional Approval: The AREB Chair 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 PI. Where appropriate, the communication will include written reasons for the required modifications. When the PI provides the Chair with evidence that the conditions have been met and the documents have been amended, the Chair confirms the revisions and the Letter of Approval Pending Final AREB Review will be sent. Following final AREB approval, the final AREB Letter of Approval will be sent to the PI. The period of approval will commence on the day the Full Approval Pending Final AREB Review 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 at a later date.
   3. 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 delegated subcommittee or a 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 at a later date.
   4. 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.
8. Upon making its decision, the AREB will inform the applicant of its decision in writing within five (5) business days of the receipt of delegated subcommittee feedback, unless otherwise notified.
9. The Approval Pending Final AREB Review Letter must include minimally the following:  
   1. The AREB reference number;
   2. The name of the applicant;
   3. The date of the delegated review;
   4. A notification that the decision of the subcommittee is not final and is pending final AREB approval;
   5. The date that the final review is to take place.
10. The Final AREB Approval Letter must include minimally the following:  
    1. The AREB reference number;
    2. The name of the applicant;
    3. The date of the meeting at which the delegated application and decision was reviewed;
    4. The duration of the approval;
    5. Information about any required follow-up reporting requirements (e.g., incident reporting, project closure, etc.).
11. 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. |