

GENERAL INFORMATION AND PROCEDURES BIONICS INSTITUTE ANIMAL RESEARCH ETHICS COMMITTEE (AREC)

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Introduction

For all animal research, ethical review is required and you need to complete and submit a full application to the Bionics Institute Animal Research Ethics Committee (AREC) for approval. ***The research must not commence before ethical approval has been granted.***

Failure to conduct research according to an approved study protocol risks researchers' legal indemnity, right to publication, opportunity to seek future funding, and may constitute a breach of the [Australian Code for the Responsible Conduct of Research](#) (the Code) or research misconduct as defined by the Code.

1. Role and membership of the committee

The AREC meets on a quarterly basis and considers applications for all animal experimentation projects to be conducted at the Bionics Institute (BI) and the Royal Victorian Eye and Ear Hospital. *Every research project involving the use of animals at these institutions must be approved by the AREC before the project can begin.* This requirement applies to pilot studies as well as to definitive projects.

The composition and activities of the AREC are governed by its Terms of Reference (see [BI AREC webpage](#)) and carried out in accordance with the '[Australian code for the care and use of animals for scientific purposes](#)', 8th edition (2013) and the '[Prevention of Cruelty to Animals Act](#) (1986) (POCTA). It is a multi-disciplinary committee which meets to consider all proposed research projects to ensure the research has scientific merit and is ethical.

Membership of the committee consists of:

- A senior representative from the Bionics Institute (Chair);
- At least one person from each of the four categories of membership (as listed below): A person with qualifications in veterinary science and with experience relevant to the activities of the institution (Category A)
- A suitably qualified person with substantial recent experience in the use of animals in scientific or teaching activities (Category B)
- A person with demonstrable commitment to, and established experience in, furthering the welfare of animals, who is not employed by or otherwise associated with the institution, and who is not involved in the care and use of animals for scientific purposes (Category C)
- A person who is both independent of the institution and who has never been involved in the use of animals in scientific or teaching activities (Category D)

Persons responsible for the routine care of animals from within the institution also attend meetings.

2. Applications [\[home\]](#)

To submit an application, download and complete the '**Project application**' form available on the [BI AREC webpage](#). To ensure you are using the latest version of the template forms, please download the document directly from this webpage each time you prepare a new application.

You will need to submit one electronic copy of the complete application plus one original signed copy. In addition to the application form, a '**Researcher's Declaration**' form (available on the [BI AREC webpage](#)) must be submitted for all researchers listed on the application.

A '**Personnel Approval**' form (available on the [BI AREC webpage](#)), along with a current CV, must be submitted by new researchers when they are named on an AREC application for the first time. When a researcher joins an already approved project, the original form and a current CV should be submitted to the Research Office (see also 'Amendments and modifications' below). In both cases, this form only needs to be submitted once.

As a general rule it is expected that anyone handling live animals, with the exception of animal technicians performing their regular animal husbandry duties, will be named as a member of the research team. An animal technician who has technical or intellectual input into a research project should be named as an investigator. Investigators who have not previously had projects approved by the committee are strongly advised to show a proposed application to one of the category B members or the Chair of the AREC prior to submission.

Researchers are advised that it is essential to present the project in terms which will be understood by a *lay person*.

Before you submit your application, please note the following requirements:

- The Principal Investigator (PI) should be an experienced researcher who is suitably qualified and able to take responsibility for all aspects of the proposed study (research higher degree students *may not* be the PI on an ethics application).
- If the application is not complete or if necessary supporting information is not provided, *the application will be returned to the PI*.
- The application, Researcher's Declaration form/s, and Personnel Approval form/s (if applicable) must be signed by all parties prior to submitting.
- The application must be lodged no later than the submission close date for the next AREC meeting (see [BI AREC webpage](#) for meeting schedule).
- All correspondence from the AREC Secretariat will be forwarded to the PI. The PI is responsible for retaining a complete record of the application, the approval letter, and all subsequent reports to, or correspondences with, the AREC Secretariat.

3. Fieldwork [\[home\]](#)

Occasionally a procedure may require the use of a location not listed on the 'Scientific Procedures Premises Licence' (SPPL)¹ or at an unapproved premise: this is termed 'fieldwork'. The AREC must be notified if this applies to your project; therefore you must contact the [Research Office](#) to discuss *before* you submit an application. This is necessary since the AREC must forward details of a fieldwork project to the Department of Economic Development, Jobs, Transport & Resources (DEDJTR), (refer to their [website](#) for further information).

4. Consideration and review of ethics applications [\[home\]](#)

The AREC Secretariat will send the Principal Investigator an invitation to attend the meeting if a new application and/or amendment to an existing project is to be considered. It is not compulsory to attend but it is encouraged and may facilitate more rapid resolution of any issues raised by the committee.

5. Notification of decisions [\[home\]](#)

PIs will be notified usually within 10 working days of the meeting. Ethical approval can be granted for up to 3 years. An approval letter is sent to the PI for each approved project application. This letter must be retained by the PI.

6. AREC Fees [\[home\]](#)

Fees apply to commercially funded and initiated studies. Any commercial or patentable information within the application should be marked 'commercial-in-confidence'. For current fees, please refer to the [BI AREC webpage](#).

Cheques should be addressed to the Bionics Institute 384-388 Albert St, East Melbourne VIC 3002 with accompanying documentation quoting the invoice number.

Tax invoices for AREC review fees will be sent by the BI directly to sponsors/public health bodies following submission of applications.

¹ A 'Scientific Procedures Premises Licence' (SPPL) authorises the use of facilities for scientific procedures. Scientific premises are listed on the licence and are regularly inspected by the Department of Economic Development, Jobs, Transport & Resources (DEDJTR) as the licensing authority, as well as by the Animal Research Ethics Committee.

7. Standard operating procedures (gaining access) [\[home\]](#)

The AREC has a number of standard operating procedures (SOPs), one or more of which may apply to work to be undertaken in a project. Reference to the relevant SOPs in the AREC application (SOP number and title) is to be made.

SOPs are available on the [BI AREC portal](#) and all PIs will be given permission to access the portal. *It is the PI's responsibility to ascertain which SOPs are applicable to their project and provide their research team with the relevant SOPs.* Copies of the SOPs are also available within the Biological Research Centre (BRC).

To access the SOP Library on the portal:

- The PI must contact the [Research Office](#) to obtain permission to access the Bionics Institute portal where the SOP library is located.
- The PI will be sent an email that provides their log-in details (username and password).
- Sign into the BI portal site as an '**outside contributor**'.
- Enter your username and password.
- When you enter the site for the first time you may wish to change your password: click on your name on the top-right of the page and choose '**change password**'.
- Access to the SOP library is via the top ribbon. Select '**Animal Ethics**' and in the drop-down menu '**SOP library**'.

8. Breeding application (GM mouse lines) [\[home\]](#)

The 'Breeding Application' form available on the [BI AREC webpage](#) is to be used for AREC approval to either generate or breed a new genetically modified strain of mice, including those from an outside source. This form can be submitted **only** when it is either accompanied by a new protocol application or when an approved protocol exists.

9. Annual reporting [\[home\]](#)

A condition of approval for all study protocols is that an annual report is submitted (form available on [BI AREC webpage](#)). Reports are usually due on the anniversary of approval, but occasionally they are requested at a more frequent interval.

The Research Office will notify researchers about the due date of the progress reports at least four (4) weeks in advance.

Ethics approval is ongoing but will lapse if this annual progress report is not received by the anniversary of the approval date or is deemed unsatisfactory by the committee.

If the committee is not satisfied with the progress report, researchers will be informed about subsequent action.

10. Amendments and modifications [\[home\]](#)

From time to time amendments or modifications are required to research projects. It is the responsibility of the Principal Investigator to seek and receive AREC approval for any modification or change to be made to the approved study protocol **prior** to implementation.

- 1) A simple administrative change (addition of new researcher) can be considered outside of an AREC meeting, and shall be reviewed by the Chair of the AREC and one other member (Category C or D). For example, if a researcher is joining an already approved project, then the 'Personnel Approval' form may be submitted to the [Research Office](#) by email. These decisions will be ratified at the next AREC meeting.
- 2) Anything other than a simple administrative change is considered a modification and a 'Project Modification' form (available on the [BI AREC webpage](#)) must be submitted to [Research Office](#) for AREC approval.

A modification may be approved by the AREC Executive (consisting of Chair and one member from each Category - A, B, C, D) between meetings and ratified at the next AREC meeting.

Please refer to table below for the types of modifications and how they may be reviewed:

Type of Amendment/Modification	Review By
Personnel change (simple administrative change)	Chair and one other member (Category C or D) out of session
Redistribution of approved animals within groups	AREC Executive out of session
Add a new drug/agent or a new group to previously approved procedures or techniques provided that it can be done within the number of originally approved animals	AREC Executive out of session
Increase in number of animals <10% of original approval	AREC Executive out of session
Increase in number of animals >10% of original approval	AREC full meeting
Change of impact to animal welfare	AREC full meeting

11. Final reporting [\[home\]](#)

Reports are due on the completion of a project or if the research is discontinued before the expected date of completion. The PI is required to submit a final report (form available on the [BI AREC webpage](#)), along with any publications developed. The AREC has adopted a policy that three (3) years is a reasonable period of time in which to conduct a single research project. If, after three years, the project has not been completed, a final report must be submitted. If the research is to continue under another project application, the relevant application forms need to be submitted.

12. Adverse incidents [\[home\]](#)

An 'incident' is something that adversely affects animal welfare as described in 'Prevention of Cruelty to Animals' Act and regulations, the 'Australian Code for the Care and Use of Animals for Scientific Purposes' (8th edition, 2013) or the 'Code of Practice for the Housing and Care of Laboratory Mice, Rats, Guinea pigs and Rabbits'.

Adverse incidents are to be dealt with immediately by the investigator and animal facility staff and/or animal welfare officer [veterinarian].

The AREC should be notified via email within 48 hours of any unexpected adverse event that impacts on the well-being of an animal in their care. The 'Adverse Incident Report' form available on the [BI AREC webpage](#) is to be submitted within 14 days. The AREC can also request that a researcher submit an 'Adverse Incident Report'.

Definition of an adverse incident encompasses:

- 1) adverse or unexpected event which impacts on animal welfare (e.g., injection of substance with unanticipated effects, mortality rates exceeding any approved contingency, unexpected death beyond contingency);
- 2) environmental incident in the animal facility that impacts on animal welfare

Actions to be taken if adverse event has occurred:

Event	Action	Report on event and action
Adverse event affecting animal welfare Death of experimental animal	Animal Facility Manager (AFM) to liaise with investigator. If response not appropriate, AFM to report to Vet	Adverse incident to be reported to BRC veterinarian or facility manager and email to AREC within 48 hours. Report to be submitted within 14 days.
Environmental event affecting animal welfare	AFM &/or vet investigate	To AREC

The AREC response is determined on a case by case basis. The AREC chairman shall investigate in the first instance and may make an interim recommendation to the Scientific Procedures Premises Licence (SPPL) holder. If no immediate action is required, the incident will be considered at the next AREC meeting and the SPPL holder will be informed of the outcome. The annual report shall refer to any adverse incidents reported in the period.

The appropriate response could be:

- AREC internal review enquiry with recommendations
- Cautioning an investigator
- Suspension of approval for a project or an individual
- Cancellation of approval for a project

The Department of Economic Development, Jobs, Transport and Resources need to be notified of serious non-compliance.

Reporting/tracking of adverse events relating to animal research and the outcomes will be forwarded to the next AREC meeting for noting/action.

13. Breach of protocol [\[home\]](#)

Where a breach of an AREC approved study protocol has occurred (e.g. using more animals than approved, unapproved personnel working on project, project expired, performing a procedure on an animal without AREC approval, or making a variation to a project without approval), the breach must be reported immediately to the Research Office by using the 'Breach of Protocol Report' form available on the [BI AREC webpage](#).

A known or suspected breach of an AREC approved study protocol will be investigated by the Research Office and the internal review will be reported to AREC for action.

14. Withdrawal or suspension of approval [\[home\]](#)

Where the AREC finds reason to believe that continuance of a research project will compromise animal welfare or that a research project is not being or cannot be conducted in accordance with its ethical approval, it should immediately seek to establish whether ethical approval for the project should be suspended or withdrawn. In exigent circumstances the Chair of the AREC may suspend approval but must convene an Executive Committee of the AREC in accordance with its Terms of Reference to confirm the suspension. In such circumstances, the suspension shall be until the next scheduled meeting where the suspension may be extended, ceased or the project's ethical approval permanently cancelled.

Whenever a project is suspended, the Research Office must immediately notify the PI of the suspension of the ethical approval. The nominee of the Scientific Procedures Premises Licence (SPPL) (i.e., the licensee) must also be immediately notified.

An investigator cannot continue with the research if ethical approval has been suspended and must comply with any special conditions imposed by the AREC.

The research may not be resumed unless:

- The investigator subsequently establishes to the satisfaction of the AREC that continuance will not compromise animal welfare and/or is to be conducted in accordance with its ethical approval;
- or
- The research is modified to provide sufficient protection for animal welfare, the modification is ethically reviewed, and the modified research is approved by the AREC.

The AREC, after consideration at a meeting, makes the final decision with regards to reinstatement or withdrawal of ethical approval. The PI (and SPPL license nominee where relevant) is notified in writing of the decision within five (5) working days.

In the case of suspension or withdrawal of ethical approval the Research Office will notify the Chief Executive Officer of the Bionics Institute.

The Research Office will update the status of the project on the research database.

15. Appealing decisions of the AREC [\[home\]](#)

In the first instance, a request for reconsideration of a decision should be made to the Chair of the AREC. The Committee shall reconsider the decision and the researcher shall have the opportunity to personally present their case and bring supporting documents. If after reconsideration, the researcher still wishes to appeal the decision the following procedure shall be followed:

- 1) Appeals must be made in writing to the committee within 30 days of a committee decision.
- 2) On receipt of an appeal, the Chair of the AREC shall supply all relevant material to the Chief Executive Officer of the BI.
- 3) The Chief Executive Officer shall convene an appeals committee that is as free from bias and conflicts of interest as possible in accordance with the [Australian Code for the Responsible Conduct of Research](#) and the principles of procedural fairness.

16. Conflicts of interest [\[home\]](#)

Researchers have a responsibility to disclose at the time of proposing and reporting research, any potential conflict of interest that may influence, or be seen to influence, any aspect of the conduct of the research. Researchers must abide by their institution's 'Conflict of Interest' policy and procedures for disclosure.

A conflict of interest, in the context of research, may exist where the interests or responsibilities of an individual or an institution have the potential to influence the way they carry out their institutional role or professional obligations in research. A conflict may relate to financial interests and/or private, professional or institutional benefits that depend significantly on the research outcome. In addition to affecting the integrity of a researcher, a conflict of interest may compromise the research process itself, as well as the institutional governance of research.

In identifying and managing potential, perceived or actual conflicts of interest, the key principles which should guide individuals are:

- full disclosure; and
- avoidance of perceived or actual conflict of interest.

For AREC committee members, the process for the disclosure and handling of potential conflicts of interest is as follows:

- 1) AREC Members are asked to declare any conflicts of interest at the time of their appointment or as they arise during their appointment.
- 2) Conflicts of interest that do not relate to a specific research project must be notified to the Chair of the Committee by the member.
- 3) For conflicts of interest that relate to specific research projects, the Chair calls for members to declare these at the beginning of the meeting.
- 4) An AREC member must, as soon as practicable during the meeting, inform the Chair if he/she has a potential conflict of interest, financial or otherwise, in a project or other related matter(s) considered by the AREC.
- 5) If the member details the perceived conflict of interest then it is the responsibility of the AREC to determine if the declaration is an actual conflict of interest for the member. If so, the member will withdraw from the meeting until the AREC consideration of the relevant matter has been completed. The member is not permitted to adjudicate on the research.

- 6) Written reviews/comments from (absent) members are to include a full disclosure of any potential conflict of interest, financial or otherwise, in a project or other related matter(s) under consideration by the AREC. The AREC will determine if the conflict of interest renders the review/comments unacceptable.
- 7) The existence of all conflicts of interest which are declared (and details where given) and the absence of member(s) during the consideration of relevant matters are minuted.

17. AREC meeting record keeping [\[home\]](#)

To ensure that the BI AREC meetings are conducted appropriately, the paperwork and outcomes are notified to researchers, and the record keeping of AREC activities is maintained as per legislation. Reports on the conduct of the meetings are reported to all relevant institutions.

17.1 Preparation of AREC Agenda

- 1) The Research Office is responsible for preparing an agenda for each AREC meeting.
- 2) All completed applications and relevant documents received by the Research Office by the relevant AREC closing date are included on the agenda for AREC consideration at its next meeting.
- 3) The meeting agenda and associated documents are prepared by the Research Office and circulated to all AREC members at least 7 days prior to the AREC meeting.
- 4) Documentation received after the closing date can be included on the agenda and/or tabled at the meeting at the discretion of the AREC Chair.
- 5) Agenda items include at least the following items:
 - a. Apologies
 - b. Conflicts of Interest
 - c. New Research Applications
 - d. Modifications to approved protocols
 - e. AREC Minutes (from the previous meeting)
 - f. Subcommittee Minutes
 - g. Annual Reports
 - h. Final Reports
 - i. Business Arising
 - j. Biological Research Centre Report
 - k. General Business
- 6) The agenda and all documentation are confidential.

17.2 Conduct of AREC Meetings

- 1) The AREC meets 4 times per year at quarterly intervals. Meeting dates and agenda closing dates are available on the BI AREC webpage.
- 2) Members attend AREC meetings in person.
- 3) The Chair may cancel a scheduled meeting if a quorum cannot be achieved. Should this occur, the AREC will convene where possible within 3 weeks of the cancelled meeting to ensure all agenda items are considered.
- 4) The AREC meeting is conducted in private, to ensure confidentiality and open discussion.

- 5) Members are advised of the meeting room details in the meeting agenda. Any documentation relating to commercial in confidence projects will be collected at the completion of the meeting and destroyed.
- 6) Notwithstanding paragraph 4, the AREC may agree to the presence of visitors or observers to a meeting.
- 7) Members who are unable to attend a meeting can contribute prior to the meeting through written submissions to the Research Office or AREC Chair. Written comments must be received prior to the meeting so that they may be discussed at the meeting by the members present. The minutes record the submission of written comments. If the comments cannot be submitted prior to the meeting then their inclusion in the minutes and/or letter to researchers is at the discretion of the AREC Chair.
- 8) A quorum will be one more than half of the membership with each appropriate category represented. Categories C plus D should represent not less than one third of the members present.

17.3 Review of Research Applications

- 1) AREC considers research applications for animal research projects at the locations nominated on the SPPL licences of the Bionics Institute, Centre for Eye Research Australia, and the Department of Otolaryngology (University of Melbourne).
- 2) The application is reviewed by all members of the AREC present at the meeting or providing written comments in lieu of attendance; except for those with a conflict of interest, who may be required to leave the room during the deliberations and must not participate in the adjudication.
- 3) The AREC ethically assesses each application in accordance with 'The Prevention of Cruelty to Animals' Act 1986 and amendments, and the 'Australian code for the care and use of animals for scientific purposes', 8th edition (2013) and other relevant guidelines and legislation or successor agreements. The AREC must ensure that it is sufficiently informed on all aspects of a research protocol, including its scientific validity, in order to make an ethical assessment.
- 4) The AREC, after consideration of a project application at a meeting, makes one of the following decisions:
 - a. To approve the project as being ethically acceptable, with or without conditions.
 - b. To provide provisional approval to the project with requested modifications, this may then be reviewed for final approval by the AREC Chair and/or AREC subcommittee.
 - c. To defer making a decision on the project until the clarification of information or the provision of further information to the AREC.
 - d. To not approve the project (at any time the researcher may choose to resubmit a revised application in order to make it complying).
- 5) The AREC endeavours to reach a decision concerning the ethical acceptability of a project by unanimous agreement. Where a unanimous decision is not reached, the decision is considered to be carried by a majority of the members who examined the project. The vote including numbers for and against (and numbers of members abstaining from voting where applicable) is noted in the minutes.
- 6) In order to facilitate consideration of an application, the AREC may invite the applicant to be present at the relevant meeting for its discussion and to answer questions. If the applicant is present at the meeting, they are asked to leave the room prior to the AREC decision being made. AREC reserves the right to refer projects to third parties for expert opinion.

- 7) For projects where the AREC has requested clarification, the provision of further information, or modification of the project, the AREC may choose to delegate the authority to review that information and approve the project between meetings to one of the following:
 - a. Chair or Deputy Chair alone
 - b. Chair or Deputy Chair, in oral or written consultation with one or more named members that were present at the meeting or who submitted written comments on the application
 - c. A sub-committee of the AREC.

In such circumstances, the AREC is informed at the next appropriate meeting, of the final decision taken on its behalf, when the approval will be ratified.

- 8) If the AREC decides that further information or responses from the investigator (as in Point 4, c & d above) should be considered at a further meeting of the AREC, the PI (and/or delegate) is invited to attend the AREC meeting in order to provide clarification and answer any further questions raised.

17.4 Preparation of AREC Minutes

- 1) The Research Office is responsible for preparing and maintaining minutes of all AREC meetings.
- 2) The format of the minutes includes at least the following items:
 - a. Apologies
 - b. Conflicts of Interest
 - c. New Research Applications
 - d. Modifications to approved protocols
 - e. AREC Minutes (from the previous meeting)
 - f. Subcommittee Minutes
 - g. Annual Reports
 - h. Final Reports
 - i. Business Arising
 - j. Biological Research Centre Report
 - k. General Business
- 3) The minutes include the recording of decisions taken by the AREC. This includes reference to views expressed by absent members.
- 4) In relation to the review of new applications or amendments, the minutes record a summary of the main ethical issues considered, including any requests for additional information, clarification or modification of the project.
- 5) In recording a decision made by the AREC, any vote including numbers for and against (and numbers of members abstaining from voting where applicable) is noted in the minutes.
- 6) To encourage free and open discussion and to emphasis the collegiate character of the AREC, particular views are not attributed to particular individuals in the minutes, except in circumstances where a member seeks to have his/her opinions or objections recorded.

- 7) Declarations of conflicts of interest by any member of the AREC and the absence of the member concerned during the AREC consideration of the relevant application are minuted (refer to Section 16 - Conflicts of Interest – in this document).
- 8) The minutes are finalised within 5 working days following the relevant meeting including review by the AREC Chair (or delegate) for accuracy.
- 9) The minutes are circulated to all members of the AREC as an agenda item for the next meeting. All members will be given the opportunity to seek amendments to the minutes prior to their finalisation. The minutes will be formally approved and signed by the AREC Chair at the next AREC meeting.
- 10) The original copy of each meeting's minutes is retained in a confidential 'AREC Minutes' file.

17.5 Notification of AREC Decisions

- 1) The Research Office reports the AREC decision in writing to the PI within 10 working days of the meeting, unless otherwise notified.
- 2) If the AREC determines that further information, clarification or modification is required for the consideration of a project, the correspondence to the PI clearly articulates the reasons for this determination and outlines the information that is required.
- 3) If the requested information is not received from the applicant within 60 days of the letter being sent the project application will be rejected and the applicant may be required to re-submit the project at a later date.
- 4) The AREC endeavours to openly communicate with researchers to resolve outstanding requests for further information, clarification or modification of projects relating to ethical issues. The AREC may nominate one (or more) of its members to communicate directly with the applicant or by inviting the applicant to attend the relevant AREC meeting.
- 5) The Research Office notifies the applicant of the ethical approval of a project only when all outstanding requests for further information, clarification or modification have been satisfactorily resolved. Notification of ethical approval is in writing, and contains the following information:
 - a. Title of project
 - b. Name of the Principal Investigator
 - c. Unique AREC project identification number
 - d. Date of AREC approval and date of AREC expiry.
 - e. Conditions of AREC approval.
- 6) If the AREC determines that a project is ethically unacceptable, the notification of the AREC's decision will include the grounds for rejecting the project. AREC member(s) or Research Office staff may be nominated to work with the researcher to assist in re-submission.
- 7) The status of the project is updated by the Research Office on the Research database.

17.6 Record Keeping

- 1) The Research Office prepares and maintains written and/or electronic records of the AREC activities, including agendas and minutes of all meetings of the AREC.
- 2) The Research Office prepares and maintains a confidential electronic and/or paper record for each application received and reviewed and records the following information:
 - Unique project identification number
 - Principal Investigator(s)
 - Title of the project
 - Ethical approval or non-approval with date
 - Approval or non-approval of any changes to the project
 - Terms and conditions, if any, of approval of the project
 - Action taken by the AREC to monitor the conduct of the research.
- 3) The paper file contains a hard copy of the application, including signatures, relevant correspondence (including that between the applicant and the AREC), all approved documents and other material used to inform potential research participants.
- 4) All relevant records of the AREC, including applications, membership, minutes and correspondence, will be kept as confidential files.
- 5) To ensure confidentiality, all documents provided to AREC members, which are no longer required, are disposed of in a secure manner, such as shredding or placed in confidential bins. Members who do not have access to secure disposal give their documents to the Research Office for disposal.
- 6) Data pertaining to research projects is held for sufficient time to allow for future reference. The minimum period for retention for data is at least 7 years following the completion of the research or termination of the study.

17.7 Reporting Requirements

- 1) The AREC shall notify the Department of Environment and Primary Industries of membership changes as they occur. New members are to be approved by the BI Executive prior to membership commencement.
- 2) The AREC shall provide copies of the minutes of meetings to the BI Executive after each meeting.
- 3) The AREC shall provide an annual report to the BI Board at a time determined by the Board on its progress, including:
 - number of meetings
 - number of projects reviewed, approved and rejected
 - monitoring procedures for ethical aspects of research in progress and any problems encountered by the AREC in undertaking its monitoring role
 - description of any complaints received and their outcome
 - description of any research where ethical approval has been withdrawn and the reasons for withdrawal of approval
 - general issues raised

- 4) The AREC will provide reports to the Department of Environment and Primary Industries in accordance with the requirements of the Code.
- 5) The AREC Terms of Reference and Standard Operating Procedures will be posted on the BI website and the BI portal, respectively.

VERSION	DATE	AMENDMENT DETAILS
1.0	June 13, 2014	First version
1.1	November 24, 2014	Bureau of Animal Welfare replaced with Department of Environment and Primary Industries (DEPI).
1.2	January 25, 2016	Adverse incident reporting
1.3	May 15, 2017	Administrative changes to submission process
1.4	February 2018	Administrative changes to amendments and adverse incident reporting