

# University of Wollongong

## Animal Ethics Committee Operating Procedures

APPROVED by UoW Animal Ethics Committee: 6<sup>th</sup> April 2017

AMENDED as per DPI Site Inspection Report: 5<sup>th</sup> October 2017

APPROVED by UoW Research Integrity Committee: 30 November 2017

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## General

These Operating Procedures:

- Come into effect upon approval by the AEC
- Are to be reviewed at least every three years from the date of approval
- Are to be publicly available (2.2.1[ii]).

Feedback on these Operating Procedures is welcome and should be addressed to RSO-AEC@uow.edu.au.

## Administrative support

The UOW Research Services Office is responsible for ensuring that the AEC has appropriate support to ensure it can meet its responsibilities under the Code, relevant institutional policies and other regulations (2.2.1[iii, iv]).

Support for the AEC must include:

- Administrative assistance including for the submission, receipt and processing of applications and reports to the AEC, and make these policies and procedures readily available (2.2.24).
- Recruiting, orientation and education of AEC members.
- Reimbursement of members' out-of-pocket expenses (2.2.19).
- Development and implementation of procedures to include management of conflicts of interest, confidentiality, appointment of and delegation of functions to an AEC Executive, meeting procedures, communication, records and documentation (2.2.20).
- Maintain communication with the Animal Welfare Unit of NSW Department of Primary Industries and the NHMRC Animal Welfare Committee.

Routine communications between the AEC and UOW shall be between the Chair and the Research Ethics Manager although these persons may, at their discretion, delegate tasks to the Deputy Chair or other staff of the Research Services Office respectively.

## Membership and quorum

Membership of the AEC must allow the Committee to meet its responsibilities. Membership must comprise at least four people, one from each of four categories of membership as set out below (2.2.1).

Membership of the AEC shall comprise at least four people and must include at least one person from each of four categories of membership (2.2.1, 2.2.4):

- Category A—a person with qualifications in veterinary science that are recognised for registration as a veterinary surgeon in Australia, and with experience relevant to the institution's activities or the ability to acquire relevant knowledge.
- Category B—a suitably qualified person with substantial and recent experience in the use of animals for scientific purposes relevant to the institution and the business of the AEC. This must

include possession of a higher degree in research or equivalent experience. If the business of the AEC relates to the use of animals for teaching only, a teacher with substantial and recent experience may be appointed. Any UOW staff member who engages in animal research and who meets the criteria for Category B membership must be prepared to serve one or more terms on the AEC as a Category B member.

- Category C—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 currently involved in the care and use of animals for scientific purposes. Veterinarians with specific animal welfare interest and experience may meet the requirements of this category. While not representing an animal welfare organisation, the person should, where possible, be selected on the basis of active membership of, and endorsement by, such an organisation.
- Category D—a person not employed by or otherwise associated with the institution and who has never been involved in the use of animals in scientific or teaching activities, either in their employment or beyond their undergraduate education. Category D members should be viewed by the wider community as bringing a completely independent view to the AEC, and must not fit the requirements of any other category.

Members of Categories C and D must together represent at least one-third of the AEC membership and one third of those present for meetings to be quorate (2.2.8).

In situations where a face to face meeting is not quorate due to absence of members and the members can't attend the meeting by video or teleconference, the Chair may seek the AEC's approval to proceed with the meeting on the condition that the absent members are given a chance to contribute to discussions of agenda items as soon as possible after the meeting. No decisions relating to the use of animals may be made at meetings where the AEC is not quorate. Decisions made after subsequent consultation with absent members must be ratified at the AEC's next face to face meeting. Projects approved by this method are not able to commence until after ratification at the next quorate meeting.

## **Responsibilities of members**

Each member is responsible for deciding whether, in their own judgement, an application or other matter under consideration by the AEC is ethically acceptable (1.3) and meets the requirements of the Code (2.2.14). A judgement as to whether a proposed use of animals is ethically acceptable must be based on information that demonstrates the principles in Clause 1.1 of the Code (outlined at the top of this document), and must balance whether the potential effects on the wellbeing of the animals involved is justified by the potential benefits (1.3).

To fulfil this responsibility, members should:

- Be familiar with the Code and other policies and guidelines relevant to the business of the AEC;
- Provide opinions on the ethical acceptability of applications and other matters under consideration by the AEC (2.2.15).

Procedures must include the declaration of interests by prospective members and the management of conflicts of interest in making appointments (2.2.10).

During their appointment to the AEC, and before any deliberations of the AEC, members and prospective members must declare any interest that could influence the objectivity of their decision making (2.2.16).

Members and others who attend meetings or who are privy to material relating to the activities of the AEC must maintain confidentiality regarding the content of applications and the Committee's deliberations in accordance with institutional requirements (2.2.17). Content of applications or other matters subject to the AEC's deliberations must not be discussed with anyone other than members of the Committee and the Secretariat, without the permission of the researcher.

Members are required to attend at least 80% of the meetings held during each year of their appointment and to provide written comments on the protocols being reviewed.

Members will be expected to participate in inspections of animal facilities.

If there are concerns that a member of the AEC is failing to meet their obligations to the work of the Committee and/or its role in ensuring compliance with the Code, the matter shall be referred to the Chair and the Research Ethics Manager for consideration. If the concerns are deemed to have substance, the matter shall be raised with the member who will be given reasonable opportunity to respond. Should the matter remain unresolved, independent assistance may be sought through channels such as mediation, UOW Human Relations advisors or the NSW Animal Welfare Unit. Strict confidentiality must be observed throughout all such proceedings and rights of appeal must be available.

## **Members not in Categories A, B, C or D**

The Ethics Officer or other suitable member of the Research Services Office must attend meetings of the AEC to provide advice and administrative support on behalf of the institution.

The UOW Animal Welfare Officer shall be a member of the Committee in an advisory capacity.

With the support the AEC, Advisory Members may be appointed to the Committee to provide advice based on their role or field of expertise. Advisory Members of the AEC should include:

- An animal technician or facility manager whose primary responsibilities relate to the routine care of animals within the institution (2.2.5).
- Additional members with skills and background of value to the AEC such as a statistician (2.2.6).
- An individual with professional expertise in ethics or relevant aspects of philosophy.

Advisory members of the AEC may serve concurrently as members in Categories A, B, C or D.

Advisory Members may contribute to discussions but will not participate directly in the AEC's final decision-making and will not be counted when determining the Committee's quorum.

The AEC may invite people with specific expertise to provide advice on an *ad hoc* basis (2.2.7).

## **Appointment and retirement of members**

Appointment and retirement of members shall be the responsibility of the Research Services Office under the supervision of the Research Ethics Manager and shall comply with general institutional personnel policies (2.2.9).

Before appointment, prospective members of the AEC must acknowledge in writing their acceptance of the Terms of Reference and Operating Procedures of the AEC and any requirements for confidentiality required by the institution (2.2.11).

The UOW Research Services Office under the supervision of the Research Ethics Manager must ensure that AEC members undergo appropriate induction, and have access to appropriate training programs and resources (2.2.12).

The membership of the Committee must be approved by the Animal Research Review Panel (ARRP) and the Deputy Vice-Chancellor (Research and Innovation) of UOW.

Members will normally hold office for three years from the date of appointment. Members' appointments are renewable, normally for up to two additional terms, unless extended under special circumstances. Ratification of renewals of appointments is made by the Deputy Vice-Chancellor (Research and Innovation) who make take advice from the Chair.

## **Chair and Deputy Chair**

A chairperson of the AEC must be appointed (the Chair).

The Chair shall be responsible for impartially guiding the operation of the AEC, resolving conflicts of interest related to the business of the AEC, and representing the AEC in any negotiations with the institution's management (2.2.13).

The Chair should either hold or have previously held a senior position in the institution or may be external and should be a person who is independent of UOW's use of animals. The Chair may be appointed in addition to Category A to D members (2.2.2, 2.2.3).

The Chair should be nominated by the Deputy Vice-Chancellor (Research and Innovation).

Appointment of the Chair must be approved by the NSW Animal Research Review Panel.

The Chair must be provided with the necessary support and authority to carry out the role.

The AEC may appoint a Deputy Chair to act in the absence of the Chair.

The positions of Chair and Deputy Chair will initially be for one year, with extension to three years as deemed appropriate by the Deputy Vice-Chancellor (Research and Innovation). The Chair and Deputy Chair will normally serve for a total of one term of three years in duration. Where deemed appropriate by the Deputy Vice-Chancellor (Research and Innovation), these positions may be extended for a period of up to three years.

## **Confidentiality**

AEC members, UOW staff and others privy to the content of applications and the deliberations of the AEC shall observe the confidential nature of those documents and discussions.

Members wishing to seek advice on confidential matters may approach the Chair or the Research Ethics Manager for assistance (2.2.22).

Minor amendments approved by the AEC Executive must be ratified at the next meeting of the full AEC.

## **Meeting procedures**

At least one member from each of the membership categories A, B, C and D must be present at meetings to establish a quorum for the conduct of a meeting, and must be present throughout the meeting. Categories C and D together must represent at least one-third of those members present (2.2.25).

Meeting procedures shall include:

- Timely distribution of meeting papers to AEC members. Papers should reach members approximately 3 weeks before the meeting date with a request that members submit any questions or comments within 10 days of receipt of papers. The members' input is then collated and forwarded to applicants for a response. The applicants' responses should be circulated to AEC members at least 3 days before the meeting date.
- The conduct of quorate AEC meetings in accordance with the Code and these Operating Procedures.
- Management of any perceived or actual conflicts in accordance with these Operating Procedures.
- Frequency of meetings, which should be sufficient to allow for effective functioning of the AEC while recognizing the workload involved, especially for external members. This will usually be at least six meetings per year.
- Review and approval of new and ongoing projects and reports in accordance with the Code and these Operating Procedures (2.2.26).

All members must have the opportunity to contribute to the decision-making process unless there is a conflict of interest. If a member is unable to attend in person they may comment on a protocol in writing before the meeting.

Investigators should have an opportunity to respond to any concerns raised by the AEC before a final decision is made.

## **Management of conflicts of interest**

All members will be asked to declare any conflict of interests at the beginning of each meeting, as a standing item of the Agenda.

Persons with a conflict of interest must remove themselves from the AEC's decision making on matters that relate to the conflict of interest (2.2.21). Once such members have withdrawn, the remaining members must constitute a quorum (2.3.12).

Members must absent themselves from the meeting during discussion of any item for which they have declared a conflict of interest. Any such absence shall be recorded in the Minutes of the meeting.

No member shall provide written or verbal comment on any application for which they have a conflict of interest unless requested by the AEC and their interest has been declared.

## Reviewing applications

The AEC may only approve projects that are ethically acceptable and conform to the requirements of the Code (2.3.2[i], 2.3.5).

Consideration of what is deemed to be ethically acceptable shall be guided by the Code which requires that:

- Respect for animals must underpin all decisions (1.1).
- Methods that replace or partially replace the use of animals must be investigated, considered and, where applicable, implemented.
- Ethical review must balance whether the potential effects on the wellbeing of the animals involved is justified by the potential benefits.
- Ethical review must be based on information from the applicant's documentation, direct discussions with the applicant and additional information if required that demonstrates the application of the Code's Governing Principles (1.3, 2.3.4, 2.3.8).

A copy of each new application must be provided to all members of the AEC with sufficient notice to allow the members to consider the application and submit questions to be addressed by the applicant(s) in time for discussion at the next meeting of the Committee.

The AEC may only consider and approve applications for new projects at quorate meetings of the AEC (2.3.6).

The AEC must base its decisions on a thorough, fair and inclusive process of discussion and deliberation by AEC members, and decisions should be made only by those able to participate throughout the discussion (2.3.10); The AEC must provide competent, fair, consistent and timely review of applications (2.3.3, 2.3.13) and make decisions as promptly as possible (2.3.13);

The AEC should make decisions on the basis of consensus. Where consensus cannot be reached after reasonable effort to resolve differences, the AEC should explore with the applicants ways of modifying the project that may lead to consensus. If consensus is still not achieved, the AEC should only proceed to a majority decision after members have been allowed a period of time to review their positions, followed by further discussion (2.3.11). A majority decision shall be determined by a vote from those members of the Committee occupying Categories A, B, C, D and other but excluding the Chair; in the event that a vote is tied, the Chair shall have the casting vote. Voting may be by a show of hands or by written ballot. Dissenting members may request that their views be formally recorded in the Minutes.

The AEC may decide that an application for a new project is approved with or without conditions, deferred subject to modification, or not approved (2.3.9).

When pilot studies are proposed, the AEC must regard these as integral to the overall project (2.3.14).

When considering approval for the reuse of animals, the AEC must take into account:

- The pain and distress, and any potential long-term or cumulative effects, caused by previous activities and conditions
- The time allowed for recovery of the animals between activities
- Whether an animal has fully recovered from the previous activities
- The pain and distress likely to be caused by the next and subsequent activities
- The total time over which an animal will be used (2.3.15);

In determining the duration of approval for individual projects, the AEC must take into account the number of years for which the project is funded, any milestones or stages outlined in the project, and any formal agreements between the institution and funding bodies (2.3.16).

## **Follow-up reviews**

The AEC must conduct follow-up review of approved projects when required including:

- Proposed amendments to an approved project.
- Review of progress of projects at least annually.
- Unexpected adverse events.

The AEC may only allow the continuation of projects that are ethically acceptable and conform to the requirements of the Code (2.3.2[iii], 2.2.32 [ii]).

Following review of an annual report for an approved project, the AEC may decide that the approval for the project is continued, suspended, modified or discontinued (2.3.9).

## **AEC Executive**

The AEC may establish an Executive.

The Executive:

- Must include the AEC Chair and at least one AEC member from Category C or D and a representative of the UOW Research Services Office.
- May be delegated to approve minor amendments to approved projects, for ratification at the next AEC meeting.
- Must not approve new applications (2.2.23).

Those AEC members participating in the AEC Executive may change depending on availability provided that the above requirements for membership are met.

## **AEC Sub-Committee**

The AEC may appoint a Sub-Committee to review major amendment applications if required between meetings of the full AEC and to deal with other business delegated to it by the full AEC.

All members of the full AEC should have the opportunity to contribute to the decision-making process of the Sub-Committee unless there is a conflict of interest. This should be done in writing before the Sub-Committee meets.

The Sub-Committee shall:

- Comprise at least one member from each of the membership categories A, B, C and D. Each category should be present at face to face meetings of the Sub-Committee where reasonably possible and Categories C and D together must represent at least one-third of those members present (excluding the Chair) to establish a quorum.



- Be chaired by the Chair of the full AEC or his/her delegate. The Chair of the full AEC may also serve as one of the membership categories A, B, C or D if the membership conditions of clause 2.2.4 of the Code are met.
- Meet once between full committee meetings unless in the opinion of the Chair and the Animal Ethics Secretariat there is insufficient business to warrant a meeting;
- Conduct face to face meetings where reasonably possible. Where this is not possible, meetings may be conducted by videoconference or telephone conference; where none of these options is possible, the Sub-Committee's business will be handled by the full AEC by email. Situations where alternatives to face to face meeting may be acceptable include:
  - Urgent animal welfare concerns;
  - Where excessive delays could adversely affect the outcomes of a project as approved by the full AEC;
  - Where the obligation for prompt decision-making under clauses 2.2.27 and 2.3.13 of the Code could not reasonably be met; or
  - Where a meeting of the Sub-Committee would impose an unreasonable burden on external members of the AEC.

The Sub-Committee shall be permitted to communicate directly with other parties as deemed reasonably necessary to achieve its goals and subject to appropriate conditions of confidentiality;

All decision of the Sub-Committee must be ratified by the full AEC at its next meeting.

The Sub-Committee must not approve applications for new projects.

## **Amendments to approved projects**

Amendments may be classified as either minor amendments or major amendments.

Minor amendments are limited to those changes to an approved project which are not likely to cause harm, pain or distress to the animals and do not increase the number of animals used (2.2.23[iii]).

Examples of minor amendments may include:

- Change of personnel or staff where they are appropriately qualified or supervised.
- Extension of existing approvals for periods of up to one year (provided that the extension does not alter other aspects of the protocol such as procedures, animal numbers, location or research aims).
- Procedural changes likely to result in improved animal welfare.
- Transfer of animals between protocols provided that this would not alter any of the conditions applying to the new protocol (e.g. total number or type of animals)
- Change of source of animals provided the new source meets supply requirements under the NSW Animal Research Act.
- Additional samples collected post mortem, or additional tests performed on samples approved to be collected when the amount collected does not need to change.

Minor amendments may be approved by email consultation with the AEC Executive. Approval of minor amendments come into effect at the time of approval but must be ratified at a meeting of the full AEC following review.

Major amendments are those with the potential to have an adverse effect on animal wellbeing. Major amendments must be approved by either the full AEC or by the AEC Sub-Committee after consultation with the full AEC and followed by ratification by the full AEC.

Where practicable, the approval of major amendments should involve a face to face meeting of the AEC or AEC Sub-Committee. However where a face to face meeting is not reasonably possible, an alternative means of communication is acceptable provided that a quorum of members of the AEC have had a reasonable opportunity to provide input.

## **Monitoring animal care and use**

The AEC must monitor the use of animals, housing conditions and the care of animals in facilities (2.3.2[iv]).

Monitoring shall include:

- Monitoring of the acquisition, transport, breeding, housing and care of animals and relevant procedures in projects approved by the AEC.
- Assessment of compliance with the Code and decisions of the AEC.
- Inspection of animals, animal housing, the conduct of procedures, records and reports (2.3.17).

The AEC shall conduct monitoring through:

- Review of reports and other relevant documents at scheduled meetings.
- Delegation of monitoring to the Animal Welfare Officer (AWO) when required and to help ensure that monitoring is regular and ongoing (2.3.18).
- Inspections of each animal facility operated by UOW (see below).

Inspections conducted by members of the AEC:

- Should take place at least twice a year and may be more frequent depending on the number and types of projects, and whether inspections can be combined with scheduled AEC meetings.
- May be announced or unannounced (2.3.21).
- Should include a Category C or D member of the Committee (2.3.20).

Procedures that are likely to cause pain or distress should be inspected by the AEC or the AWO at an early phase of the project. This requirement should be a condition of approval for the project or activity (2.3.19).

Identified problems must receive appropriate follow-up and the AEC must be advised and given opportunity for input. Outcomes of follow-up and related discussions by the Committee must be recorded in the minutes of meetings. If necessary, suspected breaches of the Code must be referred to the institution (2.3.18). Referral must be through the Research Ethics Manager in the first instance but may be escalated.

The AEC must maintain records of inspections that include the names of attendees, observations, any identified problems, recommended actions, ongoing or outstanding issues, and outcomes (2.2.30, 2.3.22).

The AEC may delegate authority to suitably qualified people to monitor and inspect animal care and use at sites that are remote or where access is difficult. The AEC should indicate the aspects to be reported on, steps to be taken to avoid conflict of interest and any ancillary evidence desired such as still images or video (2.3.23).

The findings of inspections should be reported to the Deputy Vice-Chancellor (Research and Innovation); this reporting may be as a part of minutes of AEC meetings, part of an annual report or reported separately. If findings are considered to be of a serious nature, the Deputy Vice-Chancellor (Research and Innovation) should be notified as soon as practicable.

## Unexpected adverse events

The AEC must take appropriate actions regarding unexpected adverse events (2.3.2[v]).

The Code defines an Unexpected Adverse Event as “an event that may have a negative impact on the wellbeing of animals and was not foreshadowed in the approved project or activity.” Examples include:

- Death of an animal or group of animals.
- Adverse effects on animal welfare following a procedure that were not expected.
- Adverse effects in a larger number of animals than expected.
- A greater level of pain or distress than was predicted.
- Power failures, inclement weather, emergency situations or other external factors that have a negative impact on the animals' welfare.

It must be assumed that circumstances that would cause pain and distress in humans would also cause pain and distress in animals (1.10).

Alleviating unanticipated pain or distress must take precedence over an individual animal reaching the planned endpoint of the project or completion of the project. If necessary, animals must be humanely killed without delay (1.14, 2.4.18[ix], 3.1.24).

In situations where an Unexpected Adverse Event requires urgent action and a suitably qualified member of the research group is not available, or if the Animal Welfare Officer or AEC Chair is not satisfied that significant animal welfare issues are not being adequately addressed, responsibility for ensuring an appropriate response may be taken by the Animal Welfare Officer or the AEC Chair (1.10, 1.11, 1.14). If neither of these are available, delegation of responsibility shall proceed in the following order: the Animal Facility Manager; an Animal Technician employed within the facility housing the affected animal(s); a Category A (veterinarian) member of the AEC 2.1.7 [i][b].

The welfare of the animal must be the priority at all times and may necessitate immediate intervention (2.5.6). Unless immediate intervention is considered necessary due to significant animal welfare concerns:

- A veterinarian with suitable experience should be consulted (2.1.5[v][d]).
- Reasonable steps should be taken to contact the responsible investigator (2.5.6).

Reporting of Unexpected Adverse Events:

- Initial notification of an Unexpected Adverse Events must be made to the AEC within two working days. This should be done via email to [RSO-AEC@uow.edu.au](mailto:RSO-AEC@uow.edu.au).
- An Unexpected Adverse Events form signed by the Chief Investigator must be lodged via email to [RSO-AEC@uow.edu.au](mailto:RSO-AEC@uow.edu.au) within 10 days of the incident. If further information emerges after this time, it should be provided on an updated version of the same form.

- Details to be included when reporting to the AEC should include the nature of the incident, action taken, results of necropsies and diagnostic investigations (3.1.25), and measures to prevent further incidents.

When reviewing and Unexpected Adverse Event, the AEC must ensure that:

- Animal wellbeing is not further compromised.
- The matter is addressed promptly.
- Activities that unexpectedly have the potential to adversely affect animal wellbeing cease immediately.
- Determine what further action (if any) is necessary.

Reviewing an Unexpected Adverse Event may include consulting with relevant people, insisting on appropriate amendments, or suspending or withdrawing approval for the project (2.3.24).

In the case of an Unexpected Adverse Event which is considered to be particularly serious, the AEC may suspend or withdraw approval for the project (2.3.4). When approval is to be suspended or withdrawn, care must be taken to make provision for all animals committed to the study including any that were not affected by the Unexpected Adverse Event.

If the circumstances of an incident are so urgent that consultation with the full AEC would risk further adverse effects on animal welfare, the project may be suspended by the AEC Chair or, if unavailable, either the Animal Welfare Officer or by a quorum of AEC members consisting of one member each from Categories A, B, C and D if they have reached consensus.

When a decision is taken to suspend or withdraw an approval, the Chief Investigator must be notified as soon as possible and clear reasons given.

In cases where there is an unexplained and severe outbreak of disease in animals or people (2.1.5 [v][e]), the AEC may approve the use of animals out of session if required for diagnosis. Any such approval must clearly specify the number and type of animals, the procedures to be used, measures to be taken to minimize animal pain or distress and must ensure compliance with regulations relating to the supply of animals for scientific purposes. The decision to grant approval must be based on the consensus of a quorum consisting of at least one member from each category with Categories C and D comprising at least one third (2.2.25). Communication may be conducted by email or other means if required by the urgency of the circumstances. Details of the circumstances, the approved work and justification of the Committee's decision must be documented and ratified at the next face to face meeting of the full committee.

## **Complaints relating to animal research**

Complaints concerning to the use of animals by UOW may be raised by any party including investigators, animal carers, the AEC, individual AEC members, students, employees and members of the public (Introduction to Code Section 5).

Complaints may relate to alleged breaches of the Code, relevant legislation or institutional policies (5.1).

The handling of complaints shall (5.2):

- Ensure fair, prompt, timely, effective, confidential processes that accord with procedural fairness, the principles of natural justice and protection of whistleblowers (5.2 [v]);

- Observe relevant UOW policies and procedures;
- Ensure appropriate reporting to and consultation with the institution, the AEC, government authorities, and any other relevant bodies (5.2 [vi]);
- Ensure that access to relevant procedures is available to complainants and all other stakeholders (5.2 [vii]).

Complaints will be received on the understanding that complainants will comply with all reasonable requests to assist in the investigation of their complaint and that should a complainant choose not to comply with such requests, further investigation or resolution of their concerns may be delayed or may not be possible.

Complaints may be made anonymously although it must be recognized that anonymity can hinder the investigation of complaints in some situations.

Investigation may involve consultation with other parties if deemed necessary to establish facts or obtain input considered likely to assist in reaching a fair resolution. Such consultation will be with the approval of the complainant and confidentiality will be observed wherever possible. Steps may be taken to establish that the complaint is not without genuine foundation. Complaints deemed to be without genuine foundation will not be investigated further.

Complaints should be referred in the first instance to the Research Ethics Manager and the AEC Chair who will advise the complainant on a proposed course of action including the need to consult the AEC.

If the complainant is dissatisfied with the proposed course of action, an alternative approach may be negotiated. If an agreement on a course of action cannot be reached, the complainant may take the matter to the Deputy Vice-Chancellor (Research and Innovation).

In the event that a complaint cannot be resolved by internal processes, UOW should identify an external party to whom the complainant can pursue their concerns (5.8). The complainant should also be advised that they can report alleged breaches to the Department of Primary Industries (5.11).

## **Investigation of complaints**

The investigation of complaints must give priority to the wellbeing of the animals and ensure that activities with the potential to adversely affect animal wellbeing cease immediately (5.2[i], 5.4[i]);

Complaints relating to activities that would normally require AEC approval must be referred to the AEC to investigate whether such activities are conducted in accordance with AEC approval (5.4[ii]);

Complaints that raise the possibility of 'research misconduct' as described in the [Australian Code for the Responsible Conduct of Research](#) must be handled in accordance with procedures specified in that document (5.4[iii]). Where complaints allege misconduct that falls outside the range of this the complaint must be handled in accordance with UOW processes for dealing with other forms of misconduct (5.4[iv]);

Where projects involve more than one institution and/or AEC there must be prompt communication with the other institution(s) on all relevant matters (5.3).

When the investigation of a complaint finds that activities have been conducted in accordance with an AEC approval, the activities must be reviewed to ensure that the reason for the complaint is addressed. The AEC may decide that modification to a project or activity is required, or an approval for a project or activity is suspended or withdrawn (5.5[i]).

The Research Services Office must maintain records of complaints (5.10). Records may be in the form of Minutes of AEC meetings and should include the identity of the complainant (if known), details of the complaint, copies of correspondence and meeting notes, and outcomes.

## **Regulatory breaches**

A regulatory breach is a failure to comply with the Code or other regulations relating to animal use. A regulatory breach may involve any party involved in the use of animals including investigators, animal carers, the AEC, governance officials, and external parties involved in animal use approved by the UOW AEC (2.6.3, 2.6.6)(5.1[iv]).

When a regulatory breach is detected, the AEC must ensure that:

- Animal wellbeing is not compromised.
- The issue is addressed promptly.
- Activities that have the potential to adversely affect animal wellbeing cease immediately.

In situations where urgent action is required to minimise the impact on animal welfare, responsibility for ensuring an appropriate response may be taken by the Animal Welfare Officer or the AEC Chair until such time as the matter can be considered by the full Committee.

Action to be taken by the AEC to address regulatory breaches (2.3.2[vi]) may include:

- Suspending or withdrawing approval for the project.
- Referral to UOW management (2.3.25, 5.5[ii]).
- Requiring additional training and competency assessment.
- Other measures determined by the AEC to encourage compliance and reinforce an understanding that behaviours that compromise compliance are not tolerated (5.9).
- Notification of regulatory authorities in cases where there has been a significant impact on animal welfare (5.12).

The AEC Chair shall inform the Chief Investigator in writing of the nature of the breach, the basis of the Committee's decision and any action to be taken.

The Research Services Office must maintain records of regulatory breaches (5.10). Records may be in the form of Minutes from AEC meetings and should include details of the breach, copies of correspondence and meeting notes, and outcomes.

## **Complaints about AEC process**

Complaints about the AEC process may relate to the Committee's review of an application or report, or attempts to resolve disagreements between AEC members, between the AEC and investigators, and between the AEC and the institution (5.1[ii]).

Complaints about the AEC process must be in writing and must include the name and contact details of the complainant; anonymous complaints will not be investigated.

Upon the receipt of a complaint, the Chair and Research Ethics Manager shall be informed and shall work together to propose a course of action. The course of action may involve referral of the matter to senior management or independent parties within UOW upon mutual agreement by the parties concerned.

Within the constraints imposed by privacy regulations and respect for confidentiality, the AEC should be informed of the complaint and may provide input if the matter relates to its responsibilities as defined by the Code.

Steps may be taken to establish the validity of the complaint.

If a resolution cannot be reached through internal processes, the complaint may be referred to an appropriate regulatory body or independent mediator upon mutual agreement by the parties concerned.

Following determination of a complaint about AEC process, the AEC should review the relevant procedures and re-evaluate any decisions in light of the reviewed process. However the ultimate decision regarding the ethical acceptability of an activity lies with the AEC and must not be overridden (2.2.29, 5.6).

## **Communication**

These Operating Procedures shall be implemented in a manner to ensure that applications and reports are assessed in a manner that is fair to applicants and acceptable to all AEC members and that ensures AEC members are provided with the necessary information in a timely manner (2.3.7);

The AEC shall clearly communicate its decisions, the reasons for its decisions and any conditions attached to an approval to investigators in writing as promptly as possible (2.2.27).

The AEC shall consider face-to-face meetings with applicants to resolve issues (2.2.28).

## **Approval of guidelines**

Guidelines for animal use developed by UOW must be approved by the AEC (2.3.26, 2.3.2[vii]). The AEC must also provide advice and recommendations to UOW (2.3.2[viii]).

Where appropriate, guidelines should be in the form of Standard Operating Procedures approved by the AEC.

Guidelines must include the following topics:

- Competency assessment (2.1.5[v][a]). (Ref. relevant AEC-approved Standard Operating Procedures and training information on AEC website).
- Maintenance of appropriate animal health status (2.1.5[v][b]). (Ref. relevant AEC-approved Standard Operating Procedures or parts thereof on AEC website).
- Monitoring and assessment of animals (2.1.5[v][c]). (Ref. relevant AEC-approved Standard Operating Procedures or parts thereof on AEC website).
- Actions required for unexpected adverse events and emergencies (2.1.5[v][d]). (Ref. relevant AEC-approved Standard Operating Procedures and see under 'Unexpected Adverse Events' in this document).
- Approval, in advance, for the immediate use of animals if required for the diagnosis of unexplained and severe disease outbreaks (2.1.5[v][e]). (See under 'Unexpected Adverse Events' in this document).

- Access to veterinary care, quality management and project design to safeguard animal welfare (Ref. Animal Welfare Officer contact details on AEC website).
- Procedures for students wishing to express conscientious objection to the use of animals in teaching activities (Ref. Conscientious Objection policy on AEC website).

The AEC must review Guidelines within three years of approval. Guidelines which have not been reviewed by the AEC for three years or more will lapse.

## **Approval of Standard Operating Procedures** (2.2.33 – 2.2.36)

Any Standard Operating Procedures (SOPs) relating to the use of animals must be developed in consultation with and approved by the AEC.

The AEC may only accept an SOP within an application under the following conditions:

- The SOP must have current approval from the AEC (i.e. approved within the last three years or as otherwise determined by the AEC).
- The SOP must include in its title the date of approval or last review by the AEC.
- Investigators named in the application must be competent to implement the SOP.
- Any variation to an SOP must be described in the application and should be considered as a prompt for review of the SOP.

The AEC must review SOPs within three years of approval. SOPs which have not been reviewed by the AEC for three years or more will lapse.

Approved SOPs must be made available to all relevant people, including AEC members.

## **Providing advice to the institution**

UOW must seek advice from the AEC on matters relating to the use of animals to ensure that the requirements of the Code are met (2.3.27).

The AEC must be consulted during the planning of new animal facilities or refurbishment or modification of existing facilities (2.1.6[v]). New, refurbished or modified facilities must be inspected and approved for use by the AEC prior to housing animals to establish that the facility meets the Code's requirements (2.1.6[v], 3.2.14, 3.2.17-20) and environmental conditions (3.2.17[i]).

## **Records**

Records of the AEC's business must be maintained by the Research Services Office.

Records must include:

- A register of all applications (including amendments) to the AEC, including the outcomes of deliberations (2.2.30[i]);
- Minutes that record decisions and other aspects of the AEC's operation (2.2.30[ii]);
- Records of inspections conducted by the AEC that include the names of attendees, observations, any identified problems, recommended actions, ongoing or outstanding issues, and outcomes (2.2.30 and 2.3.22);



- Details of applications to be maintained in records include:
  - Name of responsible institution
  - Project identification number
  - Principal investigator(s)
  - Short title of project
  - Ethical approval or non-approval with date
  - Date(s) designated for review
  - Details of monitoring procedures
  - Animal species and numbers used
  - Details of intended site of the holding and research on animals
  - Comments made by Committee members about protocols
  - Investigators' responses to comments by AEC members
  - Relevant correspondence

Animal care staff shall have access to records of approved projects and reports where appropriate and in consultation with the AEC (2.2.31).

## **Reporting on AEC operations**

The AEC must report on its operations to the senior management of UOW (2.3.2[ix]). The AEC must submit a written report on its operations at least annually to the governing body through the Deputy Vice-Chancellor (Research and Innovation) (DVCRI) (2.3.28).

The annual report should include

- The number of meetings held;
- The numbers and types of projects assessed, and approved or rejected;
- Results of inspections and other matters relevant to the physical facilities;
- Actions that have supported the training needs of AEC members and people involved in the use of animals;
- Outcomes or initiatives that have helped advance the 3Rs;
- Reports of any formal complaints received whether relating to animal wellbeing or AEC processes and whether originating from within or outside UOW;
- Matters such as breaches of the Code or Unexpected Adverse Events where the outcome may have broader implications for the University's use of animals or its ability to maintain regulatory compliance (2.3.29);

- Administrative or other difficulties experienced;

As part of the AEC accreditation licence, an annual report to the Animal Research Review Panel must be submitted by 31<sup>st</sup> March each year.

The Chair and the Research Ethics and Integrity Manager should meet twice yearly with the Deputy Vice-Chancellor (Research and Innovation) to discuss the activities of the AEC.

The Chair may directly notify or meet with the DVCRI on matters relating the AEC at other times at his or her discretion.

