

Terms of Reference for the XYZ Animal Ethics Committee

Introduction

As a registered user of animals for scientific purposes the Department of XYZ must comply with the requirements of the *Animal Care and Protection Act 2001* (ACPA) and the "*Australian code for the care and use of animals for scientific purposes*" (8th edition, 2013) (Scientific Use Code).

In accord with the requirements of the ACPA and the Scientific Use Code, the department has established the XYZ Animal Ethics Committee (XYZ AEC) to apply the principles that govern the ethical conduct of departmental officers (staff) whose work involves the care and use of animals for scientific purposes.

The XYZ AEC is responsible to the Director-General of the Department of XYZ through the Assistant Director-General. Accordingly, the XYZ AEC has the Director-General's approval and support to act as an AEC in accord with these Terms of Reference, the ACPA and the Scientific Use Code.

The terms of reference for the XYZ AEC are publicly available through the Department's website (www.xyz.qld.gov.au/animalethics/).

Terms of Reference for the XYZ AEC

The terms of reference for the XYZ AEC include the following provisions:

- (i) The scope of its responsibilities for ethical review, approval and monitoring of animal care and use;
- (ii) Institutional accountability;
- (iii) Mechanisms of reporting; and
- (iv) The way in which it meets the requirements for categories of minimum membership (clause 2.2.18).

Responsibilities of the XYZ AEC

The primary responsibility of the XYZ AEC is to ensure, on behalf of the Department of XYZ, that all activities relating to the care and use of animals for scientific purposes are conducted in compliance with the Scientific Use Code (clause 2.3.1).

The XYZ AEC must:

- (i) Review applications for projects and approve those projects that are ethically acceptable (see clause 1.3) and conform to the requirements of the Scientific Use Code

(Clause 1.3 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, and must balance whether the potential effects on the wellbeing of the animals involved is justified by the potential benefits.)

(Clause 1.1 Respect for animals must underpin all decisions and actions involving the care and use of animals for scientific purposes. The respect is demonstrated by:

- i. Using animals only when justified
- ii. Supporting the wellbeing of the animals involved
- iii. Avoiding or minimising harm, including pain and distress, to those animals
- iv. Applying high standards of scientific integrity
- v. Applying Replacement, Reduction and Refinement (the 3Rs) at all stages of animal care and use:
 - 1. The Replacement of animals with other methods
 - 2. The Reduction in the number of animals used
 - 3. The Refinement of techniques used to minimise the adverse impact on animals
- vi. Knowing and accepting one's responsibilities.)

- (ii) Review applications for activities associated with the care and management of animals in facilities, including procedures applicable to breeding programs integral to the maintenance of an animal line, and approve only those activities that are ethically acceptable;

- (iii) Conduct follow-up review of approved projects and activities (as per clause 2.2.32[ii]), and allow the continuation of approval for only those projects and activities that are ethically acceptable and conform to the Code;

(Clause 2.2.32[ii] Institutions, in consultation with the AEC, must develop documentation for:

[ii] follow-up review of an approved project or activity at scheduled times and when circumstances trigger additional follow-up review, including:

- (a) proposed amendment to an approved project or activity (see clause 2.7.6)
- (b) review of annual progress of an ongoing project or activity
- (c) unexpected adverse event)
- (iv) Monitor the care and use of animals, including housing conditions, practices and procedures involved in the care of animals in facilities;
- (v) Take appropriate actions regarding unexpected adverse events;
- (vi) Take appropriate actions regarding non-compliance;
- (vii) Approve guidelines for the care and use of animals on behalf of the Department of XYZ;
- (viii) Provide advice and recommendations to the Department of XYZ; and
- (ix) Report on its operations to the Department of XYZ.

Accountability

The XYZ AEC is responsible to the Director-General of the Department of XYZ through the Assistant Director-General. All communication with the Director-General should be through the Principal Project Officer (XYZ Animal Ethics Committee) to the Assistant Director-General.

The Department of XYZ conducts an annual review of the operation of the XYZ AEC to ensure that it is effective and consistent with the Scientific Use Code and institutional policies. The annual review process includes consideration of the annual report from XYZ AEC and meeting with the Chairperson of the XYZ AEC (clauses 2.1.9 [ii], 2.2.37, 2.3.28, 2.3.29).

The Department of XYZ (including the XYZ AEC) is also required to conduct an independent external review of its compliance with the Scientific Use Code, at least every 4 years, in accordance with section 6 of the Scientific Use Code.

Reporting

Annually, the XYZ AEC is required to submit a written report on its operations to the Director-General of the Department of XYZ.

The report contains the following information:

- (i) Numbers and types of projects and activities assessed, and approved or rejected;
- (ii) The physical facilities for the care and use of animals by the Department of XYZ;
- (iii) Actions that have supported the educational and training needs of AEC members and people involved in the care and use of animals;
- (iv) Administrative and other difficulties experienced; and

- (v) Any matters that may affect the Department of XYZ's ability to maintain compliance with the Scientific Use Code and any suitable recommendations (clause 2.3.29).

Membership of the XYZ AEC

The Department of XYZ must ensure that the membership of the XYZ AEC complies with the requirements of the Scientific Use Code, which includes:

- (i) Appointing at least one person from each of the four membership categories (A, B, C & D) as outlined in clause 2.2.4;
- (ii) The category C & D members must represent not less than one-third of the XYZ AEC membership (clause 2.2.8);
- (iii) Appointing a Chairperson from the existing membership (preferably a person holding a senior position in the Department) or a suitable external appointee (clause 2.2.2);
- (iv) The option of appointing a person responsible for the routine care of the animals and persons with skills and background of value to the XYZ AEC (clauses 2.2.5 & 2.2.6); and
- (v) On occasions, the XYZ AEC may invite persons with specific expertise to provide advice (non-member advisors) (clause 2.2.7).

The XYZ AEC may also select a Deputy Chairperson (from within its membership) to cover any short-term absences by the Chairperson.

The Department of XYZ has also appointed an Executive Officer to assist the Chairperson and the XYZ AEC in its operation. The Executive Officer is not a member of the XYZ AEC but works closely with the XYZ AEC.

Responsibilities of the Chairperson

The Chairperson is responsible for:

- Impartially guiding the operation of the XYZ AEC;
- Resolving conflicts of interest related to the business of the XYZ AEC;
- Representing the XYZ AEC in negotiations with the Department of XYZ's management.

Responsibilities of XYZ AEC members

Each XYZ AEC member is responsible for deciding whether, in their own judgement, an application or other matter under consideration by the XYZ AEC is ethically acceptable and meets the requirements of the Scientific Use Code. XYZ AEC members should be familiar with the requirements of the Scientific Use Code and other policies and guidelines relevant to the business of the XYZ AEC.

XYZ AEC members must comply with the terms of reference and operating procedures of the XYZ AEC.

Role of the Executive Officer

The Executive Officer will assist the Chairperson and ensure the efficient operation of the XYZ AEC by:

- being the first point of contact for applicants wishing to access the XYZ AEC;
- expediting project applications and approval processes through the provision of advice and assistance to researchers regarding ethics applications, procedures and mandatory reporting requirements. organising the distribution of information to members and scheduling meetings and monitoring sessions;
- overseeing database integrity and requirements & providing management reports;
- assisting with the conduct and recording of meetings of the XYZ AEC; and compliance with all legal and ethical responsibilities as required by the ACPA and Scientific Use Code; and
- any other duties as required by the Department of XYZ.

Operating Procedures for the XYZ AEC

Appointment and retirement of XYZ AEC members

The Executive Officer of the XYZ AEC monitors the membership needs of department's AEC in consultation with the AEC Chairperson.

If a new member is required, the Executive Officer may call for 'expressions of interest', search the Queensland Register of Nominees to Government Bodies and/or make direct approaches to representative groups (for example, RSPCA and Animals Australia). Unsolicited applications lodged periodically by departmental officers and external persons with an interest in serving on a departmental AEC may be considered also.

An interested person must complete an *AEC membership application form* to acknowledge their acceptance of the terms of reference of the AEC and indicate in writing on what basis they satisfy the relevant membership category criteria as defined in clause 2.2.4 of the Scientific Use Code. An external applicant must also complete an *Appointment to government body: Personal particulars form*. Applicants must complete any other membership form required by the relevant state jurisdiction (e.g. Form EC14 required by Biosecurity Queensland).

The completed forms must be submitted to the Executive Officer. The Executive Officer will provide any relevant forms or other information as required by any the relevant state jurisdiction (e.g. forward completed Form EC14 to Biosecurity Queensland within 28 days of the member's appointment as a member of the XYZ AEC).

The Executive Officer will confirm the availability of departmental officers with line managers. The Executive Officer, in consultation with the AEC Chairperson, will assess applications and make recommendations to the Assistant Director-General. The Assistant Director-General will recommend AEC appointments to the Director-General. The Director-General may accept or reject recommended appointments.

The Executive Officer will prepare a briefing note to the Minister and letter seeking the Premier's support for the proposed appointment(s).

The Executive Officer will obtain a signed confidentiality agreement from each prospective new member before producing letters of appointment for the Director-General's signature. Where the appointee is a departmental officer, a copy of the letter of appointment will be forwarded to the appointee's line manager.

The Executive Officer will maintain a record of all appointments to the XYZ AEC and associated documents.

Members are appointed to the XYZ AEC until either they resign, are retired by the Director-General or die. A member may resign from the AEC at any time by advising the Chairperson in writing.

Acceptance of Terms of Reference

Prior to appointment, all XYZ AEC members will acknowledge, in writing, that they accept these Terms of Reference.

Declaration of interests and management of conflicts of interest

All XYZ AEC members and experts, whose advice is sought by the XYZ AEC, are required to declare any real or perceived financial, professional or personal interests that may influence their objectivity in their decision making with regard to any business to be discussed by the XYZ AEC at its meetings. Declarations are to be made:

- (i) Prior to their appointment - by making a signed declaration of all real or potential interests as part of the member application process;
- (ii) As matters arise - by declaring all real or potential interests and the nature of that interest to either the Chair or Executive Officer of the AEC as soon as is reasonable after they become aware of that their objectivity could be impacted;
- (iii) At each meeting (as an early item of the meeting agenda) - by declaring all interests (real or perceived) which could affect their objective decision making in relation to any items on the meeting agenda or any other matter relating to membership of the AEC.

All declarations of interest (as part of the appointment process, between or at meetings) need to be recorded in the relevant meeting minutes.

Management of situations where a conflict of interest arises

When an XYZ AEC member declares an interest, the XYZ AEC member should leave the meeting temporarily while the remaining XYZ AEC members decide whether or not a conflict exists.

Once a decision has been made as to whether or not a conflict of interest (actual or perceived) exists, the decision and the method of dealing with any conflict must be recorded in the relevant meeting minutes (e.g. record when the member left and returned to the room or recording the basis on which it was decided that the member could participate in the item).

If it is determined that a conflict of interest exists, the XYZ AEC member must leave the meeting at an appropriate time (certainly before the consideration and decision making process). The remaining members must still constitute a quorum (i.e. categories A, B, C & D) in order to come to a decision.

The XYZ AEC must consider and respond to any concern or claim raised by the person with ultimate responsibility for the project or other party that an AEC member has an interest which may have influenced the objectivity of an XYZ AEC decision. The XYZ AEC should advise the complainant, in writing, of its response to any concern or claim relating to a conflict of interest.

If the complainant is not satisfied with the XYZ AEC's response, then a complaint/ grievance can be lodged as per XYZ policy (see Corporate Standard HR 4.2B "*Grievances procedures*").

Confidentiality

AEC members will sign a confidentiality agreement or deed prior to appointment.

All visitors and persons advising or assisting the XYZ AEC will sign a confidentiality agreement or deed prior to their first meeting.

Meeting procedures

The XYZ AEC will determine its meeting frequency but should aim to meet on a monthly basis.

The Chair will ensure that an agenda is produced by the Executive Officer (AEC Secretary) prior to each meeting and the meeting will consider AEC business as required to fulfil the Committee's responsibilities.

The Executive Officer (AEC Secretary) will ensure that: all relevant documents (for example, minutes, correspondence and applications) are distributed prior to the meeting allowing reasonable time for members to read, consider and prepare questions. The secretary will also maintain the 'hard copy' filing system for the animal ethics system.

Each meeting will be quorate (i.e. at least one member from each of Categories A, B, C and D). Category C and D members must represent not less than one-third of the members participating in a meeting. .

Meetings of the XYZ AEC are face to face meetings. In exceptional circumstances, when a member is required to achieve a quorum they may participate in the meeting using

videoconferencing or web conferencing if it is not possible and/or practical to attend the meeting in person. Teleconferencing is only permitted in special circumstances.

The participation of a member via videoconferencing or web conferencing or teleconferencing must be clearly noted in the AEC minutes and the member may authorise the Chair to record their support on the proposal.

The Executive Officer (AEC Secretary) will maintain minutes of decisions and other aspects of AEC business for each meeting.

Communication

The XYZ AEC will clearly communicate its decisions, the reasons for its decisions and any conditions attached to an approval to investigators, in writing, as soon as possible after the meeting.

XYZ AEC Executive

The XYZ AEC has established an AEC Executive whose membership includes the Chairperson and a Category C member.

The XYZ AEC Executive has been delegated to only approve minor amendments to approved project or activities which will be ratified at the next quorate meeting of the XYZ AEC. Minor amendments include a change to an approved project or activity where the proposed change is not likely to cause harm to the animals, including pain and distress (clause 2.2.23). The XYZ AEC Executive must not approve new applications.

Specific XYZ AEC Tasks

1. Review and decide on new and ongoing activities

The XYZ AEC must make a judgement on whether the proposed use, or continued use, of animals is ethically acceptable. This judgment is must be based on information that demonstrates that the principles in clause 1.1 of the Scientific Use Code, and must balance whether the potential effects on the wellbeing of the animals involved is justified by the potential benefits (clause 1.3).

Respect for animals must underpin all decisions and actions involving the care and use of animals for scientific purposes. The respect is demonstrated by:

- Using animals only when justified
- Supporting the wellbeing of the animals involved
- Avoiding or minimising harm, including pain and distress, to those animals
- Applying high standards of scientific integrity
- Applying Replacement, Reduction and Refinement (the 3Rs) at all stages of animal care and use:

- The Replacement of animals with other methods
- The Reduction in the number of animals used
- The Refinement of techniques used to minimise the adverse impact on animals
- Knowing and accepting one's responsibilities (clause 1.1)

The XYZ AEC may approve only those projects and activities that are ethically acceptable and conform to the requirements of the Scientific Use Code.

The XYZ AEC must base its decisions on the information it receives from the applicant in the documentation and in any direct discussions with the applicant and may use information in addition to that obtained from the applicant.

Decisions are based on thorough, fair and inclusive discussion and deliberation by XYZ AEC members present throughout the discussion. Decisions should be made on a basis of consensus. Where consensus can't be reached and reasonable efforts made to resolve differences, the XYZ AEC should explore with the applicant ways to modify the project to activity that may lead to consensus. If consensus is still not achieved, a majority decision is required after the members have been allowed time to review their positions and further follow up discussion.

Approval of an ongoing project or activity must be based on the review of the annual progress report and further information from unexpected adverse events, complaints, records and inspections.

2. Monitor the care and use of animals

The XYZ AEC monitors the care and use of animals by inspecting animals, animal housing on XYZ sites and non-XYZ sites where the AEC has approved activities and the conduct of procedures and reviewing records and reports.

The XYZ AEC must monitor all activities relating to the care and use of animals (including the acquisition, transport, breeding, housing and husbandry of animals) on a regular basis to assess compliance with the Scientific Use Code and decisions of the XYZ AEC. The XYZ AEC will monitor activities that are likely to cause pain or distress at an early stage of the activity and this will be included as a condition of approval.

All inspections by the XYZ AEC must include a Category C or D member as part of the inspection team.

Authorising suitably qualified delegates to carry out inspections of project and activities being conducted at remote sites on behalf of the XYZ AEC. Delegates must prepare written reports for the AEC following inspections.

Viewing animals during site inspections monitoring activities and ensuring that appropriate records are being kept of animal care and use. A copy of the report of the inspection or monitoring will be provided to the person with ultimate responsibility for the project and the person in charge of the animals and managers where appropriate.

Receiving reports of and commenting on unexpected or adverse effects that impact on the wellbeing of animals used for scientific purposes.

Reviewing long-term projects at least annually by requiring annual reports for each activity from the person with ultimate responsibility for the project. Annual Reports must be reviewed by the XYZ AEC to monitor that animal use is consistent with and in accord with the approved application for the activity.

Reviewing activity completion reports to confirm that animal use is consistent with and in accord with the approved application for the activity.

Annual and completion reports should contain as a minimum all detail as outlined in clauses 2.2.32 and 2.4.34 of the Scientific Use Code.

3 Taking action regarding unexpected adverse events

The XYZ AEC will take appropriate action in response to reported unexpected adverse events to ensure animal wellbeing is not compromised, the issue is addressed promptly and activities that have the potential to adversely impact animal wellbeing cease immediately (clause 2.3.24)

In taking appropriate action, the XYZ AEC can:

- Ensuring the wellbeing of the animals involved is being addressed
- Consult with relevant people including the person with ultimate responsibility for the project/ activity, other researchers, the animal facility manager, animal care staff, etc.
- Suspend or withdraw XYZ AEC approval for the project/ activity
- Take further action, if it constitutes non-compliance with the Scientific Use Code or approved project procedures (see next section).

4. Taking action regarding non-compliance

If the XYZ AEC detects a breach of the Scientific Use Code, in connection with a project or activity, the XYZ AEC will:

- Ensure that the wellbeing of the animals being used is not compromised
- Activities that have the potential to adversely affect animal wellbeing are ceased immediately
- The issue is addressed promptly by consulting with the person(s) involved
- The suspension or withdrawal of approval for the project or activity
- Refer the matter to the Director – General for further action

- Ensure appropriate follow-up of the issue is undertaken.

5 Approve guidelines for the care and use of animals

The Department of XYZ, an institution which cares for and uses animal for scientific purposes, is required to develop guidelines for the care and use of these animals in line with clause 2.1.5 [v] of the Scientific Use Code.

This process will be conducted in consultation with the XYZ AEC and the final guidelines will approved by the XYZ AEC. These guidelines are the standard which staff (and external registrants) must abide by when caring for and using animals for scientific purposes (clause 2.3.26).

The XYZ AEC will also be required to provide comment and recommendations to the Department when the guidelines are updated.

6 Provide advice and recommendations to the Department

The XYZ AEC will be required to provide advice and recommendations to the Department of XYZ regarding:

- (i) the care and use of animals for scientific purposes within the Department;
- (ii) strategies required to ensure that the requirements of the Scientific Use Code are maintained; and
- (iii) matters affecting animal wellbeing. (clause 2.3.27)

7 Reporting to the Department

The XYZ AEC must submit an annual written report on its operations to the Director-General (clause 2.3.28).

The annual report will include the following information:

- (i) The numbers and types of project and activities assessed and approved/ rejected;
- (ii) The physical facilities for the care and use of animals;
- (iii) Actions that have supported the educational and training needs of XYZ AEC members and staff involved in the care and use of animals;
- (iv) Any administrative or other difficulties experienced
- (v) Any matters that may affect the Department's ability to maintain compliance with the Scientific Use Code and any suitable recommendations, if appropriate.

Revision:

The XYZ AEC Terms of Reference will be reviewed as necessary in response to changes in legislation and departmental policy.

References:

Animal Care and Protection Act 2001

Australian code for the care and use of animals for scientific purposes

Contact:**Principal Project Officer (XYZ Animal Ethics)**

Department of XYZ

Brisbane Qld 4000

Telephone: 07 3XXX XXXX

Fax: 07 3XXX XXXX