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	Guidelines for CHM Alliance Pty Ltd Animal Ethics Committee Members	

Introduction

The *Prevention of Cruelty to Animals Act 1986* (hereinafter referred to as ‘the Act’) requires that institutions conducting research involving animals comply with the *Australian code for the care and use of animals for scientific purposes, 8th Edition 2013* (hereinafter referred to as ‘the Code’) and establish an Animal Ethics Committee (AEC) to oversee the conduct of the institution’s experimentation activities.

Section 2 of the Code ‘Responsibilities’ details the responsibilities of institutions and their AECs. This section should be read carefully with particular regard to terms of reference, operating procedures, membership for AECs, assessment of proposals, and monitoring and reporting requirements.

The Code outlines the particular attributes and responsibilities of the various members of the AEC and the guidelines are set out below according to the membership category: Chairperson, Category A, Category B, Category C and Category D members.

The Code also outlines the potential for additional members: *‘in addition to the prescribed membership categories A to D, the institution should appoint to the AEC a person responsible for the routine care of animals from within the institution. This membership is not mandatory.’* For example, an animal facility manager or technician can provide invaluable practical advice to the committee and would often benefit from membership on the committee as the animal facility is often delegated some monitoring responsibility for project animals.

Furthermore, to assist the AEC to function effectively, organisations may appoint as members, people with skills and background of value to the AEC. The AEC may also invite people (non-members) with specific expertise to provide advice as required.

When appointing additional voting members to the AEC, consideration should be given to maintenance of a quorum in accordance with the Code’s requirements. The Code states that, if the Committee has more than four members, Categories C plus D must represent no less than one third of the members. Although few AEC decisions are made by majority decision, this stipulation protects AEC’s from perceptions of bias in favour of the organisation or other parties. Members additional to the Categories A, B, C and D may be appointed as voting or non-voting members. The final membership of voting members should comply with the Code’s requirements for $\frac{1}{3}$ independent membership.

Sources of information

Various organisations publish or can access material that may provide background and/or relevant information pertaining to issues arising in an AEC. Please see the Appendix for details.

Role of the AEC

The primary responsibility of AEC's is to ensure that all care and use of animals is conducted in compliance with the Code. AEC's apply a set of principles outlined in the Code that govern the ethical conduct of people whose work involves the use of animals for scientific purposes. The role of the AEC is to ensure that the use of animals is justified, provides for the welfare of those animals and incorporates the principles of Replacement, Reduction and Refinement (the Three R's) introduced by Russell and Burch in 1959.

It is the organisation holding the relevant licence, the nominated person on that licence and the relevant investigator(s) that bear legal responsibility for the use and care of the animals. There is no offence in the legislation associated with the AEC members.

All categories of members are equally valuable and valued. The knowledge, expertise and personal opinions of individual members will obviously vary considerably, but certain overlapping characteristics and abilities are desirable if the AEC is to function well as a group and the members are to find the work rewarding. These include:

- an acceptance that ethical experiments on animals can be carried out as long as there is no alternative
- courtesy and patience in dealing with other committee members and with investigators
- willingness to listen as well as to speak
- clarity and succinctness in oral and written communication

AEC members must also in particular:

- Consider and discuss the purpose and likely benefits of the proposed research.
- Consider the need for the use of animals, the number requested, evidence of use and consideration of alternatives and reasons for rejection of known alternatives.
- Discuss the invasiveness of procedures, repetitive procedures, analgesia, anaesthesia, endpoints, euthanasia and other matters which affect the day-to-day existence of the animals and consider refinements wherever possible.
- Consider meeting procedures, executive power, decision-making procedures, dispute resolution procedures and so on, to ensure that all AEC activities are fair and reasonable.
- Ensure that scientific details are presented and explained in a manner which is understandable to lay members of the AEC.
- Regularly inspect the animal holding and all research/laboratory areas and examine and advise on housing, feeding rosters, monitoring rosters and records, bedding, lighting, environmental enrichment and other aspects of animal care.
- Consider annual and final research reports.
- Consider whether proposals are justified weighing the scientific or educational value of the study against the potential effects on the welfare of animals.

Terms of Reference and Operating Procedures

Terms of Reference

The AEC has terms of reference that are publicly available and describe procedures required by the Code (see Section 2). Terms of reference are regularly reviewed and all processes described are compliant with the Act, Regulations and the Code. They must be accepted in writing by each AEC member on appointment and whenever they are revised.

Introduction to the Committee

It is a condition of all Scientific Procedures licences that the organisation notifies the Department of Agriculture, Fisheries and Forestry (DAFF) of any change in membership of an Animal Ethics Committee within 14 days of that appointment. The department requests sufficient information about the nominee to assess their suitability for the proposed membership Category in accordance with the Code.

It is advisable for prospective members to discuss the terms of reference of the Committee with the Chairperson and have a clear understanding of the type of work undertaken at the organisation prior to accepting an offer of membership of the Committee. New members of an AEC must ensure that you have been afforded an adequate introduction to the organisation and to the other members of the AEC prior to attending their first meeting.

If appropriate, new AEC members should:

- Be provided with a list of the other AEC members and brief details of their background/role on the AEC
- Meet with the Chairperson to discuss meeting procedures and other AEC activities
- Be provided with or advised of any organisational requirements for research involving animals, confidentiality, workplace health and safety and any other requirements such as biosecurity procedures
- Be provided with a copy of the Act and the Code and any other relevant AEC guidelines
- Be provided with access to the register of approved projects to familiarise members with current and ongoing research
- Be provided with written protocols and other material to be considered at any meeting
- Be provided with access to approved SOPs
- Be made aware of their entitlements in terms of sitting fees, remuneration of travelling expenses, office expenses and the like
- Be advised of any training opportunities provided by the organisation to enhance their skills relevant to their AEC duties.

Confidentiality

Members of the AEC must sign a 'Confidentiality Agreement' prior to or soon after appointment. The agreement is designed to protect material that may be commercial in nature (for example, related to intellectual property, patents).

Any agreement should not prevent AEC members from seeking expert advice or the valued views of others, on experimentation applications or other aspects of AEC activities, providing such advice is sought on a confidential basis and does not divulge any sensitive aspects of the matter. It is possible to discuss the general merits (or otherwise) of applications or issues without breaching confidentiality. The only exception may be those applications marked 'Commercial-in-Confidence'. A confidentiality agreement should acknowledge the need of AEC members to discuss aspects of their work with others.

Potential concerns held by independent members of AEC' regarding their role on the AEC include the possibility of having to defend themselves in court against allegations of breach of confidentiality. Statutory protection may be provided to certain volunteers by the Commonwealth Volunteers Protection Act 2003 (Federal). Careful note should be made of the definitions and legal advice should be sought on the interpretation of the Act. In addition, CHM Alliance Pty Ltd may include provision for indemnity of formally appointed AEC Committee members, subject to any exceptions stated in the indemnity provision.

CHM will comply with the Code requirements (Section 2) that all aspects of confidentiality arrangements be fairly discussed with all members of the AEC, and that provision is made for AEC members to seek advice without breaching confidentiality. Organisations are advised to seek their own legal advice regarding confidentiality and provide members, particularly, independents, with any advice pertaining to their situation, especially the provision of any indemnity.

Executive composition and powers

The Code allows the AEC to appoint an Executive to make minor modifications to approved projects and deal with emergencies between full AEC meetings. One of either the Category C or the Category D members must be on the Executive. The Executive may not approve new proposals. Any decisions made by the Executive must be reviewed by the AEC at its next meeting and be recorded in the minutes.

Conflict resolution

Grievance procedures for both AEC members and investigators are clearly defined in the terms of reference and operating procedures of the AEC. The Code states that 'where possible, decisions on approvals of proposals should be made on the basis of consensus'. Furthermore 'where two or more members oppose a proposal it should not be approved until the AEC has explored ways of modifying the project that may lead to consensus'. In most instances consensus can be reached. A majority decision should only be undertaken after a review period.

(a) Conflict between an investigator and the AEC

Disputes between an investigator and an AEC may arise, and in the first instance the Chairperson of the AEC will try to resolve the dispute. If, however, the Chairperson is unable to resolve the dispute, then the dispute will be referred to the Board for review. The DAFF may be consulted on these matters if the AEC, investigator or organisation so desires.

(b) Conflict involving a member of the AEC

From time to time, members of the AEC may become dissatisfied with the functioning of the Committee or aspects of animal welfare, and / or have ideas on how the functioning of the Committee or animal welfare could be improved. The Chairperson will listen to these complaints seriously and carefully consider ideas for improvements. Members of the AEC are advised that if their concerns are not sufficiently addressed they can take their concerns in the first instance to the head of the organisation and if still unresolved to DAFF.

Chairperson

Attributes of the Chairperson

The Code sets out a number of attributes that the Chairperson should have. The Chairperson should hold a senior position in the organisation in order to facilitate quick and effective implementation of AEC recommendations. Exceptions may be entirely satisfactory where the individual has the appropriate skills and support from management. Critically, an effective Chairperson will need to be able to elicit the views and participation of all members of the AEC and to summarise and balance fairly these in arriving at acceptable group decisions.

Ideally, the Chairperson will be committed to the spirit of ethical science, to disseminating that ethical view to the organisation and the wider community and be able to understand the issues and conflicts involved in balancing the needs of investigators and the welfare of animals. In addition, to be effective, a Chairperson will need to be readily accessible to AEC members and investigators and to be able to respond quickly to matters that arise.

According to the Code the Chairperson may be an additional appointment to category A to D members.

Responsibilities of the Chairperson (see also Section 2 of the Code)

The key responsibilities of the Chairperson are to:

- Impartially guide the operation of the AEC
- Resolve conflicts of interest related to the business of the AEC
- Represent the AEC in any negotiations with company management
- Ensure that the AEC operates in accordance with the principles and requirements of the Code, the relevant policies of the organisation and the agreed AEC procedures
- Ensure that the process by which decisions about applications are made is fair to investigators and acceptable to all AEC members
- Ensure that minutes are maintained that record decisions and all other aspects of the AECs operation
- Organise the conduct of an annual review of the operation of the AEC and the effectiveness of its processes regarding complaints and non compliance
- Ensure that an independent external review is conducted at least every four years to assess the institution's compliance with the Code and to ensure the continued suitability, adequacy and effectiveness of its procedures to meet its responsibilities
- Ensure that a register of approved projects is maintained
- Ensure that AEC members inspect animal housing and research/laboratory areas regularly and that records of these inspections are maintained
- Ensure that AEC recommendations are acted on/carried out
- Ensure frequent communication with the organisation's management to ensure the AEC is adequately resourced and that the organisation's management is aware of any problems occurring
- Ensure that the AEC submits an annual report to the governing body or head of the organisation in accordance with the Code
- Recommend corrective measures/discipline to accompany breaches of protocol
- Ensure that DAFF via Biosecurity Queensland is notified of approved fieldwork (as per the Prevention of Cruelty to Animals Regulation 2012).

Other suggested duties of the Chairperson

For the smooth operation of the AEC, the Chairperson may also find it useful to:

- Encourage investigators to attend AEC meetings when their applications are under consideration – this provides Committee members the opportunity to address questions and concerns directly to the investigators
- Ensure that each member of the Committee has ample opportunity to ask questions of and discuss issues with the investigators
- Ensure that a quorum is maintained if any member of the AEC is required to leave the room during discussion of a decision on any proposal
- Ensure that the discussion of scientific aims, justification and technical details are held at a level understandable to the non-scientific members of the AEC

- Encourage questions and discussion from the non-scientific members on the Committee
- Ensure that Committee members receive applications and any other papers at least seven days before each meeting
- Ensure that the investigator(s) has left the room when the proposal is discussed by the AEC
- Support the dissemination of information on issues of animal ethics within the organisation and the community
- Co opt additional expertise to the Committee if required

If the Chairperson is a scientist/investigator whose applications are considered by the AEC, then a deputy should assume the chair when such applications are under consideration and the chairperson will have left the room.

Category A Members

The Code stipulates particular attributes of the Category A member. The Category A person is *'a person with qualifications in veterinary science and with experience relevant to the activities of the institution'*.

A Category A person will possess a degree that enables them to register as a veterinary surgeon in Australia. Where veterinarians do not have training and experience in the husbandry of the species used in the organisation, they must familiarise themselves with the biology and clinical characteristics of the species used. Ideally, a Category A member will have a good understanding of issues relevant to experimental design and the scientific method.

Responsibilities of the Category A member

Category A persons should note that the responsibility for determining the adequacy of the experience, qualifications, and technical skills of investigators rests entirely with the AEC. The Category A member should:

- Ensure that conditions provide for the humane care of animals used for scientific purposes
- Consider the potential impact on the welfare of animals against the potential scientific or educational value of the research proposal
- Advise on the nature of procedures proposed and their impact on the well being of animals involved and, where necessary, suggest more humane alternatives
- Advise the AEC whether the use of local or general anaesthetic, analgesic or tranquillising agents in the protocol is appropriate to the species and parallels used in current veterinary practice
- Ensure that proposals for animals to be used in research involve subjecting animals to the minimum of pain and distress consistent with the needs of the experiment and where possible, promote techniques that enhance wellbeing; in particular, provide technical advice on:
 - animal husbandry
 - anaesthesia and analgesia
 - techniques for obtaining blood and tissues samples
 - surgery and post operative care
 - assessment and monitoring of pain
 - humane killing of animals
 - adjuvants
 - sources of information on best practice, alternatives and the 3Rs

- regularly inspect the organisation's animal care facilities, including those for breeding animals and advise on their suitability and impact on the welfare of animals
- ensure that those involved in the care and handling of experimental and breeding animals have the necessary skills and expertise
- seek assistance, where necessary, from others and remain up to date with the relevant issues in experimental design and the care and welfare of research animals, including the recognition and control of pain in research animals
- assess and discuss with the AEC the scientific merit of research proposals, experimental design and necessity for animal usage

Category B Members

The Code stipulates particular attributes of the Category B member. The Category B person is *'a suitably qualified person with substantial recent experience in scientific or teaching activities. This will usually entail possession of a higher degree in research'*.

Responsibilities of the Category B member

The responsibilities and activities listed below outline the role of a Category B member on an AEC. For details of investigator responsibilities refer to Section 2 of the Code.

The responsibilities of a Category B member of an AEC are to:

- assess the scientific merit of proposals in terms of both experimental design and importance of contribution to knowledge base
- ensure that the experiments proposed are of the highest standard
- ask questions of the investigators relating to all aspects of the scientific process, including aims, previous studies, experimental design, choice of species, statistical methods, availability of non-animal alternatives, use of alternative procedures, anaesthesia, analgesia, endpoints, euthanasia etc.
- provide scientific expertise to the Committee
- explain details of the science in lay terms to the non-scientific members of the Committee (where required)
- consider available alternatives to animal use and implementation of the 3Rs wherever possible
- consider whether proposals are justified weighing the scientific or educational value of the study against the potential effects on the welfare of animals

Category C Members

The Code stipulates particular attributes of the Category C member. The Category C person is *'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. Veterinarians with specific animal welfare interest and experience may meet the requirements of this category as appropriate Category C members (for example, through working in shelters, other animal welfare organisation/s). In general, the Category C person while not representing an animal welfare organisation, should, where possible, be selected on the basis of active membership of, and nomination by, an animal welfare organisation.'*

A Category C member must have awareness of current community animal welfare concerns and an ability to communicate these concerns. At the outset it is important for a Category C member to understand and accept that a major role of the AEC is to approve scientific procedures involving animals where the requirements of the Code and legislation have been met.

Responsibilities of the Category C member

The Category C member should bring an ethical and animal welfare perspective to the deliberations and activities of the Committee. While all members of the AEC must consider the welfare of animals and the ethics of their use, the Category C member brings an awareness of current animal welfare concerns.

Through the Category C member of AECs, the animal welfare movement will become more knowledgeable about how work is undertaken on animals in research organisations. Similarly, researchers and teachers using animals will become more aware of the concerns of the animal welfare community.

The Category C member should promote the reforms known as the '3Rs' (ie gaining the same/similar knowledge/endpoint through (i) the replacement of animals by non-animal alternative techniques; (ii) the reduction in the number of animals used; and (iii) the refinement of techniques used to reduce the impact on animals or even enhance wellbeing) whenever possible. Most animal welfare organisations see this as the crucial role of AECs and look to Category C members to promote the 3Rs. This is not an easy role, particularly considering the diversity and complexity of research topics and research methods.

Ultimately, it is the role of all members of the AEC to consider whether proposals are justified weighing the scientific or educational value of the study against the potential impact on the welfare of animals.

Further advice for Category C members

Much of the role of an animal welfare member of the AEC will be achieved by asking questions about the aims of the proposed research, the reasons for using animals, the likely affect on the animals, the fate of the animals, the significance of the expected results etc. Other members of the AEC will be able to provide specialist information about veterinary and scientific details. Category C members may wish in particular to:

- consider and discuss the purpose and likely benefits of the proposed research
- consider the need for animals, the number requested, evidence of use and consideration of alternatives and reasons for rejection of known alternatives
- visit the animal holding area and inspect caging/housing, feeding rosters, monitoring rosters, bedding, lighting etc.
- discuss the invasiveness of procedures, repetitive procedures, analgesia, anaesthesia, arrangements for humane death and other matters which affect the day-to-day existence of the animals
- take particular interest in any aspect of proposal assessment or meeting business that coincides with their area(s) of expertise

Category D Members

The Code stipulates particular attributes of the Category D member. The Category D member is *'a person both independent of the organisation and who has never been involved in the use of animals in scientific or teaching/training activities using animals, either in their employment or beyond their undergraduate education. Category D members should be viewed by the wider community as bring a completely independent view to the AEC and must not fit the requirements of any other Category.'*

Independence from the organisation requires that the member avoid any conflict of interest that may affect their ability to perform their duties according to the Code. This does not preclude the organisation providing the member with sitting fees or remuneration of travelling or office expenses.

The Code suggests, by way of example as suitable Category D members, distinguished public figures, business people, teachers, retirees, accountants and lawyers. The person will need to have the presence to articulate a reasonable community perspective undaunted by other members who have scientific, veterinary and animal welfare expertise and interest.

Responsibilities of the Category D member

This person should bring an independent perspective and impartial view to the deliberations and activities of the AEC and should see himself/herself as representing the broad community. While all members of the AEC must consider the welfare of the animals used in research, the Category D member brings to the Committee a broad perspective of the current community values.

The Category D person should also ensure that the proper processes are carried out by the AEC, that all research and teaching applications are properly and fairly considered, and that the Code is adequately considered and adhered to.

Ultimately, it is the role of all members of the AEC to consider whether proposals are justified weighing the scientific or educational value of the study against the potential effects on the welfare of animals. Ethical science maximises scientific value and minimises effects to welfare of animals.

Further advice for Category D members

Much of the role of the independent members of the AEC will be achieved by considering the manner in which the AEC operates and how it meets the requirements of the Code. Other members of the AEC will be able to provide specialist information about veterinary and scientific details. Category D members may wish in particular to:

- consider and discuss the purpose and likely benefits of the proposed research
- consider meeting procedures, executive power, decision-making procedures, dispute resolution procedures and so on, to ensure that all AEC activities are fair and reasonable
- ensure that scientific details are presented and explained in a manner which is understandable to you and to other lay members of the AEC
- consider the need for animals, the number requested, evidence of use and consideration of alternatives and reasons for rejection of known alternatives

- visit the animal holding area, and inspect caging/housing, feeding rosters, monitoring rosters, bedding, lighting, etc.
- discuss the invasiveness of procedures, repetitive procedures, analgesia, anaesthesia, arrangements for humane death and other matters which affect the day-to-day existence of the animals
- take particular interest in any aspect of proposal assessment or meeting business that coincides with their area(s) of expertise
- consider annual and final research reports