INFORMATION PACKAGE

FOR MEMBERS OF

ANIMAL ETHICS COMMITTEES

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Preface

ANZCCART is pleased to provide this information package for members of animal ethics committees (AECs). It is particularly important for new category C (animal welfare) and D (lay) members of AECs to be provided with background information about how ethics committees function, as well as what is expected of them as members. While some animal welfare organizations such as the RSPCA offer members who are about to join an AEC fairly extensive training, other groups are not able to offer such a service.

We would therefore suggest that the information presented in this package, should be seen as supplementary to any specific training you may have received or in the absence of such, a useful starting point that will hopefully assist you in taking your place as an effective member of an AEC.

It would also be considered imperative that every member of an AEC has read and is familiar with the ***Australian code for the care and use of animals for scientific purposes 8th Edition, 2013*** as 'the Code' is the rule book that both defines the operation of every AEC as well as providing the practical and ethical framework that underpins all scientific animal use (both research and teaching) in Australia.

Some people may find joining a committee that includes a number of scientific and technical experts a bit daunting. However, you should always remember that category C and D members play a vital role on every AEC, as they are there to represent the wider community and to help provide some level of public accountability for the AEC and its decisions. It has occasionally been suggested that scientific research operates behind closed doors. This should not be accepted, as most scientific research and teaching in Australia is publicly funded and for this reason a line of accountability is essential. An AEC is accountable to the Chief Executive of its institution and must abide by relevant State and Territory legislation and the *Australian Code for the Care and Use of Animals for Scientific Purposes*. It is therefore ultimately accountable through government to the general community.

Being a member of an AEC is an important and worthwhile role to play. It is sometimes difficult work and always involves a lot of reading and the assimilation of significant amounts of occasionally quite complex information. It is particularly important that all members of AECs understand how their committee functions and their part in this process.

AEC work takes time and commitment, which means that people who cannot do the preparatory reading and get to the meetings regularly should not join or remain on a committee.

We hope these notes help you to prepare for your duties and responsibilities as an AEC member and we thank you for taking on this important role.

1. Introduction

These guidelines have been compiled to help AEC members to understand the way in which the committee functions, and to ensure that their participation is worthwhile. They are intended to assist in promoting understanding of the issues affecting AECs and how to address these, to facilitate their effective operation in compliance with the *Australian Code for the Care and Use of Animals for Scientific Purposes 8th Edition, 2013*. The AEC must ensure that all animal-based research and teaching within an institution is carried out in accordance with the Code as well as the relevant laws and institutional guidelines. In doing this, the AEC should also be mindful of and take into account legitimate public concerns about the scientific use of animals.

The use of animals for research or teaching is controversial in Western society. It is frequently the subject of media articles and of public demonstrations and arouses strong feelings in many people. The passion exhibited by some demonstrators can cause some people to respond in kind and we would recommend caution in this regard. Most institutions have fairly clear policy guidelines that define who may speak on their behalf and these would generally be very senior staff or staff members specifically authorised to speak publicly. It is also worth remembering that you will most likely have been asked to sign a confidentiality agreement with the AECs host institution when you joined the committee and so you should never speak to the media about your AEC work without the permission of that institution.

Information about the ways in which animals are used for scientific purposes is not readily available to the non-scientific community. While this is largely due to its technical nature and the interest / requirements of mainstream media outlets, it does nothing to address the perception of a communication barrier between scientists and the general community. This misconception still exists in our society and may potentially lead to mistrust or scepticism of scientists and their motives for animal-based research. This difficulty in communication is exacerbated by scientists not always being allowed, prepared or able to discuss their work in simple language with the media or community groups such as schools and clubs. Occasional emotive and potentially misleading media stories about the scientific use of animals do not help either.

This whole issue was discussed in detail many years ago now by an Australian Senate Select Committee on Animal Welfare, which published its findings in 1989. The resulting 290-page report provided a comprehensive coverage of the public debate in Australia on animal experimentation at that time. It includes chapters on the number of animals used, the moral status of animals and the ethics of animal experimentation, and on animal pain and distress. Detailed coverage is provided on how animals are used in research (biomedical, toxicological, psychological, agricultural and wildlife), on animal-house staffing, facilities and management, on the use of pound animals and on current and proposed future regulatory systems in the Australian States and Territories.

The Report concluded (p. 5) that "there is no doubt that the majority of the population supports biomedical research involving the use of animals, provided that effective controls are operating to keep the number of the animals and the level of pain and distress to a minimum. Until such time as the majority of Australians are persuaded that animal experimentation should not be carried out, and that is translated into legislative form, experimenters have a right to use animals within the regulations and guidelines imposed on such use by government and the scientific community".

This debate continues today, with animal rights groups (represented by Humane Research Australia, Animal Liberation and others), either opposing, or not supporting, animal experimentation. Other groups such as Animals Australia and the RSPCA are strong advocates for animal welfare but also work within the system and support AECs across Australia.

The public debate on animal experimentation in Australia dates from the early to mid-1970s, coinciding with the publication of Peter Singer's book *Animal Liberation* in 1975 and opponents of animal experimentation generally cite ethical and moral beliefs, while supporters argue that the benefits to society (both human and animal) flowing from such use, outweigh the costs (ethical, moral and practical). This debate is frequently passionate and sometimes heated, but always worthwhile because there are no clearly right or wrong answers in this area. It is really a matter of allowing every individual to balance out such equally valid, but disparate opinions.

A key role of every AEC is to help ensure the welfare of all animals under their jurisdiction. The key to implementation of improved welfare for animals used for scientific purposes in Australia is the *Australian Code for the Care and Use of Animals for Scientific Purposes* (2013), endorsed by the NHMRC, CSIRO, ARC Universities Australia, and most of the major research funding bodies around Australia. *The Code* is incorporated into the relevant legislation in all States and Territories and is used as the basis for animal care and use in research and teaching. *The Code* defines the functions and composition of AECs – which are clearly the linchpin of the humane animal use in research and teaching. It is therefore imperative that all AEC members are familiar with *the Code*.

Animal experimentation (the use of animals for research purposes) is often confused by the public with animal testing (the use of animals to satisfy government regulations or assurances regarding human safety). Animal testing is largely associated with the safety testing of new drugs, toxin testing or the testing of cosmetics etc. The use of animals for drug and toxin testing is occasionally done in Australia but it is rare and accounts for only a small proportion of the animals used each year. Cosmetic testing is a very controversial issue in Australia and around the world and the recent bans imposed in the European Union have reignited this debate. It is however worth noting that the Code effectively stopped cosmetic testing in Australia decades ago without the need for specific legislation. Nevertheless, the fact that many cosmetics are labelled 'not tested on animals' or 'cruelty-free' because of public concern for such testing have helped to perpetuate the idea that such testing does still occur in Australia – in site of the facts. Another well known example of animal testing would be the Draize eye test conducted in rabbits and again, in spite of public perceptions, this type of testing has not been used in Australia for a very long time due to the requirements of the Code. This raises an important issue that you should bear in mind. Most of the images used by the media and other organization to highlight instances of animal cruelty are either very old or have been obtained from overseas. One of the key features of the most recent version of the Code is a greater insistence on ensuring the wellbeing of all animals used in research and / or teaching and this is a significantly stronger stance than has been taken in earlier editions that focused on preventing or at least minimizing the pain and suffering of animals.

While we are briefly considering the issue of misuse of information, another area where this commonly occurs is with animal use statistics. Data on the number of animals used for research and the types of research undertaken in Australia each year is not readily available in all states and where it is available, the way detailed information is published does vary, which makes it difficult to do any direct or meaningful comparisons. This is an important issue; as public accountability requires access to this information. The total number of animals used annually for research purposes in Australia is approximately six million, but of these a very significant proportion are used in "observation only" studies or other such activities with minimal impact on the welfare of animals' equivalent animal use is not counted in most other countries.
ANZCCART is working with the relevant organizations as well as State and Territory Governments to address the issue of consistency and accuracy of animal usage statistics across Australia.

2. The Role and Responsibilities of all AEC members

State and Territory laws and *the Code* of Practice require AECs to scrutinise both the scientific or educational value and the ethics of all proposals to use animals in research or teaching. *The AEC may approve only those projects and activities that are ethically acceptable and conform to the requirements of the Code.*

(Code 2.3.5)

When determining the outcome of an application, the AEC will need to consider all aspects of the proposal very carefully. Each application will (or should) contain all the relevant details required to explain exactly what will happen to the animals, who will do it, how skilled they are with those techniques, the effect(s) of treatment on the animals and how they will prevent the animals from suffering any pain or distress as a result of their work. After due and careful consideration of all aspects of the proposal, the AEC will need to reach a consensus decision before approval can be granted. This may require some discussion around the table and / or additional information or potential modification by the applicant(s), so it is not uncommon for an application to come before two or more meetings of an AEC before it gains some form of approval. During this process *each member is responsible for deciding whether, in their own judgement, an application or other matter under consideration by the AEC is ethically acceptable (see Clause 1.3 in the Code) and meets the requirements of the Code.*

(Code 2.2.14)

One of the most fundamental aspects of this approval process is that animals can only be used in circumstances where there are no viable alternatives and their use is fully justified. The Code specifically addresses these issues in the following way:

> *Evidence to support a case to use animals must demonstrate that:*
> *(i) the project has scientific or educational merit, and has potential benefit for humans, animals or the environment*
> *(ii) the use of animals is essential to achieve the stated aims, and suitable alternatives to replace the use of animals to achieve the stated aims are not available*
> *(iii) the project involves the minimum number of animals required to obtain valid data*
> *(iv) the project involves the minimum adverse impact on the wellbeing of the animals involved.*
>
> (Code 1.5)

> *Projects must only be undertaken:*
>
> *(i) to obtain and establish significant information relevant to the understanding of humans and/or animals, or*
>
> *(ii) to maintain and improve human and/or animal health and welfare, or*
>
> *(iii) to improve animal management or production, or*
>
> *(iv) to obtain and establish significant information relevant to the understanding, maintenance or improvement of the natural environment, or*
>
> *(v) to achieve educational outcomes in science, as specified in the relevant curriculum or competency requirements.*
>
> (Code 1.6)

An animal ethics committee (AEC) must be satisfied that there is sufficient evidence to support a case that the proposed use of animals is justified.

(Code 1.7)

It can be extremely difficult for people outside a particular field to judge the scientific value of a project, but all members of the AEC will want to make an informed judgement. It is therefore essential that the AEC is always provided with a well written, clear and concise application that avoids the use of technical jargon or terminology that cannot be reasonably understood by a reasonably intelligent, well – educated lay person. Obviously the makeup of each AEC includes qualified scientists, who may assist lay people see the issues raised by each application clearly and compare the aims and methods with the likelihood of a successful outcome on the one hand, and the probable value to humans or animals of such an outcome on the other. The important thing though is to ensure that everyone understands what they are being asked to approve and if this is not possible, the application should be returned for clarification.

The 3Rs

The use of animals for research purposes has been underpinned (via *the Code*) by the principles of the 3Rs, which were first introduced by Russell and Burch in 1959.

The 3Rs are defined as the Replacement of animals by other methodologies not requiring animals; Reduction in the numbers used; and Refinement of the techniques so that the animals are subjected to the least possible distress. For a detailed analysis of the 3Rs, see *the Code*, Section 1, and for their historical context see Monamy (1996), pp. 31-32.

In Section 1 of the Code (Code 1.18 – 1.30) there is a clear requirement that the principles of the 3Rs must be applied at all stages:

Apply Replacement, Reduction and Refinement (the 3Rs) at all stages

Replacement

1.18 Methods that replace or partially replace the use of animals must be investigated, considered and, where applicable, implemented.

1.19 Before the use of animals is considered, all existing information relevant to the proposed aim(s), including existing databases, must be examined. Replacement techniques that must be considered include the use of epidemiological data; physical and chemical analysis; computer, mathematical and inanimate synthetic models; simulations; in vitro systems; non-sentient organisms; cadavers; and clinical cases.

1.20 Opportunities to replace the use of animals must be kept under review during the lifetime of a project. Where relevant and applicable, the outcome of this review must be implemented in current projects and taken into account in planning future projects.

Reduction

1.21 The number of animals used in a project must be the minimum necessary to achieve the proposed aim(s) and to satisfy good statistical design. The use of too few animals may invalidate the experimental result and result in wastage of animals.

1.22 The number of animals used may be reduced by the appropriate reuse of individual animals. The benefits of reusing animals must be balanced against any adverse effects on their wellbeing, taking into account the lifetime experience of the individual animal. Reuse of animals requires particular justification and specific AEC approval.

1.23 Activities involving the use of animals must not be repeated within a project or between projects unless such repetition is essential for the purpose or design of the project (e.g. sound experimental design, statistical analysis, corroboration by the same or another investigator).

1.24 Reducing the number of animals used should not result in greater harm, including pain and distress, to the animals used.

1.25 All possible steps must be taken to reduce factors that are not part of the experimental design of the project and are known to contribute to variability of experimental results, including the use of animals of known genetic, biological and behavioural background. Reduction of experimental variables may result in reduced animal use.

1.26 Where practicable, tissue and other biological material from animals being killed must be shared among investigators or deposited in a tissue bank for subsequent distribution.

1.27 Breeding of animals must be managed to avoid or minimise the production of excess animals. A new line of animal should not be generated if a similar suitable animal line is available to the investigator. When a new animal line is generated, the colony should be made available as a source for other investigators, as appropriate.

The number of animals to be used in any series of experiments will be a constant source of discussion at AEC meetings and between the AEC and investigators. Clearly there is a real need to ensure that the minimum number of animals is used in each case, but equally there is also a need to ensure that sufficient animals are used to ensure that the data obtained is statistically valid whenever this is a factor. If too few animals are used to obtain statistically significant data, then those animals that have been used were wasted, which would be unacceptable to all.

Where the proposal involves the use of laboratory animals, the usual expectation would be to see some form of statistical justification for the number of animals requested in each group. This would often take the form of a Power calculation (or equivalent), but the onus remains with the applicant to justify the numbers to the satisfaction of all members of the AEC. When it comes to studies that involve counting or trapping wild animals for example, it can be far more difficult for investigators to reliably estimate the number of animals they will encounter. While this does not absolve them from the need to provide a reasonable estimation of the number of animals they expect to observe or potentially handle, the researcher and / or the AEC may need to be a little creative when it comes to satisfying the need to answer this question.

In cases where animals may be trapped or otherwise impacted by the proposed work, it is potentially more important to resolve the issue of numbers more carefully, while still recognising that determining the number of animals and variety of species within the study area is often the aim of such work. One possibility might be to require an indication (or possibly an upper limit) on the number of animals that would need to be trapped for the investigator to be able to make an accurate estimation of the local populations. Such information might also be accompanied by an agreed ‘maximum limit’ number of animals that would be handled before the site / study is closed down. It may also be appropriate to negotiate an upper limit number of animals on the understanding that the door may be open to future applications or modifications that could extend those limits if necessary.

So while the AEC will have an understandable need to set limits on the number of animals in a study, it is reasonable to assume that this will often need to be negotiated with the applicant and both the AEC and the applicant will need to enter into such negotiation with some flexibility.

Refinement

1.28 Steps must be taken at all times to support and safeguard animal wellbeing. The effectiveness of strategies for supporting and safeguarding animal wellbeing must be kept under review during the lifetime of activities, including projects. Where relevant and applicable, the outcome of this review must be implemented in current activities and taken into account in planning future activities, including projects.

1.29 People who care for and use animals must ensure that procedures are performed competently, and

(i) be competent for the procedure they perform, or

(ii) be under the direct supervision of a person who is competent to perform the procedure.

1.30 The duration of activities must be no longer than required to meet the aim(s) of the project, and must be compatible with supporting and safeguarding animal wellbeing. Animals must not be held for prolonged periods as part of an approved project before their use, without AEC approval.

Alternatives

The availability and use of alternatives to animals in research and teaching is currently receiving a lot of attention internationally and there are now a number of organisations dedicated to the use of alternatives (e.g., Animals Australia, CAAT, FRAME, ECVAM). A glossary of these acronyms is found in Appendix 3.

AEC application forms should include a question asking whether a suitable alternative is available, which can replace or reduce the use of animals in this project. This really needs to be taken seriously by the applicant (and by the AEC).

The availability of Internet discussion groups such as that provided by ANZCCART, as well as a number from overseas (e.g., COMPMED from the USA – available to subscribers only (free) and may be accessed by sending an email request to COMPMED-request@LISTSERV.AALAS.ORG) also makes this information much easier to obtain. In the past it has been difficult to access information about alternatives, but this is now much more readily available, particularly through the database NORINA (Norwegian Inventory of Audiovisuals), which is available on the Internet at https://norecopa.no/norina (Note this website is based in Oslo, but also has an Australian mirror site).

Always remember that *the Code* requires that applications to use animals must satisfy the AEC that animal use is essential and that no suitable alternatives exist.

The application form

There is currently no standard Australia-wide application form, although there are a series of South Australian common application forms for use in broad discipline areas. That said, section 2.7 of *the Code* stipulates that each institution that sets up an AEC must, in consultation with the AEC, develop documentation (an application form) that can be used when seeking approval from the AEC for the use of animals. This section (2.7) goes on to describe the kind of information that must be sought from those who apply to the AEC for permission to use animal.

While the Code is appropriately flexible when it comes to the format of application forms (to allow for paper-based, web – based, or electronic application processes for example), it has an absolute requirement for all application to be written in plain English so that all members of the AEC can be clear about the work being proposed and participate in the discussion. Sub-section 2.7.3 states:

> *Institutions must ensure that procedures for applying to an AEC include a requirement for the use of plain English in the application, so that all AEC members are provided with sufficient information to participate effectively in the assessment of the application.*

One of the most important sections to be considered in this light is the Lay Summary. If the lay summary is not completely clear to all members of the AEC it should be referred back to the investigator for rewriting before the protocol is discussed (This is frequently done as a part of a pre-screening process to prevent wasting a lot of time during AEC Meetings). New AEC members should ask to have the institution's application form explained to them before their first meeting. It is particularly important that all members of an AEC (as well as the applicants they work with) have a clear understanding of the underlying intent of each question on the application form so they can assess the information provided appropriately.

Ethical issues

The ethics of animal experimentation is an area of which all AEC members need to have some knowledge, so that they can explain their own point of view, and appreciate the opinions of others. This is important as you must be comfortable with the idea that any and all work with animals that you approve is ethically justified.

There is a very clear and helpful overview of the debate on animal experimentation published by ANZCCART (Monamy, 1996). This short and very readable book also has an extensive bibliography for each chapter, so that the reader can follow up particular areas of interest and concern.

3. Legislation and the Code of Practice

The use of animals in research and teaching is controlled by Acts of State and Territory Parliaments in Australia, and by a national Act in New Zealand. A list of relevant Australian legislation is given in Appendix 2 of these Guidelines, along with web links to the relevant Act for your State or Territory.

The Australian Code for the Care and Use of Animals for Scientific Purposes, (2013) is incorporated into the legislation in all States and Territories. Adherence to the Code is a condition of the licence issued by the Government of each State or Territory of Australia.

The Code is regarded as the unifying document that consistently regulates the scientific use of animals across Australia and this is important because relevant legislation does vary between states / territories. Legally, you should be aware that State / Territory legislation does overrule the provisions of the Code, however you should also remember that legislation only sets the minimum standard tolerated by law. The Code sets the standards that should be applied to scientific use of animals and it is generally understood that society holds an expectation that scientific use should always meet the highest possible ethical and welfare standards. It is also worth remembering that major research funding bodies such as the NHMRC, ARC, Cancer Councils, etc., all require that any work they are supporting must be carried out in accordance with the Code.

A copy of *the Code* can be downloaded free of charge from the following web site: http://www.nhmrc.gov.au/guidelines/publications/ea28

Information about the relevant New Zealand Acts may be obtained from the ANZCCART New Zealand Web site at https://anzccart.org.nz/researchers/animal-ethics-and-legislation/ .

In addition to the Act and the *Code of Practice*, many institutions also have their own policy documents and practical guidelines devoted to the use of animals in research and teaching, and may also have administrative guidelines. Copies of all such documents should be provided to AEC members by their institution.

4. Composition of the Animal Ethics Committee

This is determined in accordance with the Code and even though the size of each AEC may vary according to the workload, variety of applications and requirements of the institution, but membership categories and their ratios within each committee will be consistent with the makeup described in the Code (Section 2.2). NB. Paragraph numbers in the section below relate to the Code.

Chairperson

2.2.4 Institutions must appoint a chairperson of the AEC. Institutions should consider appointing a chairperson who holds a senior position in the institution. If the chairperson is an external appointee, institutions must provide the chairperson with the necessary support and authority to carry out the role. The chairperson may be appointed in addition to Category A to D members (see Clause 2.2.2).

2.2.5 Institutions should consider appointing a chairperson who is independent of the care and use of animals for scientific purposes.

Members

2.2.6 Institutions must ensure that membership of the AEC comprises at least one person from each of four categories of membership:

(i) 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.

(ii) 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.

(iii) 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.

(iv) 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, and must not fit the requirements of any other category.

Additional members to assist the AEC to function effectively

2.2.5 Institutions should appoint to the AEC a person responsible for the routine care of animals within the institution.

2.2.6 Institutions may appoint additional members with skills and background of value to the AEC.

Access to expertise

2.2.7 The AEC may invite people with specific expertise to provide advice, as required.

Balance of membership

2.2.8 Categories C and D must together represent at least one-third of the AEC membership.

Appointment, reappointment and retirement of members

2.2.9 Institutions must develop procedures for the appointment, reappointment and retirement of AEC members.

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

2.2.11 Before appointment, all members of the AEC must acknowledge in writing their acceptance of the terms of reference of the AEC and any requirements for confidentiality required by the institution (see Clauses 2.1.2 [iv] and 2.2.22).

2.2.12 Institutions should ensure that AEC members undergo appropriate induction, and have access to appropriate education programs and resources.

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:

(i) an acceptance that ethical experiments on animals can be carried out, provided there is no viable alternative;
(ii) courtesy and patience in dealing with other committee members and with investigators;
(iii) willingness to listen as well as to speak; and
(iv) clarity and succinctness in oral and written communication.

The duties of each category of member can be distinguished to a certain extent, but there is a large area of overlap. The AEC works as a group, so although some specific guidelines can be given to each category of member, it is helpful to have an appreciation of the interests and expertise of members in other categories as well as your own.

Category A: Veterinary Surgeon

Veterinarians are members of AECs because they have specialised knowledge of animals and of advances in their care, treatment and general welfare. AECs rely on veterinarians for information on the variations between species in their reaction to procedures or drugs, on their housing needs and on their post-operative care. They can be particularly useful in helping the committee to assess the progress of a project or the impact of a specific procedure on the animals, by visiting an investigator and watching experiments. It is therefore essential that the Veterinarian is familiar with the species being used within the Institution(s) served by their committee so their advice reflects current best practice.

The veterinarian is often asked to explain complex procedures or unfamiliar treatments, always in lay terms. Unexpected questions are bound to be asked of veterinarians at almost every meeting. It sometimes helps the AEC to have written comments from a veterinarian. Information gleaned from veterinary journals with respect to individual species, drugs and husbandry is welcomed by AECs.

Any Veterinarian considering joining an AEC would be well advised to speak with a colleague who has experience with AEC work and may wish to refer to the ANZCFact Sheet *The Role of Veterinarians in the Care and Use of Animals in Research and Teaching by Simon Bain, Susan Maastricht, Mary Bate and Denise Noonan* who between them would have decades of experience serving on AECs.

Category B: Scientist

The role of the scientist is to assess and if necessary critique or possibly help explain the merit or demerits of an application under consideration. They are not appointed to represent the scientists' interests, although they inevitably may have an informed opinion or possibly even an appreciation of them. Pitfalls with regard to experimental design or animal welfare may also be particularly obvious to an investigator with current or recent experience of animal experimentation, as is the balance between benefit and cost of a given protocol. Most experienced scientists are required to assess the work or proposed work of other colleagues on a

regular basis as a part of the normal peer review process undertaken by journals or funding bodies, so this is a role with which most senior scientists are very familiar.

There may be occasions when an AEC may be unsure or possibly even concerned about the design of a study or series of experiments. The Category B member(s) can be an invaluable asset when it comes to helping the AEC formulate a plan that can lead to negotiating changes to the protocol with applicants prior to approval.

The question of Conflict of Interest (or more commonly, perceived C o I) will come up from time to time with Category B members in particular. It is imperative that all AEC members, but Category B members in particular declare any conflicts or potential conflicts of interest they may have with any application under consideration or agenda item at the start of each meeting. Failing that, it should be mentioned as soon as a potential conflict of interest becomes apparent as the meeting progresses. If any Category B member is named as an investigator on an application being considered by the AEC, they should step out of the room while that application is being discussed. Other conflicts or perceived conflicts of interest may require the member to step out during deliberations, but this is an issue best considered and decided by the committee itself on a case by case basis.

Category C: Animal Welfarist

Although it is not essential that this member be nominated by an animal welfare group, it is desirable as this does support their credibility as committed to animal welfare:

> *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.*
>
> (Code 2.2.4(iii))

Animal welfare groups must select their nominee with care, rather than seizing gratefully on the first volunteer. It is not at all necessary that welfarists have a background in veterinary science or animal care, though this may be the case; but they do need a good knowledge of the general context of animal welfare today. They will want to consider animal experimentation not only on its own merits, but as part of the general picture of the ways in which our society considers it acceptable to treat animals. Although they can be expected to share the views of the organisation nominating them, welfarists participate in AEC meetings as individuals and not as a representative of an animal welfare organisation. So, if they are members of an anti-vivisection society it is not their role to oppose every application on philosophical grounds, but to ensure that if a protocol is accepted, the animals are well cared for and there are no unethical procedures involved.

Category C members should not be employed by or otherwise associated with the institution and should have no current involvement with the care and use of animals for scientific purposes.

The guidelines offered below for lay members of AECs are equally appropriate for welfare members who may not have much committee experience behind them, or who may not see themselves as well-versed in science.

Category D: Lay Member

Lay members of AECs are selected to represent the interests of the general community and are independent of both the Institution and the scientific use of animals:

> *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.*
>
> (Code 2.2.4(iv))

Before accepting an invitation to join a committee, the layperson should ask themselves the following questions:

(i) Am I sure that I have enough time and interest to read lengthy applications and do any necessary background reading?
(ii) Am I prepared to ask straight-forward questions of highly qualified veterinarians and scientists, and persevere until I get a complete answer I can understand?
(iii) Am I prepared to speak my mind in meetings?
(iv) Do I feel confident that I can work with that particular committee?
(v) Am I accepting this invitation for a negative reason? Usually this would be a plea that they cannot find anyone else, or perhaps that the gender balance on the AEC is unsatisfactory. No one has a moral obligation to join a committee for such reasons.

If the prospective member can answer questions (i) to (iv) in the affirmative, then serving on an AEC will be very rewarding. Once on the AEC, a lay member who has difficulty understanding an application should contact the Chairperson, who will be able either to clarify it, or to consult the investigator. Usually, if one committee member has difficulty following an application, so do others, not least the Chairperson, who often lacks a scientific background and may already be trying to sort out obscurities. Lay members should also realise that category A and category B members will not always be able to understand all details in every application either and may well benefit from the questions you ask.

We strongly recommend that a prospective lay member should have the opportunity before agreeing to join an AEC to discuss the work with the Chairperson, to meet other members, and to tour the animal facilities. It is also a good idea for Institutions to invite a lay person to attend a meeting before becoming a member, so they can get a better understanding of what is involved and how the AEC operates.

Several essays on the role of Category D members and other related issues have been published in one form or another over the years. Three of the best were from Miss Joan Montgomery (Eminent person Category D member of the NHMRC Animal Welfare Committee for many years, published by the NHMRC as a guide for Category D members), Dr John Hatch (Long term Category D AEC member, published as an article in ANZCCART News) and Professor Graham Nerlick (Professor of Philosophy and long term Category D AEC Member). Regrettably the first one is no longer available, but the other two have been appended to this Guide. See Appendix 5 starting on Page 33

Animal Care Staff

Colloquially referred to as Category E members, Animal Care staff bring an unrivalled knowledge of the institution's animals, their housing and care, the ways in which they are used in experiments or teaching, and the requirements of the various investigators to the AEC.
Through their networks (e.g., ANZLAA and personal) they have access to valuable information on what is happening elsewhere, and can be of enormous assistance to investigators and to the AEC. These staff members can also play a most important role in assisting with the monitoring of work done in their facilities and ensuring it is done to the standards required by your AEC. In this regard, they can also serve as the eyes and ears of the AEC in the animal facility, so when it comes to the monitoring role of the AEC in particular the 'Cat E' members are like gold.

It is usually preferred that a senior member of the animal house staff be on the AEC, as they can speak and act with more authority than a junior, however this role can also be an important aspect of staff development for animal care staff who are destined to rise through the ranks.

This category of membership is strongly recommended for all AECs at institutions with holding or breeding facilities, but not mandated by *the Code* of Practice. It is however required by law in South Australia.

5. How the AEC Functions

The Code deals with the details of the way in which the AEC should function (Section 2, especially 2.2.20 - 2.2.37) and the responsibilities of AECs (Section 2.3), but members should recognise that the Code is really providing a framework that allows the AEC (in consultation with the Institution) to set up operational guidelines that determine how they operate. This will need to include all manner of processes including the following:

Administrative processes
Responsibility
Conflicts of interest
Confidentiality
Meeting procedures – including protocol appraisal
Standard operating Procedures (both for the committee and their applicants)
Communication with both applicants and the institutions senior staff
Complaints and issues of non-compliance with the Code
Keeping and maintaining records
Documentation

Your AEC will also need to consider setting up an Executive (in line with the requirements of the Code 2.2.23) and determining what their role they will play in the process. It is imperative that the Executive can help to ease the pressures on the AEC, expedite processes so that applications are not delayed, but they cannot exceed the limits of their authority. For example, the Executive CANNOT approve a new application.

The following discussion expands on the above list and covers some points that may be of particular interest to AEC members.

Administrative Processes

Most institutions that hold a licence for the scientific use of animals will have written guidelines that spell out what limits (if any) they will place on work that involves animals, where and under what conditions such work may be conducted and how the process of applying to the AEC for permission to use animals is run (the latter being set up in association with the AEC itself). Such guidelines will generally refer extensively to the Code and relevant Legislation and be widely available, so all members should be familiar with them. They may also include mention of who may apply to the AEC for permission to us animal and how that process will be managed, so it is important that committee processes are consistent with those guidelines.

Conflict of Interest

While the handling of conflicts (or potential conflicts) of interest is largely an administrative matter, it is one that can affect the operation of the AEC in a very real way. Fairly clearly, if any member of the AEC is named on an application before the committee or closely associated with an applicant, they would need to step out of the room during the consideration of that application. While such conflicts are most commonly associated with the Category B member(s) of the committee, this may not always be the case and each conflict or potential conflict should be declared and considered by the AEC as a part of their processes. It should also be remembered that every category of membership must be represented during the deliberation process associated with any new approval, so there are going to be times when it may be essential to have more than one member in each category on your AEC.

Responsibility

The AEC is accountable to the Head of the institution (for example, to the Vice-Chancellor in a university and / or the Licence Holder – who is the person named on the licence to conduct research using animals), and through that person to the community at large, usually via a State Minister. The primary responsibility of the AEC is to ensure that all activities conducted by or on behalf of the Institution, for which it acts, are in compliance with the Code and relevant legislation. All member of the AEC should have a clear understanding of the extent and limitation of their responsibilities.

Protocol appraisal

It is essential that all members of the AEC understand what is being proposed by the applicant. This requires a clear lay summary comprehensible to a person without a scientific background. If this is not provided, the AEC Secretary should discuss the application with the Chairman before the meeting and, if necessary, ask for it to be rewritten before circulation to AEC members. Sometimes, the role of pre-screening applications may be undertaken by the Executive or by one or more members authorised to undertake this role.

The protocol should state clearly what is intended to be done and why. It should include details of the number, sex, species and breed of animals requested and the number of animals requested should be statistically justified. There should be a clear experimental plan that acknowledges exactly what will happen to animals, how their wellbeing will be maintained, who will be conducting each procedure and how their recovery will be monitored. Members may find that the use of flow charts, diagrams or photographs may help them gain a better understanding of what is planned and if this is the case, this information should be conveyed to the applicants. We would strongly encourage all AEC members familiarise themselves with the PREPARE Guidelines, the ARRIVE Guidelines and the Best Practice Methodology in the use of Animals for Scientific Purposes (2017), which all highlight the important steps and processes that should be considered during the application and deliberation processes. They also aim to improve the reproducibility and therefore the value of animal – based experiments. You will find the PREPARE Guidelines checklist to be an excellent indicator of what should be in an application.

The AEC should review the application and only approve projects that are ethically acceptable and comply with the Code. This would require adequate consideration of the 3Rs of Replacement, Reduction and Refinement (as required by *the Code*). It should also evaluate the animal husbandry and housing, as well as the experience and technical expertise of the scientific and technical staff involved.

Any potential for animal pain or distress must be clearly stated and the proposed anaesthetic / analgesic regimen that will be employed to prevent such pain should be explained. Where pain cannot be prevented or adequately treated, the AEC must consider how pain will be monitored and what end points will be allowed before it must be alleviated. This includes appropriateness of the method of euthanasia (if required) and the competence of the staff to perform it humanely. It is worth remembering that humane end points should be set as early in the process as possible so that the wellbeing of animals is maintained and the quality of data obtained is not compromised by the effects of pain and / or distress.

It is often worthwhile to invite the investigator submitting a protocol, which is complex or where animal pain is involved, to address the AEC and answer questions. This is helpful to both parties and often results in improvements to the experimental design and to better animal welfare.

Decision-making

The Code gives the following advice:

Decisions should be made on the basis of consensus. Where consensus cannot be reached after reasonable effort to resolve differences, the AEC should explore with the applicant(s) ways of modifying the project or activity 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.

Consensus is clearly the most widely-used method, but as is clear from the above extract from *the Code*, there may be situations where there is profound disagreement within the committee and after all other means of resolution have been exhausted, the AEC may need to resort to a majority decision. This is a subject which individual AECs should discuss frankly. There have been interesting and provocative papers on this issue by Brennan (1996) and Hassall (1999).

Administrative support

This should not be a worry to members apart from the Chairperson; but if an AEC is not adequately serviced by the institution it cannot do the job given to it by law, and members should refuse to put up with substandard administrative support. It is generally true that the AEC secretary is the principle point of contact between the AEC and its applicants and will be faced with the rather daunting task of putting together each agenda, handling all correspondence with applicants, with the institution, with Government and with AEC members themselves. It is often the case that the way an AEC operates is often down to the Secretary and how efficiently they are able to operate.

The agenda should be distributed well in advance of each meeting. This means it should be early enough to give busy people time to study it properly, but not so early that it denies applicants a reasonable timeframe for submission of their paperwork. Some AECs stipulate ten days for the bulk of the papers, with a few items arriving four or five days before the meeting. It is not fair to AEC members for applications (particularly new initial applications) to be tabled at a meeting, and most AECs will not allow it.

Site inspections

It is normal practice, and indeed is required by *the Code* (2.3.20 – 2.3.23), for AECs to make regular formal inspections of animal facilities. In addition, in some institutions arrangements are made from time to time for the committee to be given talks and demonstrations by investigators in meetings or in their laboratories.

Site inspections may be announced in advance, so that relevant members of staff can be present; or unannounced, so that the AEC can see the facility in action on an ordinary day.

There should be at least one formal, announced site visit to each site every year, and it can be useful to invite other members of the institution or the community to attend. However, it is often undesirable to have too many people visiting a facility at the same time, because of the disturbance this will cause to the animals.

AEC members should avail themselves of all opportunities to visit animal houses and should not hesitate to make further, informal visits. Courtesy dictates that such visits by one or two members be cleared with the Chairperson or other responsible officer, and take place at a time when the supervisor of the animal facilities can arrange for them to be accompanied. The Chairperson will be in the habit of making unannounced visits, and should be contacted if that is the sort of visit an AEC member wishes to make. Animal houses are not secretive places, but some animals are in quarantine, others dislike the arrival of a stranger, others again may need absolute quiet at certain times and such factors need to be respected.

Confidentiality

The Code makes the AEC and the institution responsible for establishing how advice may be sought without breaching confidentiality:

2.2.11 Before appointment, all members of the AEC must acknowledge in writing their acceptance of the terms of reference of the AEC and any requirements for confidentiality required by the institution (see Clauses 2.1.2 [iv] and 2.2.22).

There is no written, Australia-wide rule about confidentiality as it concerns animal experiments. It has been quite widely assumed that members of AECs, like members of any committee dealing with individuals' research projects, do not discuss the applications they consider with anyone; and most institutions ask members to sign a confidentiality agreement to this effect. However, members who feel they need to consult a colleague who has more specialised knowledge about something should be free to do so in confidence, provided that such discussions would not breach a signed confidentiality agreement they have with the institution. If such an agreement or any other similar barrier is in place, AEC members should feel free to raise questions or concerns with the AEC chair, who may be in a position to grant limited licence for the member to seek advice outside the committee. It is important to remember that applicants to the AEC are taking you into their confidence and entrusting their work and possibly their intellectual property to you so if you are permitted to consult an outside person you should ensure that the person you consult knows the question and all details are confidential.

Complaints and Non-Compliance

Institutions may receive complaints relating to the scientific use of animals from a variety of sources. They may come from the general public, pressure groups, staff, students, or AEC members. Those complaints may relate to individuals, work being done, conditions under which animals are being kept or a variety of other issues and it is important they are handled properly. Accordingly, the 8th Edition of the Code has an entire section (Section 5) devoted to this issue and all AEC members should make themselves familiar with its contents.

This is an area where strong opinions, professional reputations and potentially the welfare of large numbers of animals may be under consideration, so we will rely heavily on the Code and the advice it contains in Section 5 here. That said, we have highlighted certain portions of the text that might be of extra significance and one of those sections relates to the fact that while an AEC might be challenged on the basis of process and asked to review a decision, it cannot be over-ruled. This provision not only preserves the integrity of the AEC system and the trust placed in each AEC, but it also means that every member of every AEC has a duty to work diligently and make the best decision it possibly can within the parameters outlined by the Code itself.

5.1 Institutions must have procedures for addressing complaints and non-compliance relating to the care and use of animals for scientific purposes, including:

(i) complaints concerning the care and use of animals by the institution, including conscientious objection in the case of teaching activities

(ii) complaints concerning the AEC process of review of an application or report, including resolution of disagreements between AEC members, between the AEC and investigators, and between the AEC and the institution

(ii) complaints concerning the process for independent external review

(iii) non-compliance with the Code by any party or person involved in the care and use of animals including investigators, animal carers, the AEC, governance officials, and external parties subject to agreements described in Clauses 2.6.3 and 2.6.6. Non-compliance may also involve breaches of relevant state or territory legislation, and institutions should have procedures for advising regulatory authorities (see Clause 5.12).

5.2 Institutional procedures must:

(i) give priority consideration to the wellbeing of the animals, and ensure that activities with the potential to adversely affect animal wellbeing cease immediately

(ii) clearly define the mechanisms for receiving, investigating and addressing complaints

(iii) clearly define the mechanisms for addressing non-compliance with the Code

(iv) clearly define the responsibilities of all parties

(v) ensure fair, prompt, timely, effective, confidential processes that accord with procedural fairness, the principles of natural justice and protection of whistleblowers

(vi) identify and ensure appropriate reporting to the institution, AEC, state or territory government authorities, and any other relevant bodies

(vii) be made available to all relevant people.

5.3 For projects involving more than one institution and/or AEC (see Clauses 2.6.4–2.6.7), procedures should include mechanisms for reporting between the relevant institutions and AECs on complaints and non-compliance.

Complaints concerning the care and use of animals

5.4 Institutions must ensure that:

(i) where complaints relate to activities that have the potential to adversely affect animal wellbeing, the activities cease immediately

(ii) where complaints relate to activities that would normally require AEC approval, the complaints are referred to the AEC to investigate whether such activities are conducted in accordance with AEC approval

(iii) where complaints raise the possibility of 'research misconduct', as described in the *Australian code for the responsible conduct of research*, the complaint is handled in accordance with procedures specified in that document

(iv) where complaints allege misconduct that falls outside the range of 'research misconduct', as described in the *Australian code for the responsible conduct of research*, the complaint is handled in accordance with institutional processes for dealing with other forms of misconduct.

5.5 Following the AEC's investigation of complaints referred to it by the institution, the AEC:

(i) must ensure that, where activities are conducted in accordance with an AEC approval, the activities are reviewed in consultation with all relevant people 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

(ii) should ensure that, where activities are not conducted in accordance with AEC approval, the matter is referred back to the institution for action.

Complaints concerning the animal ethics committee process

5.6 Where complaints concerning the AEC process of review of an application or report cannot be resolved by communication between the complainant and the AEC that is the subject of the complaint, the institution should ensure that the complainant has access to a person or agency external to the AEC for review of the process followed by the AEC. This person or agency may be within the institution. Following this review, the AEC may need to review its process in reaching its decision regarding the application or report, and re-evaluate its decision in light of the reviewed process. The ultimate decision regarding the ethical acceptability of an activity lies with the AEC and must not be overridden.

Complaints concerning the process for independent external review

5.7 Institutions must ensure that the process for conducting an independent external review, developed in consultation with the review panel, includes an appeals process that relates to the process for the review (see Clause 6.5).

Referral to a person or agency external to the institution

5.8 Institutions should identify a person or agency external to the institution to whom a person can take a complaint that has not been resolved by the processes referred to in Clauses 5.1–5.7.

Addressing non-compliance

5.9 Institutions must have procedures for addressing non-compliance with the Code, so that behaviours that create and support compliance are encouraged, and behaviours that compromise compliance are not tolerated.

5.10 The institution must maintain records of breaches of the Code.

Advising regulatory authorities

5.11 Any person can report alleged breaches of legislation to relevant state or territory government authorities.

5.12 The institution should advise relevant state or territory government authorities of alleged breaches of legislation that had a significant impact on animal wellbeing.

6. Institutional Guidelines

Some institutions have a handbook of operating procedures or guidelines for researchers, teachers and technical staff in working with experimental animals. This is very useful and provides a reference for AEC members as well as for researchers and teachers.

A Standard Operating Procedure (SOP) can be used to set out the conditions under which the AEC would normally be happy to approve appropriate techniques and the use of SOPs is recommended in the Code. It is not uncommon for institutions to include a list of approved SOPs in their guidelines along with the protocol for the regular review of each SOP. A list of approved SOPs might cover a variety of fairly standard techniques such as:

- Anaesthesia techniques;
- the use of adjuvants;
- production of monoclonal and polyclonal antibodies;
- standards of laboratory animal housing;
- methods of collecting blood samples from various species of animals; and
- post-operative analgesia, including dose-rates of drugs and routes and frequency of administration.

7. Other Useful Guidelines and Policies

There are a number of organisations with an interest in this area which have produced relevant fact sheets, guidelines, codes of practice or monographs. These include:

- ANZCCART
- Animal Welfare Office of NSW Agriculture
- DAFF
- NHMRC Animal Welfare Committee
- Animals Australia
- Animal Welfare Committee of SCARM

A list of addresses is found in the appendices, together with a bibliography of useful references.

8. Monitoring

Institutions and Animal Ethics Committees

The 8th edition of the *Australian Code for the care and Use of Animals for Scientific Purposes* (2013) (Section 6) requires that institutions arrange a formal external review of their AEC at least every 4 years to assess the institutions compliance with the Code and to ensure the continued sustainability, adequacy and effectiveness of its procedures to meet its responsibilities under the Code. This is consistent with the recommendations contained in the 7th Edition, which included a timeframe of every three years for such a review as this is still the aspirational timing of reviews, but due to the fact these reviews are now mandatory, the Code has allowed a 12 months' grace period that allows for circumstances that may mean that institutions occasionally struggle to meet the three-year cycle (for example, some Government run reviews). Such a review should be designed to cover all aspects of animal use within the institution and the operation of their AEC(s). A number of relevant State Government Departments also require regular review of the operation of every AEC in their region and all institutions to which they have issued a licence.

9. Discipline

While experience would indicate that the great majority of people whose work involves the use of animals, will devote a lot of time and resources towards ensuring the wellbeing of their animals, you may occasionally find that they are late with paperwork or they make mistakes.

You may also (albeit rarely we hope) encounter individuals who seem to have little regard for the Code or the welfare of their animals. While the temptation to take punitive action may be strong, the ability of an AEC to do so is really very limited.

Clearly, every AEC has the responsibility to suspend (or possibly terminate) a project or activity that falls outside the Code or the boundaries they have set, but they cannot take more direct action on their own. This is where it is essential for every AEC to have a good working relationship with the head of the institution, licence holder and / or governing body. This will mean that the AEC can recommend disciplinary action to someone in authority with the reasonable expectation of action being taken. It is also worth remembering that collaborative actions like this are usually far more effective anyway and serve everyone's best interest as the transgressions of an individual can result in the entire institution being penalised by the loss of a licence.

In this context, it is worth remembering that the institution itself (or anyone else for that matter) can and should report any transgression so serious as to constitute and breach of the legislation to the relevant state or territory government department – particularly if it has a significant impact on the wellbeing of animals. (See sections 5.11. & 5.12).

10. Conclusion

The authors of these Guidelines, who come from all membership categories, have found membership of an AEC a very rewarding and instructive experience, albeit one which took more time and energy than they had initially expected. All have found that there is great personal satisfaction to be gained from participating in a worthwhile activity where advances can be made on all fronts. We therefore commend and thank all AEC members for your dedication and the conscientious way you work for both the welfare of animals used for scientific purposes and the essential research work that relies so heavily on those animals.

Appendix 1

Bibliography and Further Reading

The following provide useful background for members of AECs, particularly members in categories C and D. All are available from ANZCCART's Adelaide office.

Australian Senate Select Committee on Animal Welfare (1989). *Animal Experimentation*. Australian Government Publishing Service, Canberra. http://www.aph.gov.au/binaries/senate/committee/history/animalwelfare_ctte/animal_experimentation/00contents.pdf

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Campbell, A. (1995). The animal rights debate. *ANZCCART News* **8**(1): 1-3.

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Hassall, G (1999) Committees and conflict resolution. *ANZCCART News **12**(1) 1-3.*

Johnson, K. (1996). Making ethical decisions when the balance keeps swinging. *ANZCCART News **9**(3): 9-10.*

ANZCCART Fact Sheet: Pain-assessment, alleviation and avoidance in laboratory animals by Paul Flecknell. This fact sheet can be accessed directly at the following address: http://www.adelaide.edu.au/ANZCCART/publications/Pain%20Assessment_9.pdf

Mellor, D. (1993). Animals in science: ethics, obligations and ANZCCART. *ANZCCART News **6**(1): 1-3.*

Monamy, V. (1996). *Animal Experimentation: A Student Guide to Balancing the Issues.* ANZCCART, Adelaide.

Morton, D.B. and Griffiths, P.H.M. (1985). Guidelines on the recognition of pain, distress and discomfort in experimental animals and an hypothesis for assessment. Article can be accessed on the ANZCCART website at: https://www.adelaide.edu.au/ANZCCART/docs/mortondb-griffithsp-recognitonpain.pdf

A*ustralian Code for the Care and Use of Animals for Scientific Purposes*. 8th Edition. Australian Government – National Health and Medical Research Council, Canberra. http://www.nhmrc.gov.au/guidelines/publications/ea28

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Russell, W.M.S and Burch, R.L. (1959). *The Principles of Humane Experimental Technique*. Please note that this book is now available on line for anyone to read. It can be found at: http://altweb.jhsph.edu/pubs/books/humane_exp/het-toc

Scott, L.R. and Carter, P.D. (1996). The role of veterinarians on animal experimentation ethics committees. *Australian Veterinary Journal* **74**(4): 309-310. May be accessed on the Wiley online library at the following address: http://onlinelibrary.wiley.com/doi/10.1111/j.1751-0813.1996.tb13785.x/epdf and on the ANZCCART Website at: https://www.adelaide.edu.au/ANZCCART/docs/scott-carter-vetsrole-1996-avj.pdf

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Useful Journals

- Animal Welfare
- Anthrozoos
- ATLA (Alternatives to Laboratory Animals)
- ILAR Journal
- Lab Animal
- Laboratory Animals

Useful Newsletters

- ANZCCART News
- ANZLAA Newsletter
- Animal Welfare Information Center of the US National Agricultural Library
- CAAT (Center for Alternatives to Animal Testing), USA
- Canadian Council on Animal Care *Resource*
- *Ethics Committee News*, from the Animal Welfare Information Network (ANZFAS)
- FRAME (Fund for Replacement of Animals in Medical Experiments), UK
- NHMRC Animal Welfare Committee
- NSW Agriculture Animal Ethics Update
- Research Defence Society, UK
- SCAW (Scientists' Center for Animal Welfare), USA
- UFAW(Universities Federation for Animal Welfare), UK

ANZCCART Publications

- Animal Pain: Ethical and Scientific Perspectives. (eds T Kuchel, MA Rose and J Burrell). Proceedings of the conference held in the Barossa Valley, SA, 1992. ISBN 0 643 05383 2.

- *Survey of Laboratory Animals and Tumour Cell Lines Maintained in Australia and New Zealand* (ed. RM Baker) 8th Edition. 1997. ISBN 0 646 12728 4.

- *Euthanasia of Animals Used for Scientific Purposes*. 1993. (ed. J Reilly) 1993. ISBN 0646 11803 X.

- *Effective Animal Experimentation Ethics Committees.* 1994. (eds. RM Baker, JH Burrell and MA Rose) Proceedings of the conference held at the University of Adelaide, Australia, October, 1992. ISBN 0 646 15418 4.

- *Animal Welfare in the Twenty-first Century: ethical, educational and scientific challenges* 1994. (eds. RM Baker, DJ Mellor and AM Nicol). Proceedings of the conference held in Christchurch, New Zealand, April, 1994. ISBN 0 9590540 6 5.

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- *Animals and Science in the Twenty-first Century: new technologies and challenges.* 1994. (eds. RM Baker, R Einstein, DJ Mellor and MA Rose). Proceedings of the conference held Melbourne, October, 1994. ISBN 0 646 22484 0.

- *Farm Animals in Biomedical and Agricultural Research*. 1996. (eds. RM Baker, R, Einstein, DJ Mellor). Proceedings of the conference held Wellington, New Zealand, August, 1995 ISBN 0 646 26379X.

- *Animal Experimentation: A Student Guide to Balancing the Issues* (V Monamy) 1996. ISBN 0 9586821 0 0.

- *Animals in Education: Value, Responsibilities and Questions.* 1997. (eds. A Brennan and R Einstein). Proceedings of the conference held in Canberra, 1996. ISBN 0 9586821 1 9.

- Annual Reports from 1993.

In addition, ANZCCART's Adelaide office also holds stocks of current publications from the Scientists' Center for Animal Welfare (USA) and the Universities Federation for Animal Welfare (UK). A list of publications is available on request.

NHMRC occasional reports and policies

Australian code for the care and use of animals for scientific purposes 8th edition (2013)	Current
Guidelines for the generation, breeding, care and use of genetically modified and cloned animals for scientific purposes (2007)	Current
Guidelines to promote the wellbeing of animals used for scientific purposes: The assessment and alleviation of pain and distress in research animals (2008)	Current
A guide to the care and use of Australian native mammals in research and teaching (2014)	Current
Principles and guidelines for the care and use of non-human primates for scientific purposes (2016)	Current
Best practice methodology in the use of animals for scientific purposes (2017)	Current

Available from the Animal Welfare Committee of the NHMRC, web site at:
http://www.nhmrc.gov.au/guidelines/publications/subject/Animal%20ethics

Guidelines on the use of animals for training interventional medical practitioners and demonstrating medical equipment and techniques (2009)	Rescinded but still available
NHMRC Guidelines for Monoclonal Antibody Production	Rescinded but still available
NHMRC Guidelines on the Care of Cats Used for Scientific Purposes (2009)	Rescinded but still available
NHMRC Guidelines on the Care of Dogs Used for Scientific Purposes (2009)	Rescinded but still available
A Guide to the use of Australian Native Mammals in Biomedical Research - Including Sections 1-3 (1990)	Rescinded but still available
A Guide to the use of Australian Native Mammals in Biomedical Research - Section 4: Care of individual species (1995)	Rescinded but still available
Guidelines on the use of animals for training surgeons and demonstrating new surgical equipment and techniques (1997)	Rescinded but still available
NHMRC Guidelines on the Care of Dogs Used for Scientific Purposes (2009)	Rescinded but still available
NHMRC Guidelines on the Care of Cats Used for Scientific Purposes (2009)	Rescinded but still available
Ways of Minimising Pain and Distress in Animals in Research (1994)	Rescinded but still available

Appendix 2

Animal Welfare Legislation and Administration in Australia and New Zealand

AUSTRALIA

Queensland
Animal Care and Protection Act 2001
Animal Care and Protection Regulation 2012

Available on-line at:
http://www.business.qld.gov.au/industry/agriculture/animal-management/land-management-for-livestock-farms/welfare-and-transport-of-livestock/animal-welfare/animal-welfare-law/animal-care-protection-act

Additional information: http://www.daff.qld.gov.au/animal-industries

New South Wales
Animal Research Act 1985
* Animal Research Regulations 2010

Available on-line at:
http://www.animalethics.org.au/legislation/animal-research-act and then click on the appropriate link.

ACT
Animal Welfare Act 1992 (Refer particularly to Part 4 "Research, Teaching and Breeding")

Available on-line at:
http://www.austlii.edu.au/au/legis/act/consol_act/awa1992128/

Victoria
Prevention of Cruelty to Animals Act 1986 (Refer particularly to Part 3 "Scientific Procedures")

Available on-line at:
http://www.austlii.edu.au/cgi-bin/disp.pl/au/legis/vic/consol%5fact/poctaa1986360/?query=title+%28+%22animal%22+%29

Tasmania
Animal Welfare Act 1993 (Refer particularly to Part 4 "Animal Research")

Available on-line at:
https://www.legislation.tas.gov.au/view/html/inforce/current/act-1993-063

NT
Animal Welfare Act 2004

Available on-line at:
http://www.austlii.edu.au/au/legis/nt/consol_act/awa128/

South Australia
Animal Welfare Act 1985
Animal Welfare Regulations 2012

Available on-line at:
http://www.legislation.sa.gov.au/LZ/C/A/ANIMAL%20WELFARE%20ACT%201985.aspx

http://www.legislation.sa.gov.au/LZ/C/R/Animal%20Welfare%20Regulations%202012.aspx

Western Australia
Animal Welfare Act 2002

Available on-line at:
http://www.slp.wa.gov.au/legislation/statutes.nsf/main_mrtitle_50_homepage.html

NEW ZEALAND

Please refer to the ANZCCART New Zealand Web site for further information on local legislation.
This may be accessed via the main ANZCCART website at www.adelaide.edu.au/ANZCCART/ or directly at: https://anzccart.org.nz/researchers/animal-ethics-and-legislation/%20

Appendix 3

List of Acronyms Commonly Encountered

AAC	Australian Agricultural Council
ATSE	Australian Academy of Technological Sciences and Engineering
AEC	Animal Ethics Committee
NZAAHCP	New Zealand Association for Animal Health and Crop Protection
AHA	Animal Health Alliance (Australia) Ltd
AMRIC	Animals in Medicines Research: Information Centre
ANZCCART	Australian and New Zealand Council for the Care of Animals in Research & Teaching
ANZLAA	Australian and New Zealand Laboratory Animal Association
ARC	Australian Research Council
ARRP	Animal Research Review Panel (NSW)
AVA	Australian Veterinary Association
AVAWE	Australian Veterinarians Associated Welfare and Ethics (Special Interest Group)
AWAC	Animal Welfare Advisory Committee
AWC	Animal Welfare Committee
BVA	British Veterinary Association
CAAT	Center for Alternatives to Animal Testing (USA)
CCAC	Canadian Council on Animal Care
CSIRO	Commonwealth Scientific and Industrial Research Organisation
ECVAM	European Centre for the Validation of Alternative Methods
FRAME	Fund for the Replacement of Animals in Medical Experiments
IACUC	Institutional Animal Care and Use Committee (USA, Canada)
ICLAS	International Council for Laboratory Animal Science
MAF	Ministry of Agriculture and Fisheries (New Zealand)
NCCAW	National Consultative Committee on Animal Welfare (Australia)
NHMRC	National Health and Medical Research Council
NZVA	New Zealand Veterinary Association
RNZSPCA	Royal New Zealand Society for the Prevention of Cruelty to Animals
RSPCA	Royal Society for the Prevention of Cruelty to Animals
SCAW	Scientists' Center for Animal Welfare (USA)
SSCAW	Senate Select Committee on Animal Welfare (Australia)
UA	Universities Australia (Formally known as the AV-CC)
UFAW	Universities Federation for Animal Welfare (UK)

Appendix 4

Sources of Additional Information

- *NHMRC Policies* and *NHMRC Newsletter*, from the Animal Welfare Committee of the National Health and Medical Research Council. The Animal Welfare Committee has produced a number of documents, mostly related to the use of specific species in biomedical research. Address: AWC Secretary, NHMRC, GPO Box 1421, Canberra ACT 2601 (phone: (02) 6289 9179; email: Research@nhmrc.gov.au).

  See also the relevant section of the NHMRC Website at:
  http://www.nhmrc.gov.au/health-ethics/animal-research-ethics

- *ANZCCART News*, from the Australian and New Zealand Council for the Care of Animals in Research and Teaching. ANZCCART also publishes monographs, conducts workshops and conferences and publishes proceedings from these conferences. Address: ANZCCART, C/- The University of Adelaide, South Australia, 5005. (phone: 8313 7585; fax: (08) 8313 7587).

- Australian Veterinarians Associated with Scientific Establishments (AVAWE), a special interest group of the Australian Veterinary Association. Address: AVA National Office, Unit 40, 2A Herbert Street, St Leonards, NSW, 2065 (phone (02) 9431 5000; fax: (02) 9437 9068).

- Bureau of Animal Welfare, Department of Natural Resources and Environment, 475 Mickleham Rd, Attwood, 3049. (phone: (03) 9417 4200; fax (03) 9217 4331, email: Animal.Welfare@dpi.vic.gov.au).

- Animal Welfare Unit, NSW Agriculture. Locked Bag 21, Orange NSW 2800 (phone: (02) 6391 3682; fax: (02) 6391 3570, email: animal.welfare@agric.nsw.gov.au).

- ALTWEB NEWS aims to be a global clearing house for information on alternatives to animal testing and is published by the Johns Hopkins School of Public Health and CAAT at http://altweb.jhsph.edu/

Appendix 5: Published Essays on the Role of Category D members

anzccart HUMANE SCIENCE NEWS

Volume 22 Number 1 2009

Animals Used for Research and Teaching
A Category D Perspective, or Ds Matter …… a Lot

Dr John Hatch, Adelaide University

Background

1985 was an important year. It was the date of the South Australian Prevention of Cruelty to Animals Act, and I joined the already quite experienced, but informal University of Adelaide AEC. Since then I have been a 'D' on one or more AECs continuously. Once a D always a D!

In the early days there were no Ds, but the Code of Practice which rapidly became the 'Bible' refined and reorganized the membership of AECs and in its fifth incarnation (dark green, 1989), the Code defines a compulsory category D as follows,

> "An independent person who does not currently and has not previously conducted experiments using animals, and who is preferably not an employee of the institution."

The (then) current Code, (Edition seven, blue and white) basically uses the same definition but with the additional comment that,

> "Category D members, (note the plural) should be viewed by the wider community as bringing a completely independent view to the AEC, and must not fit the requirement of any other category" *[Editor's Note: This sentiment has been maintained in the 8th Edition, 2013]*

A residual? No.

The Role of the D

Consider the definition of the D. It stresses **Independence. The D carries none of the baggage of the researcher, the Animal Welfarist or even the veterinarian.** I say this not to denigrate the role of other members but to point out an advantage that the D has. It points up their wider public role and make no mistake about it, the public does care about how we use animals in research. We have a constituency, which is the concerned and informed public. I sometimes

describe myself as the ignoramus on the committee, but I see ignorance as almost a virtue in this context. Ethics is about the way things '...ought to be' and therefore requires imagination as well as information.

In the collective interactive discovery process which is mandated for AECs, the freedom of the D is often crucial. Together with the Cs, but even more so, the D can be ignorant of technical matters without shame. We are not expected to possess a whole raft of scientific knowledge and I view with some apprehension overzealous attempts to train us.

My old colleague on the Adelaide University AEC, Professor Graham Nerlich wrote an excellent long letter in the June 1997 ANZCCART News where he discussed the value of the Lay Description and in doing so, implicitly the importance of the Lay Members. I commend the piece to you. Lay members can often 'smell a rat', pun intended, because they have to think harder about the protocol. Often they bring to the surface things which are ill-defined or misunderstood by the experts. As Graham Nerlich points out, if you cannot explain something broadly to an interested and educated layman, then you probably do not really understand it yourself.

Problems for the D

The D is often isolated having no regular colleagues and no apparently relevant discipline or training. This can lead to a very passive role. It should not since your interpretation of community values is vital to the process. Start by insisting that the **lay descriptions** are just that. **Send them back if they are not**.

Almost certainly some of the experts will thank you. After all, scientists have an enormous range of backgrounds. A good start is to believe in yourself and your role. **You do matter a lot and you can often change a decision or even more importantly in the long run change the way a committee works.**

anzccart HUMANE SCIENCE NEWS

Volume 10 Number 2 1997

(Extracted from Volume 10 (2), 1997.)

Letters

The point of lay descriptions

An abiding problem for all Animal Ethics Committees (AECs) is that lay descriptions are, often, not lay at all. Yet any member of a human experimentation ethics committee knows that complex experiments can be well described in lay terms. In fact, they must be so described in order that subjects are adequately informed about what the experiment will submit them to. So a human ethics committee always rejects an information sheet unless it fully, and intelligibly, informs subjects about why the experiment is being performed at all, and what will happen to them as subjects of it. In any case, subjects who don't understand what they are in for are less likely to enroll *as* subjects. So the pressure to make things plain in lay terms comes partly from the subjects themselves. Subjects are frequently naïve readers. Having long chaired one human ethics committee, I have seen ample evidence that excellent lay descriptions of complex experiments are frequently written for subjects with no very advanced reading age.

I sometimes think that, with animal experiments, the device of imagining that one has to explain to the subject of the experiments its aims, the value of its results and just what is to be done to the subject may be a helpful fiction in generating good lay descriptions. One or two of my expert colleagues think so too. Pretend that the lay description is an information sheet! I include the suggestion for whatever it may be worth and without claiming much novelty for it.

The need for good lay descriptions in the human context is clear and researchers usually give it a high priority. What are the needs for lay descriptions in the area of experiments on animals? Lay members of AECs must make informed judgments, obviously, but why not meet this by discussion between lay and expert members in committee?

A diet of barely intelligible technical descriptions tends to disempower lay members in the long term. Each member should be in a position to form a clear view of the ethical issues posed by an experiment before the meeting. Lay members may well revise their judgment in the light of discussion; so may expert members, one hopes. But the paper work should allow each member to arrive at the meeting with clear reasons, or well formulated doubts, justifiable at least in the first instance, for which the documents must provide. If lay members have no clear idea why the experiments are being done, or what is to befall the animals, then they are under pressure in committee to decide, without time for serious reflection, on what their expert colleagues have just told them. They become gradually less confident of the independence of their contributions; gradually they come merely to echo their expert colleagues. This erodes the autonomous, independent, external kind of critique envisaged by the *Australian Code of Practice for the Care and Use of Animals for Scientific Purposes.* *[Editor's note: The Code is now known as The Australian Code for the Care and Use of Animals for Scientific Purposes 8th Edition, 2013). However, exactly the same kind of*

independent, autonomous critique of every application is still considered to be an essential part of the review / approval process.]

So much may be obvious. But lay descriptions don't aid only lay members; they help ethical appraisal for every member. The submission of a protocol to an AEC ideally obliges the researcher lo step back from his absorption in the clinical details of his work and the ambitions that may be driving it, to adopt a new stance, in which he is engaged with, or attached to, the subject of his work; he is obliged to think about the value of the experiment in a broader context. The new stance is an ethical one.

The phrase "clinical detachment", is a cliché for good reason. Clinical language *is* designed for detachment as well as for precision. The value of detachment in science is well understood. It would be absurd to insist that it is impossible to appraise an experiment ethically which is (wholly or in large part) clinically described. But it is not absurd to claim that ethical appraisal is fostered for all AEC members and for researchers themselves when an experiment is couched in language which lends itself to moral concerns and values. We must all draw our ethical conclusions by thinking them out in lay language. The language of science is not an apt mode of expression for ethical thought; it cultivates a distance from pressures of emotion and evaluation, and that for the best of scientific reasons. So the researcher should not see the lay-language part of the submission as requiring him to unbend from normal rigor and precision so as to be loosely intelligible to "ignoramuses". Part of the exercise is to enable him to come to grips, himself, with evaluative issues on which, in most cases, he is no expert at all.

That points to another problem: failure to give a good lay description is failure to take an ethical stance – on the face of things, anyhow. Shouldn't the committee ask, not just whether or not the researcher is conducting an ethically acceptable experiment, but also whether or not he has considered it thoroughly enough, ethically, to understand what is needed for anyone else to consider it ethically, too. Of course, the AEC has to judge the experiment, not the researcher, but, in practice, the line between these judgments may be rather fine.

Lastly, there is the question of record. Perhaps it is another useful fiction to imagine the protocols and the minutes of meetings as being later perused and evaluated*. But perhaps not! In any case, I find it sharpens my attention on lay descriptions to suppose that the record may well be a matter of careful, perhaps litigious, scrutiny. I ask myself: under such an examination, are you confident that an impartial observer would have good reason to think that you understood what you were judging to be ethically acceptable'? That your judgment really was informed, comprehending and properly scrupulous? If such questions can't be answered positively, then there has to be a question whether the record shows that the committee and the researcher have acted with proper responsibility.

Graham Nerlich
Department of Philosophy
University of Adelaide

*Editor's footnote: This article was obviously prepared some years ago but still touches on some extremely important issues and ideals. It is however rather interesting to note that a few of the "ideals" the author espoused at that time are now reality -this being one. Since this was written, the external triennial review process was introduced in the 7th Edition of the Code and made compulsory with the adoption of the 8th Edition of the Code.

PREPARE

norecopa

The PREPARE Guidelines Checklist

Planning Research and Experimental Procedures on Animals: Recommendations for Excellence

Adrian J. Smith[a], R. Eddie Clutton[b], Elliot Lilley[c], Kristine E. Aa. Hansen[d] & Trond Brattelid[e]

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PREPARE[1] consists of planning guidelines which are complementary to reporting guidelines such as ARRIVE[2].
PREPARE covers the three broad areas which determine the quality of the preparation for animal studies:

1. **Formulation of the study**
2. **Dialogue between scientists and the animal facility**
3. **Quality control of the components in the study**

The topics will not always be addressed in the order in which they are presented here, and some topics overlap. The PREPARE checklist can be adapted to meet special needs, such as field studies. PREPARE includes guidance on the management of animal facilities, since in-house experiments are dependent upon their quality. The full version of the guidelines is available on the Norecopa website, with links to global resources, at **https://norecopa.no/PREPARE**.
The PREPARE guidelines are a dynamic set which will evolve as more species- and situation-specific guidelines are produced, and as best practice within Laboratory Animal Science progresses.

Topic	Recommendation
(A) Formulation of the study	
1. Literature searches	☐ Form a clear hypothesis, with primary and secondary outcomes. ☐ Consider the use of systematic reviews. ☐ Decide upon databases and information specialists to be consulted, and construct search terms. ☐ Assess the relevance of the species to be used, its biology and suitability to answer the experimental questions with the least suffering, and its welfare needs. ☐ Assess the reproducibility and translatability of the project.
2. Legal issues	☐ Consider how the research is affected by relevant legislation for animal research and other areas, e.g. animal transport, occupational health and safety. ☐ Locate relevant guidance documents (e.g. EU guidance on project evaluation).
3. Ethical issues, Harm-Benefit Assessment and humane endpoints	☐ Construct a lay summary. ☐ In dialogue with ethics committees, consider whether statements about this type of research have already been produced. ☐ Address the 3Rs (Replacement, Reduction, Refinement) and the 3Ss (Good Science, Good Sense, Good Sensibilities). ☐ Consider pre-registration and the publication of negative results. ☐ Perform a Harm-Benefit Assessment and justify any likely animal harm. ☐ Discuss the learning objectives, if the animal use is for educational or training purposes. ☐ Allocate a severity classification to the project. ☐ Define objective, easily measurable and unequivocal humane endpoints. ☐ Discuss the justification, if any, for death as an end-point.
4. Experimental design and statistical analysis	☐ Consider pilot studies, statistical power and significance levels. ☐ Define the experimental unit and decide upon animal numbers. ☐ Choose methods of randomisation, prevent observer bias, and decide upon inclusion and exclusion criteria.

Topic	Recommendation
(B) Dialogue between scientists and the animal facility	
5. Objectives and timescale, funding and division of labour	☐ Arrange meetings with all relevant staff when early plans for the project exist. ☐ Construct an approximate timescale for the project, indicating the need for assistance with preparation, animal care, procedures and waste disposal/decontamination. ☐ Discuss and disclose all expected and potential costs. ☐ Construct a detailed plan for division of labour and expenses at all stages of the study.
6. Facility evaluation	☐ Conduct a physical inspection of the facilities, to evaluate building and equipment standards and needs. ☐ Discuss staffing levels at times of extra risk.
7. Education and training	☐ Assess the current competence of staff members and the need for further education or training prior to the study.
8. Health risks, waste disposal and decontamination	☐ Perform a risk assessment, in collaboration with the animal facility, for all persons and animals affected directly or indirectly by the study. ☐ Assess, and if necessary produce, specific guidance for all stages of the project. ☐ Discuss means for containment, decontamination, and disposal of all items in the study.
(C) Quality control of the components in the study	
9. Test substances and procedures	☐ Provide as much information as possible about test substances. ☐ Consider the feasibility and validity of test procedures and the skills needed to perform them.
10. Experimental animals	☐ Decide upon the characteristics of the animals that are essential for the study and for reporting. ☐ Avoid generation of surplus animals.
11. Quarantine and health monitoring	☐ Discuss the animals' likely health status, any needs for transport, quarantine and isolation, health monitoring and consequences for the personnel.
12. Housing and husbandry	☐ Attend to the animals' specific instincts and needs, in collaboration with expert staff. ☐ Discuss acclimation, optimal housing conditions and procedures, environmental factors and any experimental limitations on these (e.g. food deprivation, solitary housing).
13. Experimental procedures	☐ Develop refined procedures for capture, immobilisation, marking, and release or re-homing. ☐ Develop refined procedures for substance administration, sampling, sedation and anaesthesia, surgery and other techniques.
14. Humane killing, release, re-use or re-homing	☐ Consult relevant legislation and guidelines well in advance of the study. ☐ Define primary and emergency methods for humane killing. ☐ Assess the competence of those who may have to perform these tasks.
15. Necropsy	☐ Construct a systematic plan for all stages of necropsy, including location, and identification of all animals and samples.

References

1. Smith AJ, Clutton RE, Lilley E, Hansen KEA & Brattelid T. PREPARE:Guidelines for Planning Animal Research and Testing. *Laboratory Animals,* 2017, DOI: 10.1177/0023677217724823.
2. Kilkenny C, Browne WJ, Cuthill IC *et al.* Improving Bioscience Research Reporting: The ARRIVE Guidelines for Reporting Animal Research. *PloS Biology,* 2010; DOI: 10.1371/journal.pbio.1000412.

Further information

https://norecopa.no/PREPARE / *post@norecopa.no* / *@norecopa*

National Centre
for the Replacement
Refinement & Reduction
of Animals in Research

The ARRIVE Guidelines

Animal Research: Reporting of *In Vivo* Experiments

Carol Kilkenny[1], William J Browne[2], Innes C Cuthill[3], Michael Emerson[4] and Douglas G Altman[5]

[1]The National Centre for the Replacement, Refinement and Reduction of Animals in Research, London, UK , [2]School of Veterinary Science, University of Bristol, Bristol, UK, [3]School of Biological Sciences, University of Bristol, Bristol, UK, [4]National Heart and Lung Institute, Imperial College London, UK, [5]Centre for Statistics in Medicine, University of Oxford, Oxford, UK

The ARRIVE (Animal Research: Reporting of *In Vivo* Experiments) guidelines were developed as part of an NC3Rs initiative to improve the design, analysis and reporting of research using animals – maximising information published and minimising unnecessary studies. The guidelines were published in the online journal *PLOS Biology* in June 2010 and are currently endorsed by scientific journals, major funding bodies and learned societies.

The guidelines are intended to:

- Improve reporting of research using animals.
- Guide authors as to the essential information to include in a manuscript, and not be absolutely prescriptive.
- Be flexible to accommodate reporting a wide range of research areas and experimental protocols.
- Promote reproducible, transparent, accurate, comprehensive, concise, logically ordered, well written manuscripts.
- Improve the communication of the research findings to the broader scientific community.

The guidelines are NOT intended to:

- Promote uniformity, stifle creativity, or encourage authors to adhere rigidly to all items in the checklist. Some of the items may not apply to all studies, and some items can be presented as tables/figure legends or flow diagrams (e.g. the numbers of animals treated, assessed and analysed).
- Be a guide for study design and conduct. However, some items on the checklist, such as randomisation, blinding and using comparator groups, may be useful when planning experiments as their use will reduce the risk of bias and increase the robustness of the research.

Who are the guidelines aimed at?

- Novice and experienced authors
- Journal editors
- Peer reviewers
- Funding bodies

What kind of research areas do the guidelines apply to?

- The guidelines will be most appropriate for comparative studies, where two or more groups of experimental animals are being compared; often one or more of the groups may be considered as a control. They apply also to studies comparing different drug doses, or, for example, where a single animal is used as its own control (within-subject experiment).
- Most of the recommendations also apply to studies that do not have a control group.
- The guidelines are suitable for any area of bioscience research where animals are used.

How might these guidelines be used?

The guidelines provide a checklist for those preparing or reviewing a manuscript intended for publication.

References

1. Kilkenny C, Browne WJ, Cuthill IC, Emerson M, Altman DG (2010) Improving Bioscience Research Reporting: The ARRIVE Guidelines for Reporting Animal Research. *PLOS Biol* 8(6): e1000412. doi:10.1371/journal.pbio.1000412
2. Schulz KF, Altman DG, Moher D, the CONSORT Group (2010) CONSORT 2010 Statement: updated guidelines for reporting parallel group randomised trials. *BMJ* 340:c332.

Funding

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Acknowledgements

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Further Information

www.nc3rs.org.uk/ARRIVE

enquiries@nc3rs.org.uk

@NC3Rs

	ITEM	RECOMMENDATION
Title	1	Provide as accurate and concise a description of the content of the article as possible.
Abstract	2	Provide an accurate summary of the background, research objectives, including details of the species or strain of animal used, key methods, principal findings and conclusions of the study.
INTRODUCTION		
Background	3	a. Include sufficient scientific background (including relevant references to previous work) to understand the motivation and context for the study, and explain the experimental approach and rationale. b. Explain how and why the animal species and model being used can address the scientific objectives and, where appropriate, the study's relevance to human biology.
Objectives	4	Clearly describe the primary and any secondary objectives of the study, or specific hypotheses being tested.
METHODS		
Ethical statement	5	Indicate the nature of the ethical review permissions, relevant licences (e.g. Animal [Scientific Procedures] Act 1986), and national or institutional guidelines for the care and use of animals, that cover the research.
Study design	6	For each experiment, give brief details of the study design including: a. The number of experimental and control groups. b. Any steps taken to minimise the effects of subjective bias when allocating animals to treatment (e.g. randomisation procedure) and when assessing results (e.g. if done, describe who was blinded and when). c. The experimental unit (e.g. a single animal, group or cage of animals). A time-line diagram or flow chart can be useful to illustrate how complex study designs were carried out.
Experimental procedures	7	For each experiment and each experimental group, including controls, provide precise details of all procedures carried out. For example: a. How (e.g. drug formulation and dose, site and route of administration, anaesthesia and analgesia used [including monitoring], surgical procedure, method of euthanasia). Provide details of any specialist equipment used, including supplier(s). b. When (e.g. time of day). c. Where (e.g. home cage, laboratory, water maze). d. Why (e.g. rationale for choice of specific anaesthetic, route of administration, drug dose used).
Experimental animals	8	a. Provide details of the animals used, including species, strain, sex, developmental stage (e.g. mean or median age plus age range) and weight (e.g. mean or median weight plus weight range). b. Provide further relevant information such as the source of animals, international strain nomenclature, genetic modification status (e.g. knock-out or transgenic), genotype, health/immune status, drug or test naïve, previous procedures, etc.
Housing and husbandry	9	Provide details of: a. Housing (type of facility e.g. specific pathogen free [SPF]; type of cage or housing; bedding material; number of cage companions; tank shape and material etc. for fish). b. Husbandry conditions (e.g. breeding programme, light/dark cycle, temperature, quality of water etc for fish, type of food, access to food and water, environmental enrichment). c. Welfare-related assessments and interventions that were carried out prior to, during, or after the experiment.
Sample size	10	a. Specify the total number of animals used in each experiment, and the number of animals in each experimental group. b. Explain how the number of animals was arrived at. Provide details of any sample size calculation used. c. Indicate the number of independent replications of each experiment, if relevant.
Allocating animals to experimental groups	11	a. Give full details of how animals were allocated to experimental groups, including randomisation or matching if done. b. Describe the order in which the animals in the different experimental groups were treated and assessed.
Experimental outcomes	12	Clearly define the primary and secondary experimental outcomes assessed (e.g. cell death, molecular markers, behavioural changes).
Statistical methods	13	a. Provide details of the statistical methods used for each analysis. b. Specify the unit of analysis for each dataset (e.g. single animal, group of animals, single neuron). c. Describe any methods used to assess whether the data met the assumptions of the statistical approach.
RESULTS		
Baseline data	14	For each experimental group, report relevant characteristics and health status of animals (e.g. weight, microbiological status, and drug or test naïve) prior to treatment or testing (this information can often be tabulated).
Numbers analysed	15	a. Report the number of animals in each group included in each analysis. Report absolute numbers (e.g. 10/20, not 50%[2]). b. If any animals or data were not included in the analysis, explain why.
Outcomes and estimation	16	Report the results for each analysis carried out, with a measure of precision (e.g. standard error or confidence interval).
Adverse events	17	a. Give details of all important adverse events in each experimental group. b. Describe any modifications to the experimental protocols made to reduce adverse events.
DISCUSSION		
Interpretation/ scientific implications	18	a. Interpret the results, taking into account the study objectives and hypotheses, current theory and other relevant studies in the literature. b. Comment on the study limitations including any potential sources of bias, any limitations of the animal model, and the imprecision associated with the results[2]. c. Describe any implications of your experimental methods or findings for the replacement, refinement or reduction (the 3Rs) of the use of animals in research.
Generalisability/ translation	19	Comment on whether, and how, the findings of this study are likely to translate to other species or systems, including any relevance to human biology.
Funding	20	List all funding sources (including grant number) and the role of the funder(s) in the study.

ARRIVE

The ARRIVE Guidelines: Animal Research: Reporting of *In Vivo* Experiments. Originally published in *PLOS Biology*, June 2010[1]

About ANZCCART

ANZCCART is the acronym by which the Australian and New Zealand Council for the Care of Animals in Research and Teaching Ltd. is known. We were originally known as The Australian Council for the Care of Animals in Research and Teaching (ACCART), which was established in May 1987 as a result of increased awareness within the research and teaching community of the distinctive issues that relate to the use of animals in these fields. We changed our name to ANZCCART on 1 January, 1993 following the decision by the Royal Society of New Zealand to accept the invitation of the Board of ACCART to join and to represent a consortium of New Zealand organisations. ANZCCART is now an independent organisation whose role is to encourage the ethical and humane use of animals in research and teaching by promotion of the principles of self-regulation as stated in the *Australian Code of Practice for the Care and Use of Animals for Scientific Purposes* and as required under legislation in Australian States and Territories and in New Zealand. ANZCCART is a not - for - profit company incorporated in the ACT (ACN 063 383 522).

ANZCCART's mission is to foster and promote best practice in ethical, social and scientific issues relating to the use and wellbeing of animals in research and teaching.

To achieve its mission ANZCCART will promote:

- Excellence in the care of animals in research and teaching
- Responsible scientific use of animals
- The 3Rs policy of Replacement, Reduction and Refinement
- Informed discussion and debate within the community regarding these matters.
- Strategic partnerships to contribute to the education and training of scientists, students and the broader community to support the wellbeing of animals used in research and education.

ANZCCART seeks to achieve these objectives in a number of ways. Firstly, by providing an ongoing focus on the social, ethical and scientific issues involved. Our second strategy involves providing a forum for discussion of these issues. We also facilitate access to relevant specialist advice and resources. In addition to this, through our publications and activities, ANZCCART is an on-going source of information for researchers, teachers, AEC members and the general public about how animals are used in research and teaching in Australia and New Zealand. ANZCCART operates on a purely advisory basis and its membership represents the interests of government, funding organisations, research and teaching institutions, animal welfare groups, professional organisations and the community.

ANZCCART publishes a regular newsletter, *ANZCCART News*, which includes short review articles on matters of topical interest, resource material, book reviews and citations of recent publications, activities of government, including legislative developments, and national and overseas news items. *ANZCCART News* is provided *gratis* to member organisations, animal welfare societies and to other interested organisations and individuals. ANZCCART holds an annual conference and publishes the proceedings. It also publishes monographs relating to the use of animals in research and teaching and holds workshops and seminars that address areas of specific interest. ANZCCART provides expert information to the scientific and lay community, as well as to government. Its members sit on relevant State, Territory and National government committees. It liaises with an international network of similar organisations and is regarded internationally as a leader in this field.

Perhaps most importantly to you, one of ANZCCART's key roles is to provide on-going support and advice to AEC members when required. **We are here to help where we can**.