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Code of Practice for the care and use of animals for scientific purposes **ANS on-line submission**

November 29th 2011

1. Does the document clearly and concisely set out the governing principles?

Yes, the Code clearly and concisely sets out the governing principles in Section 1. It is stated that “Respect for animals is the key governing principle that underpins the whole document.”

Principles are laid out at the beginning of each Section, but using different phrases

Section 1: Principles for the care and use of animals for scientific purposes

1.1. uses “Governing Principles”.

Section 2: Responsibilities

2.1 uses “Key principles related to responsibilities”

Section 3: Animal wellbeing

3.1 uses “General principles”

Section 4: The use of animals in teaching

4.1 uses “Key principles and responsibilities”

➤ ***Since the Governing Principles are embedded in sections 2, 3 and 4, for clarity, a suggestion would be to use the same phrase at the beginning of each section i.e.***

2.1 Governing principles related to responsibilities

3.1 Governing principles related to animal wellbeing

4.1 Governing principles related to the use of animals in teaching

2. Are the terms “should” and “must” used appropriately in the document?

A search of the Code for “should” and “must” indicated that the terms are used appropriately in the document.

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3. Does the document clearly and concisely set out, and correctly attribute, responsibilities of all parties involved?

Yes, the code clearly sets out the responsibilities of all parties involved within the Institutions and Animal Ethics Committees, as well as those of investigators and animal carers.

4. Does the document provide all relevant parties with sufficient practical guidance on the application of the principals of the Code of Practice in terms of their responsibilities?

Yes.

5. Should the document provide specific guidance regarding the responsibilities of Veterinarians and Animal Welfare Officers? Should the document provide a requirement for direct veterinary involvement in the oversight of a veterinary care program and research involving animals including, for example, the conduct of procedures such as anaesthesia and surgery?

Specifically:

“- whether the Code of Practice should include the requirement for a veterinary care program, similar to that required in some other countries. *(P6 Animal Code Consultation Pack 1)*

- whether some procedures such as anaesthesia and surgery should be performed only by a veterinarian or under the direct supervision of a veterinarian. The consultation draft requires persons performing procedures to be “competent in the procedure or under the direct supervision of a competent person”. There is no requirement for direct veterinary involvement in the performance of procedures. *(P6 Animal Code Consultation Pack 1)*”

➤ **Veterinary guidance and consultation is essential and welcomed by researchers in the planning of projects which involve anaesthesia and recovery or non-recovery surgery**

Veterinary guidance is both essential and much valued by researchers at the stage of providing training and oversight of new research personnel as they enter fields that require the humane use of animals for research purposes as well as to those already established researchers who may require refresher courses. Veterinary guidance is invaluable in the development and planning of studies and for designing specific experimental procedures when necessary. This is already enshrined in Institutions’ ethical conduct involving the use of animals where veterinarians and veterinary staff are integral members of the AEC and are responsible for approving investigators’ new or renewal applications and amendments. It should be noted that at any stage of the AEC approval process, veterinary staff can chose to view a procedure such as at the beginning of a newly approved project. Such input is highly valued by researchers, strengthens experimental design and ensures that research is of the highest quality and integrity.

➤ **Performance of procedures such as anaesthesia and surgery only by a veterinarian or under direct supervision of a veterinarian is unnecessary because researchers have the necessary skills**

The Australian Neuroscience Society comprises ~1,000 members, the majority being scientists, and a smaller proportion being clinicians, who undertake research using animals. Between them, they and their teams have developed, and continue to develop, considerable and highly

specialised expertise in surgical procedures in a very wide range of animal models used to examine diseases and disorders of the brain and mind and, of course, in the necessary anaesthesia and analgesia for such procedures. Mandatory veterinary involvement is unnecessary because expertise is already well established within, and published by, the research community and, as mentioned above, is continually refined and improved in consultation via AECs and the application process. Indeed, replacing scientists with veterinarians to undertake anaesthesia and recovery or non-recovery surgery would fail to recognise such expertise and indeed, we would argue, severely limit the potential for active development of new concepts and ideas, that come about with performing procedures and surgery on a day-to-day basis.

We take this opportunity to point out that researchers have the well being of their experimental animals first and foremost as part of their code of conduct based on respect for the animals and in the drive to undertake experiments of the highest scientific quality. They write the grants, design the experiments, undertake any surgery and anaesthesia, examine behavioural and electrophysiological functional outcomes, prepare tissue for analysis etc. Throughout, researchers monitor the animals according to strict approved protocols and thus provide a continuum of care for the duration of experiments. Veterinary involvement for one part, namely surgery and anaesthesia, would break the continuum of care and relinquish the responsibility of the researcher for that part to the possible detriment of other parts.

- **Performance of procedures such as anaesthesia and surgery only by a veterinarian or under direct supervision of a veterinarian is unnecessary because the use of animals is already highly regulated and already involves oversight from veterinarians**

Over the last decades, NHMRC and the research community have worked hard to develop extremely strict and appropriate codes of practice for the humane and ethical use of animals for scientific research. As a result, quite rightly, research communities in partnership with AECs and veterinarians are already highly regulated. Regulation involves 1) validation of the science even though this has already been approved by funding bodies, 2) extensive consultation with veterinarians and animal care workers in writing the application, and 3) feedback from the AEC prior to approval. Mandatory reporting procedures are also highly regulated and include 1) strict monitoring of all animals in ways that are relevant to the procedures being performed, 2) reporting of unexpected deaths, 3) annual documentation of animals usage, 4) annual progress reports and 5) final reports. Veterinarian input and consultation can occur at any of these stages. We consider that such codes and processes already have appropriate and welcomed veterinary input and are therefore already of the highest standard.

- **Performance of procedures such as anaesthesia and surgery only by a veterinarian or under direct supervision of a veterinarian is logistically and financially excessive, untenable and would severely compromise research output**

Mandatory veterinary involvement would necessitate the employment of veterinarians as additional members of every research team in Australia, not only in neuroscience but also in every other health and medical, as well as biological, discipline. In addition to being

unnecessary (see above), direct mandatory involvement would be both logistically and financially excessive and not “reasonably practicable”, a phrase that has been embedded in the new Australian occupational health and safety codes of practice. Indeed, current funding quotas would mean that employment of veterinarians would severely limit, or even preclude, employment of senior postdoctoral researchers as well as those more junior staff who are training in their respective fields. Loss of appropriately qualified research scientists would severely compromise the ability of research teams to generate high quality research and tackle the major issues that face the health sector.

6. As a principal-based document, the impact of the revised Code of Practice may be lost if too much detail is included. Comment is therefore specifically sought on whether there is a sufficient balance between details and detailed guidance.

It is ambiguous as to what is meant regarding “.....balance between details and detailed guidance”. However, the Code is extremely detailed but nevertheless provides detailed guidance to all of the different parties involved (i.e. Institutions, Animal Ethics Committees, investigators and animal ethics committees). The Code is also clearly structured so as to provide guidance to each of these parties.

7. Is there a clear connection between the Code of Practice and the *NHMRC Guidelines to promote the well-being of animals used for scientific purposes: The Assessment and alleviation of pain in research animals (2008) (Well-Being Guidelines)*?

Specifically:

“ 2.4 “Responsibilities of investigators”: Investigators must take all possible steps to anticipate, avoid and minimise pain and/or distress, and conduct ongoing review of such steps, including using methods that cause the least pain, distress, or lasting harm (Clause 2.2.45 [i]). (P8 Animal Code Consultation Pack 1)”

Yes, there is a clear connection.

For applications to the AEC, researchers develop very clear protocols that anticipate, avoid and minimize pain and / or distress to animals. In addition, researchers develop monitoring sheets to follow animals’ health and wellbeing throughout experiments in ways that are designed to best reflect the needs of the animals after specific procedures have been used.

With respect to conducting ongoing review of such steps, anaesthetics, analgesics as well as antibiotics are already well developed for use in animals and would need to be used for the duration of experimental series so as not to confound interpretation across different experimental groups. Nevertheless, researchers should (and indeed would) be aware of the development of new agents or methods that might work better than those currently being used and these would be incorporated either as amendments to existing protocols or at the stage when a new application was being written.

8. Do you believe that the title of the document should be amended to reflect the focus of the Code of Practice on ethical principles and best-code practice, and to more clearly indicate the scope of the Code of Practice, for example “Australian Code for the Care and Use of animals in research, science and education”.

Respect for animals is the key governing principle that underpins the Code. The foundations of the Code are laid under Section I, page 5 of the Code.

➤ ***A suggestion would be that the following title better reflects the governing principles and foundations of the Code:***

“Australian Code for the humane care and ethical use of animals in research, science and education”.

9. Is “animal” appropriately defined? Should the definition account for animals at their early stage of development (i.e. embryonic, fetal and larval forms)?

The definition of “animal” under Definitions (p2 of the Code) includes consideration of the “neurobiological development” of embryonic, fetal and larval stages. Half the gestation or incubation period would be a general guideline. For example, the legal upper limit for human abortion is ~16 weeks which is somewhat less than half a 40 week full-term gestation. The extent to which the sensory system has developed would provide a more accurate guide. However, it should be noted that procedures on developmental stages in utero, such as eutherian mammals, will involve anaesthesia of the mother and therefore also of the embryo or fetus.

10. Comment is sought regarding the proposal for category E membership for an Animal Ethics Committee (i.e. “a person who is responsible for the routine care of animals from within the Institution”) to be mandatory for Institutions that have or maintain an animal breeding or holding facilities” (see Section 2.2). How would these proposed changes outlined in Section 2.2 work for your Animal Ethics Committee?

At some Institutions, Category E personnel must read applications and approve them before they go to the Managers of Animal Care Services for signoff. This progressive assessment by members of Animal Services facilities is required before submission and directly involves Category E members from an early stage and also encourages proactive communication between the investigators and Animal Care staff.

Addition of a Category E member to the AEC would involve unnecessary duplication and workload since, assuming the above progressive sign-off has occurred, a person with such expertise will already have provided comment on the application.

➤ ***For the above reasons, mandatory inclusion of Category E membership of Animal Ethics Committees is unnecessary. One suggestion, however, would be to include in the Code that Category E personnel should be involved in reviewing applications before submission to AECs.***

11. Should the document include a guide regarding the longest duration of approval granted by an Animal Ethics Committee for a project before a submission of a new application is required?

A balance needs to be struck between ensuring that approvals are reviewed sufficiently often to remain up to date with any developments in animal welfare and at the same time not be reviewed too often so as to cause unnecessary burden and impost on AECs and research investigators and also teachers.

For research using animals, approval is generally awarded for 3, and sometime 5, years. The scientific merit and duration of such research has already received close scrutiny by the funding bodies and requires a level of excellence that is within the top 10-20% to receive funding. Researchers write AEC applications to reflect their funding cycles of 3-5 years and thus AEC approvals generally reflect the duration of an applicant's funding.

In addition, it must be noted that annual reporting is already a requirement of holding an approved application. Furthermore, if any small changes to procedures or design are required by the investigator, applications for minor amendments must be made and approved by the AEC. At some Institutions, only a limited number of amendments are permitted before triggering the need to submit an entirely new application.

- ***A guide for the longest duration of approval is unnecessary because there is a natural process already in place that guides the duration of approvals that, first, reflects the funding cycle and second, is driven by a mechanism that allows only 3 minor amendments to be submitted before triggering submission of a new AEC application. Furthermore, the processes already in place allow for changing community attitudes to be taken into account over time.***

Yours faithfully,

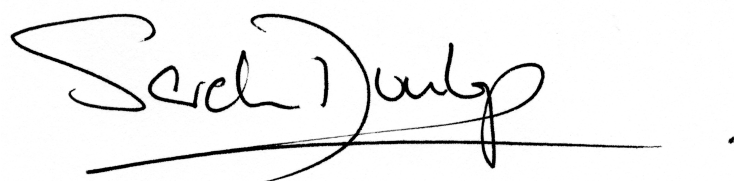
A handwritten signature in black ink that reads "Sarah Dunlop". The signature is written in a cursive style with a long horizontal line underneath the name.

Sarah Dunlop

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