



UNIVERSITY OF TASMANIA SUBMISSION

Proposed Revision to the Australian Code of Practice for the Care and Use of Animals for Scientific Purposes (NHMRC 2004, 7th edition)

Introduction

The University of Tasmania (UTas) has an Animal Ethics Committee (AEC) that has been established pursuant to the requirements of the *Animal Welfare Act 1993* (Tas) and the Australian Code of Practice for the Care and Use of Animals for Scientific Purposes (2004) (the Code). A wide range of research and teaching involving animals is undertaken at UTas, including laboratory-based, wildlife, agricultural, aquaculture and wild fisheries research. UTas has an animal welfare officer (AWO) who is a registered veterinarian pursuant to the *Veterinary Surgeons Act 1987* (Tas). The AWO provides vital assistance to the AEC in fulfilling its training and monitoring obligations. The manager of the UTas laboratory animal facility receives agenda papers and regularly attends AEC meetings as an ex-officio member. The AEC does not have a formal Category E membership requirement.

The Chair and secretariat of the UTas AEC have been primarily responsible for drafting the UTas submission in response to the proposed revision of the Code, but have consulted widely with stakeholders including researchers and teachers who use animals for scientific purposes, as well as Heads of School, and the UTas Animal Users' Group, whose primary interest is in the use of laboratory animals for research and teaching.

Public Consultation Question 1: Does the document clearly and concisely set out the governing principles?

UTas is generally supportive of the approach taken by the Code Revision Group in defining the principles of best practice, accountability, & guidance for all stakeholders. The clear enunciation of the crucial role of the principle of respect for animals in the Code is welcomed.

Section 1 of the proposed revised Code sets out these principles. While the principles are well articulated, this section is somewhat wordy and repetitive. It could be edited down. It may also need some re-organisation. For example, it would be better to include clauses 1.9 and 1.10 on wellbeing before clauses 1.6-1.8, particularly because the 3Rs are defined for the first time in clause 1.10 but previously mentioned in clause 1.6.

UTas also supports the inclusion of a new 'Animal Wellbeing' section, but it is suggested that the terminology of 'animal welfare and animal wellbeing' should be adopted more

universally throughout the Code. UTas has some reservations about the definition of wellbeing in the Code, particularly the phrase that it 'implies a positive state'. Wellbeing is something that can be impacted upon negatively or positively (see, for example, the definition of 'adverse incident'). This definition of wellbeing seems to confuse the state of wellbeing with the factors that influence that state.

Public Consultation Question 2: Are the terms 'should' and 'must' used appropriately in this document?

UTas has no concerns about the use of the terms 'should' and 'must' in the revised document. These terms will be useful in guiding AEC discussions and decision-making.

Public Consultation Question 3: Does the document clearly and concisely set out, and correctly attribute, responsibilities of all parties involved?

Responsibilities of all stakeholders are articulated well and are logical.

Public Consultation Question 4: Does the document provide all relevant parties with sufficient practical guidance on the application of principles of the Code in terms of their responsibilities?

UTas has no concerns with the practical guidance on the application of principles provided in the Code.

Public Consultation Question 5: Should the document include specific guidance relating to the responsibilities of veterinarians and Animal Welfare Officers? Should the document include 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?

UTas has no difficulty with the requirement in clause 3.7.18 that 'Personnel performing surgery must be competent to perform the procedure, or be under the direct supervision of a person competent to perform the procedure'. All UTas researchers and teachers operate within this framework already, and the UTas AEC generally imposes conditions on approval that the AWO (a vet) must be satisfied of the competence of personnel performing surgery before they are allowed to proceed. These requirements have served UTas well, and it is recommended that they should be adopted more widely as best practice. However, UTas strongly opposes the suggestion that there should be a prescriptive limitation on the types of people conducting anaesthesia and surgery. If the Code included a requirement that only registered veterinarians could conduct anaesthesia and surgery then much of the research and teaching conducted at UTas could no longer be undertaken. It is unclear how sufficient benefit would be achieved in terms of animal welfare and animal wellbeing to justify the imposition of such a

requirement. The financial implications for research and teaching may also be considerable. UTas submits that a requirement of this nature is unnecessary in an institution such as UTas that has an AWO who is a veterinarian and who is embedded in the supervision and training of staff. If there are concerns that research is conducted at other institutions without appropriately trained staff and without monitoring and supervision by an AWO, this should be dealt with appropriately without imposing an impossible obstacle for research and teaching activities in institutions that already have appropriate frameworks in place.

Taking these considerations into account, UTas would be supportive of better articulation of the role of the AWO in the revised Code.

UTas also recommends that there should be clearer obligations imposed on researchers, teachers, lab assistants and anyone else who handles animals for research and teaching purposes to engage in appropriate ethics and welfare training. This could include provision for regular (triennial?) mandatory training on animal ethics with the addition of detailed guidance on requirements for technical competency training and assessment. This should be set out in a specific section entitled 'Competency & Demonstration of Competency', which should include details on: what constitutes competency; how competency is to be assessed; what general levels of education on animal welfare and ethics are to be provided to all stakeholders including AEC members; and what are the roles of an AWO/veterinarian and Responsible Investigators in ensuring the educating and training of personnel to achieve and demonstrate 'competency'. Additionally, the role of the AEC in certification, monitoring and on-going support for 'competency' should also be articulated.

Public Consultation Question 6: Is there sufficient balance between principles and detailed guidance

While UTas is generally of the view that the balance between principles and detailed guidance is appropriate, there are some surprising omissions with regard to detailed guidance. In particular, it is somewhat surprising that there is no specific mention of the particular issues associated with research and teaching involving fish and fisheries in section 3. It is difficult to see why laboratory-based and wildlife research and teaching warrant specific attention, but there is no mention of fish. The UTas AEC and UTas fish researchers and teachers would appreciate more specific guidance.

Public Consultation Question 7: Is there a clear connection between the Code and other NHMRC guidelines?

UTas has no specific comments in relation to this question, save that cross referencing to the Code for the Responsible Conduct of Research should be made to give greater credence to institutional and researcher responsibilities.

Public Consultation Question 8: Should this document be amended to more clearly indicate its scope?

UTAS concurs with the submission by ANZCCART that the title of the Code should be amended by deleting reference to 'scientific purposes' and replacing this with 'in research & teaching'. This better promotes the ethical use of animals for all purposes across the education and research sector.

Further, all references to scientific purposes in this document should be amended to 'research & teaching'.

Public Consultation Question 9: Is 'animal' appropriately defined?

UTas has serious reservations about the amendment to the definition of 'animal' in the revised Code. It is unclear why the definition 'cephalopods such as octopus and squid' has been changed to 'octopus and squid'. The new definition would exclude nautilus and cuttlefish, which can hardly have been intended.

Public Consultation Question 10: How would the proposal for a Category E member affect your AEC?

Although the UTas AEC currently does not have a Category E membership requirement, one laboratory manager regularly attends meetings. UTas values the role, skills and experience of Category E representatives, but believes this input should be provided as an ex-officio rather than full-voting member of the committee. Mandating this role also has implications for the C+D = 1/3 of members requirement, which could be problematic for smaller institutions, particularly those without significant animal colonies/established facilities. However, the UTas AEC could readily accommodate any requirement for Category E membership if this proposed change to the Code is ultimately accepted.

Public Consultation Question 11: Should the document include a guide regarding the longest duration of approval?

UTas is supportive of the document including a guide regarding the longest duration of approval granted by an AEC for a project before submission of a new application is required. It is proposed that the Code should stipulate a period of four years as the longest durations of approval, in line with HREC requirements.

Technical comments on specific provisions in the revised draft of the Code

Definitions:

'Competence' should be included and defined as the demonstration of the skills, training or experience of the proponent in the prescribed techniques and should refer to

a specific chapter dedicated to 'Training and Competency' (see response to Public Consultation Question 5, above).

'Minor amendment' UTas agrees with ANZCCART that this definition is too exclusive. AECs should be able to consider additional animals, beneficial changes (eg pain relief) as minor in certain circumstances. We suggest: 'any change that could reasonably be expected to have a negative effect on the welfare of the animals cannot be considered as a minor amendment'

'Scientific purposes' should include 'surveillance'

'Training' should be defined more specifically for researchers and AEC members

Section 1

1.28 The word 'tissue' should be amended to biological material (thereby including genetic material, blood and sera)

1.29 UTas is supportive of the need to manage breeding of animals to minimise the production of excess animals. UTas would be supportive of further clarification on this point, for example by requiring institutions to record numbers of brood stock in animal usage numbers.

1.33 'Competency' should be better defined, including details on assessment criteria and detail that veterinary advice or oversight may be required. Readers should be referred to a section on 'training and competency' to outline the general requirements for demonstration of competency.

Section 2 Responsibilities:

'Institution' should specifically include NGOs and government agencies.

General: this section should include a reminder that Responsible Investigators should bear responsibility for all aspects of the project, including training and supervision of procedures.

2.1.7(iii) This institutional plan should be developed in conjunction with the AEC Chair and the recommendations of the most recent external review of the AEC.

2.1.13 This clause should be expanded to include individuals employed at more than one institution. Much greater guidance should be provided on the responsibilities of individual AECs in overseeing collaborative research, particularly around monitoring and reporting obligations. The document should more clearly specify what constitutes 'delegated approval' (per iv). Confidentiality requirements should be defined.

2.2.3 This clause potentially removes the independence of the AEC, which is quite contrary to the existing CoP. 2.2.2 should have a third (iii) point requiring institutions to 'respect the independent decision making authority of the AEC'.

2.2.7(ii) UTas suggests insertion of the following: 'noting that personal details identifying committee members may be kept as confidential, unless the committee member indicates otherwise'

2.2.39 Reference to the Code for the Responsible Conduct of Research & state/territory laws should be recommended in handling all investigations into non-compliance or grievances.

Part D: Conduct of Projects. In general this Part is far too focused on traditional laboratory-based research involving animals and neglects to consider that much animal research will be conducted in the field. In particular, it will be impossible to achieve many of the requirements in the 'Monitoring and record keeping' section for wildlife research, especially research of a mark and recapture nature.

2.4.4 It is recommended that reference should be made to: 'including environmental enrichment'

2.4.7 This clause should articulate the Responsible Investigator's responsibility to ensure that all personnel have the appropriate training to perform the tasks delegated to them.

2.4.8(iv) UTas recommends insertion of: 'including purchasing or breeding of animals'.

2.4.8(viii) UTas recommends insertion of: 'and comply with AEC requirements for studies of this nature'.

2.4.13(vii) UTas recommends insertion of: 'or the introduction of a companion animal'

2.4.13(viii) UTas recommends insertion of: 'and ensure an emergency management plan is in place'.

2.4.26 & 2.4.27 These clauses should align better with, and refer to the requirements of the 'Wellbeing Guidelines' (NHMRC 2008).

2.4.38(iii) The final report should contain references to the significance of research outcomes and dissemination of results.

2.4.47 UTas recommends the addition of a sub-clause on Pilot Studies, stating that they should be undertaken where new techniques with uncertain animal welfare outcomes are being proposed to 'enable assessment of the feasibility of the project and the potential for Refinement & Reduction.' (from CoP, 2007)

2.5 It is suggested that a clearer delineation needs to be made between the Responsible Investigator and the Facility Manager, stipulate when the duty of care falls to each person.

2.5.15 This clause appears to imply that it is the Facility Manager's role to be aware of and to seek the required permits. It should be reinforced that this is the Responsible

Investigator's role, but the Manager should have a system in place to record which permits have been received and make sure none are outstanding .


2.5.18 This clause should indicate that Facility Managers have responsibility for all animals under their care until such time as they are allocated to a specific project, at which time the Responsible Investigator assumes over-arching responsibility, unless the day-to-day care of experimental animals is delegated to the Facility Manager. NB all stakeholders have a duty to ensure animal welfare standards are upheld.

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