



**PUBLIC CONSULTATION ON PROPOSED REVISION
OF THE *AUSTRALIAN CODE OF PRACTICE FOR
THE CARE AND USE OF ANIMALS FOR SCIENTIFIC
PURPOSES 2004***



An invitation from the NHMRC CEO to make a submission

You are invited to make a submission regarding the proposed revisions to the *Australian code of practice for the care and use of animals for scientific purposes, 7th edition* (2004) (Code of Practice). The NHMRC is keen to ensure that the Australian community has the best opportunity to participate in developing NHMRC guidance on matters of health and research ethics and now seeks your comments on these proposed revisions. Please draw this opportunity to the attention of anyone whom you believe would be interested in providing comments.

The Code of Practice aims to ensure the ethical and humane care and use of animals for scientific purposes. The Code of Practice is a national document that provides guidance for investigators, teachers, institutions, Animal Ethics Committees and all people involved in the care and use of animals for scientific purposes.

The revision of the 7th edition of the Code of Practice seeks to ensure that the document continues to be a relevant, accurate and applicable guide. In preparation for public consultation, advice has been sought from a broad range of stakeholders including researchers, research institutions, teachers, Animal Ethics Committees, animal welfare organisations, veterinarians and state and territory jurisdictions.

To support the public consultation, a discussion paper has been developed which outlines the background and intent of the revision of the Code of Practice, and raises some specific issues on which NHMRC is particularly interested in receiving comment.

NHMRC is pleased to provide you with a draft revised *Australian code of practice for the care and use of animals for scientific purposes*.

Additional copies of this consultation package are available from the consultation page of the NHMRC website (<http://consultations.nhmrc.gov.au>).

NHMRC looks forward to receiving your comments on these proposed revisions.

Yours sincerely

A handwritten signature in black ink, appearing to read 'Warwick Anderson', with a long, sweeping underline.

Professor Warwick Anderson AM
Chief Executive Officer

23 September 2011



Draft revision of the *Australian code of practice for the care and use of animals for scientific purposes (7th Edition 2004)*

AN INVITATION TO MAKE SUBMISSION

The National Health and Medical Research Council is conducting public consultation on the above draft document which provides guidelines on the care and use of animals for scientific purposes. You are invited to make a submission about the draft guidelines. This invitation is made under section 13 (d) (iii) of the *National Health and Medical Research Council Act 1992*.

Information regarding this review and on how to make a submission, and a copy of the draft revision are available from: <http://consultations.nhmrc.gov.au> or can be obtained by phone or email as listed below.

How to make your submission:

Online submissions are strongly preferred.

If online submission is not possible:

- Please make your submission in writing (preferably typed or word processed) or by audio recording, and submit it by e-mail or mail.
- A form seeking authorship and other details is also included in the documentation. Please complete and attach the form to your submission. **Submissions that do not have the completed form attached will not be accepted.** *Please note that it is acceptable to type your name in the signature box of the submission form as your electronic signature.*
- If you would like your submission to be treated as confidential, please indicate this clearly, for example, by marking **CONFIDENTIAL** on each page.

As part of usual practice NHMRC places all submissions on the NHMRC website, unless individuals or organisations express any concerns about this.

If NHMRC posts submissions on our website, we will remove all names and address information.

NHMRC is a Commonwealth agency subject to *the Freedom of Information Act 1982* (the FOI Act). As such, your submission may be subject to an FOI request.

Where this occurs, NHMRC will need to assess whether your submission is covered by an exemption or a conditional exemption for release under the FOI Act. Where you have marked your submission as confidential, we may consult you before deciding whether to release your submission.

WORKING TO BUILD A HEALTHY AUSTRALIA

www.nhmrc.gov.au

GPO Box 1421, Canberra ACT 2601

16 Marcus Clarke Street, Canberra City ACT 2600

T. 13 000 NHMRC (13 000 64672) or +61 2 6217 9000 F. +61 2 6217 9100 E. nhmrc@nhmrc.gov.au

ABN 88 601 010 284

We will consult you on whether your personal information should be excluded from the release of your submission.

For further information about the FOI Act, please visit our website at <http://www.nhmrc.gov.au/about/freedom-information>

Please submit your submission via:

1. Online: [Online Submission Page \(Preferred Option\)](#)
2. Email: ethics@nhmrc.gov.au
3. Post: Project Officer – *Australian code of practice for the care and use of animals for scientific purposes*
Health & Research Ethics Section
Research Translation Group
National Health and Medical Research Council
GPO Box 1421
Canberra ACT 2601

Closing Date: 5pm AEST Friday 2 December 2011

Please draw this consultation process to the attention of anyone who you believe would be interested in making a submission.

Further information:

Further information and hard copies of the draft documents and forms can be obtained by contacting the Health & Research Ethics Section:

Email: ethics@nhmrc.gov.au

Telephone: (02) 6217 9070

Facsimile: (02) 6217 9175



Proposed revisions to the Australian code of practice for the care and use of animals for scientific purposes (7th Edition 2004) - Consultation Submission Form

PLEASE COMPLETE THE FORM BELOW AND INCLUDE IT WITH YOUR SUBMISSION. SUBMISSIONS THAT DO NOT HAVE THIS FORM ATTACHED WILL NOT BE ACCEPTED

1. Does this submission reflect the views of the organisation or an individual?
 An individual An organisation

If the submission reflects the views of an organisation please include details of the organisation at Q2:

2. Contact Details

Name: _____

Organisation: _____

Address: _____

Phone no: _____ Fax: _____

Email: _____

3. My submission is confidential/not confidential. (Please Note: You should be aware that any submission made to the NHMRC may be subject to the requirements of the Commonwealth *Freedom of Information Act 1982*.)
 CONFIDENTIAL NOT CONFIDENTIAL

4. The National Health and Medical Research Council (NHMRC) has my permission to place my submission about this consultation draft on the NHMRC website. (Please Note: The NHMRC retains the right to determine whether or not it will post submissions on the NHMRC website.)
 YES NO

5. The NHMRC has permission to quote from my submission in any reports prepared about this document. (If you do not agree to your submission being quoted, the issues you raised in your submission may be referred to. However, no direct quote would appear.)
 YES NO

I am aware that if I agree to release information from my submission, it will be widely available, e.g. it may be placed on the NHMRC website and made available in hard copy. I am also aware that the information may be further referenced in later publications. If I have named an organisation at question 2, I agree that my comments are representing the views of the organisation.

Any personal information provided, e.g. contact details, will only be used for the purpose of developing this document and will only be disclosed to members of the NHMRC's Australian Health Ethics Committee. Such information will not be used or disclosed for any other purpose, without prior written consent.

Name (please print) _____

Signature: _____ (if completing electronically – please type your name)

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Proposed revisions to the *Australian code of practice on the care and use of animals for scientific purposes* (2004)

Public guide to the technical Discussion Paper endorsed by NHMRC Council

This information is based on the Discussion Paper endorsed by the NHMRC Council in its role of providing advice to the NHMRC Chief Executive Officer (“Revision of the Australian code of practice on the care and use of animals for scientific purposes 2004”). A copy of this paper is included with the public consultation pack.

Introduction

The *Australian code of practice for the care and use of animals for scientific purposes* (Code of Practice) provides an ethical framework and governing principles for the circumstances when an animal may be used, and then how it must be cared for and treated.

The humane and ethical care and use of animals for scientific purposes has been a primary consideration in the development of this consultation draft. The review is intended to ensure that the information in the Code of Practice continues to be relevant and applicable for all circumstances when animals may be used for such purposes, accurate and based on contemporary scientific knowledge, and take into account international views.

Feedback from the community is sought to ensure that the proposed revisions provide clearer, stronger, contemporary ethical guidance and accountability for all those involved with the care and use of animals for scientific purposes.

There is currently a broad spectrum of philosophical views about the use of animals for scientific purposes, which includes that the use of animals for scientific purposes is a privilege granted by society provided the animals are used ethically and treated humanely, that animal research is essential for progressing scientific knowledge, and that animals should not be used for scientific purposes. NHMRC is aware of and respects the different views regarding the use of animals for scientific purposes..

Background to the Code of Practice and this review

The Code of Practice aims to ensure the ethical and humane care and use of animals for scientific purposes.

The Code of Practice has been in place since 1969 and has been revised periodically since that time. The current edition (7th edition, 2004) covers all aspects of the care and use of animals for scientific purposes in medicine, biology, agriculture, veterinary and other animal sciences, along with industry and teaching. It provides an ethical framework and governing principles of good conduct, to inform the process of ethical review and provide guidance for investigators, teachers, institutions, Animal Ethics Committees (AECs) and all people involved in the care and use of animals for scientific purposes.

The types of animals currently protected by the Code of Practice are all live non-human vertebrates and higher order invertebrates such as octopus and squid.

The current edition of the Code of Practice was revised by NHMRC and endorsed by Commonwealth Scientific and Industrial Research Organisation (CSIRO), Universities Australia (UA) and the Australian Research Council (ARC).

All States and Territories have variously incorporated the Code of Practice into their animal welfare or animal research legislation.

The process taken to arrive at this consultation draft

The initial phases of the review have ensured the full involvement of interested stakeholders including institutions, members of Animal Ethics Committees, researchers, teachers, veterinarians, animal welfare organisations, state and territory regulators and the co-authors of the current edition.

Comments were considered by the Office of NHMRC, NHMRC advisory groups and working committees (Code Writing Groups, Code Reference Group, Animal Welfare Committee), NHMRC Research Committee and Council. This led to the preparation of the current consultation draft.

Differences between the current version and the consultation draft

The major changes from the 2004 edition include:

- Identification of the governing principles that can be applied in all relevant situations.
- New structure with the governing principles used consistently throughout all sections.
- Clearer guidance regarding responsibilities and accountabilities of all parties.
- Capacity for reference to external guidelines for detailed advice.
- Separate sections for governance of an Animal Ethics Committee (AEC) and the specific responsibilities of an AEC.
- New “Animal Wellbeing” section that provides the principles that can be applied to any situation (including teaching and wildlife research) and to any species.
- New section on complaints and non-compliance.
- New section on external review within the body of the document rather than in an Appendix.
- Section 4 “The use of animals in teaching” now outlines the principles that are unique to the teaching situation and clearly links to other sections.
- Inclusion of a mandatory Category E membership of AECs in certain situations.

A detailed mapping of the major changes from the 2004 edition is included with the public consultation pack.

Public Consultation questions

During the development of the consultation draft, specific issues were identified as requiring particular consideration. Your comment is invited on these matters.

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

Is this matter a new element of the Code of Practice, or is it a change?

The consultation draft is intended to provide a clearer, contemporary outline of the governing principles for the care and use of animals for scientific purposes, and builds on the principles contained in the current version (7th edition). The principle of respect for animals now clearly underpins the Code of Practice.

Where can I find the information in the consultation draft?

The governing principles are outlined in Section 1. These principles are used consistently through the other sections of the Code, particularly in terms of responsibilities.

Why is it important that we consult on this issue?

The governing principles are the key part of the document. If the governing principles are clear, then their uptake and implementation by all those involved with the care and use of animals is more likely to be successful.

Background

The Code of Practice is intended to apply to all situations where animals may be used for scientific purposes. It provides the framework under which judgements can be made in specific situations. Respect for animals is the key governing principle that underpins the whole document.

Governing principles rather than prescriptive details can be applied in any situation or context.

(You may also like to refer to the Discussion Paper endorsed by the NHMRC Council that is included with the public consultation pack.)

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

Is this matter a new element of the Code of Practice, or is it a change?

The Code of Practice has always contained “should” and “must” statements. However the use of these terms has been reviewed in the consultation draft. Definitions of both terms are also included for the first time.

Where can I find the information in the consultation draft?

The terms are defined in the “Definitions” section at the beginning of the document, and are used throughout the document

Why is it important that we consult on this issue?

The Code of Practice is incorporated in legislation in all States and Territories. To prevent an unnecessary regulatory burden, careful use of the terms “should” and “must” is necessary.

Background

The intention of the use of these terms is that:

- “Should” indicates a strongly recommended component of the Code. In some instances a recommended component of the Code is an example of how it is anticipated a person will meet the obligatory requirement of the Code.
- “Must” indicates an obligatory component of the Code.

The legislative framework for the use of animals remains the responsibility of the States and Territories.

(You may also like to refer to the Discussion Paper endorsed by the NHMRC Council that is included with the public consultation pack.)

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

Is this matter a new element of the Code of Practice, or is it a change?

The consultation draft is intended to provide a clearer outline of the responsibilities of all parties involved with the care and use of animals for scientific purposes. This information builds on that contained in the current version (7th edition).

Where can I find the information in the consultation draft?

Responsibilities are now contained in Section 2, which includes separate sections on the responsibilities of:

- Institutions
- Institutions with respect to the governance of an Animal Ethics Committee
- Animal Ethics Committees for ethical review, approval and monitoring
- Investigators
- Animal carers.

Why is it important that we consult on this issue?

The responsibilities and accountabilities of all relevant parties need to be very clear to ensure that the principles of the Code of Practice are understood. It is important to ensure that the responsibilities described for a particular person or group are correct, and that responsibilities are described for all relevant persons or groups.

Background

A key governing principle in the consultation draft is that respect for animals is demonstrated by “persons involved with any aspect of the care and use of animals for scientific purposes knowing and accepting their responsibilities” (Clause 1.1 [v]). The consultation draft intends to provide clearer information on the responsibilities and accountabilities of:

- Institutions - to ensure that policies and procedures are in place to support all aspects of the care and use of animals.
- Investigators and animal carers - so that those directly involved with the care and use of animals are fully aware of their responsibilities.
- Animal Ethics Committees (AECs) – to ensure that responsibilities of an institution for the governance of an AEC are clearly separated from the responsibilities of an AEC for ethical review, approval and monitoring of animal care and use.

(You may also like to refer to the Discussion Paper endorsed by the NHMRC Council that is included with the public consultation pack.)

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

Is this matter a new element of the Code of Practice, or is it a change?

The information in the consultation draft builds on that contained in the current version (7th edition).

Where can I find the information in the consultation draft?

The governing principles are outlined in Section 1. Specific responsibilities for all relevant parties are outlined in Section 2. The application of the governing principles and responsibilities are described throughout the document.

Why is it important that we consult on this issue?

Successful implementation of the Code requires all those involved with the care and use of animals to be aware of their responsibilities, and what they need to do to meet these responsibilities. Provision of sufficient practical guidance is therefore essential.

Background

The approach taken in the development of the consultation draft has been to identify the governing principles in Section 1, with these principles used consistently through the other sections of the document, particularly in terms of responsibilities.

A key governing principle in the consultation draft is that respect for animals is demonstrated by “persons involved with any aspect of the care and use of animals for scientific purposes knowing and accepting their responsibilities” (Clause 1.1 [v]). The consultation draft is intended to provide clearer information regarding the responsibilities of all parties and improved guidance on the application of these responsibilities.

(You may also like to refer to the Discussion Paper endorsed by the NHMRC Council that is included with the public consultation pack.)

5. Should the document include specific guidance regarding 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?

Is this matter a new element of the Code of Practice, or is it a change?

Information on the roles and responsibilities of veterinarians and Animal Welfare Officers builds on that contained in the current version (7th edition).

Where can I find the information in the consultation draft?

The consultation draft does not have a specific section that outlines the roles and responsibilities of veterinarians and Animal Welfare Officers. Relevant information appears throughout the document and in Section 2.5 “Responsibilities of animal carers”.

Why is it important that we consult on this issue?

During development of the consultation draft, questions were raised as to whether there is sufficient guidance to ensure appropriate involvement of veterinarians in all aspects of the care and use of animals. Should the Code of Practice require a higher level of direct involvement of veterinarians than currently proposed? (International approaches regarding the roles and responsibilities of veterinarians are provided under “Background”.)

Background

Advice from veterinarians is essential in order to ensure the ethical and humane care and use, and the health and wellbeing, of animals for scientific purposes. The roles of veterinarians are diverse, and can include:

- membership of an Animal Ethics Committee (Category A, B or C)
- management of laboratory animal production and maintenance colonies
- provision of veterinary advice regarding the design of research and teaching projects
- provision of veterinary clinical care and management of the wide range of species of animals used for scientific purposes
- institutional Animal Welfare Officer involved with the compliance and monitoring of animal care and use
- training researchers and students in the humane and ethical care and use of animals.

During the development of the consultation draft, questions were raised as to whether there is sufficient information and guidance to ensure appropriate involvement of veterinarians. In particular, is there sufficient information and guidance regarding:

- the responsibilities of veterinarians in diverse roles
- the institutional support that should be provided to allow veterinarians to fulfil their roles and responsibilities
- the requirements for provision of veterinary clinical care
- whether the Code of Practice should include the requirement for a veterinary care program, similar to that required in some other countries
- 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.

Some international approaches regarding the roles and responsibilities of veterinarians can be found in documents available from the following websites:

NZ: [Animals in research, testing and teaching](#)

UK: [Home Office](#) and [Home Office Guidance](#), Paragraphs 4.59 – 4.67

EU: [European Commission](#) – Click on EU [Directive 2010/63/EU](#)

US: [Guide to the care and use of laboratory animals 2010](#) (PDF Free Download)

Canada: [Canadian Council on Animal Care Policy](#) (Chapter 7 – “Animal care and use operations headed by veterinarians and animal care staff”)

(You may also like to refer to the Discussion Paper endorsed by the NHMRC Council that is included with the public consultation pack.)

6. As a principles-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 sufficient balance between principles and detailed guidance.

Is this matter a new element of the Code of Practice, or is it a change?

The current version (7th edition) contains both governing principles and detailed guidance information. The consultation draft provides improved referencing to external guidelines for detailed and contemporary advice regarding specific matters.

Where can I find the information in the consultation draft?

The governing principles are outlined in Section 1. These principles are used consistently through the other sections of the Code. Information on practical guidance is provided throughout the document.

Why is it important that we consult on this issue?

If the Code of Practice contains too much detailed guidance information, it can quickly become out-of-date or difficult to apply under all relevant circumstances. Too little guidance on how to apply the governing principles may create difficulties for the practical implementation of the Code of Practice. Therefore, there needs to be the right balance between provision of governing principles and inclusion of detailed guidance information.

Background

The current version (7th edition) contains detailed advice on specific matters. This information can quickly become out-dated with changes in accepted scientific, veterinary and medical practice, and administrative and governance procedures.

The intent of this revision is to focus the content of the Code of Practice on governing principles that can be applied in any situation or context, and to refer to external best

practice and evidence-based guidelines for detailed advice regarding specific matters. Because such guidelines can be more easily updated in response to changes, the Code of Practice can continue to be a relevant, accurate and applicable guide.

External guidelines to support the implementation of the Code of Practice include those produced by the NHMRC, most importantly the *Guidelines to promote the wellbeing of animals used for scientific purposes: The assessment and alleviation of pain and distress in research animals* (2008). Other guidelines and policies include:

- *Guidelines on the use of animals for training interventional medical practitioners and demonstrating new medical equipment and techniques* (2009)
- *Guidelines on the care of cats used for scientific purposes* (2009)
- *Guidelines on the care of dogs used for scientific purposes* (2009)
- *Guidelines for monoclonal antibody production* (2008)
- *Guidelines for the generation, breeding, care and use of genetically modified and cloned animals for scientific purposes* (2006)
- *Policy on the care and use of non-human primates for scientific purposes* (2003)
- *A guide to the use of Australian Native Mammals in Biomedical Research* (1-3) (1990) and *A guide to the use of Australian Native Mammals in Biomedical Research, Section 4: Care of Individual Species* (1995).

Guidelines produced by external organisations and bodies, and endorsed by NHMRC, may also be useful documents to support the Code of Practice.

(You may also like to refer to the Discussion Paper endorsed by the NHMRC Council that is included with the public consultation pack.)

7. Is there clear connection between the Code of Practice and the NHMRC *Guidelines to promote the wellbeing of animals used for scientific purposes: The assessment and alleviation of pain and distress in research animals* (2008) (Wellbeing Guidelines)?

Is this matter a new element of the Code of Practice, or is it a change?

The consultation draft provides the governing principles for ensuring the wellbeing of animals. Detailed guidance on topics such as the conduct of specific procedures and techniques is now provided via reference to appropriate guidelines, for example, the “Wellbeing Guidelines”.

Where can I find the information in the consultation draft?

References to appropriate sections in the “Wellbeing Guidelines” appear throughout the consultation draft, particularly in Section 3 (“Animal Wellbeing”)

Why is it important that we consult on this issue?

The consultation draft includes reference to the “Wellbeing Guidelines” as a source of information on how to ensure animal wellbeing. For the Code of Practice to be a relevant, practical and applicable guide, there needs to be a clear connection between the Code of Practice and the “Wellbeing Guidelines”.

Background

A key governing principle in the consultation draft is the promotion of the wellbeing of the animals used for scientific purposes (Clause 1.1 [ii]). Use of accurate information, based on contemporary scientific knowledge and current best-practice, is essential to ensuring animal

wellbeing. The consultation draft includes reference to the “Wellbeing Guidelines” as a source of information.

A specific example of the links between the consultation draft and the “Wellbeing Guidelines” is provided below, using the subject of “anaesthesia and analgesia”:

- Section 1 “Principles”: *Respect for animals must underpin all decisions and actions involving the care and use of animals for scientific purposes. This respect is demonstrated by.... (iii) avoiding or minimising harm, including pain and distress, to those animals (Clause 1.1 [iii]).*
- Section 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]).*
- Section 3 “Animal Wellbeing. “*The choice and administration of anaesthetics, analgesics and sedatives must be suitable for the species and the aims of the project, and must take into consideration the age and physiological status of the animal, the type of procedure and the scientific or educational aims. The use of such agents should at least be comparable with their use in current medical or veterinary practice.” (Clause 3.7.2)*
- “Wellbeing Guidelines”: *Factsheet I: Pain management: anaesthesia, analgesia and anxiolytics.*

(You may also like to refer to the Discussion Paper endorsed by the NHMRC Council that is included with the public consultation pack.)

8. Do you believe the title of this document should be amended to reflect the focus of the Code of Practice on ethical principles and best-practice guidance, 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”? If so, suggestions for a title would be helpful.

Is this matter a new element of the Code of Practice, or is it a change?

The title of the consultation draft is identical to that of the current version (“*Australian code of practice for the care and use of animals for scientific purposes*”). Comment is invited on whether the title should be changed so that what is covered by the Code of Practice is clearer.

Where can I find the information in the consultation draft?

The suitability of the title should be considered in terms of the types of animals, procedures and situations that are to be covered by the Code of Practice. This information is found in the “Definitions” section, and throughout the document.

Why is it important that we consult on this issue?

The Code of Practice title must be clear so that people can easily recognise that the Code of Practice applies to their activities. If people are not aware that they must read and comply with the Code of Practice, the ethical and humane care and use of animals may be compromised.

Background

During the development of the consultation draft, questions were raised regarding the suitability of its title. The title could be amended to:

- more clearly indicate the types of animals and activities that are covered by the Code of Practice.
- reflect the focus of the Code of Practice on ethical principles and best-practice guidance
- reduce the potential for confusion of the Code of Practice with existing model codes of practice for the welfare of various species produced by Department of Agriculture, Fisheries and Forestry and other organisations/government departments.

(You may also like to refer to the Discussion Paper endorsed by the NHMRC Council that is included with the public consultation pack.)

9. Is “animal” appropriately defined? Should the definition account for animals at the early stage of their development (i.e. embryonic, fetal and larval forms)? If you disagree with the definition, it would be very helpful if you could provide evidence for your view.

Is this matter a new element of the Code of Practice, or is it a change?

The definition of “animal” in the consultation draft builds on information in the current version (7th edition).

Where can I find the information in the consultation draft?

“Animal” is defined in the “Definitions” section at the beginning of the document.

Why is it important that we consult on this issue?

The correct definition of “animal” will mean that the Code of Practice can be applied in all appropriate situations.

Background

The current version (7th edition) covers “any live non-human vertebrate, that is, fish, amphibians, reptiles, birds and mammals, encompassing domestic animals, purpose-bred animals, livestock, wildlife, and also cephalopods such as octopus and squid” (Introduction, page 1). The current version also advises that emerging knowledge and ethical values should be taken into account when proposing to use other animal species not covered by the Code, and animals at early stages of their development (i.e. embryonic, fetal and larval forms).

Given that the current version was published in 2004, it is appropriate to review the definition of the “animal” in light of advances in scientific knowledge and ethical values.

(You may also like to refer to the Discussion Paper endorsed by the NHMRC Council that is included with the public consultation pack.)

10. Comment is sought regarding the proposal for the Category E membership category for an Animal Ethics Committee (“a person who is responsible for the routine care of animals from within the institution”) to be mandatory for institutions that have or maintain 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 (Animal Ethics Committee)?

Is this matter a new element of the Code of Practice, or is it a change?

Category E membership of an AEC has been the subject of discussion for many years. In the current version (7th edition), Category E membership is recommended but not mandatory.

The consultation draft proposes that the composition of AECs for institutions that have or maintain animal breeding or holding facilities must include a Category E member.

Where can I find the information in the consultation draft?

- Section 2.2 outlines the membership of an AEC. Particular consideration should be given to the description of the membership category (Clause 2.2.15 [iv]), committee composition (Clause 2.2.16), quorum requirements (Clause 2.2.26) and AEC executive requirements (Clause 2.2.13).
- Section 2.3 outlines the responsibilities of an AEC. Clauses related to decisions of an Animal Ethics Committee are relevant to this question, in particular, Clause 2.3.6 which requires continuity of membership and does not support alternate members.

Why is it important that we consult on this issue?

Inclusion of a mandatory Category E membership for an AEC may be difficult to implement in some situations.

Background

The proposed changes arose from consideration of the long-standing discussions regarding mandatory Category E membership of an AEC. For many years, Category E membership has been recommended but not mandatory. The consultation draft outlines how mandatory Category E membership will work in practice, and if this requirement should be limited to AECs for institutions that have or maintain animal breeding or holding facilities. By providing information in this way, people will be able to more easily consider the implications of the proposed changes.

Factors to consider include:

- Creation of this membership category is a positive step as it provides recognition of the importance of the role of animal carers, and the value of their expertise to the AEC.
- Category E membership is a proactive mechanism for ensuring communication to the AEC about problems occurring with animal facilities.
- The effectiveness of the person responsible for the care of animals during AEC meetings is enhanced by full membership compared to *ex officio* status.
- Mandatory Category E membership affects the requirements for balance of membership and quorum.
- The proposal is that Category E membership will not be mandatory for AECs considering non institutional-based research where animals are not cared for at the institution. Category E membership may not be relevant or practical in these situations.
- Mandatory requirement for Category E membership can be difficult in situations where an AEC serves many external institutions.
- An increase in the requirements for membership of AECs can create difficulties for organisation of meetings.
- Responsibilities of Category E members are often met by Category A members (veterinarians).
- The proposed change should be considered in context of Clause 2.3.6 which applies to all AEC membership categories, requires continuity of membership and does not support alternate members.

(You may also like to refer to the Discussion Paper endorsed by the NHMRC Council that is included with the public consultation pack.)

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

Is this matter a new element of the Code of Practice, or is it a change?

The current version (7th edition) provides guidance related to the annual reporting of approved projects. However, there is no guidance on the length of approval granted by an AEC before a new full application is required. The consultation draft also does not address this matter.

Where can I find the information in the consultation draft?

While the consultation draft does not include information on this matter, information related to approval and annual reports is relevant. This information is contained in:

- Clause 2.2.46 which provides guidance related to the documentation required for annual reporting of approved projects.
- Clauses 2.2.29 – 2.2.33 which outline the review procedures and decision-making for an AEC.
- Clause 2.3.5 (ii) which outlines the decisions of an AEC related to an annual report.

Why is it important that we consult on this issue?

During the development of the consultation draft, questions were raised regarding this matter. While a proposal is not included in the consultation draft, comment is invited.

Background

An Animal Ethics Committee AEC may approve an activity involving animals only if it is satisfied that the proposed use of animals is ethically acceptable. This decision is based on information provided in an “application for approval”. The length of time covered by this approval varies, and may be years.

Annual reports are required for approved projects to allow the AEC to review the progress of the project. The information required in an annual report is significantly different to, and less detailed than, that required in a full “application for approval”.

Changes in societal attitudes and scientific knowledge and standards, and changes in AEC membership may mean that the ethical acceptability of the ongoing use of animals should be reviewed. This can only be achieved via the consideration of a new “application for approval”. It may therefore be appropriate for the operating procedures of an AEC to specify a limit to the length of approval granted by an AEC, and/or require the submission of a new “application for approval” at specified times.

(You may also like to refer to the Discussion Paper endorsed by the NHMRC Council that is included with the public consultation pack.)

REVISION OF THE AUSTRALIAN CODE OF PRACTICE ON THE CARE AND USE OF ANIMALS FOR SCIENTIFIC PURPOSES (2004)

TECHNICAL DISCUSSION PAPER ENDORSED BY NHMRC COUNCIL

Introduction

The *Australian code of practice for the care and use of animals for scientific purposes* (the Code of Practice) encompasses all aspects of the care and use of animals for scientific purposes in medicine, biology, agriculture, veterinary and other animal sciences, along with industry and teaching. It provides an ethical framework and guiding principles of good conduct, to inform the process of ethical review and provide guidance for investigators, teachers, institutions, Animal Ethics Committees (AECs) and all people involved in the care and use of animals for scientific purposes. The Code of Practice covers all live non-human vertebrates and higher order invertebrates.

The National Health and Medical Research Council (NHMRC) provides a leadership role in development of guidelines and advice for animal research. The Code of Practice is part of a suite of three national guidelines for research in Australia:

- *Australian code for the responsible conduct of research* (2007) (Code of Conduct)
- *National statement on ethical conduct in human research* (2007) (National Statement)
- *Australian code of practice for the care and use of animals for scientific purposes* (2004) (Code of Practice)

The Code of Practice was originally produced in 1969 and has been revised periodically since that time, with oversight for these reviews provided by the NHMRC Animal Welfare Committee (AWC). The AWC provides advice on all matters pertaining to the conduct and ethics of using animals in biomedical research. They are responsible to NHMRC, through its Research Committee, for the regular review and, if necessary, revision of the Code of Practice, and on the development and revision of other NHMRC documents related to using animals in biomedical research. The Code of Practice is further endorsed by the Commonwealth Scientific and Industrial Research Organisation (CSIRO); Universities Australia; and the Australian Research Council (ARC). All States and Territories have variously incorporated the Code of Practice into their animal welfare legislation.

Scope and aims of the review

The intent of the current review of the Code of Practice is:

- to ensure that the Code of Practice continues to be a relevant, accurate and applicable guide
- to focus the content of the Code of Practice on ethical principles and best-practice guidance
- to reflect the need for best-practice guidance to be principles-based and evidence-informed
- to consider how the *Guidelines to promote the wellbeing of animals used for scientific purposes: The assessment and alleviation of pain and distress in research animals* (2008) could supplement the Code of Practice as a reference document for best practice guidelines
- to be aware of, and take into account, international views.

You should note that the “Introduction” and Appendices 2-6 will be updated at a later stage in the revision process. You are welcome to provide comments and suggestions for content in these sections.

Specific issues requiring particular consideration

During consultation with stakeholders during the initial phases of this review, specific issues have been identified as requiring particular consideration. Your comment is invited on these issues as follows:

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

As outlined above, the intent of this revision of the Code of Practice includes a focus of the content of the document on ethical principles and best-practice guidance. It is anticipated that provision of a clear outline of the principles that should govern the ethical use of animals for scientific purposes, rather than use of a prescriptive approach to the content of the Code of Practice, will facilitate the application of these principles in any context by AECs, investigators and all those involved with the care and use of animals.

2. Does the document clearly and concisely set out, and correctly attribute, responsibilities of all parties involved?
3. Does the document provide all relevant parties with sufficient practical guidance on the application of principles of Code of Practice in terms of their responsibilities?
4. Are the terms “should’ and “must” used appropriately in the document?

The intention of the use of these terms is that:

- “should” indicates a strongly recommended component of the Code. In some instances a recommended component of the Code is an example of how it is anticipated a person will meet the obligatory requirement of the Code.
- “must” indicates an obligatory component of the Code.

5. Is there clear connection between the Code of Practice and the NHMRC *Guidelines to promote the wellbeing of animals used for scientific purposes: The assessment and alleviation of pain and distress in research animals* (2008) (Wellbeing Guidelines)?

The intent of this revision of the Code of Practice includes provision for the Code of Practice to refer to best practice and evidence-based guidelines for detailed advice regarding specific matters. In contrast to the body of the Code of Practice, such guidelines can be more easily updated in response to changes in accepted scientific, veterinary and medical practice, and administrative and governance procedures.

With respect to specific techniques and procedures, it is intended that guidance is provided in the following manner:

- The governing principles are to be outlined in Section 1 (Principles) and Section 2 (Responsibilities), with clear referencing to the “Animal Wellbeing” section (Section 3).
- The “Animal Wellbeing” section (Section 3) is intended to outline the principles related to specific procedures and techniques based on the governing principles, with cross-referencing to appropriate sections in the Wellbeing Guidelines.
- The Wellbeing Guidelines are intended to provide evidence-based guidelines for specific techniques and procedures.

The following is an example of the correlation between different sections of the Code of Practice and supporting guidelines using the subject of “humane killing”:

- Section 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.*
- Section 3 Animal Wellbeing: *When it is necessary to kill an animal, the procedures used must be humane and avoid pain or distress, produce rapid loss of consciousness until death occurs, result in reliable and reproducible effects, be compatible with the scientific or educational aims. Methods of killing must be appropriate to the species, age, developmental stage and health of the animal.*
- Wellbeing Guidelines: *Factsheet H: Humane killing and euthanasia.*

6. As a principles-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 sufficient balance between principles and detailed guidance.
7. Is “animal” appropriately defined? Should the definition account for animals at the early stage of their development (i.e. embryonic, fetal and larval forms)? If you disagree with the definition, it would be very helpful if you could provide evidence for your view.
8. Do you believe the title of this document should be amended to reflect the focus of the Code of Practice on ethical principles and best-practice guidance, 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*”?
9. Comment is sought regarding the proposal for the Category E membership category for an Animal Ethics Committee (“a person who is responsible for the routine care of animals from within the institution”) to be mandatory for institutions that have or maintain animal breeding or holding facilities (see Section 2.2)

How would these proposed changes outlined in Section 2.2 work for your AEC?

Some of the implications of the proposed changes include:

- Creation of this membership category is a positive step as it provides recognition of the importance of the role of animal carers, and the value of their expertise to the AEC.
- Category E membership is a proactive mechanism for ensuring communication to the AEC about problems occurring with animal facilities.
- The effectiveness of the person responsible for the care of animals during AEC meetings is enhanced by full membership compared to *ex officio* status.
- Mandatory Category E membership affects the requirements for balance of membership and quorum.
- For AECs considering non institutional-based research where animals are not cared for at the institution, Category E membership may not be relevant or practical.
- Mandatory requirement for Category E membership can be difficult in situations where an AEC serves many external institutions.
- An increase in the requirements for membership of AECs can create difficulties for organisation of meetings.
- Responsibilities of Category E members are often met by Category A members (veterinarians).

- The proposed change should also be considered in context of Clause 2.3.6 which applies to all AEC membership categories and which requires continuity of membership and does not support alternate members.
10. Should the document include a guide regarding the longest duration of approval granted by an AEC for a project before submission of a new application is required? The submission of a new application for a continuing project would be to take into account factors such as changes in societal attitudes and scientific knowledge and standards, and changes in AEC membership?
 11. Should the document include specific guidance regarding the responsibilities of Animal Welfare Officers and veterinarians? 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?
 12. You are invited to comment on any issues that are not covered in the Code of Practice that you think should be covered in the document.

Revision of the *Australian code of practice on the care and use of animals for scientific purposes (2004)*

**Mapping of structure
Current 2004 version and Consultation Draft**

Heading in Code of Practice (2004)	Position in Consultation Draft
Introduction	To be developed following public consultation with respect to purpose and scope
Definitions of terms used in the context of the Code	Definitions
Section 1 General principles for the care and use of animals for scientific purposes	Section 1, Principles for the and use of animals for scientific purposes
Section 2 Responsibilities of institutions and their animal ethics committees	Section 2, Responsibilities
2.1 Responsibilities of institutions	Section 2, 2.1 Responsibilities of institutions
	Section 2, 2.2 Responsibilities of institutions for the governance of an Animal Ethics Committee
2.2 Responsibilities and operation of AECs	AEC governance: Section 2, Part 2.2 Responsibilities of institutions that establish an Animal Ethics Committee
	AEC Ethical Review and monitoring of animal use: Section 2, Part 2.3 Responsibilities of AECs
	Section 5, Non-compliance and complaints
Section 3 Responsibilities of investigators and teachers	Section 2, Part 2.4 Responsibilities of investigators. Includes responsibilities of researchers (including those involved with wildlife studies) and teachers
	Information related to procedures and techniques: Section 3, Animal Wellbeing
Section 4 Acquisition and care of animals in breeding and holding facilities	Information related to responsibilities of personnel: Section 2, Part 2.5 Responsibilities of Animal Carers
	Information related to supply, housing and care of animals: Section 3, Animal Wellbeing
Section 5 Wildlife studies	Information related to responsibilities of wildlife researchers: Section 2, Part 2.4 Responsibilities of investigators
	Information related to procedures and techniques: Section 3, Animal Wellbeing, in particular Part 3.8
Section 6 The use of animals in teaching	Section 4, Use of animals in teaching
Appendix 1 External review of the operation of institutions and their animal ethics committees	Section 6, External review of the operation of institutions and their animal ethics committees

Heading in Code of Practice (2004)	Position in Consultation Draft
Appendix 2 Legislation and codes of practice	To be updated at a later time
Appendix 3 Policies & guidelines	To be updated at a later time
Appendix 4 Information sources	To be updated at a later time
Appendix 5 Alternatives to the use of animals	To be updated at a later time
Appendix 6 Organisations endorsing the code	To be updated at a later time

Proposed revisions to the *Australian code of practice on the care and use of animals for scientific purposes* (2004)

Question and Answers

What is the *Australian code of practice for the care and use of animals for scientific purposes*?

The *Australian code of practice for the care and use of animals for scientific purposes* (Code of Practice) provides an ethical framework and governing principles for the care and use of animals for scientific purposes in medicine, biology, agriculture and animal sciences, as well as teaching and industry.

All States and Territories have variously incorporated the Code of Practice into their animal welfare legislation.

Why is NHMRC proposing these changes?

The current edition of the *Australian code of practice for the care and use of animals for scientific purposes* was published in 2004. A review is necessary to ensure that it continues to be relevant for all circumstances, accurate and based on contemporary scientific knowledge, and takes into account international views.

Who has been involved in the writing of the consultation draft?

The initial phases of the review have ensured the full involvement of interested stakeholders including institutions, members of Animal Ethics Committees, researchers, teachers, veterinarians, animal welfare organisations, state and territory regulators and the co-authors of the current edition.

Comments were considered by the Office of NHMRC, NHMRC advisory groups and working committees (Code Writing Groups, Code Reference Group, and Animal Welfare Committee), NHMRC Research Committee and Council. This led to the preparation of the current consultation draft.

What has it taken so long?

A targeted consultation for this revision was undertaken in mid-2009. There has been a delay in the finalisation of the document since that time. The use of animals is an evolving subject area. NHMRC wished to ensure adequate consideration of comments received from stakeholders, and incorporation of current international best practice.

Why has the structure been changed?

The approach taken in the development of the consultation draft has been to identify the governing principles in Section 1. The new structure with these governing principles used consistently throughout all sections is intended to provide clearer guidance regarding responsibilities and accountabilities of individuals and groups.

Why are there no references to state and territory legislation in the consultation draft?

The Code of Practice is a national document that provides guidance for all those involved in the care and use of animals for scientific purposes. While the Code of Practice may be variously incorporated in State and Territory legislation, the Code of Practice itself is not a legislative

document. The regulatory framework remains remain the responsibility of the States and Territories.

The focus of the revision is on the provision of ethical principles that can be applied in all relevant situations, regardless of the State or Territory where the activity occurs. It is therefore not appropriate to include references to State and Territory legislation in the body of the Code of Practice. The preamble for the document will be developed at a later stage during the revision process, and will include a statement “*Institutions and individuals must be cognisant of all relevant legal requirements*” or similar.

Why has information from the previous version been omitted?

The consultation draft seeks to provide ethical principles and best-practice guidance that can be applied to all relevant situations and to any species. Information has been ordered in a different way. However, key information has been retained and is strengthened.

What has happened to the section on animal breeding and holding facilities (Section 4)?

This section of the current edition refers mainly to animals in biomedical research. It contains a mix of information related to ensuring the wellbeing of animals during their housing and care, and the responsibilities of those who manage and work in animal breeding and holding facilities.

Information related animal breeding and holding facilities has been updated to apply to all situations and to any species. The information has then been separated into two main areas of the consultation draft:

- responsibilities of those who care for animals regardless of the situation (Section 2.5)
- principles related to animal wellbeing, including their supply, housing and care (Section 3 “Animal wellbeing”).

It is anticipated that these proposed changes will:

1. clarify the responsibilities of animal carers
2. outline the principles related to the wellbeing of animals during their supply, housing and care, regardless of the species involved and the nature of their situation
3. allow for reference to best-practice and evidence-based guidelines for animal supply, housing and care that can be rapidly updated in response to advances in knowledge and standards.

What has happened to the section on “Wildlife Studies” (Section 5)?

Rather than have different sections that outline different types of activities, the consultation draft seeks to present information that can be applied to any situation and to any species. Information related to wildlife research has been clarified under:

- responsibilities of those involved with the care and use of wildlife species (Section 2 “Responsibilities of investigators” and “Responsibilities of animal carers”). Part F of Section 2.4 provides for “Additional investigator responsibilities for specific activities”, including wildlife studies.
- information on specific techniques used in wildlife studies (Section 3 “Animal wellbeing”).

It is anticipated that these proposed changes will:

1. ensure the applicability of the ethical principles in any situation

2. ensure clarity of the responsibilities of persons involved with the care and use of wildlife species in terms of their roles as “investigators” and “animal carers”
3. allow for reference to best-practice and evidence-based guidelines for techniques and procedures used in wildlife studies that can be rapidly updated in response to advances in knowledge and standards.

Will the revision result in a lot of information being removed from the Code of Practice and put into guidelines that are not enforceable?

The intent of the revision of the Code of Practice is intended to ensure that it continues to be relevant for all circumstances, accurate and based on contemporary scientific knowledge, and takes into account international views.

If the Code of Practice contains detailed advice (for example, regarding specific procedures and techniques, and administrative and governance procedures), this information can quickly become out-of-date with advances in knowledge and standards. Rather than include detailed advice in the body of the document, inclusion of reference to external evidence-based and best-practice guidelines for detailed and contemporary advice can ensure the currency and relevance of the Code of Practice itself.

Too little guidance on how to apply the governing principles may create difficulties for the practical implementation of the Code of Practice. Therefore, there needs to be the right balance of governing principles and detailed guidance so that the practical implementation of the Code of Practice is not difficult.

Comment is specifically sought during public consultation on whether there is sufficient balance between principles and detailed guidance.

Why is it now mandatory for an Animal Ethics Committee to have a Category E member (“a person who is responsible for the routine care of animals from within the institution”)? This will not work for my Committee.

Category E membership of an AEC has been the subject of discussion for many years. In the current version (7th edition), Category E membership is recommended but not mandatory. The consultation draft outlines how it will work in practice if mandatory Category E membership is included, and if this requirement is limited to AECs for institutions that have or maintain animal breeding or holding facilities. By providing information in this way, consideration of the implications of the proposed changes will be easier.

Implications of this proposal are outlined in the public consultation discussion paper, and comment is sought on how the proposed changes would work for your Animal Ethics Committee.

There should be a stronger role for veterinarians in the care and use of animals for scientific purposes. Why has this not been considered?

Information on the roles and responsibilities of veterinarians and Animal Welfare Officers builds on that contained in the current version (7th edition).

During development of the consultation draft, questions were raised as to whether there is sufficient guidance to ensure appropriate involvement of veterinarians in all aspects of the care and use of animals. However, firm recommendations were not made.

Comment is invited on whether the document should include specific guidance regarding the responsibilities of Animal Welfare Officers and veterinarians. Comment is also invited on whether the document should include a requirement for some procedures such as anaesthesia and surgery to be performed only by a veterinarian or under the direct supervision of a veterinarian.

There are too many “must” statements in this draft revised *Australian code of practice for the care and use of animals for scientific purposes*. Given that the document is incorporated into State and Territory legislation, will this mean that incidents of non-compliance will rise because of interpretation of the Code of Practice?

The Code of Practice has always contained “should” and “must” statements. Because the Code of Practice is incorporated in legislation in all States and Territories, careful use of the terms “should” and “must” is necessary to prevent an unnecessary regulatory burden

The use of these terms has been reviewed in the development of the consultation draft. Definitions of both terms are also included for the first time:

- “Should” indicates a strongly recommended component of the Code. In some instances a recommended component of the Code is an example of how it is anticipated a person will meet the obligatory requirement of the Code.
- “Must” indicates an obligatory component of the Code.

Comment is specifically invited on whether these terms are used appropriately in the document.

Are methods used for the slaughter of animals in abattoirs covered by the *Australian code of practice for the care and use of animals for scientific purposes*?

No. The methods of slaughter of animals in abattoirs are not relevant to the Code of Practice as they relate to animals used for food consumption rather than animals used for scientific purposes.

Recent concerns regarding the live export trade and the slaughter of cattle in Indonesian abattoirs are not relevant to this review.