



Australian Government  
National Health and Medical Research Council

NH|M|R|C

*Australian code for the care and use of animals for  
scientific purposes, 8<sup>th</sup> Edition 2013*  
Major changes

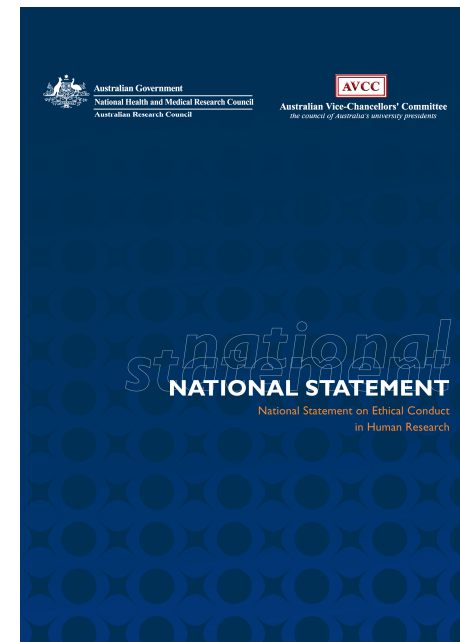
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WORKING TO BUILD A HEALTHY AUSTRALIA

## OUTLINE

- National research frameworks
- How the 8<sup>th</sup> edition was developed
- Key areas that are preserved
- Key areas of change, requirements are clarified

# The 3 national research standards



National Health and Medical Research Council  
Australian Research Council  
Universities Australia  
CSIRO (Code only)

## NHMRC supporting documents



GUIDELINES TO PROMOTE THE WELLBEING OF ANIMALS USED FOR SCIENTIFIC PURPOSES

THE ASSESSMENT AND ALLEVIATION OF PAIN AND DISTRESS IN RESEARCH ANIMALS

WORKING TO BUILD A HEALTHY AUSTRALIA

- Policy on the care and use of non-human primates for scientific purposes (Under review)
- Guide to the use of Australian native mammals in biomedical research (Under review)
- Guidelines for the generation, breeding, care and use of genetically modified and cloned animals for scientific purposes
- Guidelines for monoclonal antibody production
- Guidelines on the use of animals for training interventional medical practitioners and demonstrating new medical equipment and techniques
- Guidelines on the care of cats used for scientific purposes
- Guidelines on the care of dogs used for scientific purposes

## Developing the 8<sup>th</sup> edition

- NHMRC as a facilitator
- Extensive stakeholder involvement throughout

<b>2009</b>	Jul-Sept: Targeted consultation. 70 submissions
<b>2009–2011</b>	Review of submissions & advice on specific sections of 7 <sup>th</sup> edition by Code Editorial Advisory Group Considered by NHMRC's Code Reference Group, Animal Welfare Committee, Research Committee and Council
<b>2011</b>	Oct-Dec: Public consultation. 246 submissions
<b>2012–2013</b>	Consideration of submissions & development of 8 <sup>th</sup> edition by Code Reference Group
<b>2013</b>	Considered by NHMRC's Animal Welfare Committee, Research Committee and Council, and CEO
<b>2013</b>	Endorsed by ARC, CSIRO and UA

## Important areas that have not changed

- Scope of the Code
- Replacement , reduction and refinement
- Assumption that procedures and conditions that would cause pain and distress in humans cause pain and distress in animals, unless there is evidence to the contrary
- Institutional responsibility for compliance
- Membership of an AEC
- Ethical review and approval from an AEC
- Personal responsibility of investigators for an animal throughout the period of use approved by the AEC

## Major areas - change and clearer guidance

- Key elements of the 8<sup>th</sup> edition
- Structure
- Governing principles
- Responsibilities
- Animal ethics committees
- Animal wellbeing
- Unexpected adverse events and emergencies
- Complaints and non-compliance
- Independent external review
- Teaching

## Key elements of the 8<sup>th</sup> edition

- Governing principles for the care and use of animals for scientific purposes, to be applied in all situations
- Constant reference to these principles throughout the document
- Clearer guidance on responsibilities
- Clearer distinction between 'musts' (obligatory) and 'shoulds' (strongly recommended; how a person may meet obligatory requirements)



## **New Code structure**

- Section 1: Governing principles
- Section 2: Responsibilities
- Section 3: Animal wellbeing
- Section 4: The care and use of animals for the achievement of educational outcomes in science
- Section 5: Complaints and non-compliance
- Section 6: Independent external review of the operation of institutions

## Governing principles (Section 1)

- Clearly identified, to be applied in all situations
- “Must consider the governing principles in Section 1 when applying the Code to their specific circumstance”
- Used consistently throughout the document
- Prescriptive detail removed when unnecessary for the application of the governing principle
- **If unsure, look to the governing principles**

## **Governing principles (Section 1)**

- 1.1 Respect for animals must underpin all decisions and actions involving the care and use of animals for scientific purposes.
- 1.2 The care and use of animals for scientific purposes must be subject to ethical review.
- 1.3 A judgement as to whether a proposed use of animals is ethically acceptable must be based on information that demonstrates the principles in Clause 1.1, and must balance whether the potential effects on the wellbeing of the animals involved is justified by the potential benefits.
- 1.4 The obligation to respect animals applies throughout the animal's lifetime during its care and use for scientific purposes.

## **Governing principle 1.1**

Respect for animals is demonstrated by:

- using animals only when it is justified
- supporting the wellbeing of the animals involved
- avoiding or minimising harm, including pain and distress, to those animals
- applying high standards of scientific integrity
- applying Replacement, Reduction and Refinement (the 3Rs) at all stages of animal care and use
- knowing and accepting one's responsibilities.

# Responsibilities

- Clearer guidance – Responsibility for actions attributed to a person or body
- Ambiguities reduced by defining ‘must’ and ‘should’
- Institutions, AECs, and all those involved must be aware of and accept their responsibilities (1.31)
- Institutions must:
  - provide adequate resources to ensure all can meet their responsibilities (2.1.5 [ii])
  - Identify clear lines of responsibility, communication and accountability (2.1.7)
  - ensure that all understand their responsibilities (2.1.8)
- Identification of ‘*person with ultimate responsibility*’ – definition, projects (2.4.5), and animal care (2.5.3)

## Responsibilities (Section 2)

- 2.1: Institutions
- 2.2: Institutions – Governance of AECs
- 2.3: AECs
- 2.4: Investigators
- 2.5: Animal carers
- 2.6: Other responsibilities: Institutions, AECs, investigators
  - Use of AECs established by other institutions
  - Investigators without access to an AEC
  - More than one institution and/or AEC
  - Projects conducted in other countries
- 2.7: Institutions – Developing AEC application forms

## Animal ethics committees

- Clearer separation of AEC governance, and AEC responsibilities for ethical review, approval and monitoring
- Quorum for AEC decision-making (2.3.12) the same as the quorum for the conduct of an AEC meeting (2.2.25)
- Clarify that all activities require ethical review and approval from AEC:
  - *'projects'* conducted with the aim of achieving a scientific purposes
  - *'activities'* associated with care and management of animals in facilities
- AEC Executive may approve a 'minor amendment' (2.2.23 [ii])
  - AEC to provide guidance on what is a minor amendment
  - For example, a change that is not likely to cause harm to the animals, including pain and distress

## Animal wellbeing

- Must be considered in terms of the cumulative effects of the animal's lifetime experience (1.8)
- *Supporting* animal wellbeing during their care and management, and *safeguarding* animal wellbeing during conduct of procedures
  - How to support and safeguard animal wellbeing – now in new 'Animal Wellbeing' section (Section 3)
  - 'Current best practice'
  - All procedures must be performed competently



## **Animal wellbeing (Section 3)**

- Applies to all situations and all species
- 3.1: How to approach supporting and safeguarding the wellbeing of animals
- 3.2: Supporting the wellbeing of animals during their care and management
- 3.3: Safeguarding the wellbeing of animals during the conduct of specific procedures
- 3.4: Provisions for animals at the conclusion of their use

## Current best practice

- Defined – to provide guidance for evaluation of acceptability of procedures and practices
- Definition allows for situations where the evidence for current best practice is:
  - up-dated
  - not available – accepted practice may be appropriate
- Practices and procedures used for the care and management of animals (1.9, 2.5.4 [ii], 2.5.15 [vii])
- Projects - methods and procedures (1.16; 2.4.8 [viii])
- If current best practice for animal care and management is precluded, specific AEC consideration and approval required (1.9, 2.7.4 [xiii])

## Competence

- *Procedures must be performed competently* by a person who is competent for the procedure, or under the direct supervision of a person who is competent (1.29)
- Institutional responsibilities
  - Guidelines (in consultation with AEC) – how competence will be assessed and ensured (2.1.5 [v] [a])
  - Ensure people are competent or under direct supervision (2.1.8)
  - Ensure access to appropriate education programs & resources (2.1.8)
- Investigator responsibilities
  - Ensure procedures are performed competently (2.4.4 [vi])
  - Education and training, and competency assessment, in accordance with institutional and AEC policies and procedures (2.4.4 [v])
  - Person with ultimate responsibility: education, training and supervision of those involved (2.4.5)
- Animal carer responsibilities
  - Ensure duties are performed competently (2.5.5 [i])
  - Facility manager: staff education, training & supervision (2.5.15 [iv])

## Unexpected adverse events and emergencies

- Governing principle – prompt action (1.14)
- Institutions must have guidelines for actions required, developed in consultation with AEC (2.1.5 [v] [d])
  - Should include timeframes, prompt reporting to AEC, liaison between animal carers and investigators, circumstances when consultation with a veterinarian, the performance of a necropsy by a competent person, and access to diagnostic investigations are required
- Investigators and animal carers must follow these guidelines
- AEC must take appropriate action (2.3.2 [v]). Guidance - 2.3.24
- Institution must identify clear lines of responsibilities, communication and reporting so that appropriate actions are taken (2.1.7 [i] [b])
- Unexpected adverse events do not always mean non-compliance

## Complaints and non-compliance (Section 5)

- Clearer guidance – responsibilities of institutions and AECs in managing these situations
- Institutions must have procedures (2.1.7 [ii])
- Initial report – usually to an institutional representative rather than directly to the AEC
- Clearer guidance for AECs
  - Complaints (5.4 [ii], 5.5 [i])
  - Non-compliance (2.3.25, 5.5 [ii])

## Independent external review (Section 6)

- 7<sup>th</sup> edition:

- Recommended at least every 3 years
- Details in Appendix 1

- 8<sup>th</sup> edition:

- Must be conducted at least every 4 years.
- Details in Section 6

- Institutions must ensure that an independent external review is conducted

## The care and use of animals for the achievement of educational outcomes in science (Section 4)

- Clearer definition:
  - 7<sup>th</sup> edition: .... in any area of science
  - 8<sup>th</sup> edition: .... to achieve an educational outcome in science, as specified in the relevant curriculum or competency requirements
- Principles that are unique to the teaching situation, with reference to other sections
- As with the 7<sup>th</sup> edition:
  - Teachers are considered to be ‘investigators’
  - Teaching institutions are considered to be ‘institutions’

## Further information:

- NHMRC website

- <http://www.nhmrc.gov.au/guidelines/publications/ea28>
- Includes additional resources as they become available

- Contact: [ethics@nhmrc.gov.au](mailto:ethics@nhmrc.gov.au)