



Guidelines on the Use of Animals for Training Interventional Medical Practitioners and Demonstrating New Interventional Medical Equipment and Techniques

Formerly: Guidelines on the use of animals for training surgeons and demonstrating new surgical equipment and techniques.

To be read in conjunction with the Australian Code of practice for the care and use of animals for scientific purposes.

APRIL 2009 CONSULTATION DRAFT

National Health and Medical Research Council

Draft Guidelines on the Use of Animals for Training Interventional Medical Practitioners and Demonstrating New Interventional Medical Equipment and Techniques

An Invitation To Make Submissions

The National Health and Medical Research Council is conducting public consultation on the above draft document which provides guidelines on the use of animals for training interventional medical practitioners and demonstrating new interventional medical equipment and techniques. 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*.

How to make your submission

Electronic submissions are strongly preferred. If this is not possible, please make your submission in writing (preferably typed or word processed) or on audio tape and submit it by mail. Electronic submissions should be emailed to the address below.

Please ensure that the author of the submission and organisation (if applicable) is clearly stated. If you would like your submission to be treated as confidential, please indicate this clearly (for example, by marking 'CONFIDENTIAL' on each page of your written submission). Submissions may be subject to release under the Freedom of Information Act 1982. All submissions will have personal contact details removed prior to becoming publicly available on the NHMRC website.

Please e-mail your submission to e-mail ethics@nhmrc.gov.au or post to:

Project Officer – Animal Welfare
Health and Research Ethics Section
NHRMC
GPO Box 1421
CANBERRA ACT 2601

Closing Date:

The closing date for submissions is 5pm AEST on Friday 15 May 2009.

Further information:

Hard copies of the draft guidelines and forms can be obtained by contacting the Health and Research Ethics Section on (02) 6217 9070 or by e-mail ethics@nhmrc.gov.au

Guidelines on the Use of Animals for Training Interventional Medical Practitioners and Demonstrating New Interventional Medical Equipment and Techniques

To be read in conjunction with the Australian Code of practice for the care and use of animals for scientific purposes.

Preamble

This document was developed in response to requests from Animal Ethics Committees (AECs) for guidance when they are considering applications from interventional medical practitioner training programs for the use of animals to train interventional medical practitioners in new techniques and how to use new technology. Such applications may be outside the previous experience of AECs. The National Health and Medical Research Council (NHMRC) and the Royal Australasian College of Surgeons (RACS) have developed the following guidelines jointly to assist AECs in evaluating such applications. ***It is intended that this document be read in conjunction with the Australian Code of practice for the care and use of animals for scientific purposes*** (the Code). These guidelines are also intended to inform participants in training programs of the issues of animal care and welfare when animals are used in interventional medical training settings.

The use of animals for interventional medical training and demonstration and for the development of new interventional medical and trauma procedures may be beneficial in those circumstances where it can be demonstrated that a suitable alternative is not available. Failure to properly train interventional medical practitioners in new procedures can have serious implications for patient care. For example, the use of anaesthetised animals is an essential component of training or retraining interventional medical practitioners in laparoscopic techniques and for continuing development in the fields of cardiology and anaesthesiology. Patients undoubtedly benefit if these new techniques are used competently, but the techniques are also associated with new risks that can be best appreciated by experience with living animals. Nevertheless, AECs must ensure that such use is justified, according to the following conditions, which are based on the Code.

These guidelines apply to surgeons and other interventional medical practitioners, associated personnel, AECs and institutions planning to undertake interventional medical training or demonstration of new techniques in animal models, or who are engaged in the development or further development of new techniques.

General Guidance

The following principles should inform the use of animals for interventional medical training and ensure compliance with the Code.

Training methods which do not use animals must be adopted wherever possible. Training in basic interventional medical skills such as suturing, knot tying and the anastomosis of hollow viscera and blood vessels can, to a large extent, be performed on non-living material. Other skills such as approaches to surgical sites can be learnt directly from observing or assisting more experienced medical practitioners operating on human patients.

I Guidance For Trainers and Participants

The following guidance should be adhered to by all trainers and participants using animals to demonstrate surgical and other interventional medical techniques.

- 1.1 Training procedures in which animals are to be used must be undertaken at institutions which have properly constituted Animal Ethics Committees. Applications must be submitted to that Committee, and must be approved before commencement. [Refer to 2004 Code clause 2.1.1(i)].
- 1.2 The AEC can only consider such an application if there are enough trained personnel to provide proper monitoring of all the animals during the procedure and proper care of the animals before the procedure. Only non-recovery procedures should be undertaken.
- 1.3 Prior to the commencement of the workshop all participants must be informed of, and fully understand, their ethical and legal responsibilities regarding the use of live animals. They should also be informed of their right to report incidents of incompetence, misconduct or other breaches of the Code to the institutional AEC. The institutional AEC must ensure that a printed information sheet is available to all participants prior to the use of the animals for training. The information sheet must include, at a minimum:
 - 1.3.1 The name of the interventional medical practitioner who accepts primary responsibility for the entire training exercise
 - 1.3.2 The name and qualifications of a person(s) competent in veterinary anaesthesia and in the care of the species to be used
 - 1.3.3 A description of the educational merit of the project and why animals are necessary
 - 1.3.4 The source of animals
 - 1.3.5 Details of the housing and care of the animals at the facility where the procedures are to occur
 - 1.3.6 The relevant Codes should be on site at the training venue and readily available for the interventional medical practitioner in charge, workshop participants and demonstrators to access and refer to, including as a minimum:
 - i. *Australian Code of practice for the care and use of animals for scientific purposes 2004*
 - ii. *Australian Code for the Responsible Conduct of Research 2007.*
- 1.4 If the animal is to be killed, it must be killed humanely, preferably by overdose of anaesthetic at the end of the training procedure prior to regaining consciousness. If the animal is not to be killed, this must be approved in advance by the AEC, and must be in accord with the 2004 Australian Code of Practice clauses 3.3.25-3.3.38.
- 1.5 Proposals for medical practitioners to perform the same procedure repeatedly on anaesthetised animals in a single workshop may be approved provided anaesthesia and analgesia are maintained and the animals are euthanased at completion of the workshop. [Refer also to 2004 Code clause: 3.3.11].

- 1.6 Applications to an AEC for approval to use animals for interventional medical training should contain the following information in addition to the information for written proposals required by the Code and set out in clauses 2.2.15-2.2.16:
 - 1.6.1 The name of the interventional medical practitioner who accepts primary responsibility for the entire training exercise
 - 1.6.2 The name and qualifications of a person(s) competent in anaesthesia and in the care of the species to be used
 - 1.6.3 A description of the educational merit of the project and why animals are necessary
 - 1.6.4 The source of animals
 - 1.6.5 Details of the housing and care of the animals at the facility where the procedures are to occur.
- 1.7 Trainers should be encouraged to record the training session to provide preliminary training of future trainees.

2 Guidance for AECs

The following guidance is for AECs to consider when assessing all applications to use animals for interventional medical training or other demonstration purposes.

- 2.1 The institutional AEC must be satisfied that the use of live animals is essential for the stated learning objective of the training or demonstration and that the species chosen is the most appropriate for that purpose. The AEC must consider what intervention is acceptable to meet the stated learning objectives while also meeting the welfare needs of the animals.
- 2.2 The institutional AEC must be satisfied that the procedure planned for the training exercise is suitable given the prior training and capabilities of the workshop participants.
- 2.3 The AEC must be satisfied that adequate veterinary supervision of animal handling and anaesthetic techniques is in place.
- 2.4 The AEC must ensure that the welfare of the animals will be considered at all times; before, during and after procedures. This includes provision of appropriate holding facilities, food and water, minimisation of pain and distress and euthanasia.
- 2.5 The AEC should carefully evaluate the benefits of holding interventional medical workshops sponsored by a commercial organisation where animals are required for the demonstration of new equipment. Workshops should not be held by commercial operators purely for promotional or commercial reasons. Animals should only be used where the educational value of learning new techniques or participation at demonstration of equipment are likely to lead to significant benefits in the performance of human or animal surgery.
- 2.6 Proposals for medical practitioners to perform the same procedure repeatedly on anaesthetised animals in a single workshop may be approved provided anaesthesia and analgesia are maintained and the animals are euthanased at completion of the workshop. [Refer also to 2004 Code clause: 3.3.11].
- 2.7 Relevant animal welfare legislation in the Australian States or Territories or in New Zealand should be referred to for special conditions relating to the use, care and housing of animals in order to ensure that the institution complies with them [Refer to 2004 Code clause 2.1.1(ii)] and for any guidelines governing the use of animals for the training of interventional medical practitioners and demonstrating new interventional medical equipment and techniques.

- 2.8 The numbers of animals approved for use must be carefully considered in the context of the planned process of training, the number of workshop participants, and the capacity of the facility to adequately care for any given number of animals prior, during and after the procedure.
- 2.9 A distinction between 'demonstrated' and 'performed' procedures should be made. The educational benefit for each participant using or sharing use of an animal must be justified.

3 Checklist for AECs

- 3.1 What are the benefits of the proposed training workshop?
- 3.2 Is the use of animals justified?
- 3.3 Has the applicant provided evidence that the use of alternatives has been fully considered?
- 3.4 Is the person conducting the workshop competent in the procedures to be performed?
- 3.5 Has provision been made for adequate housing and care of the animals? Does the species to be used have particular requirements?
- 3.6 Have details been provided to the AEC regarding pre-operative handling, sedation and expertise with anaesthesia of the species being used? Are they adequately explained?
- 3.7 Is the number of animals used justified?
- 3.8 Will animals be used for more than one invasive procedure in any one session/workshop?
- 3.9 What provisions have been made for the disposal of animal carcasses?

Further Reading:

Australian Code of practice for the care and use of animals for scientific purposes. 7th edition, 2004. Published by the National Health and Medical Research Council in conjunction with CSIRO, the Australian Research Council and the Australian Vice-Chancellor's Committee. http://www.nhmrc.gov.au/publications/synopses/_files/ea16.pdf.

Australian Code for the Responsible Conduct of Research, 2007. Published by the National Health and Medical Research Council, the Australian Research Council and Universities Australia. http://www.nhmrc.gov.au/publications/synopses/_files/r39.pdf

Guidelines for ACECs considering the use of animals for postgraduate surgical training. Developed by the NSW Animal Research Review Panel and available from the Animal Welfare Branch, NSW Department of Primary Industries, Locked Bag 21 Orange NSW 2800 <http://www.animaletics.org.au/reader/animals-teaching/arrp-postgraduate-training.htm>

Guidelines to promote the wellbeing of animals used for scientific purposes: The assessment and alleviation of pain and distress in research animals, 2008. Published by the National Health and Medical Research Council. <http://www.nhmrc.gov.au/publications/synopses/ea18syn.htm>