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Principles and guidelines for the care and use of non-human primates for scientific purposes

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Introduction

The care and use of non-human primates for scientific purposes must be conducted in accordance with the *Australian code for the care and use of animals for scientific purposes* (the Code) and relevant Commonwealth, state and territory legislation, and must be ethically reviewed and approved by an institutional animal ethics committee (AEC).

Many of the concerns associated with the use of non-human primates are common to those associated with the use of other sentient animals: the potential for pain, suffering or distress as a result of the impact of scientific procedures, the level of confinement experienced in a research setting, and the killing of animals for the purpose of the research.

However, the use of non-human primates for scientific purposes also raises special ethical and welfare issues over and above these issues. The primary reason that some non-human primates are used as an animal model in biomedical research is their close phylogenetic relationship to humans, which often translates into unique characteristics that are difficult to adequately study in other models. However, it is precisely because of these similarities that they are the subject of special concern.

The complex and highly social behaviour and advanced cognitive capacity of many non-human primates make it difficult to adequately provide for their needs in a captive environment or research setting. In addition, many non-human primates have long lifespans and are often used in long-term research programs or re-used in multiple experiments over the course of their lives, presenting additional challenges for their care and welfare. Consequently, there is concern that the compromise to their life associated with their confinement and use in scientific research may cause greater psychological suffering than with other species.

The Australian breeding colonies were established to centralise breeding, provide a consistently high standard of animal care and management, and to allow access to non-human primates for research. Colonies currently exist for macaques (*Macaca nemestrina* and *Macaca fascicularis*), marmosets (*Callithrix jacchus*) and baboons (*Papio hamadryas*).

Role of this document

Regulatory responsibility for animal welfare, including the care and use of non-human primates, rests with the state and territory governments. Regulatory responsibility for the importation and exportation of non-human primates rests with relevant Commonwealth government departments. The state and territory governments, and institutional AECs, may adopt guidelines related to the care and use of animals for scientific purposes, including this document.

The National Health and Medical Research Council (NHMRC) requires research that it funds to be conducted in accordance with relevant legislation, the Code, and other relevant NHMRC animal welfare guidelines. NHMRC requires compliance with this document as part of its funding agreement. On some issues, this document represents an aspirational standard which may not currently be supported by state and territory legislation and in which case the state and territory legislation takes precedence.

This document is intended to:

- outline basic principles and best practice guidance for the care and use of non-human primates for scientific purposes to assist investigators, teachers and animal carers
- assist institutional AECs in considering applications for the use of non-human primates for scientific purposes.

Structure of this document

The document is divided into three parts:

- Part A sets out the principles for the care and use of non-human primates for scientific purposes.
- Part B provides guidelines for the care of non-human primates.
- Part C provides a checklist for members of institutional AECs considering applications involving the care and use of non-human primates, a checklist for those conducting inspections of facilities used for housing of non-human primates and a flowchart outlining the checkpoints in supply of these species.

Definitions

Captive bred: refers to animals that have been bred in human controlled environments with restricted settings, including wildlife reserves, zoos and other conservation facilities, and the Australian breeding colonies. The Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) provides an internationally accepted definition of 'bred in captivity' which can be referred to at: <http://www.cites.org/eng/resources/terms/glossary.php#b>

Competent: the consistent application of knowledge and skill to the standard of performance required regarding the care and use of animals. It embodies the ability to transfer and apply knowledge and skill to new situations and environments.

Current best practice: a practice, procedure, method or process that has proven to be most effective in supporting and safeguarding animal wellbeing, and that:

- takes into consideration the relevant aspects of species-specific biology, physiology and behaviour
- is based on the best available scientific evidence (or, in the absence of scientific evidence, accepted practice), which includes the potential adverse impact of conditions and procedures on the wellbeing of the animals
- includes strategies to minimise adverse impacts.

Scientific purposes: all activities conducted with the aim of acquiring, developing or demonstrating knowledge or techniques in all areas of science, including teaching, field trials, environmental studies, research (including the creation and breeding of a new animal line where the impact on animal wellbeing is unknown or uncertain), diagnosis, product testing and the production of biological products.

For other relevant definitions, see the *Australian code for the care and use of animals for scientific purposes*: <http://www.nhmrc.gov.au/guidelines/publications/ea28>

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Part A: Principles for the care and use of non-human primates for scientific purposes in Australia

The structure and principles set out in Part A of this document reflect that of the *Australian code for the care and use of animals for scientific purposes* (the Code). All of the principles in the Code must be applied to the care and use of non-human primates for scientific purposes. Part A highlights the principles that are of particular relevance to the care and use of non-human primates and provides additional information regarding the application of these principles.

- Respect for non-human primates must underpin all decisions and actions involving their care and use for scientific purposes.
- The care and use of non-human primates must be subject to ethical review.
- Before the use of non-human primates for scientific purposes is considered, investigators must be satisfied that a case can be made that the proposed use is ethically acceptable in accordance with the Code.
- The obligation to respect non-human primates and the responsibilities associated with this obligation, apply throughout the life of the non-human primates.

Using non-human primates only when justified

1. Non-human primates must not be used for scientific purposes except when:
 - i) no alternative to the use of non-human primates is suitable to achieve the stated aims of the project, and
 - ii) the potential effects on the non-human primates are justified by the potential benefits.

Use of great apes

2. As the closest species to human beings with the most advanced social and behavioural skills, the use of great apes (gorilla, orang-utan, chimpanzee and bonobo) raises even greater ethical concerns than that of other non-human primates.
3. No great apes are held in Australia specifically for scientific purposes. The only great apes held in Australia are in zoological collections for conservation breeding purposes.
4. Great apes must not be imported from overseas for use for scientific purposes.
5. The use of great apes for scientific purposes in Australia is permitted only when their use:
 - i) will not have any appreciable negative impact on the animals involved, e.g. observational studies, activities already being undertaken for management or veterinary purposes
 - ii) will potentially benefit the individual animal and/or their species.
6. No other use of great apes in Australia is permitted under this guideline.
7. The institution should ensure that the Animal Welfare Committee (AWC) of NHMRC is notified of projects involving the use of great apes for scientific purposes approved by the institutional animal ethics committee (AEC), before the project commences. For NHMRC-funded research, this requirement is mandatory.

Supporting the wellbeing of non-human primates

Care and management

8. The care and management of non-human primates must accord with current best practice as defined by the Code and in Part B of this document.
9. Practices and procedures used for the care and management of non-human primates must be designed to address their species-specific physical, social and behavioural needs, and cognitive capacity.
10. The wellbeing and good health of non-human primates must be maintained throughout the lifetime of the non-human primates.
11. Accommodation for non-human primates that accords with current best practice must be available before the non-human primates are acquired.

Breeding of non-human primates

12. New breeding colonies of non-human primates must not be created outside of the established Australian breeding colonies unless as an integral component of the research project, and must be approved by an institutional AEC and relevant regulatory authorities. The institution should ensure that the AWC of NHMRC is notified before a new breeding colony is established. For breeding colonies funded by NHMRC, this requirement is mandatory.
13. Imported species of non-human primates must not be used to establish a breeding colony outside the established Australian breeding colonies.
14. Non-human primates must always be accompanied by a documented complete and current life history that includes source; housing, care and management at both source facility and subsequent facility (facilities); clinical history; health status; behaviour; and transport.

Avoiding or minimising harm, including pain and distress

Cognitive ability and capacity to experience pain and distress

15. The capacity for the particular species of non-human primate involved to experience pain and distress must be taken into account when making decisions about the possible impact of procedures or conditions on the wellbeing of an individual non-human primate.

Sourcing, supply, importation

16. When non-human primates are supplied to a project approved by an institutional AEC, the animals must be obtained from an established Australian breeding colony unless another source is approved by the AEC.
17. When importation of non-human primates is proposed, the investigator must provide the institutional AEC with all available information regarding animal welfare at the source facility. This information should include housing conditions, social grouping, environmental enrichment, diet, health status and breeding performance of animals. Information provided should also include arrangements and conditions for transport between the source colony and the institution.
18. Non-human primates that are imported from overseas must be captive bred and must be accompanied by documentation to certify their captive-bred status.

19. Importation of non-human primates for scientific purposes must comply with relevant legislation and must not occur unless appropriate Commonwealth and state or territory government permits, licences and approvals are in place.
20. Ordering and dispatch of non-human primates must be accompanied by evidence of an institutional AEC approval for the project.
21. The institution should ensure that the AWC of NHMRC is notified of the importation of non-human primates after approval from the institutional AEC has been obtained. For NHMRC-funded activities, this requirement is mandatory.

Monitoring

22. The health and wellbeing of non-human primates used for scientific purposes must be regularly monitored and assessed by a competent person to ensure that:
 - i) a health status of the animals is maintained that safeguards animal wellbeing and meets the requirements of their proposed use
 - ii) any harm, including pain and distress, is promptly detected and managed.

Provisions at the conclusion of their use

23. Provisions for non-human primates at the conclusion of their use must take into account their long-term welfare. Retirement must be considered as an option if suitable in terms of the health and temperament of the animal, and space and resources are available at a facility that can meet their species-specific physical, social and behavioural needs.
24. When non-human primates are humanely killed for any reason, all possible attempts should be made to inform other interested investigators of the availability of tissues and organs and the disease status of the animals. This may be achieved effectively through the managers of the established Australian breeding colonies, who can disseminate the information to interested investigators.
25. Non-human primates originally sourced from another country must not be exported from Australia.
26. Australian-bred non-human primates must not be exported unless:
 - i) for a specific purpose. Examples of specific purposes would be maintenance of genetic diversity or provision of overseas researchers with a model of a primate disease
 - ii) prior approval has been obtained from the institutional AEC by those responsible for the export
 - iii) export is to an institution with animal welfare standards that comply with the Code at a minimum
 - iv) there are adequate animal protection laws in the destination country, and an active organisation with the legal authority to enforce animal protection laws
 - v) appropriate Commonwealth and state or territory government permits, licences and approvals are in place.
27. The institution should ensure that the AWC of NHMRC is notified of the export of non-human primates after approval from the institutional AEC has been obtained. For NHMRC-funded institutions, this requirement is mandatory.

Applying high standards of scientific integrity

Use of the most appropriate species

28. Justification must be provided to the institutional AEC for the use of non-human primates and the particular species chosen.

Applying Replacement, Reduction and Refinement (the 3Rs) at all stages

29. Replacement, Reduction and Refinement (the 3Rs) must be applied at all stages of the care and use of non-human primates (see Clauses 1.18-1.30 of the Code):
 - i) the *Replacement* of animals with other methods
 - ii) the *Reduction* in the number of animals used
 - iii) the *Refinement* of techniques used to minimise the adverse impact on animals.
30. Procedures must be in place at all non-human primate breeding facilities to ensure that the breeding programs are matched to the demand for animals, and to avoid or minimise the production of excess animals. Investigators must discuss their requirements for non-human primates with the management of the supply facility early in the planning stages for the project to assist with management of breeding programs.

Responsibilities of investigators and animal ethics committees

Approval from an institutional AEC

31. Before any research using non-human primates commences, approval must be obtained from the institutional AEC where the work is to be undertaken. Where more than one institution is involved, each AEC must approve, or the delegate AEC must approve, the activities to be conducted by members of its institution.
32. All activities associated with the care and management of non-human primates for scientific purposes must be approved by the institutional AEC. This includes their acquisition (including importation), transport, breeding, housing and husbandry.

Competence

33. All persons involved with the care and use of non-human primates must have a sound knowledge of the species in their charge. Education and training for new and inexperienced investigators and animal carers must be provided.
34. Investigators and animal carers involved with the care and use of non-human primates must ensure that procedures are performed competently, and
 - i) be competent for the procedure they perform and the species with which they are working, or
 - ii) be under the direct supervision of a person who is competent to perform the procedure and with the particular non-human primate species involved.

Projects conducted in other countries

35. If a project involving the use of non-human primates is to be conducted in another country, Clauses 2.6.9- 2.6.14 of the Code must be upheld. The conduct of a project in another country should not be used as a mechanism for avoiding compliance with Code.

Part B: Guidelines for the care of non-human primates used for scientific purposes

The care and management of non-human primates that are used for scientific purposes must comply with all relevant sections of the *Australian code for the care and use of animals for scientific purposes* (the Code) and must accord with current best practice. This part of the document provides guidance on how the relevant principles in the Code may be met when caring for non-human primates.

1. Animal health

- 1.1 Institutions responsible for the care of non-human primates used for scientific purposes must establish and implement policies and procedures to manage the health of the animals at all stages of their care and use to ensure a high standard of animal care and to minimise the risk of disease transmission between humans and non-human primates.

Health hazards and prevention of disease

- 1.2 Non-human primates and humans are susceptible to a number of the same diseases. Institutions must establish and implement preventative veterinary and medical health programs to minimise the risks to humans and non-human primates (see also Section 9).

Monitoring

- 1.3 The institution must ensure that the health and wellbeing of non-human primates are regularly assessed by a competent person.
- 1.4 For animals used in projects, qualified individuals not involved in the project, such as animal welfare officers and veterinarians experienced in managing the health of non-human primates, should also assess the animals at a frequency determined by the institutional AEC. When determining the frequency of monitoring, the AEC should take into consideration the potential impact of the presence of unfamiliar persons on the wellbeing of the animals.

Animal deaths

- 1.5 When a non-human primate dies unexpectedly, or is humanely killed due to unforeseen complications, prompt and appropriate action must be taken to ensure the ongoing health wellbeing of other animals. A post-mortem examination must be performed by a veterinarian.
- 1.6 The person with ultimate responsibility for the animal must ensure prompt notification to the institutional AEC of such deaths, any remedial action taken, and the results of the post-mortem examination.
- 1.7 If the animal was being used as part of an approved project, reasonable steps must be taken to ensure the investigator is present at the post-mortem examination. The investigator must also ensure that the results of the post-mortem examination are forwarded to the manager of the relevant Australian breeding colony to assist them in maintaining the health status of the colony and relevant records.

2. Transport of animals

- 2.1 Approval for the project from an institutional AEC must be in place before the animals are transported for use.
- 2.2 Before non-human primates are transported, the following factors must be considered and addressed:
 - i) the competence of persons responsible for the animals from point of departure to destination including during any break in the journey
 - ii) physical containment of the animals
 - iii) whether an individual animal is fit to travel considering its physical and psychological condition at the time of the journey
 - iv) the likelihood of sudden or extreme changes in temperature during transport and how any such changes will be managed
 - v) whether animals will best be transported singly, in pairs or as a group
 - vi) the total time for transportation, which will influence the timing of feeding and watering
 - vii) if non-human primates are imported, whether all relevant Commonwealth and state or territory requirements have been met.
- 2.3 Transport conditions must be designed to minimise stress (see Clauses 3.2.5–3.2.8 of the Code).
- 2.4 Non-human primates transported by road must be transported in a temperature-controlled compartment of a vehicle, and the vehicle must be attended at all times.
- 2.5 Non-human primates transported by air must travel in a pressurised and temperature controlled compartment in accordance with current best practice and international standards (e.g. International Air Transport Association).
- 2.6 When non-human primates are transported, twenty-four hour contact details must be secured on the transport container in case of an emergency.

3. Admission of new animals to breeding and holding facilities

- 3.1 Animal movement and admission of new animals to facilities raise specific issues that should be negotiated with the relevant facility, in accordance with the facility's Standard Operating Procedures.

4. Acclimatisation and conditioning

- 4.1 Acclimatisation and conditioning of non-human primates should be negotiated with the relevant facility, in accordance with the facility's Standard Operating Procedures and the research protocol approved by the institutional AEC.

5. Housing and care

- 5.1 Consideration must be given to the provision of a complex environment, social interaction and environmental enrichment to meet the biological needs of non-human primates.
- 5.2 Accommodation for non-human primates that accords with current best practice and as described in this section must be available before the animals are acquired.

- 5.3 When new caging is required, the persons responsible for planning and financing the project should first seek advice from the managers of the Australian breeding colonies. Before using non-human primates, facilities where the animals will be housed and used must be inspected by an institutional AEC.
- 5.4 The major concerns in the design of housing for non-human primates should be the wellbeing of the animals and staff safety. A well-designed facility will have the added benefit of improving the conditions for those responsible for the animals' care while maximising the quality of the scientific research conducted. During planning, advisers and architects must be informed of the particular needs of the species based on information provided by the managers of the Australian breeding colonies and the institutional AEC.
- 5.5 The requirements for vertical and horizontal space differ between species of non-human primate. For example, the provision of vertical space is more important for marmosets and macaques than baboons. Efforts should be made to ensure that full advantage is taken of available vertical space through the provision of perches, climbing frames, nest boxes, vantage points etc.
- 5.6 Facilities and working areas must be designed to prevent the escape of animals and access by intruders.

Social interaction

- 5.7 While non-human primates as a group are social, there is considerable species-variation in social requirements that must be taken into account when planning or assessing management strategies and housing conditions.
- 5.8 Care and management must, as a minimum, ensure that there is social interaction between the non-human primates. Animals should be held in appropriate social groupings unless the institutional AEC has specifically approved individual caging for a particular project. In most cases, isolation is only justifiable for short periods during the experimental procedure or during essential veterinary treatment.
- 5.9 When individual caging of animals is unavoidable, every effort should be made to ensure that this is for a minimum time, and that the individually-housed animal is given auditory and visual contact with other animals in the colony. If it is necessary to maintain a socially-incompatible individual separately from other animals, strategies should be considered to provide for close social contact.
- 5.10 Singly-housed animals must have the opportunity to fulfil behavioural needs in a suitably-constructed enclosure. Housing must ensure provision of an increased variety of environment enrichment beyond that provided for socially-grouped non-human primates.

Environmental enrichment

- 5.11 Housing of non-human primates should be designed with the aim of satisfying the physical, social and behavioural needs of the particular species. The environment should stimulate activities, improve cognitive capabilities and facilitate social interaction while encouraging the animals to display a more complete range of normal behaviours and providing opportunities for the expression of choice. For instance, it should be recognised that individuals within social groupings will at times seek privacy, which may be achieved by the inclusion of opaque barriers and nesting boxes in animal enclosures.
- 5.12 Emphasis must also be placed on appropriate and varied enrichment of the physical environmental that may include:
 - i) elevated perches and tree branches
 - ii) toys, including balls, stainless steel mirrors, plastic containers, tyres, PVC pipes, milk containers and water tanks

- iii) facilities for foraging e.g. feeding puzzles, non-toxic browse foliage and food in foraging material
- iv) novel, challenging but safe cage furniture
- v) visual and auditory contact with other non-human primates
- vi) the animal carers themselves.

Access to an outside enclosure

- 5.13 Non-human primates must be provided with housing that presents them with as many choices of environment as possible. Outside enclosures are important to increase the variety of stimuli perceived. The external environment provides elements of enrichment.
- 5.14 Non-human primates must be provided with access to an outside enclosure if they are to be held for six weeks or longer unless specific approval is obtained from the institutional AEC. This requirement may not apply to non-human primates held in PC2, PC3 or PC4 conditions. If non-human primates are to be held for six weeks or longer without access to an outside enclosure, the institution should ensure that the AWC of NHMRC is notified of these housing conditions after approval from the AEC has been obtained. For NHMRC-funded activities, this requirement is mandatory.
- 5.15 If non-human primates do not have access to an outside enclosure, housing must ensure provision of a complex environment and exposure to UV lighting to meet biological needs.

Temperature

- 5.16 Temperature control may be required, depending upon both the climate and the species of non-human primate. Marmosets, for example, are particularly susceptible to the cold. Animal holding areas may require air-conditioning, central heating and heated sleeping benches. Where temperature control is necessary, it is essential that a suitable back-up system is available in the event of power or equipment failure.

Lighting

- 5.17 Lighting (including UV lighting) should be set at a level appropriate for the species. The use of skylights and windows for natural lighting is encouraged.

Caging

- 5.18 The expectation is that cage size and design should exceed international best practice standards and allow sufficient space for each individual animal.
- 5.19 Caging should be large enough to allow the animals to perform varied and stimulating activities. The cage fixtures should allow the animals the opportunity for privacy from others in the group and from humans.
- 5.20 Concrete surfaces should be sealed for ease of cleaning and to ensure that floors can be dried rapidly after cleaning.
- 5.21 The use of substrate litter for foraging should be considered. Under-substrate drainage may be necessary.
- 5.22 Thorough cage cleaning must be supplemented by the use of an effective disinfectant.
- 5.23 Measures to achieve vermin control must be considered and included in the design.
- 5.24 It is essential to provide a mechanism for the safe and efficient capture and handling of animals. This should be considered at the time of cage design or purchase.

6. Food and water

- 6.1 Good nutrition is essential to the health and wellbeing of non-human primates. Species-specific diets are commercially available and additional dietary information may be obtained from managers of the Australian breeding colonies. Particular attention is drawn to the requirements of non-human primates for Vitamin C and, when non-human primates not exposed to sunlight, for Vitamin D. Clean, fresh drinking water must be available at all times.
- 6.2 The quantity and type of food and the way it is presented must meet the nutritional requirements of all members of a colony, taking into account the physiological states and behaviours of individuals. This will ensure that for animals housed in groups, those of lower social standing within the colony will receive adequate nutrition. For example, consideration should be given to the provision of private areas where timid animals may escape the influence of dominant animals in a social group.
- 6.3 Sudden change of diet may impact on the health and wellbeing of the animal. It is important to discuss the current diet and, if necessary, how to introduce dietary change, with the managers of the relevant Australian breeding colonies.

Foraging

- 6.4 In the wild, foraging may take up to 70% of waking hours of non-human primates. Measures should be taken to increase the time that animals used for scientific purposes spend foraging. Foraging activity can reinforce social behaviour and reduce boredom and is encouraged by, for example, feeding several times a day and mixing small food particles with clean litter and floor substrate. Consideration should be given to husbandry procedures and experimental designs that include foraging for food and water as part of the protocol.

Preparation and storage

- 6.5 Kitchen facilities for the hygienic preparation and storage of food must be provided. Facilities should also be provided for sterilising utensils.

7. Reward-based training

- 7.1 When undertaking the training of non-human primates, training methods must not be based on approaches that involve punishment such as pain or psychologically distressing stimuli.
- 7.2 In particular, reward-based training using positive reinforcement techniques should be considered as part of the experimental designs. The aims of reward-based training in non-human primates include:
 - i) assisting in captive management, by seeking the animal's compliance with routine husbandry and behavioural training
 - ii) improving the animal's welfare, by training to facilitate the conduct of routine procedures without the need for chemical restraint
 - iii) ensuring the quality of the scientific data collected.

8. Competence

- 8.1 To ensure the wellbeing of the animals and to facilitate their management, all persons working with non-human primates must be well trained in handling methods and have a sound knowledge of the species in their charge. All investigators and animal carers working with non-human primates must ensure that procedures are performed competently in accordance with the Code, and
- i) be competent for the procedure they perform and the species with which they are working, or
 - ii) be under the direct supervision of a person who is competent to perform the procedure and with the particular non-human primate species involved.
- 8.2 Investigators and animal carers must be familiar with all aspects of the care and use of non-human primates, before obtaining animals or commencing projects. When preparing an application to the institutional AEC for a research project involving the use of non-human primates, investigators should consult with the managers of the Australian breeding colonies as a source of helpful information. The application to the institutional AEC must document evidence of the competence of all investigators with the species to be used.
- 8.3 When the research project involves extended interaction with non-human primates, training for new or inexperienced animal carers and investigators must be arranged in consultation with the managers of the Australian breeding colonies. Training through the Australian breeding colonies will facilitate familiarity between the animal and the investigator and the transition of the non-human primates to a new environment.

9. Work health and safety

- 9.1 Institutions must ensure that that all personnel working with non-human primates, or tissues derived from them, are informed of the diseases transmissible between non-human primates and humans and injury during handling, and are instructed on the measures needed to prevent disease transmission and injury.
- 9.2 Institutions should ensure that a local doctor, or medical staff at a local hospital, is informed that the institution is conducting research involving the use of non-human primates. Medical personnel should be made aware of the possible disease risks associated with such work. Ideally, base-line serological data from individuals working with non-human primates should be stored at a nominated local hospital.
- 9.3 A protocol should be developed to cover non-human primate bites to humans, in particular those from macaques that may carry and transmit herpes B virus.
- 9.4 Many common transmissible human diseases may be readily transferred from humans to non-human primates. Transmission may occur via saliva, respiratory aerosols, mucosal contamination, body fluids or faeces.
- 9.5 To minimise the risk of infecting the colony, persons working with non-human primates should be screened regularly for tuberculosis. Those with an infectious disease, including a cold, influenza, herpes, measles, mumps, chickenpox or upper respiratory tract infections, should avoid contact with animals.

Immunisation

9.6 All persons working with non-human primates must be immunised, in accordance with advice from health professionals who have relevant knowledge and experience, and according to jurisdictional regulations that are binding to employees. Relevant immunisations include tetanus, and infectious diseases known to be carried by non-human primates.

Personal hygiene

9.7 Personal hygiene is the first line of defence in preventing the transmission of disease. To minimise the risk of disease transmission and/or injury, personnel should:

- i) employ best laboratory practice while working in the facility
- ii) avoid eating and drinking in the animal holding areas
- iii) ensure that all staff are appropriately vaccinated
- iv) wash hands thoroughly with antiseptic soap on entering and leaving the animal holding areas
- v) wear gloves, protective clothing, dedicated footwear or overshoes and safety glasses when entering the animal rooms
- vi) use handling methods that minimise discomfort to the animals and maximise safety for the handlers
- vii) wear clothing and gloves sufficient to provide protection against bites and scratches when handling animals
- viii) wear a dust mask when cleaning litter trays
- ix) consider wearing hearing protection which is recommended and must be available
- x) wear gloves, protective clothing and safety glasses when handling unfixed primate tissues
- xi) ensure that caging is secure
- xii) exclude unwell people from the animal holding areas
- xiii) restrict access to visitors
- xiv) use a pre-entry questionnaire to screen staff and visitors to the animal facility for any recent potential exposure to pathogens
- xv) keep a record of all personnel who enter the facility to enable trace-back
- xvi) maintain a first aid kit wherever non-human primates are handled.

10. Emergency management

10.1 Institutions responsible for the housing of non-human primates must ensure that plans are in place to ensure prompt detection and effective management of emergencies such as fire, power failure and biosafety issues.

10.2 Where re-location of the animals is feasible, the emergency plan should include details of the new location for housing and the mode of transport.

10.3 All staff must be familiar with the emergency plan.

10.4 If the re-location of animals is feasible during an emergency or natural disaster, animals must not be moved until the situation has been assessed and direction given by the responsible person.

Part C: Checklists and flowchart

Checklist: Assessing applications for AEC approval for projects involving non-human primates

For advice on all aspects of the care and use of non-human primates for scientific purposes, institutional animal ethics committees (AECs) should consult with the managers of the Australian breeding colonies in the first instance. This checklist, which is not intended to be comprehensive, is to be used in conjunction with the *Australian code for the care and use of animals for scientific purposes* (the Code). The principles of the Code must be applied and particular consideration must be given to the justification for the use of non-human primates; the highest possible standards of scientific integrity; any prior and current attempts through their broad research agenda to reduce, refine and replace non-human primate use; minimisation of harm, including pain and distress; and the provision of the richest possible environment throughout all stages of the care and use of the non-human primates.

1. Has the applicant provided sufficient evidence that the use of non-human primates is essential to achieve the aims of the project?
2. Has the applicant provided sufficient justification for the use of non-human primates and for the particular species chosen for the project?
3. Has the applicant provided sufficient evidence that there are no alternatives to the use of non-human primates?
4. If the use of great apes is proposed, will their proposed use have no appreciable negative impact on the animals involved, and will the proposed use benefit the individual animal and/or their species?
5. Is the AEC convinced that the proposed use of non-human primates is ethically acceptable, based on information provided by the applicant that demonstrates the principles in the Code, and balancing whether the potential effects on the wellbeing of the non-human primates are justified by the potential benefits of the proposed use?
6. Has the applicant provided evidence that the non-human primates are suited to the purposes of the project or activity (e.g. behaviour, genetic makeup, temperament and behavioural conditioning, microbiological and nutritional status, and general state of health)?
7. Has the applicant provided acceptable information about the source of animals?
 - 7.1 Will animals be obtained from an established Australian breeding colony? If not, is the AEC satisfied that the source of the animals is appropriate?
 - 7.2 If non-human primates are to be imported:
 - Has importation been justified?
 - Is there adequate evidence that the animals are captive bred?
 - Has adequate and acceptable information been provided regarding the health and welfare of the animals at the source facility?

8. Has the applicant provided adequate justification for the number of animals requested? Will the project involve the use of the minimum number of animals necessary to achieve the proposed aim(s) of the project and to satisfy good statistical design?
9. Has adequate consideration been given to the opportunities for sharing (access to animals, tissues and protocols) and reuse?
10. Does the proposed care and management of the non-human primates accord with current best practice, and satisfactorily address the physical, social and behavioural needs and cognitive capacity of the particular species being held?
 - 10.1 Where will the animals to be housed?
 - 10.2 Will appropriate accommodation be available prior to the arrival of the non-human primates at the facility?
 - 10.3 Will the size of cages or enclosures allow adequate room (vertical and horizontal dimensions) for species-specific behavioural requirements?
 - 10.4 Will environmental factors, such as air quality, temperature, humidity, light and noise, be within the limits compatible with the health and wellbeing of the particular species being used?
 - 10.5 Has adequate justification been provided for any social isolation of animals (in transport as well as in single housing) as being critical to the project design? Are adequate measures in place to minimise the impact of any social isolation?
 - 10.6 Will access to an outside enclosure be available to non-human primates held for six weeks or longer? If not, has adequate justification been provided for lack of access to an outside enclosure?
 - 10.7 If there is no access to an outside enclosure, will the animals be provided with a complex environment and exposure to UV lighting to meet biological needs?
 - 10.8 How is an enriched environment being managed and reported?
 - 10.9 Are there satisfactory arrangements in place for the transport of the non-human primates from the source facility (including overseas facilities) to the facility where they will be housed and used?
 - 10.10 Are there adequate provisions for veterinary oversight of the program of veterinary care for the non-human primates during their care and use in the project?
11. Proposed procedures
 - 11.1 Have all procedures been adequately described?
 - 11.2 Have all procedures been fully evaluated or justified?
 - 11.3 Has any proposed reuse of non-human primates been appropriately considered and adequately justified?
 - 11.4 Are training methods based on positive reinforcement techniques, and are they adequately described in the experimental design?
 - 11.5 Are there adequate and appropriate provisions for the non-human primates at the conclusion of the project? Retirement must be considered as an option if suitable in terms of the health and temperament of the animal, and space and resources are available at a facility that can meet their species-specific physical, social and behavioural needs.
12. Minimisation of potential adverse impacts on the wellbeing of the non-human primates
 - 12.1 Have potential adverse impacts on the wellbeing of the non-human primates been adequately identified (experimental and non-experimental)?

- 12.2 Are adequate measures in place to avoid or minimise potential adverse impacts on their wellbeing?
- 12.3 Is there an adequate protocol for the monitoring and assessment of the wellbeing of the non-human primates (including frequency of monitoring, actions to be taken, criteria for intervention points and humane endpoints)?
- 12.4 Will the health status of the individual non-human primate and the colony be adequately monitored, assessed and maintained?
- 12.5 How will the care and use of non-human primates in the project, including the monitoring of animal wellbeing, be recorded?
- 13. Investigators
 - 13.1 Is the competence of investigators adequate for the proposed project?
 - 13.2 Is there adequate training and/or supervision for inexperienced investigators?
- 14. Permits and approvals
 - 14.1 Has the applicant provided sufficient evidence that relevant permits, approvals and licences are in place for the proposed use of non-human primates, including those related to the source of the animals?
- 15. Work health and safety
 - 15.1 Has the applicant provided evidence that adequate procedures are in place to address work health and safety responsibilities?

Checklist: Inspections of facilities used for housing of non-human primates

Institutional animal ethics committees (AECs) should inspect facilities used for the housing of non-human primates at least annually for the purposes of reviewing all aspects of the care and use of non-human primates for scientific purposes. The aim of the inspection should be to ensure the health and wellbeing of individual non-human primates, as well as the colony, is maintained, and that activities are conducted in compliance with the *Australian code for the care and use of animals for scientific purposes* (the Code) and relevant AEC approvals. This checklist, which is not intended to be comprehensive, is to be used in conjunction with the Code.

AEC approval

1. Is there appropriate AEC approval in place for relevant activities conducted in the facility?

Animal care

2. What measures are taken to track animal involvement in a particular research project?
3. How are the strategies for minimising harm, including pain and distress, and providing the richest possible environment throughout all stages of animal care and use, being monitored?
4. Is the use of positive reinforcement actively managed as part of overall management?

Housing

5. Where and how are the animals housed?
6. Does housing meet the specific-specific physical, social and behavioural needs, and cognitive capacity of the particular species being held?
7. Is consideration being given to the social requirements of the animals (during transport as well as housing) such that any single housing arrangements continue to be justified as critical to any project design?
8. How is housing and transport (and quarantine) monitored?
9. How is light and temperature control managed to meet species-specific requirements?

Environment

10. How is outdoor housing being managed including the timing of access?
11. How is an enriched environment being managed and reported?
12. What evidence is being provided by individual research teams to reach environmental enrichment objectives?

Breeding and supply

13. Are adequate procedures in place to manage breeding of animals to avoid or minimise the production of excess animals?
14. Are animals supplied only to protocols that are approved by an institutional AEC?
15. Is the breeding performance of the animals regularly assessed and satisfactory?

Competence

16. Is the competence of those working with non-human primates adequate?

Monitoring and colony safety

17. Are there adequate provisions for veterinary oversight of the program of veterinary care?
18. How is the colony monitored (health status, animal wellbeing, breeding performance)?
19. What are the management commitments to colony monitoring?
20. Is the health and wellbeing of the animals regularly assessed by investigators and animal carers?
21. Have all procedures been monitored in accordance with the protocol approved by the AEC?
22. Are unexpected adverse events reported and monitored in accordance with institutional and AEC policies and procedures?

Emergencies

23. What emergencies are risks to the facility?
24. Are there procedures in place in case of these emergencies?

Provisions for animals at the conclusion of their use

25. Are provisions for animals made in accordance with protocols approved by the AEC?

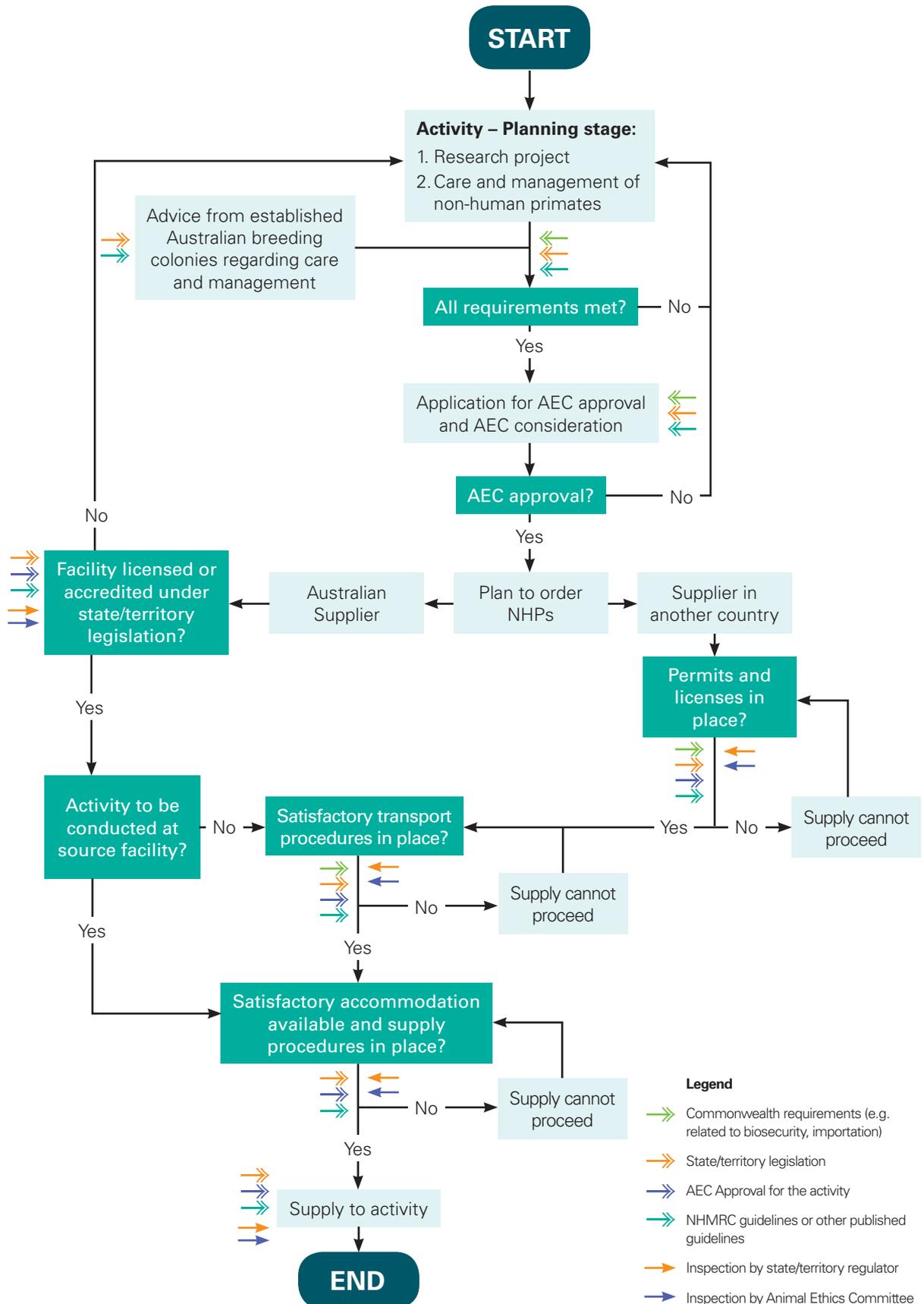
Permits, licences and approvals

26. Are the appropriate Commonwealth, and state or territory government permits, licences and approvals in place for the holding and supply for non-human primates.

Records

27. Are there appropriate records of the acquisition, and supply of the non-human primates?
28. Are there adequate records of the assessment of the health status and wellbeing of the animals?
29. Are there adequate records of the monitoring of the housing and environment of the animals?
30. For facilities involved with the breeding of non-human primates, are there adequate records of the breeding performance of animals?

Flowchart: Checkpoints in supply of non-human primates



Appendix 1: Process report

Background

The review of NHMRC's *Policy on the care and use of non-human primates for scientific purposes (2003)* (the Policy) was overseen by NHMRC's Animal Welfare Committee with advice from an expert working committee established under section 39 of the *National Health and Medical Research Act 1992* (NHMRC Act).

Animal Welfare Committee

NHMRC's Animal Welfare Committee (AWC) provides advice to NHMRC on issues pertaining to the conduct and ethics of using animals in biomedical research. The terms of reference and details of membership of the AWC are provided in Appendix 2.

Non-Human Primate Policy Revision Working Committee

The Non-Human Primate Policy Revision Working Committee (Working Committee) was established to provide advice to the AWC regarding the review of the Policy. Membership of the Working Committee included representatives from the AWC, veterinarians, members with expertise in the ethical review of the care and use of non-human primates, animal welfare representatives, members with an understanding of community attitudes to the care and use of animals for scientific purposes, and representatives from the Australian non-human primate breeding colonies to provide relevant species-specific advice.

The terms of reference and membership of the Working Committee are provided in Appendix 3.

Disclosure and management of interests

Throughout the review, disclosure of interests and management of conflicts of interest was undertaken in accordance with the requirements of the NHMRC Act and NHMRC's *Policy on the disclosure of interests requirements for prospective and appointed NHMRC committee members*. A record of interests was managed by NHMRC and relevant information was made publicly available on the NHMRC website to ensure transparency.

Other contributors

NHMRC project team

Ms Jillian Barr
Ms Mary Bate
Ms Catherine Chippendale

Development of the Guidelines

Key steps in the development of *Principles and guidelines for the care and use of non-human primates for scientific purposes* (the Guidelines) included:

- establishment of the Working Committee
- development of the draft Guidelines for public consultation
- public consultation on the draft Guidelines
- revision of the draft Guidelines based on feedback to the public consultation
- consideration of the final Guidelines by the AWC, Research Committee and the Council of NHMRC.

Public consultation

Public consultation on the draft Guidelines was conducted in accordance with the NHMRC Act. Consultation was undertaken for the period 27 March 2015 to 8 May 2015. Fifty-eight submissions were received from a range of individuals and organisations including institutions, researchers, animal ethics committees, veterinarians, animal welfare organisations, and state and territory regulators. Copies of all submissions were provided to the Working Committee and the AWC. Where permission was granted, submissions received during public consultation were published on the NHMRC website.

Finalisation of the Guidelines

Following public consultation, all submissions were reviewed and considered by the Working Committee. Members gave due regard to all comments received, and reached a consensus in each case.

The draft Guidelines recommended by the Working Committee were considered by the AWC on 30 November 2015. The draft Guidelines were then considered by Research Committee on 24 February 2016, and Council of NHMRC on 10 March 2016 and again out-of-session in May 2016. The Council of NHMRC advised NHMRC's CEO to issue the Guidelines. The CEO issued the Guidelines under Section 7(1a) of the NHMRC Act.

Appendix 2: Terms of reference and membership of the Animal Welfare Committee

Terms of reference

1. To advise NHMRC on issues pertaining to the conduct and ethics of using animals in biomedical research.
2. To advise NHMRC on the regular review and, if necessary, revision of the *Australian code of practice for the care and use of animals for scientific purposes (2004)*, and on the development and revision of other NHMRC documents related to using animals in biomedical research.

Membership

2012–2015 Triennium

Member	Area of expertise
Professor Edna Hardeman (Chair)	Person with expertise in the use of animals for health and medical research
Dr Simon Bain	Person with expertise in veterinary science and the care and use of animals for scientific purposes
Professor Neil Dear	Person with expertise in the use of animals for health and medical research
Professor Andy Giraud	Person with expertise in the use of animals for health and medical research
Dr Bidida Jones	Person with experience in furthering the welfare of animals
Dr Mark Lawrie	Person with expertise in veterinary science and the care and use of animals for scientific purposes
Ms Robin Matthews	Person with an understanding of community attitudes to the care and use of animals for scientific purposes
Mr Paul Power	Person with an understanding of community attitudes to the care and use of animals for scientific purposes
Dr Carole Webb	Person with experience in furthering the welfare of animals

Appendix 3: Terms of reference and membership of the Non-Human Primate Policy Revision Working Committee

Terms of reference

1. To advise NHMRC and its Animal Welfare Committee on the revision of the *Policy on the care and use of non-human primates for scientific purposes (2003)*.

Membership

1 March 2014 to 31 December 2016

Member	Area of expertise
Professor Edna Hardeman (Chair)	Chair of Animal Welfare Committee
Mrs Elizabeth Grant AM	Person with an understanding of community attitudes to the care and use of animals for scientific purposes
Dr Bidha Jones	AWC member; person with experience in furthering the welfare of animals
Dr Simon Bain	AWC member; person with expertise in veterinary science, the care of non-human primates and the ethical review of their use in research
Professor Annemarie Hennessy	Person with experience in the management of a non-human primate colony (baboons)
Professor Marcello Rosa	Person with experience with the care and use of non-human primates in research
Ms Rachel Borg	Person with experience in the management of a non-human primate colony (marmosets and macaques)

