INQUIRY INTO USE OF PRIMATES AND OTHER ANIMALS IN MEDICAL RESEARCH IN NEW SOUTH WALES

Organisation: National Health and Medical Research Council (NHMRC)

Date Received: 30 March 2022





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The Hon. Greg Donnelly MLC Chair Portfolio Committee No. 2 - Health Parliament House Macquarie Street Sydney NSW 2000

Dear Mr Donnelly

Re: Inquiry -Use of primates and other animals in medical research in New South Wales

Thank you for the opportunity to provide input to the committee's inquiry about into the use of primates and other animals in medical research in New South Wales. I am pleased to provide the attached submission to the inquiry on behalf of the National Health and Medical Research Council (NHMRC).

I also give permission for NHMRC's submission be published in full.

Yours sincerely

Prue Torrance

Executive Director
Research Quality and Priorities Branch



Inquiry: Use of primates and other animals in medical research in New South Wales

Introduction

The National Health and Medical Research Council (NHMRC) is the Australian Government's lead agency for supporting health and medical research in Australia. NHMRC's mission is building a healthy Australia. NHMRC's legislated functions under the *National Health and Medical Research Act 1992* (NHMRC Act) are to fund health and medical research and training, and to issue guidelines and advise on improving health outcomes, through prevention, diagnosis and treatment of disease and the provision of health care. NHMRC also has a role in promoting the highest standards of ethics and integrity in health and medical research.

NHMRC's submission to the review of the use of primates and other animals in medical research in New South Wales, focusses on:

- NHMRC's role as a funder of health and medical research, which addresses:
- (a) the nature, purpose and effectiveness of medical research being conducted on animals in New South Wales, and the potential public health risks and benefits posed by this research
- (b) the costs associated with animal research, and the extent to which the New South Wales and Federal Government is commissioning and funding the importing, breeding and use of animals in medical research in New South Wales
- NHMRC's role within the regulatory framework for ethical, humane and responsible care and use of animals for scientific purposes, which addresses in particular the following terms of reference:
- (c) the availability, effectiveness and funding for alternative approaches to animal research methods and technologies, and the ability of researchers to meet the 3 R's of Replacement, Reduction and Refinement
- (d) the ethical and animal welfare issues surrounding the importing, breeding and use of animals in medical research
- (e) the adequacy of the current regulatory regime regarding the use of animals in medical research, particularly in relation to transparency and accountability

NHMRC does not have a role in the importation or breeding of animals and has no comment on those aspects of term (d).

NHMRC has no comments on terms of reference (f) or (g).

NHMRC-funded research

Any NHMRC-funded research that involves animals must be of high quality and significance, as determined by NHMRC's peer review process. This process includes the assessment of the applicability and suitability of the proposed animal model for the intended outcome of the research. The work must be reviewed and approved by an Animal Ethics Committee (AEC) before it begins. It must also be conducted in accordance with relevant legislation, the <u>Australian code for</u>



the care and use of animals for scientific purposes 8th edition (2013, updated 2021) and other relevant NHMRC guidelines. These requirements apply to any institution and researcher that receives NHMRC funding and are a condition of NHMRC funding.

NHMRC funding for research at NSW Administering Institutions where animal use was proposed is provided in Table 1.

Table 1. Number and value of NHMRC grants to NSW Administering Institutions where animal use was proposed at the time of application, 2016 to 2020

Application Year	Number of NSW Administering Institutions	Number of grants	Total amount of funding
2016	9	84	\$81,512,750.80
2017	9	98	\$79,703,617.49
2018	7	79	\$56,562,821.92
2019	7	57	\$65,746,762.26
2020	6	48	\$52,019,239.98
Total	38	366	\$335,545,192.45

Source Notes:

NHMRC collects data on animals proposed for use in NHMRC supported research. It does not collect the numbers actually used. Please note that the data is current at the time of application submission, and that figures are subject to change due to factors such as institutional animal ethics clearances.

Regulatory framework

In Australia, the state and territory governments are responsible for the regulation of animal welfare, including the care and use of animals for scientific purposes. NHMRC provides national leadership on the ethical, humane and responsible care and use of animals for scientific purposes through provision of guidance in the <u>Australian code for the care and use of animals for scientific purposes 8th edition (2013, updated 2021)</u>. The Code has been developed and published by NHMRC since 1969, and has been adopted into legislation in all jurisdictions including New South Wales. The Code therefore acts as the basis for national consistency for regulation of the care and use of animals for scientific purposes. The scope of 'scientific purposes' as defined in the Code includes 'research' such as medical research.

The Code provides an ethical framework and governing principles to guide the decisions and actions of all those involved in the care and use of animals for scientific purposes. It details the responsibilities of institutions, institutional animal ethics committees (AECs) and researchers, and describes processes for accountability.

Any use of animals for scientific purposes must be conducted in accordance with relevant state and territory legislation and must be approved by an AEC before it begins. The AEC must be satisfied that the use of animals is justified and that the 3Rs have been applied.



The governing principles in the Code include the necessity for the application of the 3Rs at all stages of animal care and use; that is:

- there is no other way to obtain the necessary information without the use of animals (Replacement)
- where the use of animals is absolutely necessary, that the minimum numbers are used (Reduction)
- that the methods used have the least effects on the animals and support their wellbeing (Refinement).

The 3Rs are part of the fundamental framework for the ethical, humane and responsible care and use of animals for scientific purposes in Australia. They are accepted internationally, and in Australia through adoption of the Code in state and territory legislation. The 3Rs underpin the requirements in the entire Code including the responsibilities of institutions, AECs, investigators and animal carers.

NHMRC guidance

Guidance and resources to support implementation of the Code

NHMRC produces guidelines and resources to support the implementation of the Code. These include:

- <u>Best practice methodology in the use of animals for scientific purposes, 2017.</u> This document provides guidance for the conduct of high-quality animal-based studies, including the application of the 3Rs.
- Principles and guidelines for the care and use of non-human primates for scientific purposes. 2016. This document outlines principles and best practice guidance for this specialised area.
- A guide to the care and use of Australian native mammals in research and teaching, 2014. This
 document provides advice about how the specific and unique needs of Australian native
 mammals can be met when these animals are used for scientific purposes.
- <u>Guidelines to promote the wellbeing of animals used for scientific purposes: The assessment and alleviation of pain and distress in research animals (2008)</u>. This document provides guidance on how to support and safeguard the wellbeing of animals used for scientific purposes. Note that this guideline is more than five years old and may no longer reflect current evidence or best practice. It is available on NHMRC's website as a source of information.
- Resources: Genetically modified and cloned animals. These resources are intended to assist investigators and AEC members to consider the ethical and welfare issues about the use of genetically modified and cloned animals.

NHMRC's Research Quality Strategy

High quality research that is rigorous, transparent and reproducible:

- contributes to scientific progress
- is essential for the translation of outcomes into practical and clinical applications and evidencebased policy



- delivers the highest possible value for research investment
- respects research participants, the wider community, animals and the environment
- promotes community trust in scientific findings.

NHMRC's <u>Research Quality Strategy</u>, published in 2019, aims to ensure the highest quality of NHMRC-funded research by providing guidance and supporting good research practices throughout the research cycle. The Strategy applies to all NHMRC-funded research, including animal-based research.

NHMRC will continue to develop guidance for the conduct of high-quality research as part of its implementation of the Strategy.

The 3Rs

As outlined above, the governing principles in the Code include the necessity for the application of the 3Rs at all stages of animal care and use. The 3Rs underpin the requirements in the entire Code including the responsibilities of institutions, AECs, investigators and animal carers.

NHMRC's <u>Information paper: the implementation of the 3Rs in Australia (2019)</u>, is intended to present information about the implementation of the 3Rs in Australia, to promote informed discussion of the issues and guide recommendations for improvement if required. The Information Paper also identifies factors that enable or hinder the development and adoption of the 3Rs in Australia.

Research conducted in Australia contributes to creation of knowledge about the replacement, reduction and refinement of animal use here and around the world. This includes research funded by NHMRC. Under the NHMRC Act, NHMRC funding for research is restricted to medical research. However, research projects funded by NHMRC have indirectly led to the development of a 3R technique or method even though the primary aim of the research was for another purpose.

Further information

Further information about the Code and NHMRC's guidance for the care and use of animals for scientific purposes is available on NHMRC's website.