Submission No 229

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

Organisation: Hunter Medical Research Institute

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Hon Greg Donnelly MLC
Chair,
Parliamentary Inquiry into the use of primates and other animals in medical research in New South Wales

Thank you for the opportunity to make a submission to this Parliamentary Enquiry.

Researchers based at the Hunter Medical Research Institute (HMRI) are affiliated within HMRI Research Programs; however they are generally employed by the University of Newcastle (UON). Our comments are made from HMRI's perspective, but often refer to the UON guidelines and procedures, which are adhered to by researchers based at HMRI.

There is widespread consensus among medical researchers that it is critical to have a well-defined ethical framework for the conduct of animal research for medical and public health benefits. Australia has a proud history of leading in the responsible use of animals in research. Our animal ethics committee system and guidelines, written with the support of the National Health and Medical Research Council (NHMRC) in the early 1980s set the scene for a responsible and publicly engaged animal research approval system. We operate with two levels of oversight:

1) NSW government legislation; and
2) National Acts/Codes such as the Animal Research Act (1985) and the Australian Code for the Care and Use of Animals for Scientific Purposes (2013).

It is a requirement of federal funding (i.e. federally funded research projects) that we operate within national guidelines. Most States, including NSW, have embedded some of these guidelines into legislation. The Australian system of ethics approval require that animal welfare advocates and veterinarians sit on every Animal Care and Ethics Committee (ACEC). We recognise that these members may be opposed to animal research, and we seek not to compromise their position, but to seek their advice on the best possible animal welfare. Thus, we feel the current legislation has a high level of scrutiny and accountability for animal research in NSW, with procedures for approval, monitoring and review of animal research at HMRI (enacted and overseen by our partner organisation, the University of Newcastle) sufficiently rigorous to uphold the framework laid out in the 'Australian code for the care and use of animals for scientific purposes'.

TERMS OF REFERENCE

(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.

The benefits of using animals in medical research have been enormous, and invaluable for public health and medical advancement, for example Covid-19 vaccines. We believe that the use of animals in research is morally and ethically justified when balanced against these benefits and subject to strong regulatory requirements for approval and ongoing review. The current procedures in place at the UON provide a robust framework for this approval and the monitoring requirements, annual reviews, spot inspections and adverse reporting systems function well to support the ongoing wellbeing of animals during the course of experimental work.

The quality and effectiveness of medical research is determined during rigorous peer-review procedures in the competitive grant application process e.g., NHMRC, where projects undergo a thorough examination by national and international experts to ensure that the research is of high quality and significant public health benefit. The inclusion of animal use is submitted on animal ethics applications and any modifications/additional work that may be added is required to undergo an additional peer-review process before being submitted to the ACEC for approval.

The animal-based research conducted in NSW has, and will continue to lead to novel therapeutic options. An example is the asthma research led by Professor Paul Foster from the 1990's through to the present. Animal research allowed the Foster laboratory to gain a detailed understanding of how the immune system interplays with the respiratory epithelium to mediate the symptoms of allergic asthma. Identification of key molecules in this process allowed for proof-of-concept work that was a critical step in the discovery pipeline for an array of new asthma drug treatments, used in clinical settings today. These treatments have had a significant positive impact on outcomes for asthma patients worldwide They represent a whole new class of drugs that would not have been developed without animal work - there is no alternative system for modelling the immune system for complex diseases such as asthma, even today.

(b) The costs associated with animal research, and the extent to which the NSW and Federal Government is commissioning and funding the importing, breeding and use of animals in medical research in New South Wales.

We recognise that there are costs associated with using animals in medical research, however, the economic and health benefits are substantial and we believe they far outweigh the economic cost incurred. For example, the time taken for a new discovery to enter clinical use is between 7 and 17 years, and many phase 3 cancer and cardiovascular clinical trials in humans can cost hundreds of millions or even billions of dollars. Given the timeframes and costs involved only those drugs that stand the best possible chance of success can proceed to clinical trial. Animal studies, therefore, must be used to identify those drugs with the best chance of success.

(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.

The effectiveness of alternative methods to animal research differs on a case-by-case basis depending on the scientific questions being examined. Determination of effectiveness requires review from a panel of experts. The University of Newcastle animal ethics application and annual review processes ensure that researchers evaluate and continuously review the use of the 3 R's in their work.

The training and supervision requirements dictated by the UON ACEC, and the specialised courses provided by the University, are thorough and ensure that minimal numbers of animals are used to complete scientifically valuable research, and that animal impacts are minimised. Wherever possible, multiple tissues are collected from individual animals, minimising the number of animals required to collect sufficient replicate data for all parameters to be tested and facilitating tissue sharing/biobanking between groups. These processes facilitate both the refinement of research and the reduction of animal numbers required to achieve significant benefits. Cutting-edge *in vitro* technologies such as air-liquid interface culture and the generation of 3D organoids are already routinely used at HMRI and in some circumstances this can be used to reduce the use of animals for drug discovery. But this approach is already being used as much as it possibly can be, therefore, it

does not offer much further scope for reductions. Although these technologies can reduce some use of animals in research they are limited in their ability to reproduce the *in vivo* or 'whole body' environment, and so they cannot be used to replace animals in research.

(d) The ethical and animal welfare issues surrounding the importing, breeding and use of animals in medical research.

Guidelines on animal welfare surrounding the importing and breeding have previously been established according to the 'Australian code for the care and use of animals for scientific purposes'. The UON ethics approval process ensures that researchers comply with this code. Researchers and Animal Services staff work collaboratively to match the number of animals generated from breeding programs to the number required for research to minimise surplus. Technologies such as cryopreservation of sperm/eggs have allowed genetically modified strains to be retained for future discovery without the requirement for constant breeding.

(e) The adequacy of the current regulatory regime regarding the use of animals in medical research.

We believe that the current UON Animal Ethics Committee framework for approval and ensuring ongoing compliance is rigorous and adheres to the 'Australian Code for the care and use of animals for scientific purposes'. The Code clearly articulates the responsibilities of the relevant stakeholders – institutions, animal ethics committees, investigators, and animal carers, as well a providing a clear structure for overnight and ensuring ongoing compliance. The UON application procedures, training, animal monitoring, inspections, adverse event reporting and annual review of animal research facilitate high quality and beneficial research that adheres to the principals of the 3 R's and is under ongoing review as new technologies emerge.

(f) Any other related matters.

While HMRI does not use primates in current research, we are aware that in the mid-1990s Australia introduced housing of primates for research in zoo like conditions, i.e. caged as well as access to the outdoors; as well as consolidating the housing of primates into a single, national facility (Monash University, Melbourne).

As a member of the Association of Australian Medical Research Institutes (AAMRI), HMRI is in full support of the response submitted to this inquiry by AAMRI.

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