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

Organisation: Australia and New Zealand Laboratory Animals Association

Date Received: 31 March 2022



Introduction

Formed in 2006, the Australian and New Zealand Laboratory Animal Association amalgamated three organisations with a history of 30 years. ANZLAA is a volunteer association with over 800 members, covering the full spectrum of professional expertise in the care and welfare of animals in research throughout Australia and New Zealand. New South Wales represents over 20% of our membership of welfare and technical subject matter experts from world-class research institutes, universities, and service providers. Examples of this expertise include daily animal care, technical skill, veterinary support, ethics, regulatory management, training and the supply of equipment and services.

ANZLAAs activities support and promote:

- · High standards of husbandry, health management, and welfare for animals involved in research and teaching.
- High ethical conduct in research and teaching that involves animals.
- The free exchange of information within the animal care, teaching, and research communities.
- Co-operation between organisations and institutions to encourage and promote the implementation of the 3Rs, including the development and support of alternatives to animals, improving and refining techniques and care strategies, and methodology that reduces animal numbers while ensuring statistical validity.

ANZLAA's response to the inquiry's terms of reference reflects the association's remit and objectives. Overall, ANZLAA supports and understands the need for animal-based research and its benefits to "One Health". Further, ANZLAA embraces the 3Rs, including promoting efforts to develop techniques to further reduce, refine and replace animals in biomedical research. Finally, ANZLAA would like to draw the committee members' attention to our expertise, knowledge, and perspectives in demonstrating to the NSW Government where improvements are needed.

ANZLAA response

- 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 ETHICAL AND ANIMAL WELFARE ISSUES SURROUNDING THE IMPORTING, BREEDING AND USE OF ANIMALS IN MEDICAL RESEARCH.

The laboratory animal science and welfare community (LASW) approach all decisions and actions in caring for and use of animals throughout their lifetime from a place of respect and dignity. As regulated under the *Australian Code for the Care and Use of Animals for Scientific purposes* 8th edition (2013) (Code).

These obligations exceed the requirements of research and teaching institutions, competitive grant funding schemes and other objectives and milestones placed on competitive medical research.

As a mandatory requirement, representatives from the LASW govern the nature, purpose, and effectiveness of all animal studies before commencement, together with scientific peers, and members of the NSW community.

ANZLAA members provide expertise to various Australian Standards review committees, for example, *AS 2243 - Safety in Laboratories* and *HE-030: Biological and Clinical Evaluation of Medical Devices*. In addition, members innovate and share knowledge with local and international peer groups such as the International Council for Laboratory Animal Science (ICLAS), Federation of European Laboratory Animal Science Associations (FELASA) and the American Association for Laboratory Animal Science (AALAS).

Biomedical research proposals are first assessed for scientific merit and validity through competitive grant funding schemes. Once funded, they must undergo rigorous Animal Ethics Committee application processes within overarching institutions before any work can commence.

NSW medical research institutions are recognised as world-leading experts developing new scientific knowledge translated into new drugs, vaccines, treatments, and devices for humans and animals.

The importation and breeding of animals used in medical research is strictly controlled. In NSW, the industry regulator is the Department of Primary Industries Animal Research Review Panel. The impact of stress on an animal is a welfare issue known to have adverse effects on research and reproducibility. Therefore, strict conditions and criteria are in place to actively manage and minimise the risk of exposure to stressors during transport.

A recent study of Australian survivor, parent, and community views on animal-based research involving patient derived xenografts to inform treatments for children with cancer indicated that a large proportion of the Australian population believes that in these circumstances the potential benefits outweigh the costs.¹

Based on the foundation of respect for all animals and the high level of research integrity in the NSW community, ANZLAA believes that the potential for risks to public health is low to negligible and is outweighed by the potential benefits to worldwide human and animal populations. The potential ethical and welfare issues surrounding the import, breeding and use of animals remain an on-going priority for ANZLAA. We believe a proactive risk management approach is vital to minimising any adverse impacts on animals and public safety.

ANZLAA also recognises the importance of One Health and the required multidisciplinary effort locally, nationally and globally, to attain optimal health for people, animals and our environment.

¹ The Avatar Acceptability Study: Survivor, Parent and Community Willingness to Use Patient-Derived Xenografts to Personalise Cancer Care. 2018

- C. 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.
- D. 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.

Direct costs associated with animal research are typically funded by competitive research grants from Commonwealth government agencies, charitable organisations, and industry. The overarching organisation subsidises the remaining or 'indirect' running costs including staff resourcing and operating expenses. However, animal facilities and their operation are unlikely to fully recover costs by competitive research grants, as the costs of maintaining highly specialised vivarium are higher than a typical biomedical research laboratory.

The importation and breeding of animals for research is limited to the two key suppliers, one on the east and one on the west coasts of Australia, Australian BioResources (NSW) and Animal Resource Centre (WA). To ANZLAA's knowledge, neither organisation receives federal funding. In addition, ABR does not receive funding from NSW Government.

Recently, the WA Government has undertaken a review of the ARC with the intent to exit ownership and operational control and cease all operations of the ARC. The national response identified the serious national impact this would have on Australian research and the reversal of progress in addressing the 3Rs. As a result, the WA government is now in the planning stages to identify an independent provider to acquire the ARC's assets and continue its operations.

These centralised supply facilities were established by the Australian scientific community to comprehensively manage the following critical components of animal research and directly address the 3Rs:

- Well managed ethics and animal welfare, research quality & reproducibility through various promotional initiatives
- Transparent and sustainable operating models at a national level
- Support those successful in securing competitive grant funding through a range of financial sustainability initiatives
- Champion public health, employment, and industry by retaining industry subject matter expertise and businesses.

The recent ANZLAA position statement addressed the Importance of a National Laboratory Animal Resource Model in response to the announced closure. It can be found on the website <u>HERE</u>.

There is a lack of evidence suggesting that either state or federal governments provide funding to support the aims reflected above. There are no national or local government funded programs to promote the 3Rs (Replacement, Reduction, Refinement of animals in research). This lack of funding translates to slower progress in the ability to validate innovations and advancements as evidence-based models.

Furthermore, the single TAFE qualification for animal technicians was removed from the course offerings in NSW. As a direct result, the NSW LASW community suffer significant workforce shortages. These staff members are vital to providing primary care and welfare for animals. Institutions are forced to recruit unqualified staff, investing substantial expenses in the training and education needed for these roles to promote high levels of confidence in their ability to care for and ensure the welfare of animals. The gaps in qualification offerings in NSW severely impact the ability to attract and retain high-quality LASW staff within the industry. Without the support of high quality technical and welfare programs, oversight and support, there is a high risk that the current NSW medical research effort will not compete in the international arena.

For the above-mentioned reasons, industry associations and employers are mainly taking responsibility for the creation, development and implementation of education and training for continued professional development (CPD) in animal welfare. This is particularly important for roles such as veterinarians who are required to participate in CPD Programs to continue to carry their license to practice. ANZLAA hosts and supports various meetings, conferences, symposia and

workshops each year with content spanning animal health and welfare education and innovations, research case studies and general management, leadership, and mental health support for all types of staff.

The actions and initiatives presented above demonstrate the LASW community's success in implementing the 3Rs. The effectiveness of these initiatives is evidence in the 29 pages of reported 3Rs strategies implemented in the 2019 NSW Animal Use statistics provided by the NSW Department of Primary Industries and Animal Research Review Panel.

E. THE ADEQUACY OF THE CURRENT REGULATORY REGIME REGARDING THE USE OF ANIMALS IN MEDICAL RESEARCH, PARTICULARLY IN RELATION TO TRANSPARENCY AND ACCOUNTABILITY.

The legislation of animal based biomedical research is carefully considered and effective.

Underlying support from the Animal Research Act, further enhanced and maintained by the Office of the Gene Technology Regulator, Australian Standards, NHMRC Australian code for the care and use of animals for scientific purposes, Department of Primary Industries Animal Research Review Panel, and local animal care & ethics committees, have enhanced the education and awareness of the regulations. Regulatory requirements are also communicated through initiatives such as the Australia and New Zealand Council for the Care of Animals in Research and Teaching (ANZCCART) Competency Passport.

Stakeholders must be consulted to ensure regulatory changes and improvements are made with extensive consultation and the knowledge obtained from industry subject matter experts.

Despite these efforts, there are genuine concerns within the LASW community about engaging with the public about Animal Research. While participating in transparency and openness initiatives has been a primary focus for the ANZLAA community, these initiatives will not reach their full potential without assurance of personal safety and respectful discussion.

This response was developed through contributions from ANZLAA members based in NSW and was approved by submission by the ANZLAA Executive. We would like to thank those who contributed to this response.

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