Submission No 237

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

Organisation: CSIRO

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CSIRO submission to parliamentary inquiry into the use of primates and other animals in medical research in New South Wales

Overview

CSIRO conducts research activities involving animals and currently maintains two (2) Animal Ethics Committees (AECs) that are licensed in New South Wales (NSW). CSIRO stakeholders using animals in medical research, or with expertise in this respective area, were invited to contribute to a combined organisational response to the parliamentary inquiry into the use of primates and other animals in medical research in New South Wales. Relevant comments in response to the terms of reference set for the inquiry were provided and compiled for submission.

Most of the research undertaken in NSW by CSIRO staff and affiliates is classified as environmental studies or the improvement of animal management or production. Between 2015 to present only 5 studies have been classified as the understanding of human or animal biology or the maintenance and improvement of human or animal health and welfare. Of those 5 projects, only one was dedicated to human medical research. At present there is no active or planned research using primates at any CSIRO facilities.

On a national scale, The Australian Centre for Disease Preparedness (ACDP) (formerly known as the Australian Animal Health Laboratory) is a CSIRO a high-containment research facility designed to allow scientific investigation into infectious agents of global significance (i.e. COVID-19 and Japanese encephalitis). ACDP is physically located in Victoria, however CSIRO strongly encourages national consistency across jurisdictions wherever possible.

Overall, CSIRO maintains that the use of animals in medical research must meet the requirements of the Australian code for the care and use of animals for scientific purposes (8th edition 2013), particularly in actively embracing the principles of replacement, reduction, and refinement (the 3R's).

Response to inquiry 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.

Historically, the contributions to medical research from investigations conducted on animals are arguably vast. Much of the basis of human understanding of disease and associated pathologies is attributed to scientific investigations utilising various animal models. Drug and vaccine

development, exploratory and investigative biomedical studies, and pre-clinical trials all currently rely on the use of animals. In recent years, the validity and reproducibility of animal models in medical research have been called into question (Pound & Ritskes-Hoitinga 2018; Smith *et al* 2018; Robinson *et al* 2019) along with the subsequent translation of animal experimentation to clinical applications (Pound & Ritskes-Hoitinga 2018). For medical research to be conducted on animals effectively and to provide greatest benefit to public health, it is essential that research adheres to best practice recommendations (particularly in relation to study design and justification) and incorporates the 3R's at all stages of work.

Potential further promotion and incorporation of the PREPARE (Smith *et al* 2018) and ARRIVE (Percie du Sert *et al* 2020) guidelines would assist researchers in their ability to achieve reproducible, impactful and transparent scientific results and potentially further improve the effectiveness of medical research using animals.

Public health risks posed by medical research using animals is minimal due to the biocontainment regulations and requirements required for the work to be conducted. For medical research that carries a potential health risk (infectious disease research, etc) it is critical that this work is conducted within the appropriate purpose-built containment facilities (such as ACDP in Victoria) and under controlled and regulated conditions.

(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.

The continuation of the Animal Resource Centre (ARC) in some form (following its planned transfer from the WA Government to an independent provider in 2022), and support for other large breeding facilities (such as Australian BioResources) will be important in the ongoing importing, breeding and use of animals in medical research. ARC is a national resource that is the major rodent supplier to the Australian biomedical research industry.

There are significant costs associated with meeting regulatory requirements for animal research in Australia. While ensuring best practice standards are maintained at all times and protecting animal welfare is of utmost importance increased standardisation of reporting and administrative processes required for regulatory compliance would assist in reducing these costs.

For work involving pathogens, additional costs are also incurred, associated with biosafety and biosecurity. Such costs will vary, depending on the animal species and the Hazard Group of the pathogen being handled but can also be significant.

(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.

Additional funding and incentives focussed on the discovery, implementation and promotion of research that meets or exceeds the 3R's would be advantageous to animal research and would support best practice. Currently only a few individual institutions in Australia provide specific internal funding grants (usually at a very small scale) focussed on 3Rs research. The allocation of specific funding for research in this area as part of mainstream grant programs would help provide

new insights and further incentivise innovation in new methods and techniques that support the 3Rs.

As an organisation CSIRO requires all animal research to demonstrate the ability to meet 3R requirements and organisational awards for excellence in the area of the 3R's are awarded annually.

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

Without a centralised services such as ARC, individual organisations would need to operate in-house breeding and maintain small scale animal production. The results of such small-scale breeding include increased wastage of excess animals, poor quality research outcomes due to genetic and microbiome variabilities, reduced agility in Australian research (particularly on an international scale.

In instances where there may be an urgent need, such as a pandemic response, there is a high dependence on sovereign capability that can only be met if animals are available in Australia. Depending on the type of animals required there can also be challenges regarding animals provided by independent breeders which may not meet the stringent health standards required for planned studies.

Additional challenges regarding the importation of animals include the time taken to source and arrange importation, quarantine and post-receipt screening. Variations among genetic lines can also lead to challenges in establishing reliable models when animals are sourced from different overseas suppliers.

(e) the adequacy of the current regulatory regime regarding the use of animals in medical research, particularly in relation to transparency and accountability.

Transparency and accountability are a national issue and are currently being addressed in part by the ARRIVE guidelines and the development by ANZCCART of an Openness Agreement on Animal Research in Australia. CSIRO supports the development and implementation of an Openness Agreement in Australia and the use of the ARRIVE guidelines. Further transparency and accountability would be supported by increased consistency and standardisation of requirements and reporting across state regulatory bodies. The variety of regulatory approaches that are currently in place in each state can be confusing for research that is being conducted across multiple jurisdictions and prevents the collection and reporting of national statistics regarding animal use in Australia.

(f) overseas developments regarding the regulation and use of animals in medical research.

Openness Agreements have now been developed and implemented in the UK, Belgium, France, Germany, Portugal, Netherlands, Spain and New Zealand.

According to Vasbinder, MA. and Locke, P (2016) the globalization of science is continuing to increase. As a result the challenges and benefits of working across jurisdictions is likely to lead to additional efforts at harmonisation of laboratory animal welfare programs and standards. This might take place through a variety of mechanisms such as treaties (i.e. country to country negotiations and agreements), accreditation and/or the development of corporate policies and practices. Below are a few organisations currently providing accreditation that applies common sets of global performance standards to animal care and use programs:

Organisation	Acronym	Website
American Association for Accreditation of Laboratory Animal Care	AAALAC	https://www.aaalac.org/
Council for International Organizations of Medical Sciences	CIOMS	https://cioms.ch/
The International Council for Laboratory Animal Sciences	ICLAS	https://iclas.org/

(g) any other related matters.

There is a significant need for greater consistency in animal research related regulations across state jurisdictions. This would support greater multi-stakeholder collaboration.

References

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