Submission No 231

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

Organisation: The University of Newcastle

Date Received: 31 March 2022

PROFESSOR ZEE UPTON
DEPUTY VICE-CHANCELLOR
(RESEARCH AND INNOVATION)

THE UNIVERSITY OF NEWCASTLE AUSTRALIA

31 March 2022

Hon Greg Donnelly MLC
Committee 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 Inquiry. Recent world events (COVID-19 pandemic) underscore the important role animal-based research can play in developing vaccines and essential treatments for human diseases. Accordingly, this inquiry is both timely and highly relevant. To ensure our responses are relevant to the published terms of reference, we will address each question in turn below.

(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 from animal research are far reaching and not well broadcast. Both the Animal Research Act (1985) (ARA) and the Australian Code for the Care and Use of Animals for Scientific Purposes (2013) (The Code) stipulate that the use of animals must be deemed essential to the research work to be undertaken, and charge a legally constituted Animal Ethics Committee (AEC) with the responsibility of ensuring the use of animals is not only essential, but also ethical. Where these criteria are met, the use of an appropriate animal model and the results obtained from that work, plays a key role in guiding further studies along what is often termed a translational research path 'from bench to bedside'. That is, the generation of a new treatment, drug or therapeutic agent that can help treat disease. While the use of animals is rarely the first step in this process (generally being based on results obtained from *in vitro* studies), it is also not the last step in the process and at best will generally lead to limited clinical (phase 1) studies being done in humans. Animal studies therefore provide the essential link between data obtained from cell cultures that allow that data to be further tested in a complete living animal, so the potential efficacy and toxicity of candidate drugs can be assessed before use in humans. Animal models are constantly being refined and they remain the gold standard for target validation.

While animal models do not always perfectly mimic what will happen in the human body, unfortunately neither do *in vitro* studies or human studies for that matter, and this is best exemplified by the occasional need to withdraw a drug from the market due to undesirable side effects. Clearly, animal models failed to adequately demonstrate those problems during testing, but so too did the *in vitro* test models and the human clinical trials. Animal models do; however, provide an essential degree of confidence and guidance that allows early clinical testing to proceed more safely.

(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

Unfortunately, medical research is not a cheap undertaking and medical research that requires the use of animals comes with additional costs. These are commensurate with the expense of breeding and maintaining research animals under the high standards such work requires.
One excellent NSW based resource that has helped to raise and maintain the standards of medical research in this state has been the establishment of Australian Bioresources (ABR) at Moss Vale. This specialist mouse breeding facility is producing consistently high-quality mice for use in research by multiple NSW institutions, with an economy of scale that no individual institution could achieve if the mice were all bred in-house.

Establishing a common source for mice used in research brings multiple benefits to the State's medical research endeavours. The simple fact of a common source of animals, means fewer variables between experiments conducted by researchers at different institutions. It also provides substantial welfare benefits though efficiency of scale, so the number of animals bred that end up being surplus to requirement will be greatly reduced by virtue of having a larger pool of researchers to supply. There are also significant cost savings for partner institutions through reduced need for specific infrastructure and the associated staffing costs that follow on from not having to devote resources to breeding those animals in each institution.

(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 use of animal models is both expensive and very time consuming, so even allowing for the requirement outlined in the Code and enforced by AECs aside, researchers would always choose to use alternate methods where possible. Unfortunately, funding for the development of alternatives to the use of animals is extraordinarily limited as a result of major granting bodies having to direct their limited funds to projects with the greatest chance of achieving therapeutic outcomes.

Making significant funding for research into alternatives to animal use would be widely applauded as a very positive step forward.

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

The breeding of animals for medical research requires very high standards to ensure the ready availability of high quality, healthy, 'happy' animals, as stressed animals or animals in sub-optimal health will confound experimental outcomes. Accordingly, there has been an increasing trend towards sourcing animals from specialist large scale breeders where possible. This has a number of advantages, both in terms of the quality and consistency of animals supplied and reducing the loss of life associated with culling unused ones. Institutional breeding programs lack the economy of scale required for efficient, ethical and humane breeding of animals. Larger scale operations that supply multiple institutions are far better in this regard, as there is a greater likelihood of excess animals being used by other researchers in other institutions. This is why larger suppliers, such as the ARC in Perth, have recently been recognised as an essential part of Australia's national research infrastructure. ABR in New South Wales is another very good example, albeit on a smaller scale.

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

The regulatory regime underpinned by the Code is recognised internationally for the excellent way in which it achieves both transparency and accountability. The fact that external, independent lay members and external, independent animal welfare members are an essential part of the membership of every AEC is a major part of this, as is the need for an independent, external review of the institution and operation of their AEC every three to four years. Both approaches ensure the system is kept accountable. The other essential aspect here is the requirement for all institutions or organisations undertaking research that involve the use of animals, to be licenced and monitored by the relevant state government department. This helps to ensure these aims are achieved at an appropriate standard and are adequately monitored.

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

As mentioned above, the Australian Code for the Care and Use of Animals for Scientific purposes is so highly regarded internationally, it has in fact been adopted by a number of other countries. This is an excellent example of how Australia is helping to set and maintain high standards when it comes to the regulation and use of animals in medical research.

Yours sincerely,

Professor Zee Upton
Deputy Vice-Chancellor (Research and Innovation)