

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

Organisation: Tree of Compassion Incorporated

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Tree of Compassion Inc.

www.treeofcompassion.org

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ABN 67645692404

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SUBMISSION TO THE NSW INQUIRY INTO THE USE OF PRIMATES AND OTHER ANIMALS IN MEDICAL RESEARCH

Tree of Compassion welcomes this inquiry into the use of primates and other animals in medical research.

TERMS OF REFERENCE QUESTIONS

(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.

Whilst NSW publishes annual statistics of animals used in research giving some indication of the nature and purpose, the effectiveness of this research is not clear. To simply state that the use of animals in medical research is necessary without a detailed and accurate explanation as to why, is not acceptable. Where is the data to back this up? Where is the investigation into the effectiveness into the use of animals in medical research? And the explanation about the limitations of using animals in medical research?

There needs to be rigorous investigation into the most beneficial research methods applicable to humans. Decades of research using animals costing billions of dollars has still not provided a cure for some of our most debilitating diseases. It is clear that a new approach is needed, one that is humane and does not use animals. In the past, animal research was the done thing. In this day and age, we need to move on from such cruel and outdated methods. Medical research using animals should not continue based on historical or cultural reasons but should be based on valid scientific reasons that demonstrate a significant and overwhelming contribution towards the development of human medicine that cannot be achieved by non-animal means.

In terms of evaluating effectiveness and potential public health risks and benefits, whilst there has no doubt been medical advancements that are attributed to using animals in research, how many failures have there been? And could these advancements have been made using alternatives to animals? It seems that none of this has been effectively evaluated in NSW.

There is also the issue of conducting animal experiments for no good reason. Studies using animals to ascertain something when the knowledge is already known, does nothing but waste money and cause suffering to animals. And then here are studies where the results in animals have been detrimental but clinical trials on humans have proceeded despite this.

We understand that the majority of animals used in medical research in Australia are used in basic research as opposed to applied research. The clinical relevance of this research is low. It appears that this basic research is undertaken simply to satisfy scientific curiosity and publish more papers rather than actually have a clinical application.

Tree of Compassion calls for the following:

- That an independent investigation be conducted to evaluate the effectiveness and usefulness of research using animals;
- Mandatory retrospective assessments of animal research be made public and be a condition of funding;
- Greater scrutiny of basic research using animals; and

- Pre-registration of all animal experiments to prevent duplication.

Medical research using animals is shrouded in secrecy. Whilst we understand there are some issues around privacy, this should not negate the need to be transparent and accountable with regard to the use of animals. To that end, we request that the following be made public:

- Grant evaluation reports for all publicly funded research;
- Applications to animal care and ethics committee for animal-based research (to enable scrutiny of the proposed cost/benefit assessment);
- Statistics of adverse drug responses; and
- Clinical trial failure rates.

(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.

As stated earlier, the use of animals in medical research is shrouded in secrecy. There is limited detail currently available from research institutions regarding what procedures they undertake on animals, for what purpose and with what funding. This information should be made public. Publishing this data would provide transparency for consumers and funders alike. Publicly funded projects in particular should publish a record of their expenditure regarding research involving the use of animals.

It should also be noted that costs associated with animal research should also include programs to rehabilitate and rehome animals used in research.

Funding should be provided for replacements to animals in research. Currently, there is little public information regarding funding provided for the development of alternative methods to the use of animals in research. Expenditure for the development and validation of methods that do not use animals should be provided, recorded and publicly reported.

Other costs to consider include the costs to people when data obtained from animal research does not translate to humans and also costs from misleading information that results in aborted treatments because they have failed in animals but may actually be effective in people.

(c) the availability, effectiveness and funding for alternative approaches to animal research methods and technologies, and the ability of researchers to meet the 3 Rs of Replacement, Reduction and Refinement

As stated above, there is little information available about funding for alternative approaches to animal research methods. There are plenty of alternatives to using animals in research and education. These include in-vitro methods using microorganisms, tissues, whole or part cells in test tubes and Petri dishes, computer based methods, studies with human volunteers, and virtual reality based and physical model based.

The Humane Research Association (www.humaneresearch.org.au) contains a wealth of information about alternative approaches to animal research and the 3Rs.

There have been reports (conveniently available through Humane Research Association) which illustrate the scientific and economic benefits of non-animal research methods. Microfluid devices lines with living human cell like the organs-on-chips, is just one example (<https://wyss.harvard.edu/technology/human-organs-on-chips/>). Whilst in the UK, the New Approach Methodologies are becoming increasingly popular and the National Centre for the Replacement, Refinement and Reduction of Animals in Research recently ran a workshop on the subject (<https://nc3rs.org.uk/events/increasing-confidence-new-approach-methodologies-regulatory-decision-making>). These technologies are multi-million dollar industries reflecting an increasing demand to move away from using animals in research.

In terms of the ability of researchers to meet the 3 Rs of Replacement, Reduction and Refinement, again, this is difficult to determine. Some of this information is provided in the published NSW annual animal use research statistics but this is very limited.

In 2020, the NSW Animal Research Review Panel and the Department of Primary Industries undertook a survey on education and training of Animal Ethics Committees (https://www.animaethics.org.au/data/assets/pdf_file/0008/1321388/AEC-survey-summary.pdf). The survey showed that there is strong support for training and education on replacement methods. A 2019 information paper published by the National Health and Medical Research Council (<https://www.nhmrc.gov.au/about-us/publications/information-paper-implementation-3rs-australia>) highlights that funding is needed in order to support the implementation of the 3Rs as well as scientific and technological innovation.

There appears to be a lack of Government funding for the development of alternatives to using animals in research and researchers tend to rely on overseas funding and the odd small grant for universities. In order to implement the 3Rs, funding is needed as well as appropriate scientific and technological advancement. Australia seems to be well behind much of the world in this regard. There needs to be both state and federal government funding and commitment for the development of scientific testing without the use of animals. There needs to be grants, awards and scholarships to provide incentives to researchers. And to promote and support the development of non-animal based alternatives, a national centre needs to be established.

There is also the issue of relevance of research using animals. There needs to be more focus on robust scientific design. Animal Ethics Committees need to scrutinise this more and they need to be provided with evidence that alternatives to using animals have been sought. Whilst it is of course relevant to consider animal welfare, this should not be a justification for using animals nor should the claim that an entire biological system is needed. There needs to be strong and scientifically valid reason and value for using animals rather than because it has always been done that way and their needs to be merit to the research and expected outcomes.

The use of animals in research needs to be phased out.

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

Using primates and other animals in research is of no benefit to the animals used. All it does is subject them to harm and suffering and hence is unethical since they do not consent to this.

Some tests are particularly inhumane and should be banned immediately. These include forced inhalation research for cigarettes and other hazardous materials currently being undertaken at the University of Newcastle and the Centennial Institute and forced swim tests such as those being used at Macquarie University and the University of Wollongong. And the lethal dose test.

These methods are particularly inhumane and cause significant distress. The forced inhalation nose-only method risks suffocation of the animal in the tube and also impacts such as weight loss and hypothermia. The animals suffer painful conditions induced to recreate the condition in humans. But as with all animal experiments, the data obtained is not accurately transferable to humans. The forced swim test, requires an animal to be dropped in a beaker of water where they paddle furiously to stop from drowning until they give up. This obviously results in stress and terror in the animal. It is used to supposedly to test the efficacy of anti-depressant drugs when all it does is record the time the animal takes to give up its' desperate struggle to swim to survive.

The use of primates presents the ethical dilemma of subjecting animals with high cognitive abilities and well-developed social structures to harm and suffering. Using these animals as mere tools for research is actually of little value as data from such research, as with any other non-human animal species, is poorly predictive of human outcomes and hence is ineffective at providing substantial contributions to biomedical research.

If the general public knew exactly what dogs and cats were subjected to in medical research, the vast majority would be horrified. Dogs and cats are social animals and no amount of enrichment in a

laboratory can replace or make up for the social deprivation they are subjected to. The distress these companion animals endure in the name of medical research when the data cannot be accurately transferable to humans is not justified. The time and resources spent on these tests would be far more valuable and valid if spent on advancements in human biology-based methods of research where the results can be directly translated to human health outcomes.

Research involving non-human primates, dogs, cats, and other animals should be phased out with an immediate ban on importing primates. And in the meantime, it should be mandatory rather than voluntary (as is currently) to rehome animals such as dogs, cats, rabbits, and rodents used in research and a sanctuary established for primates. And it should be mandatory that the fate of all animals used in research should be publicly reported.

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

The issue of a lack of transparency and accountability has already been raised in previous questions above. Even a list of accredited animal research institutions in NSW is not available.

In terms of the current regulatory system, we consider this to be inadequate. It largely relies on self-regulation via animal ethics committees. Animal ethics committees are largely reliant on the Category C member to be vigilant and question animal welfare but the Category C member is unlikely to be knowledgeable about robust scientific design and whether the research is actually justifiable. And even if they were, there are issues with pressure from other members of the committee, particularly from members who are internal to the institution, including the chair who is often a senior person from the research institution, that a Category C or D member of an animal ethics committee may not actually feel comfortable to raise any concern or opposition.

There is also the issue of how adequately animal ethics committees oversee research currently being conducted and how inspections are undertaken both by animal ethics committees and the Animal Research Review Panel. Additionally, the Animal Research Review Panel needs to have members that have a demonstrated knowledge and commitment to alternatives to the use of animals in medical research.

In order to increase transparency and accountability, there needs to be:

- CCTV cameras in research institutions,
- published details on the numbers of animals bred, but not used (ie, killed instead), for medical research,
- access by the media and animal welfare organisations to primate breeding facilities,
- Approvals for lethal dose test by the Minister should be made public,
- Making mandatory the annual reports of research institutions and external reviews of these institutions, and
- Increased powers of investigation and breaches regularly penalised.

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

As stated earlier, Australia has been much slower at developing and implementing alternatives to the use of animals in research. Many countries have centres for validation of alternative methods including Brazil, Canada, Germany, the US, the Netherlands, Japan, the UK, South Korea, Switzerland and there is also a European Centre for the Validation of Alternative Methods.

Many countries have specific initiatives to stop using animals in research. For example, the Netherlands plan to phase out toxicology tests for chemicals, food ingredients, pesticides, veterinary medicines, and vaccines by 2025. The US introduced amendments to the Food and Drug and Cosmetic Act via the FDA Modernization Act 2021 to use alternative testing methods to animal testing to investigate the safety and effectiveness of a drug. The European Parliament passed a recent resolution calling for an action plan to end the use of animal experimentation. Brussels has banned

the commercial animal testing using cats, dogs and primates. South Korea has proposed federal legislation that would prioritise funding for human biology-based approaches in biomedical research.

(g) any other related matters.

As already mentioned, we call for the use of animals in research to be phased out and an immediate ban on some test and the use of primates. The reliance on using animal models is not only unethical but is a waste of resources and misleading as it is not accurate.

We note that the recommendation from the Commonwealth inquiry in 1989 to fund research into alternatives to the use of animals in experiments has not yet been implemented. We hope that as a result of this inquiry, at least in NSW such an action will be implemented.

We strongly urge that NSW Government to commit to a timetable to prohibit the use of animals in research as soon as possible and not delay this for years and to commit funds to the development of alternatives.

We look forward to the end to the use of animals in medical research and the use instead of modern, humane alternatives that produce more dependable and accurate results.

Kind regards,

Phil Hunt
Secretary
Tree of Compassion