# Information Sheet 4 Animal Experimentation

If animals are close enough mentally and physically to substitute for humans in research, then that's a powerful reason not to use them.

## Policy

The Animal Justice Party (AJP) will seek to rapidly phase out animal experimentation throughout Australia because it is cruel, outdated and ineffective. We must urgently stop funding animal experimentation and transition towards effective alternatives.

The AJP recognises new frameworks for research focused on animal wellbeing and where animals are considered participants. This means that research is done for the benefit of the animal participant themselves. This is similar to humanbased research frameworks where someone participates in research that may alleviate their own suffering. The AJP supports this form of research which respects animals' agency, individual lives, and is intended to directly benefit the animal participating in the research.

# **Key Objectives**

- 1. Develop a national plan for phasing out animal experimentation, including milestones and an end date.
- 2. Develop an approach beyond the 3Rs (Replacement, Reduction, Refinement) towards best practice, animal wellbeing focused research.
- 3. Immediately ban particularly cruel research, including but not limited to, forced swim tests, forced smoking tests, Draize tests, LD50, poison bait experiments, xenotransplantation and primate research.
- 4. Cease state and federal government funding of animal experimentation, and establish a national fund for the development of non-animal methods (NAMs). This will include grants to upskill researchers in NAMs.
- 5. Introduce a public register of all animal research projects and mandate prospective registration of animal studies. Mandatory pre-registration of animal studies will allow experts to advise on available NAMs and also stamp out publication bias.

- 6. Require animal ethics committees to release the methods and outcome summaries of animal research projects and make these available to the public. A summary should at least describe in plain English the aim of the study, procedures animals have been subjected to, the number and species of animals, the outcomes of the study and the funding.
- 7. Require states and territories to collect and publish data on animal research in a way that allows for compilation of a nationally consistent data set.
- 8. Update the definition of "animal" used by research to include all sentient beings.
- 9. Introduce mandatory rehoming of animals used in experimentation, and provide financial support to organisations who rehome them.

## Background

Animal experimentation consists of the use of nonhuman animals in scientific research, testing and teaching. It involves methods ranging from benign observation to forcing live animals to undergo procedures that cause them pain, suffering and lasting harm. In many cases the animals are killed after the experiment.

Almost all animal experiments utilise animals as objects rather than treating them as participants, however, alternative approaches are possible. An animal wellbeing focused approach to animal research<sup>1</sup> would regard animals as participants who would benefit directly from the research. These are the principles that underpin human research protocols. For example, a dog might be enrolled in a clinical trial for new procedures or medications which might directly benefit the dog.

We do not know how many animals are used for animal experimentation each year. In Australia, responsibility for animal welfare is delegated to the states and territories, and not all jurisdictions collect and publish data on numbers of animals used, types of animals used, types of procedures and purpose of research projects. The figures from 2020 indicate that at

 $^{1} https://www.cambridge.org/core/journals/cambridge-quarterly-of-healthcare-ethics/article/animal-research-that-respects-animal-rights-extending-requirements-for-research-with-humans-to-animals/9787C539ACD4D7B34102C8B622D6FC58$ 

<sup>2</sup>https://www.animalethics.org.au/\_\_data/assets/pdf\_file/0007/1395466/INT21-148540-2020-Animal-use-in-research-statistics-report.pdf <sup>3</sup>https://agriculture.vic.gov.au/\_\_data/assets/pdf\_file/0009/880047/2020-Statistics-of-animal-use-in-research-and-teaching-report\_FINAL.pdf <sup>4</sup>https://nre.tas.gov.au/Documents/Animal%20Research%20Statistics%20Tasmania%20Annual%20Report%2025.pdf



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least three to four million animals were used in NSW<sup>2</sup>, Victoria<sup>3</sup> and Tasmania<sup>4</sup> alone. These figures will be significant underestimates. The data for other states is unavailable.

Those jurisdictions that publish animal use data provide their statistics with different detail and composition, making it difficult to collate the data for a national overview.

The types of research projects that use animals include basic research (also called fundamental research), applied research (human disease research) and testing (regulatory testing). Basic research aims to yield data and increase scientific knowledge. It is driven by curiosity and not strictly meant to provide useful results for human or veterinary medicine. Applied research is designed to solve specific problems, such as using mice as a model to seek a treatment or cure for a human disease. New consumer products, medicines, industrial and agricultural chemicals are tested to ensure they comply with government regulations, and are effective and safe for humans, animals and the environment.

#### **Effectiveness of animal experimentation**

"The history of cancer research has been a history of curing cancer in the mouse. We have cured mice of cancer for decades—and it simply didn't work in humans." Richard Klausner,<sup>5</sup> M.D., former director of the National Cancer Institute (USA), 1998. This is still true today<sup>6</sup>.

Using animals as models for human physiology and disease rarely translates into human benefits. This means that the billions of dollars of funding and resources spent on animal research each year are very often wasted and would be better spent on human-relevant research (see below).

A European study noted that "[o]ver 90% of new drugs fail to progress to the market due mainly to a<sup>7</sup>lack of efficacy or unexplained toxicity<sup>8</sup>. This suggests that reliance on animal models is failing to identify novel therapies." Overall, reviews of the usefulness of animal research have concluded that its validity (that is how well it reflects the reality it claims to represent) is lacking (for example,here<sup>9</sup>, here<sup>10</sup> and here<sup>11</sup>). In media reports, 'breakthroughs' in drug development are often based on animal research before they have been proven to be safe and effective for humans. Such reports inflate<sup>12</sup> the value or success of animal testing.

Xenotransplantation, that is transplanting organs or tissues from animals to humans, can result in the transmission of

disease to humans from animals. While progress in genetic engineering<sup>13</sup> has reduced such xenozoonotic risks, researchers cannot fully prevent "transmission of pathogens from animals to the recipients and the public<sup>14</sup>". As the COVID-19 pandemic showed, newly emerging viruses that transmit easily from animals to humans are problematic.

Scientific journals tend to publish only studies with positive results (publication bias). Researchers<sup>15</sup> have estimated the non-publication of animal studies at 33%. This creates the impression that animal tests are more effective than they really are. It may also result in repeating animal studies that have already been proven unsuccessful, but were never published.

Despite these well-known problems with animal experiments, peer-reviewers and journal editors still "request<sup>16</sup> that animal data be provided to validate studies produced using nonanimal-based approaches" (animal methods bias). Similarly, a study<sup>17</sup> found that "most researchers exhibited a strong resistance to relinquishing them".

To find better treatments and cures, we need data relevant to humans. While "reliance on animal<sup>18</sup> models is failing to identify novel therapies", methods that provide human-relevant data are available and their development should be encouraged.

#### Alternatives to animal research

Animal experimentation as a means of informing human health has little predictive value. Instead of using animals, AJP supports the use of human-centred research methods and technologies. That is, ethical research on humans for humans.

Ethical and effective research methods that do not use live animals can be grouped into in-vitro methods, in-silico methods, studies with human volunteers and simulators. In-vitro (Latin for "in the glass") tests and experiments are generally performed outside living organisms. They use tissues, microorganisms, cells or other small parts of biological material. Examples include organoids<sup>19</sup> (mini versions of organs) and organs-on-chips<sup>20</sup>, stem-cell technologies<sup>21</sup> and robotic testing<sup>22</sup> (high throughput testing).

Computer-based (in-silico) methods are particularly useful to study the adverse effects of chemical substances on living

<sup>10</sup>https://www.sciencedirect.com/science/article/pii/S2452302X1930316X

<sup>&</sup>lt;sup>5</sup>https://www.latimes.com/archives/la-xpm-1998-may-06-mn-46795-story.html

<sup>&</sup>lt;sup>6</sup>https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3902221/

<sup>&</sup>lt;sup>7</sup>https://www.mdpi.com/2076-2615/12/17/2180

<sup>&</sup>lt;sup>8</sup>https://www.mdpi.com/2076-2615/12/17/2180

<sup>&</sup>lt;sup>9</sup>https://www.sciencedirect.com/science/article/pii/S1743919119302808

<sup>&</sup>lt;sup>11</sup>https://www.bmj.com/content/348/bmj.g3387

<sup>&</sup>lt;sup>12</sup>https://openscience.bmj.com/content/4/1/e100039

<sup>&</sup>lt;sup>13</sup>https://onlinelibrary.wiley.com/doi/epdf/10.1111/tri.13104

<sup>&</sup>lt;sup>14</sup>https://www.sciencedirect.com/science/article/pii/Si350946220300483

<sup>&</sup>lt;sup>15</sup>https://journals.plos.org/plosone/article?id=10.1371/journal.pone.o223758

<sup>&</sup>lt;sup>16</sup>https://www.biorxiv.org/content/10.1101/2022.03.24.485684v2

<sup>&</sup>lt;sup>17</sup>https://openscience.bmj.com/content/4/1/e100041.abstract

<sup>&</sup>lt;sup>18</sup>https://www.mdpi.com/2076-2615/12/17/2180

<sup>&</sup>lt;sup>19</sup>https://www.science.org/content/article/scientist-building-miniature-guts-livers-and-lungs-could-save-your-life-one-day

<sup>&</sup>lt;sup>20</sup>https://onlinelibrary.wiley.com/doi/full/10.1002/advs.202002030

<sup>&</sup>lt;sup>21</sup>https://www.sciencedirect.com/science/article/pii/S0927776517304630

<sup>&</sup>lt;sup>22</sup>https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9521367/

<sup>&</sup>lt;sup>23</sup>https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7223298/

organisms (toxicology) and predict toxicity<sup>23</sup>. Computer models can also be used to produce virtual organs or the human body, and to examine aspects of diseases.

Other methods like population-based research, microdosing and post-mortem studies have a long history. For example, post-mortem brain studies have contributed knowledge about Alzheimer's disease<sup>24</sup>. Microdosing involves taking a very small dose of a drug to test its safety or effectiveness. It is used early in the drug development process and also with vulnerable groups<sup>25</sup> (such as children, pregnant women, people with kidney disease) who are usually excluded from clinical trials. Simulators are popular in medical and veterinary training. They use virtual reality devices or physical models<sup>26</sup>.

The EU Reference Laboratory for alternatives to animal testing (EURL ECVAM<sup>27</sup>) maintains a data base<sup>28</sup> of non-animal methods and each year publishes a status report<sup>29</sup> on the latest relevant research, development and validation activities.

Unlike Australia, many countries have centres dedicated to the replacement, reduction and refinement (3Rs) of animal use in experiments. In particular, many 3Rs centres were established in the<sup>30</sup>European Union<sup>31</sup> following the European Parliament's Directive 2010/63/EU<sup>32</sup> on the protection of animals used for scientific purposes. 3Rs centres are mostly part of academic institutions. Some centres focus exclusively on replacement, such as the Canadian Centre for Alternatives to Animal Methods (CCAAM<sup>33</sup>) and the Canadian Centre for the Validation of Alternative Methods (CaCVAM<sup>34</sup>).

#### **Regulation of animal experimentation**

Regulatory testing on live animals is generally mandated by governments for new medicines, industrial and agricultural chemicals to check whether they are effective and safe for humans, animals and the environment. However, the requirements for animal testing of new chemicals and products is slowly changing as new non-animal methods and technologies are being developed. For example, legislation<sup>35</sup> in the US no longer requires animal testing for new drugs. Since 2019, the use of animals for testing finished cosmetic products is banned<sup>36</sup> in Australia. The ban does not apply to chemical cosmetics ingredients that may also be used in other products.

Animal experimenters are legally permitted to use procedures that cause pain and suffering. If not exempted by legislation,

<sup>34</sup>https://www.uwindsor.ca/ccaam/

<sup>36</sup>https://www.legislation.gov.au/Details/C2021C00493

these procedures would be unlawful (see our Animal Law Policy<sup>37</sup>). States and territories have incorporated the Australian Code for the Care and Use of Animals for Scientific Purposes<sup>38</sup> into legislation. The Code covers live fish, amphibians, reptiles, birds, mammals and cephalopods. Decapod crustaceans<sup>39</sup> and insects<sup>40</sup> are not protected by the Code despite accumulating evidence that they may feel pain.

The Code's guidance to limiting harm includes the principle of the 3Rs: Replacement (of animals with other methods), Reduction (in the number of animals used) and Refinement (of techniques used to minimise the adverse impact on animals). Research<sup>41</sup> has shown that "the cumulative effect of any such replacements has not prevented the overall number of animals used from steadily increasing since the 2000s". The 3Rs were developed in a paradigm which assumes animal use for humans is acceptable and therefore is not an effective tool to prevent harm.

Institutions and companies that use live animals for experimentation or testing have to obtain a licence from their state or territory government. They are also required to appoint and manage animal ethics committees (AECs). AECs are tasked to approve, review and monitor animal research projects. They include a chairperson, as well as one or more veterinarians, scientists or teachers, persons with a background and commitment to animal welfare, and independent community members. In theory, AECs are meant to represent a wide diversity of perspectives, but in practice they are often dominated by stakeholders who have a vested interest in promoting animal research or who do not have the knowledge and skills to use or assess new technologies<sup>42</sup>that do not require the use of animals.

AEC approval is usually sought after project funding has been secured. Given that the institution that receives the grant is also appointing and managing the AEC, it is in their interest that applications to the AEC are approved. AECs are also responsible for monitoring the care and use of animals. However, it is unclear whether or to what extent this occurs. While AECs keep records about their activities, this information is not publicly available. Thus, "[T]hose engaged in animal experimentation do so legally and do not have to convince regulators or funders that they are not doing anything wrong. To deal with public opinion, the default strategy in many coun-

<sup>&</sup>lt;sup>24</sup>https://alzres.biomedcentral.com/articles/10.1186/s13195-015-0126-1

<sup>&</sup>lt;sup>25</sup>https://www.tandfonline.com/doi/full/10.1517/17425255.2013.786042

<sup>&</sup>lt;sup>26</sup>https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6205286/

<sup>&</sup>lt;sup>27</sup>https://joint-research-centre.ec.europa.eu/eu-reference-laboratory-alternatives-animal-testing-eurl-ecvam\_en

<sup>&</sup>lt;sup>28</sup>https://data.jrc.ec.europa.eu/dataset/

<sup>&</sup>lt;sup>29</sup>https://publications.jrc.ec.europa.eu/repository/handle/JRC127780

<sup>&</sup>lt;sup>30</sup>https://journals.sagepub.com/doi/10.1177/02611929221140909

<sup>&</sup>lt;sup>31</sup>https://journals.sagepub.com/doi/10.1177/02611929221140909

<sup>32</sup>https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:276:0033:0079:en:PDF

<sup>33</sup>https://www.uwindsor.ca/ccaam/

<sup>&</sup>lt;sup>35</sup>https://www.science.org/content/article/fda-no-longer-needs-require-animal-tests-human-drug-trials

<sup>&</sup>lt;sup>37</sup>https://www.animaljusticeparty.org/animal\_law

<sup>&</sup>lt;sup>38</sup>https://www.nhmrc.gov.au/about-us/publications/australian-code-care-and-use-animals-scientific-purposes

<sup>&</sup>lt;sup>39</sup>https://www.crustaceancompassion.org/do-crustaceans-feel-pain

<sup>&</sup>lt;sup>40</sup>https://theconversation.com/insects-may-feel-pain-says-growing-evidence-heres-what-this-means-for-animal-welfare-laws-195328

<sup>&</sup>lt;sup>41</sup>https://brill.com/display/book/edcoll/9789004391192/BP000002.xml

<sup>42</sup>https://digitalcommons.calpoly.edu/bts/vol15/iss1/8/

tries, including Australia, has been to<sup>43</sup>keep the public largely ignorant<sup>44</sup>".

#### **Related policies**

Health Policy<sup>45</sup>

Genetic Manipulation Policy<sup>46</sup> Vaccinations Policy<sup>47</sup> Animal Law Policy<sup>48</sup> Revised: November 2023

<sup>43</sup>https://brill.com/display/book/edcoll/9789004391192/BP000012.xml?language=en <sup>44</sup>https://brill.com/display/book/edcoll/9789004391192/BP000012.xml?language=en <sup>45</sup>https://www.animaljusticeparty.org/health

<sup>46</sup>https://www.animaljusticeparty.org/genetic\_manipulation
 <sup>47</sup>https://www.animaljusticeparty.org/vaccinations
 <sup>48</sup>https://www.animaljusticeparty.org/animal\_law



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