Response ID ANON-823Y-XGK9-S

Submitted to **Medical Research Future Fund consultation to inform the second Australian Medical Research and Innovation Priorities 2018-2020**
Submitted on **2018-08-15 13:02:44**

Introduction

1 What is your name?

Name:

2 Are you affiliated with an organisation?

Yes

3 What kind of organisation do you work for?

Non-government organisation

4 Are you representing your organisation in making this submission?

Yes

5 What state or territory do you live in?

Victoria

6 Which 2016–2018 MRFF Priorities do you think need further focus? (please select a maximum of three Priorities)

MRFF infrastructure and evaluation, Biomedical translation

7 How can the 2016–2018 MRFF Priorities you identified in Question 6 be extended or re-emphasised in the 2018–2020 MRFF Priorities?

How can the most important Priority identified in Question 6 be extended or re-emphasised? (max 500 words):
Scientific literature raises questions about the reliability and predictive value of animal testing in research for humans. Systematic reviews continue to show that animal experiments are not sufficiently predictive of human outcomes and can be dangerously misleading.
Humans differ from animals anatomically, genetically and metabolically and interspecies variations are a high cause of clinical trial failure of pharmaceutical products. Not only does this mean that results cannot be accurately extrapolated to humans, but it also means that some possibly successful treatments are being ruled out pre-clinically due to adverse reactions or responses in animals. Animal use in research and safety studies is therefore misleading and causes abandonment of effective therapeutics.
Even in primates – used in research due to their genetic similarity to humans – significant species differences render them inappropriate models on which to base human disease.

If you identified a second Priority in Question 6 please explain how it needs to be extended or re-emphasised? (max 500 words):
According to FDA (U.S. Food and Drug Administration), in spite of huge research effort and expense, development of new treatments has slowed, as preclinical success has not followed through into clinical trials. Latest figures have revealed a 95% failure rate of clinical trials following 'successful' animal trials.
In a discussion paper addressing health and medical research, the Victorian government recognised the challenges of "PhD students and scientists confronted by issues related to career progression, security and remuneration." Page 19 of the discussion paper states that "Australia punches far above its weight by producing 3 per cent of global research publications with only 0.3 per cent of the world's population. However, compared with international standards, Australia has a poor record of commercial translation…".

If you identified a third Priority in Question 6 please explain how it needs to be extended or re-emphasised? (max 500 words):

8 What unaddressed gaps in knowledge, capacity and effort across the healthcare system and research pipeline need to be addressed in the 2018–2020 MRFF Priorities?

Most important gap identified that needs to be addressed in the 2018-2020 MRFF Priorities (max 500 words):
There is an urgent need to address the shortcomings of animal use in medical research and to find replacements if we are to accomplish genuine medical progress
The 3R's principle (Replace, Reduce and Refine animal experiments) was adopted by the National Health and Medical Research Council in 1984. It is a universally-accepted principle aimed at guiding the humane treatment of animals used in experiments whilst ultimately seeking their replacement.
In 1989, the Senate Select Committee on Animal Welfare, in its report to the Australian Government, recommended "that the Commonwealth Government establish a separate fund for research into the use of alternatives to animal experimentation and that grants be disbursed from this fund by a board composed of representatives from the scientific community, animal welfare organisations, ACCART [now ANZCCART] and government authorities." As confirmed by ANZCCART, this fund has never been established.
Australia has made very little progress in replacing animals in research, as illustrated by the vast numbers of animals used each year (Australia has been cited as the fourth highest user), and with growing concern within the research community that flawed animal studies are contributing significantly to failures in translational research - this is an area that requires urgent attention.

If you identified a second gap please explain how it needs to be addressed in the 2018-2020 MRFF Priorities (max 500 words):

The use of animals in research is, according to the code, for cases where no alternative exists, but alternatives will never exist without support for the development of non-animal based scientific testing. There have been international moves towards supporting alternatives to animals in research. Techniques such as computer modelling, genomics, nanotechnology, microdosing and microfluidic chips, just to name a few, have been developed with government funding and support to provide human-relevant models.

It is acknowledged that Australian funding bodies will accept applications for "3R's research", however their systems of application review mean that those applications do not stand a realistic chance of success. Therefore, the only way such applications would succeed through the system would be for dedicated funds being set aside specifically for this area of research.

In fact, due to such disincentives, Australian researchers keen to pursue alternatives research have had to resort to overseas funding.

Australian federal, state and territory governments should now be making a commitment to fund research into seeking alternatives to animal use – as is already the case in other countries.

The NHMRC, despite being responsible for drafting the Australian code for the care and use of animals for scientific purposes 8th edition (2013) - which advocates the 3Rs Principle - and despite distributing hundreds of millions of dollars in federal funding to medical research each year, consistently defer responsibility for animal welfare to state and territory governments.

Around the world, a number of government-funded initiatives are acknowledging the need to further develop and validate non-animal methods of research:

NC3Rs - The National Centre for the Replacement, Refinement and Reduction of Animals in Research is an independent UK organisation established in 2004.

ECVAM - The European Centre for the Validation of Alternative Methods (ECVAM) was established 1991.

ICCVAM - In the U.S., the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) was established in 1997.

ZEBET - established in 1989, is the Centre for Documentation and Evaluation of Alternatives to Animal Experiments, which forms part of the German Federal Institute for Risk Management, Berlin.

While other nations forge ahead in the area of alternatives research, Australia is missing an opportunity to excel in clinical translation.

Personal discussions with researchers have revealed their acknowledgement of the challenges posed by using other species to extrapolate data to human medicine, however they have also expressed concern about a lack of resources and incentive to develop alternatives to animal use. Clearly, this is an area in which Australia is greatly lagging.

In a 2014 British Medical Journal article the author stated, "…if research conducted on animals continues to be unable to reasonably predict what can be expected in humans, the public's continuing endorsement and funding of preclinical animal research seems misplaced."

"Public acceptance of the use of animals in biomedical research is conditional on it producing benefits for humans". Pandora Pound and Michael Bracken argue that "the benefits remain unproved and may divert funds from research that is more relevant to doctors and their patients."

If you identified a third gap please explain how it needs to be addressed in the 2018-2020 MRFF Priorities (max 500 words):

9   What specific priority or initiative can address the above gaps?

What specific priority or initiative can address the first gap identified in Question 8? (max 500 words):

Legislative changes are currently underway to ban the testing of cosmetics products on animals – illustrating that it is both possible and preferable to adopt non-animal methodologies. As a next step, we must consider the use of animals in other areas of research. Ideally, Australia should establish a government-funded institution dedicated to the replacement of animals in medical research. The following are suggested measures that could be taken in the interim.

Allocate a percentage of funding earmarked for medical research to be used specifically for the development of research methods that will replace animals.

Award a national prize for innovative research that has replaced animals.

Implement a grant, or series of grants, to encourage researchers to seek replacements to animals in medical research.

Hundreds of millions of dollars are distributed for medical research every year. HRA merely proposes that a small proportion be allocated for the development of a funding stream to provide financial incentives for researchers to develop these alternatives – as is already happening in other nations. There is no reason why Australia should not be at the forefront rather than lagging behind the rest of the world in this escalating and promising area of research.

If you identified a second gap in Question 8 what specific priority or initiative can address this gap? (max 500 words):

Australia urgently needs to provide more incentive for the development and validation of non-animal methods of testing. This would eliminate the wastage of precious resources as it would focus on research that is directly applicable to the human species.

Considering the growing evidence that animal research does not demonstrate best practice for medical research, and that the Australian public is opposed to the use of animals in this way, it would be remiss for the government to exclude provision for research to replace animals in medical research and waste the opportunity to illustrate their commitment to the 3R's Principle, which would in turn contribute to more innovative, high-quality and translatable research.

If you identified a third gap in Question 8 what specific priority or initiative can address this gap? (max 500 words):

10   What Strategic Platforms (identified in the MRFF Strategy document) would the Priority/ies you identified in Question 8 fall under?

Strategic and international horizons, Data and infrastructure, Capacity and collaboration, Trials and translation

11   How can current research capacity, production and use within the health system be further strengthened through the MRFF? (max 500 words)

Please give us your views:

Recognition and subsequent action to address the need for human-relevant methods of research, as outlined in above responses.

12   Do you have any additional comments on the Discussion Paper? (max 250 words)

Please give us your feedback on the Discussion Paper:

HRA welcomes this opportunity to provide a submission to the MRFF as we consider that current methods of research (ie dependence on data from animal tests) are not conducive to fulfilling clinical application and resulting in positive health outcomes for patients.

There is growing evidence to suggest that research on animals is not sufficiently predictive of human outcomes and so does not translate well to clinical practice

and commercial application, hence the need to address this important issue within the Review.

When using animals, scientists are legally obligated to follow the 3R's principle of Replace, Reduce, Refine. HRA continually hears that despite widespread acknowledgment that animals are not the best models on which to base human health, there is no incentive, nor financial resources, available to pursue alternatives research.

It is therefore apparent that an urgent need exists to provide these incentives to ensure that Australia will be at the forefront rather than lagging behind the rest of the world in this escalating and promising area of research and the following pages provide an overview. The Medical Research Future Funds provides this opportunity to address this urgent need.

13 Do you consent to this submission being made public on the MRFF website?

Yes