## Structural Review of NHMRC's Grant Program Public consultation

## Template for written submissions

The NHMRC will consider submissions that address the consultation questions and use the template provided. The consultation questions are listed below for each of the three models canvassed in the discussion paper, with a general question at the end of this template. You may answer as many of the questions as you wish. The questions can also be found on page 22 of the consultation paper.

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## Alternative model 1

*Refer to information about alternative model 1 in the consultation paper and respond to the consultation questions below.* 

## Question 1.1:

How effectively would the model optimise NHMRC's public investment in health and medical research by meeting the aims of this Review, including the major objectives of NHMRC's grant program found on page 12 of the consultation paper? (500 words max)

## Question 1.2:

What advantages and disadvantages of this model do you see for you or your organisation if the model was introduced? (For example, what impact would it have on a researcher at your stage of experience? Would it support research in your research area?) (500 words max)

## Question 1.3:

Can you identify negative consequences for Australia's health and medical research system if the model was introduced and how might these be mitigated? (500 words max)

The proposed model does not make provision for research into the replacement of animals in experiments – a commitment that should be made by the NHMRC in accordance with the 3R's Principle (Replace, Reduce, Refine). (See below – Question 4)

#### Question 1.4:

Could the model be adjusted to optimise its impact? If so, how? (500 words max)

# **Question 1.5:** Do you have other comments about the model? (500 words max)

## Alternative model 2

*Refer to information about alternative model 2 in the consultation paper and respond to the consultation questions below.* 

#### Question 2.1:

How effectively would the model optimise NHMRC's public investment in health and medical research by meeting the aims of this Review, including the major objectives of NHMRC's grant program found on page 12 of the consultation paper? (500 words max)

Question 2.2:

What advantages and disadvantages of this model do you see for you or your organisation if the model was introduced? (For example, what impact would it have on a researcher at your stage of experience? Would it support research in your research area?) (500 words max)

Question 2.3:

Can you identify negative consequences for Australia's health and medical research system if the model was introduced and how might these be mitigated? (500 words max)

The proposed model does not make provision for research into the replacement of animals in experiments – a commitment that should be made by the NHMRC in accordance with the 3R's Principle (Replace, Reduce, Refine). (See below – Question 4)

Question 2.4:

Could the model be adjusted to optimise its impact? If so, how? (500 words max)

## Question 2.5:

Do you have other comments about the model? (500 words max)

## **Alternative model 3**

*Refer to information about alternative model 3 in the consultation paper and respond to the consultation* questions *below.* 

#### Question 3.1:

How effectively would the model optimise NHMRC's public investment in health and medical research by meeting the aims of this Review, including the major objectives of NHMRC's grant program found on page 12 of the consultation paper? (500 words max)

#### Question 3.2:

What advantages and disadvantages of this model do you see for you or your organisation if the model was introduced? (For example, what impact would it have on a researcher at your stage of experience? Would it support research in your research area?) (500 words max)

## Question 3.3:

Can you identify negative consequences for Australia's health and medical research system if the model was introduced and how might these be mitigated? (500 words max)

The proposed model does not make provision for research into the replacement of animals in experiments – a commitment that should be made by the NHMRC in accordance with the 3R's Principle (Replace, Reduce, Refine). (See below – Question 4)

#### **Question 3.4:**

Could the model be adjusted to optimise its impact? If so, how? (500 words max)

**Question 3.5:** Do you have other comments about the model? (500 words max)

## General

## Question 4:

Do you have comments on the other issues discussed in this paper? (500 words max)

The NHMRC adopted the The 3R's principle (Replace, Reduce and Refine animal experiments) following a report by the Senate Select Committee in 1984. It aimed at guiding the humane

treatment of animals used in experiments whilst ultimately seeking their replacement. Australia has made very little progress in replacing animals in research, as illustrated in the vast numbers of animals used each year (Australia is the fourth highest user), and with growing concern within the research community that animal models are not adequate human proxies for research, this is an area that requires urgent attention.

The structural review of the grant system is an opportunity to include a commitment by the NHMRC to fund research into seeking alternatives to animal use – as is already the case in other countries. (Further information available upon request)

## **Predictability**

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 predictive of human outcomes and can be dangerously misleading (Knight, 2011) (Langley, 2015). Humans differ from animals anatomically, genetically and metabolically and interspecies variations are a high cause of clinical trial failure of pharmaceutical products. Animals have different metabolic pathways, present broad ranges of physiological defences, and differ in the way their organ systems respond to toxic insults (Knight, A. 2011) (Bailey, J. 2016). Not only does this mean that results cannot be extrapolated to humans, but it also means that some possibly successful treatments are being ruled out preclinically due to adverse reactions or responses in animals. Animal use in research and safety studies is misleading and causes abandonment of effective therapeutics (Akhatar, A 2015).

## **Research Translation**

In spite of huge research effort and expense, development of new treatments has slowed, as preclinical success has not followed through into clinical trials. The U.S. Food and Drug Administration (FDA) recently reported a 92 percent failure rate of clinical trials following successful animal trials. It stated that in 2004, animal experimentation was a factor in the declining delivery of new therapies (Lidbury, 2015).

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." (Şentürk, 2015).

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 methods (Eurovoc, 2014). 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 a human-relevant model. The process has been slow, as old habits persist and development of new techniques takes time. The field of epidemiology is also providing information about the human species, as is the highly developed field of imaging techniques (Knight, 2011).

## <u>Summary</u>

It would be remiss for Australia to exclude provision for research to replace animals in the current review 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.