26 July 2018

Small Business Entities & Industry Concessions Unit
The Treasury
Langton Crescent
PARKES ACT 2600

To whom it may concern,

Re: Consultation on R&D Tax Incentive Bill

The University of Melbourne welcomes the opportunity to respond to the consultation on the draft *Treasury Laws Amendment (Research and Development Incentive) Bill*.

The R&D tax incentive is a major component of Government support for research and development in Australia, with an estimated $3.1b worth of support for R&D delivered through the program in 2017/18. The program is the primary mechanism by which the Government seeks to increase the level of R&D activity in the private sector. As the Government seeks to further increase industry-university research collaboration, it is timely to adjust the program to ensure it is properly targeted. The amendments proposed should be framed such that the program achieves the intended outcome of driving R&D activity that would not occur otherwise.

The following comments address two key issues in the design of the R&D tax incentive. Firstly, a 'collaborative premium' was recommended in the recent review of the R&D tax incentive, but has not been included in the suite of changes announced in the Budget. A premium incentive rate for businesses that engage research institutions to conduct R&D would help ensure an optimal return on the public investment and advance the aims articulate in the Government's National Innovation and Science Agenda (NISA).

The University of Melbourne also offers a response to Consultation Question 4, relating to the proposed exemption of clinical trials from the $4m refund cap for the refundable component of the tax incentive. While we support this exemption, we have concerns about the narrow definition of 'clinical trials'.

A collaboration premium

Australia is seeking to raise the level of collaboration between industry and public research institutions. Australian businesses are much less likely to conduct R&D activity with the research sector than businesses in other OECD nations. However, the public investment made through the R&D tax incentive is not fully leveraging its influence to increase industry-research collaboration. The *Review of the R&D Tax Incentive* found that in 2013/14, only 9.5 per cent of projects registered under the program reported collaborating with public research organisations.[1] The Review also emphasised the economic benefits of industry-research collaboration. *"Collaborative R&D, especially between companies and publicly-funded research organisations (PFROs), is considered to be more likely to produce spillovers, so adjusting the programme to encourage collaborative R&D could increase the programme's effectiveness".*[2]

Improvement in this area depends upon getting the policy settings right, such that the framework of public support provides adequate incentives both for researchers and for businesses. Changes to university research funding announced in the Government's 2015 NISA statement addressed one half of this

[1] https://www.industry.gov.au/data-and-publications/review-of-the-rd-tax-incentive (p.13)
[2] Ibid. (p.30).

equation, with a greater share of research block grant funding being linked to research income sourced from industry and other end-users.

The *Review of the R&D Tax Incentive* recommended the introduction of "a collaboration premium of up to 20 per cent for the non-refundable tax offset" to heighten the incentives for businesses to collaborate with the research sector. Innovation and Science Australia (ISA) made the same recommendation in its *Australia 2030: prosperity through innovation*, released in 2017.

The University of Melbourne urges the Government to implement this recommendation. This would ensure that the program's design reflects the policy intent of encouraging additional R&D activity, and that it better contributes to Australia's collaborative research ecosystem.

Exemption for clinical trials from the cap on refundable component

4. Does the definition of clinical trials for the purpose of the R&DTI appropriately cover activities that may be conducted now and into the future?

The Government is proposing to make clinical trials exempt from the new $4m cap on annual refunds repayable under the refundable component of the tax incentive. The University of Melbourne welcomes this exemption. Clinical trials are a critical component of medical research in Australia, which itself represents a significant share of all business investment in R&D. It is appropriate that expenditure on trials be exempt from the cap, so that the new arrangements do not constrain the research effort in this area.

We do, however, have concerns about the definition of 'clinical trials' to be used to determine eligibility for the exemption. The proposed definition is that used by Therapeutic Goods Administration (TGA):

> *"A clinical trial is a planned study of the safety or efficacy in humans of an intervention (including a medicine, treatment or diagnostic procedure) with the aim of achieving at least one of the following:*
>
> *– the discovery, or verification, of clinical, pharmacological or other pharmacodynamic effects;*
>
> *– the identification of adverse reactions or adverse effects;*
>
> *– the study of absorption, distribution, metabolism or excretion."*

Our concerns relate to the narrowness of the definition. On advice received, the definition has the effect of limiting clinical trials to therapeutic device and drug trials, and of excluding other clinical interventions such as cognitive behaviour therapy and music therapy trials. There is, in our view, no policy basis for limiting the proposed tax exemption in this way. The trial activity thereby excluded is an increasingly important part of medical research, and ought to be included in the exemption from the new cap on the refundable component.

The University of Melbourne suggests adopting a broader definition that is more reflective of the diverse nature of clinical research. The World Health Organisation (WHO) defines clinical trial as follows:

> *"a clinical trial is any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes."*

The WHO definition uses the general term 'health-related interventions', and is therefore agnostic as to the type of clinical intervention being trialled. Consequently, this definition is broad enough to capture trials that would be excluded under the proposed TGA definition. Importantly, there is an international trend towards this broader definition of clinical trials. The National Institutes of Health (NIH) in the US also defines clinical trials broadly (in terms of 'interventions') for the purposes of determining eligibility for research grants. Adopting the WHO definition would bring Australia into line with international practice.

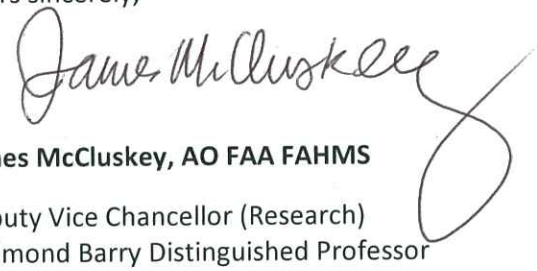
Recommendations

The University of Melbourne recommends that the Government:

- introduce a collaboration premium of up to 20 per cent for the non-refundable tax offset, as was recommended in the 2016 *Review of the R&D Tax Incentive*, and by Innovation and Science Australia.
- adopt a broad definition of 'clinical trials', such as that used by the WHO, to ensure that the new cap on cash refunds does not impede Australia's research effort.

For further information, or to discuss the submission, Professor Jim McCluskey, Deputy Vice-Chancellor (Research) can be contacted at dvc-research@unimelb.edu.au or on (03) 8344 3238.

Yours sincerely,



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