Dear Committee Secretariat,

Re: Treasury Laws Amendment (Research and Development Tax Incentive) Bill 2019

The University of Melbourne welcomes the Standing Committee on Economics Inquiry into the Treasury Laws Amendment (Research and Development Tax Incentive) Bill 2019.

The R&D Tax Incentive is a major component of Australian Government support for research and development, with more than $2b projected to be provided through the program this financial year. Given the scale of this investment and the importance of research to Australia’s society and economy, it is appropriate that the program be reviewed to ensure the subsidy produces R&D activity that would not occur otherwise.

We refer to the University’s response to the Committee Inquiry into the Treasury Laws Amendment (Making Sure Multinationals Pay Their Fair Share of Tax in Australia and Other Measures) Bill 2018. The Bill currently before the Senate proposes broadly the same amendments as the 2018 Bill, containing only minor changes relating to start dates and to the offset rates for the intensity threshold. Since the current Bill is substantially similar to the earlier one, we remain concerned about the two issues raised in our response in 2018:

• the failure to introduce a premium incentive rate for collaborative R&D; and
• the narrow definition of “clinical trials” to be used for the purposes of the exemption from the $4m refund cap.

The following comments address these issues in turn.

Collaboration premium

The introduction of “a collaboration premium of up to 20 per cent for the non-refundable tax offset” was one of six recommendations made by the expert panel of the Review of the R&D Tax Incentive.1 In broad terms, the panel found that a collaboration premium would make a positive contribution to Australia’s collaborative research ecosystem. It would help to break down cultural barriers between industry and research, as well as generating spill-over benefits, with the panel noting that collaborative R&D projects are more likely than non-collaborative projects to provide the basis for disruptive innovations.2 A collaboration premium was also recommended in Innovation and Science Australia’s Australia 2030: Prosperity through Innovation Strategic Plan.3

Given that it was one of small set of recommendations made by the expert panel, it is disappointing that this has not been included in the Government’s proposed changes to the R&D tax incentive. This will be a missed opportunity to drive improvements in Australia’s innovation performance. The University of Melbourne

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2 Ibid. p.30
urges the Government to implement the collaboration premium that was recommended in the *Review of R&D Tax Incentive*. This would help lift the level of engagement between industry and research institutions and would enhance the benefits to Australia’s economic and social wellbeing that are intended in the program.

**Definition of ‘clinical trials’**

The Bill proposes to exempt clinical trials from the new $4m cap on annual refunds payable under the refundable component of the tax incentive. While the University supports this exemption, we have concerns about the definition to be used for the purpose of administering it. The Bill proposes applying the definition used by the Therapeutic Goods Administration (TGA). As noted in our response to the Committee’s Inquiry into the 2018 Bill, the University is concerned that the TGA definition has the effect of limiting the exemption to therapeutic device and drug trials, thereby excluding other clinical interventions such as cognitive behaviour therapy and music therapy trials. Trials of non-drug interventions to address intimate partner violence are an example of a promising area of research that would not be covered by the exemption. The activities excluded represent an important part of Australia’s medical research effort. Since they generate the same type of benefits as device and drug trials, it is appropriate that they also be covered by the proposed exemption from the cap on annual refunds.

The University of Melbourne suggests adopting a broader definition that reflects the diverse nature of clinical research. The World Health Organisation (WHO) defines a clinical trial as “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”.\(^4\) The term ‘health-related interventions’ leaves open the particular type of intervention being trialled, and therefore captures clinical research that would be excluded under the proposed TGA definition. We note also that the National Institutes of Health (NIH) in the United States has adopted a broader definition for the purposes of determining eligibility for research grants. Similarly adopting a broad definition would align Australia 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 World Health Organisation, to ensure that the new cap on cash refunds does not impede the translation of Australia’s research effort into health benefits.*

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.

Kind regards,

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\(^4\) [https://www.who.int/topics/clinical_trials/en/](https://www.who.int/topics/clinical_trials/en/)