UNIVERSITY RESEARCH COMMERCIALISATION



ABOUT RESEARCH AUSTRALIA

We are the national peak body representing the whole of the health and medical research pipeline.

Our vision: Research Australia envisions a world where Australia unlocks the full potential of its world-leading health and medical research sector to deliver the best possible healthcare and global leadership in health innovation.

Our mission: To use our unique convening power to position health and medical research as a significant driver of a healthy population and contributor to a healthy economy.

Our goals:

Engage	Connect	Influence
Australia in a conversation	researchers, funders	government policies that
about the health benefits	and consumers to	support effective health
and economic value of its	increase investment	and medical research
investment in health and	in health and medical	and its routine translation
medical research.	research from all sources.	into evidence-based
		practices and better
		health outcomes.

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UNIVERSITY RESEARCH COMMERCIALISATION

RESPONSE TO THE CONSULTATION

Introduction

Research Australia is the national peak body for health and medical research and health innovation. We envision a world where Australia unlocks the full potential of its world-leading health and medical research sector to deliver the best possible healthcare and global leadership in health innovation. Our membership spans the entire health and medical research and innovation pipeline, including universities, not for profit research organisations, charities and corporations.

Our response to the consultation paper follows the Chapter headings and questions posed.

1. Mission-driven research

- a) Are Missions the appropriate priority-setting mechanism? Should they be accompanied by smaller, targeted Challenges?
- b) What criteria should be used to select Missions?
- c) Is Australian research sufficiently linked to demand? Where are the opportunities to link supply to demand?
- d) How can university researchers identify this demand?

Missions can be an effective way of directing resources and building capability, particularly if they drive product development all the way to commercialisation, manufacture and distribution. Missions can be useful in developing a critical mass of infrastructure, expertise and capability in a particular area, creating spillover benefits in the medium to long term where these have broader application beyond the Mission.

On the downside, Missions have the potential to compete with other researcher and business generated ideas, drawing resources away from them. For a paper on the commercialisation of research, the focus on Missions can seem a little incongruous. This is because the Consultation Paper describes Missions as 'usually set by a government agency and/or group of experts' (rather than industry, entrepreneurs or investors). There is a real risk that Missions will not directly meet the needs of a business that is looking for assistance with the development of a product or idea for which it has a prospective market. There is also a risk they won't assist the researcher whose research has a potential application as a product that is not related to a Mission, but which might be commercially viable if it can be developed and marketed successfully.

Some of the risk of a Mission failing to meet a market need can be mitigated if the Government is itself a customer for the product the Mission will develop. This is feasible in areas where the Government is a significant purchaser of products or services, such as medical products and services. It is an approach identified by Innovation and Science Australia (now Industry Innovation and Science Australia) in its 2016

Performance Review of the Australian Innovation, Science and Research System¹. The US Government's Biomedical Advanced Research and Development Agency is a successful overseas example of this approach.²³

Research Australia suggests that if Missions are to be part of the proposed scheme, they need to be chosen carefully with attention to the value of the Mission objective itself, and the potential for spillover benefits in areas that will benefit the broader research commercialisation ecosystem.

Examples of the use of Missions in the Australian context can be found in the MRFF missions.⁴ While not focused exclusively on a commercial outcome, all have the potential to lead to new commercial products and services and could be a model for other areas. Broader than a Mission, and thus avoiding some of the downside of a narrow focus, the MRRF Frontier Health and Medical Research Initiative is a commercially oriented program with an HMR-wide scope that provides substantial and long-term support to bring research-based innovations to market.⁵

In relation to supply and demand, part of the issue is that from the university, the demand from industry for university research is not evident or is opaque. Research Australia would like to see more clarity about what industry wants from universities – as the convenor of both ends of the pipeline we'd be happy to play a role in facilitating that connection by working with the Department to run a pilot in the HMR sector which could be extended to other sectors.

¹ Innovation and Science Australia (2016) Performance Review of the Australian Innovation, Science and Research System 2016. Commonwealth of Australia. Canberra. Page 29

² https://www.phe.gov/about/barda/Pages/default.aspx See also Research Australia's Pre Budget submission at https://www.phe.gov/about/barda/Pages/default.aspx See also Research Australia's Pre Budget submission at https://researchaustralia.org/wp-content/uploads/2021/01/Research-Australia-Pre-Budget-Submission-Jan-2021-FINAL-.pdf

³ BARDA's anthrax vaccine development program at https://www.phe.gov/about/barda/anthrax/Pages/default.aspx

⁴ https://www.health.gov.au/initiatives-and-programs/medical-research-future-fund/mrff-research-themes/research-missions

⁵ https://business.gov.au/grants-and-programs/frontier-health-and-medical-research-initiative

2. Stage-gated Scheme design

- a) Is a stage-gated model suited for the purpose of the Scheme?
- b) What is the appetite from industry and private investors to participate in such a Scheme?
- c) How should any stage-gating process be defined to ensure any additional incentive is maximised?
- d) How should projects be selected?
- e) How should the success of projects be measured?

The discussion in the Consultation paper in this section conflates two important topics. One is the stage-gated approach, typically used in business for product development. This can be applied to research commercialisation at the right stage.

The other idea is the 'Proof of Concept' experiment or stage, typically identified as too late for standard research funding, but too early for commercial investment – the 'valley of death'. There is an opportunity for properly designed funding programs to use a stage-gating approach to address the Proof of Concept experiment stage and the valley of death.

In Australia, we currently have some government funded commercialisation programs, but these are fragmented, each supporting only one part of the research and development pathway. For example, an NHMRC Ideas Grant may progress research to a particular point, but not typically fund the Proof of Concept experiment. This experiment may be able to be funded through an NHMRC Development Grant but requires a fresh application through the NHMRC's annual funding calendar; any successful application will be funded some 18 months later.

We need to streamline this current collection of separate grants and create a single process, where the ultimate objective of developing a new product is identified at the outset, and where progress towards this objective is better planned for and evaluated at each stage, with progress to the next stage and funding assured if the appropriate requirements (scientific and commercial) have been met. Doing this requires a new mindset, changes to what is funded, and when. It can be a suitable use of stage-gating.

The underlying idea behind stage-gating is that there is a clearly defined outcome being worked towards, with clear criteria for success against which progress can be measured at key stages. This idea of clear, outcome focused research needs to be explored more as does the question of how research is identified as suitable for such a commercialisation scheme. What is the selection process? Does the researcher or institution self-identify? If not, how are industry partners made aware of the research? Or does the research originate with an idea from a non-research partner? The 1500-word limit on responses does not allow these questions to be explored sufficiently here, but Research Australia has looked at the question of measurement closely in the context of the MRFF and is happy to advise the Department on both research impact and return on investment models to measure success

Stage-gating can be 'fast fail' but only if the process is well managed and is resource intensive as it necessitates continual monitoring and assessment of progress. This is very different to the existing typical Australian grant administration processes.

A co-investment approach such as that adopted in the Biomedical Translation Fund, where management of the individual commercialisation projects is devolved by professional investment managers, may help provide the necessary rigor to the process.⁶ The BTF is best characterised as late-stage venture capital investment, well beyond the Proof of Concept stage, but there is an opportunity to introduce similar models at earlier stages of the commercialisation and investment cycle.

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⁶ https://www.business.gov.au/grants-and-programs/biomedical-translation-fund

3. Incentives for participation

- a) What broader incentives influencing the business and university sectors may influence their participation in a Scheme?
- b) What would motivate businesses, universities or private investors to invest in this Scheme?
- c) Aside from co-funding, should universities or businesses have any additional requirements for participation?

If commercialisation is the objective of the research, and the reason a project has been included in the Scheme, then it is reasonable to expect commercial incentives to outweigh publication incentives. The real question is at what point is the potential for commercialisation realised and the commercialisation pathway chosen? Who makes the decision about this and who has input? It is important these questions are addressed at an appropriately early stage; to ensure for example, that publication of findings does not jeopardise the future assertion of intellectual property rights.

Missing from 3b) above is consideration of what incentives would motivate the individual researcher to participate. Factors include the support and training provided to the researcher to help them pursue commercialisation as well as appropriate recognition in terms of (academic) career progression. This can include providing recognised leave from a university for a period of time to purse commercialisation. (Not all researchers will want to do to this; some will be happy to hand over the commercialisation of findings to others and return to the pursuit of new knowledge.)

In relation to co-funding, the key question is when it becomes appropriate. Co-funding is raised in the context of 'de-risking'. The Biomedical Translation Fund provides a co-investment model in which the Government tips the risk/reward ratio in favour of the other investors as a way of incentivising and de-risking their participation.⁷

De-risking of research can also be achieved by providing Government funding for research until it is at a later stage of development- for example the 'Proof of Concept' experiment referred to earlier. It can also occur through the provision of appropriate support and expertise to researchers through well-resourced technology transfer offices.

When considering incentives, it is important to recognise that engagement can be initiated in both directions. There can be a product idea that originates with a researcher, who needs assistance with commercialisation and development; and there are ideas and concepts that originate outside universities where the entrepreneur needs the input of researchers to develop the product. These are two very different paths and need different incentives and approaches. What are the incentives for a researcher to undertake research at the behest of an external business?

The Fraunhofer model provides one exemplar for engagement; universities, with support from governments, undertake applied research on behalf of industry customers through a number of cross disciplinary and multi university groupings around particular industries and themes, for example molecular biology and materials recycling.⁸

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⁷ Programme Guidelines, Biomedical Translation Fund, 3 August 2016 Clause 8.10 Terms and Distributions, give non-Government investors a disproportionately high share of investment returns; at https://www.business.gov.au/grants-and-programs/biomedical-translation-fund#investee-companies

⁸ <u>https://www.fraunhofer.de/en/institutes.html</u>

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4. Industry-university collaboration

- a) How may the Scheme incentivise or support better industry-university collaboration?
- b) Would an Industry PhD program help improve collaboration outcomes?
- c) Are there skills gaps in academia or business that inhibit collaboration or commercialisation?
- d) How can we increase collaboration between university researchers and industry, particularly amongst SMEs?

Creating the right environment for industry-university collaboration requires not only the incentives addressed in the preceding section but consideration of the capacity building needed to address a lack of commercialisation skills in both the research sector and in businesses (especially SMEs). These are skills in areas as diverse as product design, market validation and IP strategy, for example. In the HMR context, work undertaken by Research Australia and others for MTP Connect as part of the MRFF funded REDI Program has identified many of these gaps. MTP Connect must now prioritise which gaps the REDI Program will seek to address and how. In the context of the University Research Commercialisation Scheme, identifying and addressing capacity gaps need to be considered, and could build on the work undertaken for the REDI program to extend it to other sectors.

Anecdotally at least, negotiating commercial agreements between researchers, research institutions and industry remains a significant barrier, with conflicting views on how early stage research findings should be valued and rewarded. There are many resources and varied guidance available to researchers on this topic. Previous attempts to develop 'standard' agreements appear to have failed but may be worth revisiting, perhaps starting with those agreements used by successful partnerships. Government funding programs for research with prospects for commercialisation could provide policies and/or requirements on how future research is to be commercialised and future potential profits shared.

All the questions posed in this section of the Consultation paper need to be considered in the context of what currently exists. Some of the answers may involve existing programs; reference has already been made to NHMRC Development Grants and the REDI Program, but there are others like the MRFF Funded Biomedical Translation Bridge Program, the BioMedTech Horizons Program (also MRFF funded) and the NSW Government funded Medical Devices Program which are worthy of consideration. The Industry PhD program is raised regularly and could be trialed in Australia.

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⁹ https://www.mtpconnect.org.au/reports/redi-skills-gap

¹⁰ See for example https://www.nhmrc.gov.au/about-us/resources/innovation/how-what-when-and-why-commercialisation

¹¹ https://www.mtpconnect.org.au/programs/biomedicaltranslationbridgeprogram

¹² https://www.medicalresearch.nsw.gov.au/medical-devices-fund/

5. Governance arrangements

- a) What stakeholders should be involved, and where, in the governance arrangement?
- b) What type of governance arrangement is best suited for the Scheme?
- c) How should projects be selected and managed?
- d) How can the governance arrangement minimise administrative burden whilst also minimising risk?

Australian Government representation needs to include multiple Government Departments and at least one agency: Industry, Innovation and Science Australia. Representation from at least some state and territory governments, to promote alignment with their various programs and initiatives would also be useful, e.g. NSW Medical Devices Fund and the Breakthrough Victoria Fund.

Representation from universities is also necessary, and Research Australia supports including medical research institutes and other non-profit research organisations that are closely aligned with, and work with, universities. Research Australia is uniquely able to represent universities, medical research institutes, NFPs and health innovators and we would be pleased to play a role in any selection/steering committee formed for the purposes of this Scheme.

Business representation needs to come from large and small industry representative bodies, and from the investment sector.

It is difficult to consider Governance arrangements or how projects should be selected or managed in greater detail at this stage when the structure and size of the Scheme is not clear. Research Australia has provided examples of several existing programs and initiatives with different governance arrangements and selection processes which could form partial models for the University Research Commercialisation Scheme

Conclusion

Research Australia's response to the Consultation Paper has been necessarily brief, in accordance with the request to limit submissions to 1500 words. We would be very pleased to elaborate further on any of the responses we have provided and/or to provide further information to this important consultation.

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