Joint Response to the HERC IP Framework Consultation

Introduction

Research Australia, Medicines Australia, the Medical Technology Association of Australia (MTAA) and AusBiotech welcome the opportunity to respond to the HERC IP Framework Consultation paper. Together, we represent a significant proportion of the health R&D sector and consider it positive that the Department has identified barriers to negotiating and executing commercialisation agreements between universities and business.

However, while we believe the development of a standard IP Framework could be of great assistance to all parties in reaching agreement on commercialisation arrangements, this is an incredibly complex area that requires careful and in-depth consultation. The consultation launched on 20 September 2021 contains 17 questions but only allows submissions to be a maximum of 1500 words in total. This limited word count does not allow stakeholders to provide the detailed comments that are justified given the importance of the consultation.

We strongly encourage the Department to extend the consultation process and organise a series of sector-specific workshops to allow all stakeholders to explore the potential issues of a standard IP Framework in detail.

Apart from the need to conduct an in-depth consultation, the major issue of concern with the Framework relates to the proposal to make use of the IP Framework mandatory in many circumstances. We do not believe this is warranted for the reasons outlined below.

The IP Framework should be voluntary

As with any policy measure, making the IP Framework mandatory should be a last resort. It should only occur where there is evidence that the same outcome cannot be achieved through less onerous means, such as voluntary participation.
The Australian Government Office for Best Practice Regulation outlines a seven step approach for use in developing regulation and assessing its impact, which is broadly in line with theories of regulatory policy development.[1] Among other things it seeks to ensure that any regulatory response is effective and proportional.

The IP Framework proposed by the Department appears to meet Step 1: *Clearly identify and define the problem you are trying to solve*; and Step 2: *Clearly identify why there is a legitimate reason for government to intervene.*

Step 3 is *Identify a range of genuine and viable alternative policy options*. Step 4 is *Identify who is likely to be affected by each regulatory option and assess the economic, social and environmental costs and benefits.* It is not apparent from the Discussion Paper that alternatives to making the IP Framework mandatory have been considered, or that an assessment of the relative costs and benefits of alternative approaches has been undertaken. In the absence of these steps being satisfied, use of the IP Framework should not be mandated.

Mandatory contracts may well deter some large businesses and SMEs, despite the intention to the contrary. The mandatory nature of the contracts is likely to make some people suspicious of the Framework, and/or they may be provided with legal advice against using the Framework. Large and multinational companies are likely to have their own global standard agreements and terms they prefer to use, particularly for lower value investments and transactions. These factors will prevent engagement between universities and businesses in some circumstances. We are unable to quantify this risk, but a voluntary approach to the use of the IP Framework would allow the acceptability of the IP Framework to be assessed (particularly if the proposed pilot is adopted as outlined below).

It appears from the discussion paper that making the Framework mandatory requires legislation. This adds another layer of complexity to the Framework's introduction, and the potential for delay, reducing the Framework's potential benefit.

Making parts of the IP Framework mandatory complicates the introduction of the Framework, with a complex timetable for its introduction and phasing out of existing agreements. This complexity, and the requirement to manage and comply with the timetable, imposes a regulatory compliance burden on universities and the Department and/or the Australian Research Council. (Refer to Step 4 of the OBPR's *7 steps*.)

The Discussion paper proposes restricting the use of the IP Framework to particular organisations initially, and only making it more broadly available at a later date.

> 'It is intended that, over time, the HERC IP Framework will also be available for research grants and contracted research being conducted by businesses, particularly SMEs who may lack access to suitable agreements.' (page 11)

[1] https://obpr.pmc.gov.au/resources/guidance-impact-analysis/7-ris-questions

This has the potential to prevent parties that could benefit from using part or all of the Framework from the doing so until some future date. Making use of the IP Framework immediately available to all who might wish to use it avoids this risk.

Making the Framework mandatory has the very real potential to stifle innovation in Australia, in the types of commercial agreements that can be reached and even in the format the contracts can take. It will also make it more difficult to adapt the Framework to accommodate new innovation and approaches in IP Framework development, commercial negotiation, dispute resolution and contract execution.

Where one of the parties is an international organisation, there may be a preference to adopt an international jurisdiction for the agreement. It is unlikely the Framework will be able to accommodate these situations. (The UK's Lambert toolkit, an exemplar of a beneficial kit, is only for use where English law applies.)

We note that mandatory models are the exception rather than the rule where similar programs have been implemented elsewhere around the world. We expect that many of the issues raised by us here are the reason for this.

Our proposal

Research Australia, Medicines Australia, MTAA and AusBiotech propose that rather than making the IP Framework mandatory it should be made available without restriction for all entities to use from the date of its release.

We also propose that the Department invite participation in a formal pilot of the IP Framework to collect information about the performance of the Framework in its first few years. This will involve participants providing information and feedback about the IP Framework and the experience with using different elements of it. Critically, this could include providing feedback on the circumstances in which all or parts of the IP Framework are not used and the reasons for this. This will enable a comparison of the performance of the IP Framework to be made against 'business as usual'.

The pilot would involve participants providing the Department and/or the Australian Research Council with information about utilisation of the IP Framework including:

- which parts of it were used,
- the length of time and cost associated with using the various parts and stages of the Framework, and
- reasons for not using parts of the Framework in some circumstances, and which party did not wish to use part/s of the Framework.

Similar data could be collected on a group of commercialisation agreements made without the IP Framework.

This pilot could be used to evaluate the relative effectiveness of the IP Framework in meeting its stated objectives of:

- 'Cutting complexity and transaction times/costs

- Providing an easier entry point for negotiations - particularly important for SMEs, individual researchers and startups
- Promoting best practice.' (page 8)

It would provide a strong evidence base from which to alter the IP Framework and collect information on the effectiveness of these changes, supporting its continuous improvement. It would also provide useful information to support measures to further promote the use of the IP Framework, and to identify other measures with might further support the IP Framework. This could include, for example, specific support for SMEs to assist them to engage with universities and negotiate agreements.

Longer term, a permanent register of commercialisation agreements could be kept to support the ongoing evaluation of the effectiveness of the IP Framework.

Research Australia, Medicines Australia, MTAA and AusBiotech would be pleased to work with the Department on the further development and implementation of a pilot of the IP Framework.

Following completion to the pilot, and assuming the IP Framework is retained, it could remain entirely voluntary in most cases but potentially move to an opt out model for certain types of research funding, with the parties required to consider utilising the IP Framework, and document their decision if they choose not to use it. Once again, this would provide information to the Department which could be used to further refine and develop the IP Framework.

About Research Australia

Research Australia is the national peak body for Australian health and medical research (HMR), representing the entire pipeline from the laboratory to patient and the marketplace. Research Australia works to position Australian HMR as a significant driver of a healthy population and a healthy economy.

About Medicines Australia

Medicines Australia is the peak body representing the innovative, research-based, medicines industry in Australia. Our members develop, manufacture and supply critical medicines and vaccines available on the Pharmaceutical Benefits Scheme (PBS) and the National Immunisation Program (NIP). Our membership comprises small, medium and large Australian and multi-national companies.

About the Medical Technology Association of Australia

The Medical Technology Association of Australia (MTAA) is the national association representing companies in the medical technology industry. MTAA aims to ensure the benefits of modern, innovative and reliable medical technology are delivered effectively to provide better health outcomes to the Australian community.

About AusBiotech

AusBiotech is Australia's biotechnology organisation, working on behalf of 3,000 members for more than 35 years to promote the global growth of Australian biotechnology. AusBiotech covers the life sciences, including therapeutics, medical technology (devices and diagnostics), and agricultural biotechnology sectors, as well as the pipeline of development from early research to market.

Contact Person

This submission has been prepared on behalf of the respondents by Greg Mullins, Head of Policy, Research Australia. Any questions or requests for further information should be directed to Greg at greg.mullins@researchaustralia.org