



AAMRI Submission to the Innovation Review

Declaration of interest:

The Association of Australian Medical Research Institutes (AAMRI) represents 36 independent not-for-profit medical research institutes around Australia. AAMRI has an interest in the review of the National Innovation System as it relates to health and medical research. Members of AAMRI are recipients of funding from Australian and State and Territory government programs including the NHMRC, NCRIS, CRC program and the ARC.

Professor Garry Jennings, President

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Introduction

The Association of Australian Medical Research Institutes (AAMRI) represents 36 independent medical research institutes (MRIs) across Australia. The MRIs are independent, not-for-profit organizations, closely affiliated with the health sector and hospitals and higher education and universities. The MRIs employ more than 6000 researchers and support staff, and train more than 1500 post-graduate students each year. They have a combined research income of more than \$350 million per annum, winning most of that from competitive grant funding. About half of this is derived from the NHMRC, and a significant amount is awarded by international funding agencies.

AAMRI members carry out much of Australia's most distinguished and world-renowned health and medical research, in almost every aspect of human health and disease and are major partners in commercialization of Australian biomedical discoveries.

AAMRI is pleased to have the opportunity to contribute to the Australian Government's Innovation Review. We are particularly interested in the opportunity to have a look at innovation across different sectors and our national innovation priorities.

AAMRI believes that the health of our nation needs to be given a high priority for many reasons including that a healthy population provides the best environment for a healthy and productive workforce. An active and vibrant medical research sector provides the best insurance that full value is obtained from the over \$50 billion in government health expenditure each year.

Health as an industry continues to grow and we have increased demands and higher expectations from our health system. Increased life expectancy also comes with an expectation that we will live longer, healthier and more productive lives. Like the submission from Research Australia, AAMRI supports retaining the current national innovation priority: "Promoting good health and well being for all Australians". We also support the associated goals of

- A healthy start to life
- Ageing well, ageing productively
- Preventive healthcare
- Strengthening Australia's social and economic fabric

Health and medical research can play key roles in improving the health of our population and creating new techniques, technologies and improvements in public health and the creation of new discoveries and inventions and the industries that are associated with them.

This review provides the opportunity to have a fresh look at the current systems. Much of our health and medical research funding comes from the NHMRC. This funding is crucial for much of the important work to take place. It is important to note that by and large the current system works very well and has supported the work of the MRIs over a number of years. Australian research is highly regarded and the close linkages with the health system are vital to ensure that our research is informed by our health system and the health status of our population.

Australia has the opportunity to build on its international reputation in health and medical research and remain a global leader.

Australia's health and medical research and innovation systems need to promote the discovery of new ideas, technologies and health care delivery as well as better ways of addressing our health challenges.

The following are nine areas that AAMRI believes can be improved or built on to ensure Australia makes the most of its investment in health and medical research.

1. A national scheme for funding the indirect costs of research:

Current funding allocated via NHMRC and ARC only supports the direct costs of research. There is a gap in the funding for indirect costs of research. This includes buildings and equipment and other 'soft' infrastructure such as IT, licenses, support for international collaborations, costs of technology transfer, support systems for very early stage commercialisation and for capturing and maintaining intellectual property.

MRIs get 20 cents/ dollar of direct NHMRC peer review grant support through the Independent Research Institutes Infrastructure Support Scheme (IRIIS) but receive no infrastructure support for competitive grants from other agencies. This 20 cents/dollar is much less than the real cost and should be increased. This scheme was introduced on the proviso that the state governments also agreed to contribute towards the 'indirect costs' of research and that their funding level was maintained. This has not been the case in recent times. Such funding from state governments varies considerably and again both equity and 'value for money' arguments support a uniform national system.

AAMRI supports the proposals put forward in the Baker IDI submission and the following is an extract from that submission:

Internationally, there is no perfect model for reimbursement of indirect research costs. However, the US system which has evolved over the past half century is based on the principle that indirect research costs are fully reimbursed by the Federal Government through the A-21 Directive process¹ Funding formulas designed to support the underlying research infrastructure (indirect) costs of work funded by research grants are negotiated with federal agencies and are as high as 70% for some institutions. In most instances funding still falls below the true indirect costs of research,³ however the level of reimbursement in the US is still far greater than that currently achieved in Australia, where funding shortfalls inevitably lead to a steady erosion of research capabilities.

While imperfect, the US A-21 Directive process does provide transparency and would provide a useful model. The Australian solution should draw on this model to create a unified national infrastructure system which is less divisive and more collaborative,

¹ May RM, Sarson SC. Revealing the hidden costs of research. *Nature*. 2008;398:457-459.

thus better serving the national interest. In the current political landscape Australia is ideally poised to comprehensively address this issue through the Council of Australian Governments (COAG).

Recommendations:

- ***As an interim measure, increase the scope of an IRIISS like scheme to cover all competitive peer review grants from all national and international granting bodies irrespective of research provider***
 - ***Increase the IRIISS like scheme indirect support rate progressively from 20 cents/dollar to 40 cents/dollar***
 - ***Provide government support for appropriate consolidation of commercialisation service provision to ensure the growth of the unique skill base of commercialisation staff and increase commercial productivity from smaller institutions.***
 - ***Negotiate agreement with the states and territories that their infrastructure programs provide a minimum allocation of at least 20 cents/dollar to support direct grant funds from peer review sources***
 - ***Adopt a single 'across government' support scheme for the research sector whereby infrastructure support is 'bundled up' with ARC and NHMRC direct grant funding and provided in the same way to Universities, MRIs and other agencies.***
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2. Promoting national and international collaborations:

Having increased funding for medical research to cover the full costs of research and to cover the indirect costs of research will encourage greater collaboration. This will remove the current disincentives for large collaboration and allow greater scope for national and international collaboration and for this to occur across disciplines.

"On 1 March 2008, Australia officially became the first associate member of the European Molecular Biology Laboratory (EMBL), the leading European life sciences research organization in March 2008

EMBL is supported by 20 member states, has laboratories in Germany, France, Italy and the UK, and a staff of more than 1,400 researchers from 60 nations.

Australia's membership has been made possible by funding through the National Collaborative Research Infrastructure Strategy and financial commitments from the NHMRC, CSIRO, Monash University, The University of Sydney, The University of Queensland and The University of Western Australia".²

While this initiative is to be applauded, a previous opportunity to become a partner in the Human Frontiers Research Organisation took many years before Australia become a partner, thereby significantly limiting the ability of Australian's to contribute to, and more importantly to lead, international research consortia.

² Source the FEAST website (<http://www.feast.org/?article&ID=910>) Written by the Group of Eight.

Recommendation:

- ***Ensure adequate funding remains available to allow for participation in international research consortia that will be to the national advantage.***
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3. Translation of medical research:

Health and medical research contributes to national health and wellbeing in two ways. Firstly it offers the possibility of cheaper and more effective health solutions through prevention and better treatment and diagnosis of the health challenges affecting the community. Secondly, it is a window to the biotechnology industry, one of the most significant and growing industries of the future. Close linkage between health and medical research and health services under the health portfolio are vital for both of these to flourish.

Another issue for discussion here is the erosion of funds from the state health agencies, which is available for research. Such funds used to cover a lot of translational research in hospitals and provided important support for clinicians engaged in translational research. Given the increasing constraints on state health care budgets, and the lack of transparency in earmarking funds for direct patient care versus clinical research, such funds have all but disappeared and this threatens future translational research capacity. Australia has a potentially unique opportunity to be a leader in clinical trials, drug trials, and translational research in general, since we have well trained doctors, patients who are generally not opposed to being involved in research studies and ethical requirements that are rigid and well regarded world-wide, but are not draconian (although they are moving that way). So restoring some of the state health budgets for translational research would be a big step forward and again is an issue that could well be brought up at COAG meetings.

Translational research requires a shared commitment from fundamental researchers, clinicians and policy makers. A research-enabled clinical workforce is an essential conduit to translating research knowledge to better outcomes for Australians. A mechanism to enable and support effective partnerships between researchers, clinicians and policy makers and build the infrastructure required to underpin translation (e.g. data managers, health economists, biostatisticians) is required.

A CASE STUDY - Translation into the clinic of world-class laboratory-based research has made possible early detection of relapse in children with acute lymphoblastic leukaemia. As a direct result of research at Children's Cancer Institute Australia for Medical Research (CCIA), a clinical trial has been established that involves the introduction of intensified therapy for patients with molecular evidence of residual leukaemia, and is changing the clinical management of children in Australia with this disease. Approximately two thirds of all Australian children diagnosed with acute lymphoblastic leukaemia since September 2002 are currently participating in this clinical trial, in which multiple bone marrow samples from each patient on trial are sent to CCIA for molecular testing. The molecular testing paradigm developed by the

Institute now underpins similar clinical trials being undertaken by numerous European paediatric oncology centres.

AAMRI supports the statement from the recent 2020 Summit that as part of Australia's long term national health strategy the role of health research and research translation is vital. Keeping the funding for health and medical research under the auspices of the NHMRC within the health portfolio is critical to achieve this.

Recommendations:

- ***COAG to look at the issue of providing specific funds for clinical research (health service research and health service delivery) via research enabled workforce as the best way to translate knowledge into better health outcomes***

4. Reducing the barriers to commercialisation:

In order for an MRI to be eligible for support through one of the NHMRC or ARC commercial grants, the MRI needs to have an industry partner. Funding is hard to find for proof of concept studies and early stage development as well as the costs associated with intellectual property. The so called "chasm of lost opportunity" for good ideas prevents the translation of discoveries into applications to benefit our health. Currently there is support for commercialization available, however, it is not always obtainable at crucial stages.

Most commercial opportunity development is outside a scientist's core activity, mind-set and skill-set, and therefore takes additional funds and resources to support. An initial step is protection of intellectual property, but this alone is a costly exercise. The dilemma for MRIs is that they are not funded for IP protection and commercialisation yet are pushed, indeed required, to ensure that the machinery is in place to protect and support these things.

Many institutions have sought to overcome the 'early stage' funding gap by establishing pre-seed funds (either in-house or external). The Medical Research Commercialisation Fund Pty Ltd (MRCF) is an example of such a measure. When managed well these funds can support early stage opportunities and ensure greater success in the marketplace. However the use of superannuation funds for high risk investment creates pressure to "de-risk" opportunities and push for more maturity in their investments, away from the early stage context.

All current government schemes for commercial funding support require the formation of a new venture. Yet studies from the US (AUTM Survey), Europe (ASTP Survey) and Australia (DEST Survey) have shown that the vast majority of commercial outcomes are generated by licensing rather than new venture formation. This suggests that innovation would increase if a grant scheme was devised to enable research institutions to compete for funds specifically earmarked for commercialisation. This approach has been used in the UK since 1999 and has been considered highly successful (Third Stream Funding). The UK system has now been running long enough that implementation and operational lessons could be identified and built upon.

In addition to Government funding initiatives targeted at proof-of-concept research, tax incentives that stimulate private investment are also needed. Singapore provides a useful model of this. As mentioned in the Baker IDI submission: Baker IDI discovery research in Singapore is most likely to be translated into practice with positive impacts on health outcomes, sooner than comparable work undertaken in Australia. This is due to the 60% increase in private sector investment in R&D in Singapore between 2002 and 2006, stimulated largely by a 5-year "tax holiday" to overseas companies undertaking R&D in Singapore.³

Recommendations:

- **An Endowment Fund should be considered for medical research commercialization. This could follow a model used in some other countries whereby revenue is returned to the fund if and when a successful invention starts to produce significant revenue (i.e. a HECS type scheme for early stage commercialisation)**
- **Review tax arrangements in relation to early stage commercialisation with a view to making private investment in this sector more attractive to commercial and philanthropic partners.**

5. Ongoing growth in medical research funding is essential:

The health and well being of the Australian population is critical to our success as a nation. Like most advanced economies, the portion of GDP spent on health is increasing, representing around 10%. Australian researchers have led the world in the analysis of the burden of disease⁴ and in examining the avertable risk of disease.⁵ In some areas, no matter how much investment was made in health treatment and prevention, less than half of the burden of disease could be addressed. Thus, without additional health and medical research, we will not have the necessary tools to further reduce the burden of disease.

To continue to have a positive impact on Australia's health and retain Australia's position as a high achiever in the field, growth in funding needs to be incorporated into the funding system. This should be across the board for both the Universities who have many funding challenges and for the independent medical research institutes. Salary support for researchers would benefit from an increase in funding. In order to attract and retain the best researchers there needs to be increased salary support.

³ R&D Credit Coalition. International R&D Tax Incentives <http://www.ibm.com/ibm/governmentalprograms/global-rd-incentives-2008.pdf>, 2008.

⁴ Murray CJL, Lopez AD. The Global Burden of Disease: a comprehensive assessment of mortality and disability from diseases, injuries and risk factors in 1990 and projected to 2020. Cambridge, Mass: Harvard University Press on behalf of the World Health Organization and the World Bank, 1996.

⁵ Andrews G, Issakidis C, Sanderson K, Corry J, Lapsley H. Utilising survey data to inform public policy: comparison of the cost-effectiveness of treatment of ten mental disorders. Br J Psychiatry. 2004 Jun;184:526-33.

Simonella L, Marks G, Sanderson K, Andrews G. Cost-effectiveness of current and optimal treatment for adult asthma. Intern Med J. 2006 Apr;36(4):244-50.

Andrews G, Simonella L, Lapsley H, Sanderson K, March L. Evidence-based medicine is affordable: the cost-effectiveness of current compared with optimal treatment in rheumatoid and osteoarthritis. J Rheumatol. 2006 Apr;33(4):671-80. Epub 2006 Mar 15.

The Research Australia submission proposes a further doubling of the NHMRC funding from 2010-11 to reach a new base of \$1.4 billion by 2014-2015. This would equate to less than 2% of the health budget which makes it a relatively modest investment in this growing area. This would increase Australia's level of funding which is currently at risk of declining relative to the international community.

It is crucial that health and medical research funding remain under the NHMRC and as part of the health portfolio. These close links provide the best opportunity for research to impact on the health system and health care delivery.

Recommendation:

- ***Increase the scale of support for health and medical research to a new base of \$1.4b by 2014-15***
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6. Funding the best research wherever it occurs:

Australia is a world leader in medical research and we need to make the most of our precious investment in research. We should fund the best and brightest researchers irrespective of their institutional affiliation. Funding schemes should be competitive and should result in our top researchers being rewarded and supported to carry out their research.

The Innovation Review provides an opportunity to take a fresh look at the current funding systems. Just as the Universities compete for NHMRC funding (in 2007 they received around two thirds of NHMRC funding), scientists in MRIs should be eligible to compete for ARC funding.

As mentioned above, we recognise that the University sector is in need of more substantial funding across the board. It is also the case however, that MRIs support very productive researchers in terms of publication impact^{6 7} (citations per paper) and discoveries. Currently MRIs do not have access to most ARC managed funding programs such as discovery and industry linkage grants. The work of MRIs in providing innovative research programs would benefit from the ability to compete for these programs. The potential for collaboration with pharmaceutical companies, as well as the biotech and device companies is promoted by the ARC programs and restrictions should be removed.

Recommendation:

- ***To support the best research, wherever it occurs, MRIs and other research organisations should be eligible to apply to all federal funding schemes, including ARC programs.***
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3 Bourke P, Butler L. Mapping Australia's basic research in the medical and health sciences. *Med J Aust.* 1997;167:610-3.

⁷ Thomson Scientific. Thomson Scientific ranks Australian Universities and Research Institutions. <http://scientific.thomson.com/press/2007/8413422/>. Australia; 2007.

7. Strong career structures and attracting the best young minds into research

There must be a focus on positioning Australia as a 'smart country'. This will need a robust and well-supported career path to build research capacity and attract and retain high-calibre researchers and intellectual capital in Australia. AAMRI supports the recommendations in the WEHI submission to this review on education including initiatives to attract and retain the best possible science teachers at primary and secondary level and to encourage and support women in research careers.

A recent survey by the Australian Society for Medical Research (ASMR) showed significant dissatisfaction among the Australian health and medical research workforce. Of particular concern were employment insecurity and the lack of a career structure. As highlighted by the Telethon Institute for Child Health Research (TICHR) in its submission for this review, inadequate salary support has meant that some of their staff are moving into University or private sector positions in Australia or overseas. There is an increasing gap between the salary levels for staff in universities compared to MRIs. Research funding needs to be able to attract and retain the very best people in research and this will pave the way for greater innovation from health and medical research.

Providing ongoing growth in medical research funding, as mentioned earlier, will help as will the provision of adequate indirect research costs support.

Recommendations:

- ***Career development schemes such as the NHMRC Research Fellowship program are critical to providing a skilled and qualified health and medical research workforce to meet the national health challenges.***
- ***Elite schemes such as the Federation Fellowships and Australia Fellowships, designed to attract world leading researchers, and to recapture outstanding expatriate Australians must be retained***
- ***The proposed development of a national mid-career support scheme (Future Fellowships) to support 1,000 of our nations best and brightest, and accessible to researchers, wherever they are based, is welcomed by AAMRI.***

8. Minimising the transactional costs of research:

AAMRI supports a robust regulatory system for research as this best protects the needs of our community and the livelihoods and reputations of our researchers. However, it is worth asking the question: do some of our best minds spend too much of their time dealing with paperwork and fulfilling regulatory requirements rather than engaged in their research. There is an opportunity to have an audit of the various requirements and make an assessment of the time taken for important checks and balances versus research time.

Lengthening the duration of research grants from 3 to 4 or 5 years, and thereby reducing the frequency of grant writing and submitting process would mean that more time was spent researching rather than writing and assessing grants. In addition, this would lead to efficiencies in peer review and administration. At present a scientist must submit a grant renewal at the beginning of the third year of funding, making three year grants effectively operate on a 2 year innovation cycle. This time frame is not sufficient to allow the development and reduction of new discoveries.

Recommendations:

- ***Audit regulatory requirements for researchers with a view to maintain standards but reduce the red tape***
- ***Extend the standard period for research grant support from 3 to 4-5 years to minimise the transactional costs of research***

9. Provide a new Innovation Incentive Scheme:

AAMRI supports the "Innovation Incentive Scheme" as proposed in the submission from the Walter and Eliza Hall Institute of Medical Research (WEHI). These grants could be made available across the board to universities and MRIs for cutting edge research that may not necessarily fit the requirements of other funding programs. As outlined in the WEHI submission, by indexing against the total research income received by the organisation from all competitive sources, government can be assured that such a Scheme will support excellence. The funding index for the Innovation Incentive should be 20% over and above the direct grants. This could replace existing schemes such as the NHMRC Development and Enabling Grants, ARC linkage and equipment grants. This would also save on overhead and administrative costs for these agencies. The funding for each organisation should be for 5 to 7 years (similar to CRC funding), indexed for inflation and continuation should be dependent on innovation performance against agreed criteria. This could include: recruitment of star scientists, especially from outside Australia; establishment of novel programs or technologies; patents and IP licensing; establishment of spin-off companies; development of new therapies, diagnostics or preventative strategies; and clinical trial participation.

This provides a real opportunity for Australia's best minds to be given some scope to pursue some high risk/clever ideas and drive innovation. This would create an environment that would encourage creativity and could include multi-disciplinary approaches, using expensive platform technologies and access to many kinds of expertise.

Recommendations:

- ***Establish a new Innovation Incentive Scheme, worth 20% additional to the direct grants, for 5 to 7 years indexed for inflation (based on the proposal contained in the submission to this review from WEHI)***

Conclusion:

AAMRI believes that greater innovation in health and medical research in Australia will be generated by a well resourced sector that provides an environment for our best minds to flourish and have time to focus on their research.