Issues Paper

Inquiry into Health and Medical Research in South Australia

13 March 2020
About the South Australian Productivity Commission

The Commission provides the South Australian Government with independent advice on facilitating productivity growth, unlocking new economic opportunities, supporting job creation and removing existing regulatory barriers.

The Department of the Premier and Cabinet (DPC) Circular PC046 sets out the objectives and functions of the Commission; how inquiries are referred to the Commission, undertaken and reported on; and how the Commission and public sector agencies work together.

The Commission was established to assist the government to:

- improve the rate of economic growth and the productivity of the South Australian economy in order to achieve higher living standards for South Australians;
- improve the accessibility, efficiency and quality of services delivered or funded by government;
- improve South Australia’s competitiveness for private sector investment;
- reduce the cost of regulation;
- facilitate structural economic changes while minimising the social and economic hardship that may result from those changes;
- take into account the interests of industries, employees, consumers and the community;
- increase employment;
- promote regional development; and
- develop South Australia in a way that is ecologically sustainable.

The Commission is supported by the Office of the South Australian Productivity Commission (OSAPC) which is an attached office of the Department of the Premier and Cabinet. The Chair of the Commission also serves as the Chief Executive of the OSAPC.

For more information on the Commission, including DPC Circular PC046, visit the website at [www.sapc.sa.gov.au](http://www.sapc.sa.gov.au)

Disclosure

The Commissioners have declared to the South Australian Government all personal interests that could have a bearing on current and future work. The Commissioners confirm their belief that they have no personal conflicts in regard to this inquiry.
Terms of reference

SOUTH AUSTRALIAN PRODUCTIVITY COMMISSION INQUIRY INTO HEALTH AND MEDICAL RESEARCH

I, Steven Marshall, Premier, hereby request that the South Australian Productivity Commission (the Commission) undertake an inquiry into health and medical research.

Background

Health and medical research is an important part of South Australia’s healthcare system. It:

- Fosters innovation and improvements in health service delivery that lead to improved health outcomes for the community and provide cost savings to the health system
- Attracts investment and funding to South Australia, with economic reports indicating that annual rates of return from health and medical research can be up to $5 for every $1 spent
- Encourages staff development that promotes high professional standards, which plays a significant role in attracting and retaining medical and other health professional staff.

Health and medical research is a substantial industry. The peak body, Research Australia, estimates that $6.5 billion is spent on health and medical research in Australia each year, accounting for 20 per cent of all Research and Development in Australia. The Association of Australian Medical Research Institutes commissioned research in 2018 that indicated a benefit cost ratio of 3.91.

South Australia has a history of excellence health and medical research. South Australia has been able to secure:

- $48,443,505 in funding through National Health and Medical Research Council (NHMRC) in 2016
- $8,466,735 in grant funding since 2016-17 through the Australian Government’s $20 billion Medical Research Future Fund
- $675,000 from the Australian Government for clinical trials
- The establishment of Health Translation SA in 2015 as part of the Australian Health Research Alliance to improve the health of Australians through collaboration for faster, outcome-driven research.

The South Australian Health and Medical Research Institute (SAHMRI) was established in 2009 in response to the Review of Health and Medical Research in South Australia conducted by Professor John Shine and Alan Young in 2008. The aim of SAHMRI was to increase South Australia’s health and medical research capacity.

In recent years, South Australia’s ability to attract investment in health and medical research has been diminishing, most clearly demonstrated by a declining percentage of NHMRC grants being won by South Australian researchers.

Ten years on from the Shine and Young review and SAHMRI’s establishment, it is timely to evaluate the health and medical research landscape to ensure the effectiveness and competitiveness of South Australia against other jurisdictions.

The Commission is asked to consider and report on the following matters:

1. Assess the performance of health and medical R&D in South Australia, including a comparative analysis of South Australia's share of national grant funding benchmarked against other jurisdictions, with particular reference to how health and medical R&D in South Australia:
   a. Fosters innovation and improvements in health care service delivery that lead to improved health outcomes for the community and provide cost savings to the health system
   b. Encourages staff development that promotes high professional standards and supports recruitment and retention.

2. Identify and assess the key factors influencing the level of public sector (including universities) and private sector health and medical research output and activity in South Australia including:
   a. Talent and the capacity to attract new talent
   b. Industry structure and composition
   c. Funding, including Australian government funding
   d. Access to data: regulation affecting access to data; and efficiency of collection and acquisition
   e. Connectivity of the Biomedical Precinct and the planned Flinders precinct
   f. Potential for greater connectivity between the Local Health Network medical workforce and university recruitment
   g. Integration of research partners with SA Health.

3. Identify and assess existing collaboration on health and medical research between research organisations (public and private) and linkages between organisations and industry. Identify innovative collaboration models to drive R&D.

4. Identify and assess opportunities for increased commercialisation of health and medical research in South Australia

5. Identify and assess measures of the productivity and impact of research activity (including by key areas of research), South Australia's share of national funding programs such as the Medical Research Future Fund, and the performance of publicly funded research institutions in South Australia compared to other jurisdictions, including overseas.

6. Identify and assess the characteristics of South Australia and its population that may give rise to areas of competitive advantage compared to other jurisdictions in health and medical R&D, and identify methods of maximising these opportunities.

7. Identify industry needs and current barriers to undertaking health and medical R&D in South Australia and identify models to facilitate industry health and medical R&D in South Australia.

8. Recommend action that the South Australian Government might take to:
   a. Increase the state's share of Australian Government funding for health and medical R&D
   b. Increase the scale and productivity of publicly funded and public health and medical research institution R&D as well as private sector R&D
c. Increase the impact of health and medical R&D activity in South Australia on the state's economic growth.

9. Recommend changes to the structure, governance and operation of publicly funded health and medical research and development to increase research output, productivity and translational impact.

Scope

In its consideration of the above matters, the Commission is expected to have regard to the South Australian Government's Growth SIate initiative and relevant state and national policies.

Note the Department for Health and Wellbeing is implementing recommendations of the 2018 Birch Review to improve SA Health governance and support for clinical trials.

Inquiry Process

The Commission will consult with the SA Chief Scientist, SA agencies, universities, research institutions, industry, relevant peak bodies and other key stakeholders during the inquiry.

The Commission may second and/or engage staff with required analytical expertise and knowledge of health and medical research for the period of the inquiry.

The Commission is to issue an issues paper at the beginning of the inquiry process and to issue a draft report containing recommendations for consultative purposes. A final report is to be provided to me as soon as possible, but not later than eight months after receipt of these terms of reference.

Hon Steven Marshall MP
PREMIER OF SOUTH AUSTRALIA
2/12/2020
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# Acronyms

<table>
<thead>
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<th>Acronym</th>
<th>Full Form</th>
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<tbody>
<tr>
<td>AAMRI</td>
<td>Association of Australian Medical Research Institutes</td>
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<tr>
<td>ABS</td>
<td>Australian Bureau of Statistics</td>
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<td>ACNC</td>
<td>Australian Charities and Not-for-Profits Commission</td>
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<td>AIHW</td>
<td>Australian Institute of Health and Welfare</td>
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<tr>
<td>AHRA</td>
<td>Australian Health Research Alliance</td>
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<tr>
<td>AMRAB</td>
<td>Australian Medical Research Advisory Board</td>
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<tr>
<td>ANZCTR</td>
<td>Australian New Zealand Clinical Trials Register</td>
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<tr>
<td>ARC</td>
<td>Australian Research Council</td>
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<tr>
<td>ASMR</td>
<td>Australian Society for Medical Research</td>
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<tr>
<td>BHI</td>
<td>Basil Hetzel Institute for Translational Health Research</td>
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<tr>
<td>BTF</td>
<td>Biomedical Translation Fund</td>
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<tr>
<td>CCB</td>
<td>Centre for Cancer Biology</td>
</tr>
<tr>
<td>CALHN</td>
<td>Central Adelaide Local Health Network</td>
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<tr>
<td>CEIH</td>
<td>Commission on Excellence and Innovation in Health</td>
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<tr>
<td>CSIRO</td>
<td>Commonwealth Scientific and Industrial Research Organisation</td>
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<tr>
<td>CTN</td>
<td>Clinical Trial Notification</td>
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<tr>
<td>CTX</td>
<td>Clinical Trial Exemption</td>
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<tr>
<td>DESE</td>
<td>Department of Education, Skills and Employment</td>
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<td>DHW</td>
<td>Department of Health and Wellbeing</td>
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<tr>
<td>FIXE</td>
<td>Future Industries Exchange for Entrepreneurship</td>
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<tr>
<td>HERD</td>
<td>Higher Education Expenditure on Research and Development</td>
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<td>HREC</td>
<td>Health Research Ethics Committee</td>
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<td>HMR</td>
<td>Health and Medical Research</td>
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<tr>
<td>iMRI</td>
<td>independent Medical Research Institutes</td>
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<tr>
<td>MRCF</td>
<td>Medical Research Commercialisation Fund</td>
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<tr>
<td>MRFF</td>
<td>Medical Research Future Fund</td>
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<tr>
<td>NCRIS</td>
<td>National Collaborative Research Infrastructure Strategy</td>
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<td>NHMRC</td>
<td>National Health and Medical Research Council</td>
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<tr>
<td>NALHN</td>
<td>Northern Adelaide Local Health Network</td>
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<tr>
<td>NISA</td>
<td>National Innovation and Science Agenda</td>
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<tr>
<td>RCSF</td>
<td>Research Commercialisation and Startup Fund</td>
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<td>SAHMRI</td>
<td>South Australian Health and Medical Research Institute</td>
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<tr>
<td>SALHN</td>
<td>Southern Adelaide Local Health Network</td>
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<tr>
<td>SAVCF</td>
<td>South Australian Venture Capital Fund</td>
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<td>SRI</td>
<td>Science Research and Innovation</td>
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<tr>
<td>TGA</td>
<td>Therapeutic Goods Administration</td>
</tr>
<tr>
<td>UniSACRI</td>
<td>University of South Australia Cancer Research Institute</td>
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<tr>
<td>WCHN</td>
<td>Women’s and Children’s Health Network</td>
</tr>
</tbody>
</table>
1. Introduction

1.1 Purpose of inquiry

Health and medical research (HMR) and innovation can make important contributions to the productivity of health care and public health outcomes while creating jobs and new industries and bringing broader economic benefits to the state.

In recent years, South Australia’s ability to attract funding in HMR has been diminishing. This is demonstrated by a declining percentage of National Health and Medical Research Council (NHMRC) grants being won by South Australian researchers.

The South Australian Productivity Commission (the Commission) has been asked to identify and assess factors that have affected the state’s capacity to secure funding and identify opportunities to improve South Australia’s capability to attract investment in HMR.

In doing so, the Commission will assess the productivity and impact of HMR, the performance of publicly funded research organisations and South Australia’s competitive advantages compared to other jurisdictions, having regard to the South Australian Government’s Growth State initiative.

The Commission has also been asked to recommend action that the South Australian Government might take to increase research output, productivity and translational impact, including changes to the structure, governance and operation of publicly funded HMR and development.

1.2 Commission’s approach

The Commission is required to take a broad perspective in developing advice for the South Australian Government. It must consider the interests of industry, business, consumers and the community, regional South Australia, social-economic implications and ecological sustainability.

The Commission conducts its own independent quantitative and qualitative analysis. It also draws on the experience, evidence and views of all inquiry stakeholders.

The release of this issues paper supports interested parties to participate in the inquiry by highlighting the key issues and by raising questions to generate feedback.

It is important to emphasise that the Commission has no predetermined views on the matters covered by the inquiry. This issues paper sets out the Commission’s initial understanding of the relevant matters. Feedback from stakeholders will assist further analysis and review that will contribute to the development of a draft report.

1.3 Inquiry process

Make a submission

The Commission invites submissions on the issues paper by 8 May 2020. Submissions may address any of the issues covered by the paper and the terms of reference.
An electronic submission in Word or PDF format is preferred, along with any supporting documentation containing facts, figures, data or examples:

- through our website facility www.sapc.sa.gov.au; or
- via email at sapc@sa.gov.au; or
- via post at: South Australian Productivity Commission GPO Box 2343, ADELAIDE SA 5001

If you would like to discuss how best to communicate with the Commission, the Office of the SAPC can be contacted at 08 8226 7828.

A draft report will be published in July 2020. The draft report will be the start of a further round of consultation with stakeholders, following which the Commission will consider all feedback received, finalise its views, and submit its final report and recommendations to the Premier by 6 October 2020. The Commission is required to publish the report within 90 days of providing it to the Premier.

**Confidentiality**

Transparency is an important part of the Commission’s independent process for gathering evidence and other elements of the inquiry process. It provides confidence to stakeholders that their views have been heard and accurately shows to the wider public the breadth of views and information that have been put to the Commission in reaching its independent conclusions and recommendations. To that end the Commission will publish the submissions that it receives on its website unless the author clearly indicates that the submission is confidential or the Commission considers the material to be offensive, potentially defamatory, beyond the scope of the inquiry’s terms of reference, or an abuse of process.

If you wish to submit material in confidence, please advise us why your submission should remain confidential and we will contact you to discuss. We reserve the right to decline your submission if we do not agree with the rationale provided for it to be confidential. Material accepted as confidential will be read only by our Commissioners and staff and will not be referred to in our reports. Later, if we consider the confidential information to be important for conclusions drawn by the Commission, we will seek your permission to refer to it in a form that is acceptable to you.

Confidential submissions may be subject to the *Freedom of Information Act 1991* that provides applicants the right, subject to some restrictions, to access documents created and held by the government.

Avoid the use of personal or identifying information in submissions, e.g. contact details or names of people referred to in submissions. The Commission will try to ensure that all personal contact details are removed from submissions before they are published on our website.

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**Key dates**

- **6 February 2020**
  Notice of inquiry
- **13 March 2020**
  Issues paper published
- **March/June**
  Initial public consultation
- **8 May 2020**
  Submissions to issues paper due
- **July 2020**
  Draft report published
- **July/September**
  Draft report public consultation
- **4 September 2020**
  Submissions due on draft report
- **6 October 2020**
  Final report presented to the Premier
- **6 January 2021**
  Due date to be available to the public
2. Overview of health and medical research in South Australia

2.1 Background

Provision of world class, economically sustainable health care in South Australia (SA) faces challenges that arise from multiple factors, including an ageing population as well as new lifestyle and technological demands.

The 2019 Joyce report argued that population ageing and rising income levels will continue to generate substantial growth in demand for health and medical goods and services nationally and globally.

Health and medical research (HMR) is a substantial industry. The peak body, Research Australia\(^1\), estimates that $6.5 billion is spent on health and medical research in Australia each year, accounting for 20 per cent of all research and development in Australia. The Association of Australian Medical Research Institutes (AAMRI) commissioned research in 2018 indicated that each $1 invested in HMR leads to a $3.9 return in health benefits\(^2\).

High quality research and development is an essential component of the South Australian Government’s health policy mission:

> an active research culture across our health system is vital to supporting innovation, attracting high quality clinical and medical staff, and delivering strong population health, social and economic benefits for South Australia.\(^3\)

2.2 HMR industry

Health and medical industries bring together research, education, clinical care and production of other health and medical goods and services. Some of the key participants are listed in Table 2.1

<table>
<thead>
<tr>
<th>Australian Government</th>
<th>State Government</th>
<th>Universities</th>
<th>Independent Research Institutes</th>
<th>Private Sector</th>
<th>Precincts</th>
</tr>
</thead>
<tbody>
<tr>
<td>National Health and Medical Research Council</td>
<td>SA Health • Department of Health &amp; Wellbeing • CALHN • NALHN • WCHN • Regional LHNs • Commission on Excellence and Innovation in Health</td>
<td>The University of Adelaide University of South Australia Flinders University</td>
<td>South Australian Health and Medical Research Institute</td>
<td>CMAX Bellberry Pty Ltd Advance Clinical Syneos Health Medical device companies Pharmaceutical companies Biotechnical Companies Private Hospitals</td>
<td>Adelaide BioMed city Tonsley Innovation District Lot 14</td>
</tr>
<tr>
<td>Australian Medical Research Advisory Board</td>
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<tr>
<td>Therapeutic Goods Administration</td>
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<tr>
<td>Health Translation SA</td>
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</tbody>
</table>

\(^1\) [https://researchaustralia.org/category/hmr-facts/]
2.3 Relative performance of South Australia

South Australia is falling behind in its ability to attract funding for health and medical research (see Table 2.2). This is despite the state improving its performance relative to the Australian average in other areas, including medical exports and growth in the number of clinical trials.

Table 2.2. Relative performance of South Australian HMR.4

<table>
<thead>
<tr>
<th>Topic</th>
<th>South Australian Performance</th>
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</thead>
<tbody>
<tr>
<td>Research funding NHMRC MRFF</td>
<td>Australian Government NHMRC funding to SA for HMR has grown from $18.3m in 2000 to $57m in 2018, but the state’s share of national NHMRC expenditure has fallen from 10.9% to 6.6% over this period. As at September 2019, SA had received 3% of national MRFF funding.</td>
</tr>
<tr>
<td>R &amp; D ABS 8111.0</td>
<td>Higher education expenditure on R&amp;D (HERD) in medical and health sciences was $240m in 2016. While its importance to SA has grown, accounting for 34% of state HERD, SA’s share of national HERD activity has steadily fallen over the last 30 years to 7.8% in 2016.</td>
</tr>
<tr>
<td>Higher education staff DESE</td>
<td>The number of health and medical teaching and research staff at SA’s universities has risen from 472 in 2001 to 876 in 2017. SA’s share of national staff has remained steady over this period at just under 12%.</td>
</tr>
<tr>
<td>Postgraduates DESE</td>
<td>From 2001 to 2013 SA’s share of national postgraduate enrolments in health and medical fields was between 10% and 12%. This share has fallen from a peak of 11.7% in 2013 to 9.7% in 2018.</td>
</tr>
<tr>
<td>Overseas students DESE</td>
<td>SA’s share of overseas student enrolments in health and medical fields in Australian universities peaked at 11.5% in 2006 but has declined since to 10.1% in 2018.</td>
</tr>
<tr>
<td>Clinical trials ANZCTR</td>
<td>The number of registered clinical trials in SA has increased from 180 in 2015 to 313 in 2018. The state’s share of clinical trials registered nationally has also risen over this period from 13.1% to 15.2%.</td>
</tr>
<tr>
<td>Exports ABS 5368.0</td>
<td>SA exported $80.4m of pharmaceutical products in 2018-19. This accounted for 1.4% of national pharmaceutical exports, compared to 1.7% in 2008-09. SA exported $70.4m of medical device products in 2018-19. SA’s share of national medical device exports remained constant at 3.9% from 2008-19.</td>
</tr>
</tbody>
</table>

4 The snapshot of South Australia’s HMR activity presented in Table 2.2 is constrained by data limitations. Further details are available in appendix 1.
3. Policy environment

3.1 Background

Health and medical research (HMR) in Australia is subject to a range of legislative, regulatory, ethical and policy requirements. The HMR sector in Australia is not led or actively regulated by a single agency at the national level.\(^5\)

Approval and governance responsibilities in relation to HMR are shared between the government and non-government sectors, including universities, medical research institutes and public sector health organisations. Agencies of the Australian Government and the governments of the states and territories, including state health departments, also exercise responsibilities in relation to HMR. The dispersion of responsibilities in the sector is partly a reflection of the fact that research and public health institutions are ultimately legally accountable for HMR conducted under their auspices.

3.2 National Health and Medical Research Council

The National Health and Medical Research Council (NHMRC) is the Australian Government’s peak expert body in health and medical research. Under the National Health and Medical Research Council Act 1992 (the NHMRC Act), the NHMRC is also solely responsible for administering the Australian Government’s grants program for HMR, with the agency overseeing the distribution of approximately $889 million in grant funding in 2018-19.\(^6\)

The NHMRC’s legislation does not establish it as a national regulator, but its constituting statute requires it to issue guidelines on matters related to the conduct of HMR in Australia. One of the most significant of these guidelines is the National Statement on Ethical Conduct in Human Research (the national statement).\(^7\)

The national statement addresses a range of ethical and procedural issues that are likely to confront institutions undertaking HMR. The NHMRC Act makes clear that the national statement is not a legislative instrument, but is intended to create a nationally-consistent ethical framework for the conduct of HMR.

One of its most significant functions is to set out the formation, membership and responsibilities of Human Research Ethics Committees (HRECs), which all research institutions active in human research are required to establish and maintain (either individually or in collaboration with another institution).\(^8\) The national statement requires that HRECs exercise primary responsibility for reviewing and approving HMR projects that involve human research, including clinical trials involving unapproved therapeutic goods.\(^9\) HRECs also exercise significant functions in relation to the monitoring and governance of HMR, on the basis of guidelines outlined in the Australian Code for the Responsible Conduct

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\(^8\) The full list of registered HRECs, including those operating in South Australia, is available from the NHMRC, <https://www.nhmrc.gov.au/sites/default/files/documents/attachments/publications/human-research-ethics-committees-registered.pdf>

\(^9\) See, in particular, the national statement, sections 3.4 and 5.
of Research 2018.\textsuperscript{10} In practice, the fact that HRECs have primary responsibility for the approval and monitoring of HMR has effectively devolved regulatory responsibility to the institutional level.

The NHMRC also takes a leading role in reviewing the processes that apply to scientific and ethics approval, including in relation to reducing regulatory burden. One of the most significant recent reforms involved the implementation of the ‘National Mutual Acceptance’ (NMA) scheme for scientific and ethical review. This scheme enables an approval granted by a participating institution to be applied at other institutions participating in the same HMR project, including institutions in different jurisdictions.\textsuperscript{11}

### 3.3 Legislation

The type and stage of any proposed research will have a considerable effect on the legal obligations that institutions and researchers are required to meet.

HMR conducted in South Australia is subject to provisions contained in a range of state acts, including, but not limited to, the \textit{Mental Health Act 2009} (SA); the \textit{South Australian Health Care Act 2008} (SA); the \textit{Controlled Substances Act 1984}; the \textit{Transplantation and Anatomy Act 1993} (SA); the \textit{Assisted Reproduction Treatment Act 1988}; and the \textit{Radiation Protection and Control Act 1982}.\textsuperscript{12}

HMR research that has advanced to the clinical trial stage is subject to provisions contained in the \textit{Therapeutic Goods Act 1989} (Cth), principally in relation to obtaining approval from the Therapeutic Goods Administration (TGA) to make use of unapproved therapeutic goods or devices. Approval is provided under either the Clinical Trial Notification (CTN) scheme or the Clinical Trial Exemption (CTX) scheme, both of which are administered by the TGA.\textsuperscript{13}

All HMR involving animals falls under state and territory legislation. In South Australia, the use of animals in research is regulated under the \textit{Animal Welfare Act 1985} (SA). The conduct of HMR is also subject to common law obligations, such as an institution’s duty of care to research participants.

South Australia’s three public universities are all incorporated under state legislation, with their respective constituting statutes specifying many of their functions and governance arrangements. The South Australian Health and Medical Research Institute (SAHMRI) is incorporated as a company limited by guarantee, pursuant to the \textit{Corporations Act 2001} (Cth). As a registered charity, SAHMRI is regulated by the Australian Charities and Not-for-Profits Commission (ACNC). Its current governance arrangements are outlined in its constitution.\textsuperscript{14}

### 3.4 Australian Government policy

Since December 2015 with the launch of the \textit{National Innovation and Science Agenda} (NISA), the Australian Government’s policy and funding priorities in the overlapping areas of

\textsuperscript{10} For further details, see Australian Code for the Responsible Conduct of Research 2018, <https://www.nhmrc.gov.au/about-us/publications/australian-code-responsible-conduct-research-2018>. The Australian Code was jointly developed by the NHMRC, the ARC and Universities Australia.

\textsuperscript{11} For additional information about the NMA, see <https://www.nhmrc.gov.au/research-policy/ethics/national-certification-scheme-ethics-review-multi-centre-research>

\textsuperscript{12} Australian legislation with a potential bearing on HMR includes the Privacy Act 1988 (Cth), especially in relation to the disclosure of identifiable health-related data, or legislation on research involving human embryos, particularly the \textit{Research Involving Human Embryos Act 2002} (Cth) and its state and territory equivalents. Other pertinent Australian legislation includes the Patents Act 1990 (Cth); the Trade Marks Act 1995 (Cth); the Foreign Acquisitions and Takeovers Act 1975 (Cth); the Migration Act 1958 (Cth); and the Venture Capital Act 2002 (Cth).

\textsuperscript{13} For further details on both the CTN and CTX schemes, see <https://www.tga.gov.au/clinical-trials>

\textsuperscript{14} For details of SAHMRI’s constitution, see <https://www.acnc.gov.au/charity/97d42a631462673d500bb7fc93d5ee8c#financials-documents>
research, development and innovation have been guided by the goal of harnessing research, science and innovation as drivers of economic growth.

The NISA establishes four key ‘pillars’ that support thirty initiatives funded by the Australian Government. These include the Global Innovation Strategy, which seeks to increase Australia's science, research and innovation connections internationally, and Data Sharing for Innovation, which aims to link anonymised government data more effectively, including with the states and territories.\(^\text{15}\)

The Australian Government supports private sector R&D activity through the Research and Development Tax Incentive scheme. It provides a refundable tax offset for R&D-active companies, including in HMR, with an aggregate turnover of less than $20 million per annum. Other eligible entities can apply for a non-refundable tax offset.\(^\text{16}\)

In addition to funding through the NHMRC, the Australian Government’s Medical Research Future Fund (MRFF), established in 2015, provides competitive funding to HMR research in a range of priority areas. The MRFF’s strategic priorities are set by the independent Australian Medical Research Advisory Board (AMRAB) on the basis of statutory provisions outlined in the Medical Research Future Fund Act 2015. At present, MRFF funding is directed at twenty separate priority initiatives, arranged under four research themes.\(^\text{17}\)

### 3.5 South Australian Government policy

Unlike some Australian jurisdictions, such as Victoria, South Australia currently does not have a whole-of-government HMR strategy. The Department of Health and Wellbeing (DHW) has developed a portfolio HMR strategy, Research Focus 2020, which is intended to support research within the SA public health system. The strategy outlines a number of key areas in which the department aims to assess performance, such as the number of HMR projects undertaken across South Australia’s public health system and the extent of clinical trial activity in South Australian public hospitals.\(^\text{18}\)

On a whole-of-government level, there is a broad strategic focus on supporting and enhancing the state’s performance in science, research and innovation. Successive state governments have sought to develop the state’s R&D capacity, including in HMR, through a range of support programs and strategies, including initiatives like Adelaide Biomed City and Tonsley Innovation District. Current initiatives are largely centred on the new Lot 14 precinct, including the Office of the Chief Entrepreneur. In addition, several government programs in support of research and development (R&D) and innovation have recently been consolidated under the Future Industries Exchange for Entrepreneurship (FIXE) strategy.\(^\text{19}\)

Two of the South Australian Government’s general R&D initiatives are potentially open to businesses or institutions in the HMR sector, including the:

- $28 million Research Commercialisation and Startup Fund (RCSF), which is designed to support proposals that build industry R&D capability in South Australia; and

\(^{15}\) For a comprehensive overview of the initiatives currently undertaken by the Australian Government, see Ibid., available at <https://www.industry.gov.au/strategies-for-the-future/boosting-innovation-and-science>

\(^{16}\) For further details, see the Australian Taxation Office’s overview of the R&D Tax Incentive, including eligibility criteria, <https://www.ato.gov.au/Business/Research-and-development-tax-incentive/>

\(^{17}\) For additional details on the themes and initiatives funded by the MRFF, see <https://www.health.gov.au/initiatives-and-programs/medical-research-future-fund/mrff-research-themes>

\(^{18}\) Research Focus 2020 was released in 2017 and is aligned with both the department’s Health Strategic Plan 2017-2020 and its Clinical Excellence: Developing Strategic Direction to Build Allied Health Research and Translation Capacity.

\(^{19}\) For an overview of the programs under the FIXE umbrella, see <https://www.fixe.org.au/support>
• South Australian Venture Capital Fund (SAVCF), which enables innovative South Australian ventures to accelerate growth into national and global markets. The SAVCF will only support HMR companies or institutions if they can demonstrate the successful completion of stage 1 clinical trials or the equivalent stage for medical devices.  

The South Australian Government’s current investment in HMR is not structured by a funding framework or strategy that is specifically focussed on supporting the growth of HMR in the state. By contrast, a number of other jurisdictions, including NSW and Victoria, have adopted a more structured approach to the provision of financial support to their HMR sectors, as outlined in Table 3.1.

**Table 3.1: Support programs for HMR in other Australian jurisdictions**

<table>
<thead>
<tr>
<th>State</th>
<th>Year</th>
<th>Amount</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>New South Wales</td>
<td>2012</td>
<td>$200 million</td>
<td>Medical Research Support Program for the NSW Government</td>
</tr>
<tr>
<td>Queensland</td>
<td>2018-19</td>
<td>$10 million</td>
<td>Annual contribution - approx 14% of total revenue</td>
</tr>
<tr>
<td>Western Australia</td>
<td>2017</td>
<td>$8.465,661</td>
<td>RIS and MH Research Infrastructure Fund</td>
</tr>
</tbody>
</table>

HMR conducted in the state’s public health system is also supported by DHW through policy development, coordination and governance support. The Office for Research (OFR) has a role in coordinating research conducted under the auspices of the department, including in relation to clinical trials. OFR is also principally responsible for the development and implementation of research policy for the South Australian public health system, including policies that relate directly to health research ethics (founded on the national statement) and research governance obligations.

The Commission notes that the government recently established the Commission on Excellence and Innovation in Health (CEIH) within the DHW portfolio. The CEIH is broadly modelled on similar agencies in other jurisdictions, such as the Agency for Clinical Innovation in NSW, and is responsible for providing leadership and advice on a range of issues in the health system. These include supporting clinical innovation and enhancing collaboration between stakeholders in the public and private sectors.

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20 For more details, see <https://innovationandskills.sa.gov.au/innovation/sa-venture-capital-fund-savcf>
Along with responsibilities in relation to human-centred design and clinical informatics, the CEIH is also responsible for enhancing the capacity of the state’s public health system to foster innovative ways of improving patient care.

An expert Advisory Council supports the CEIH in the delivery of its mandated functions, including the development of its future work program. Its members possess expertise in a range of health-related fields, including areas that are important for the further development of HMR in South Australia, such as clinical research and research translation.

**Information request 3.1: policy environment**

- Is the division of policy responsibilities between national and state governments clear?
- What, if any, areas of duplication, gaps or inconsistencies exist?
- Is there alignment between state and national policy and research priorities?
- How should HMR research priorities be determined?
- How efficiently are regulatory arrangements administered? How significant is the compliance burden on researchers/institutions?
- Have recent reforms to ethics approvals processes, such as the introduction of mutual acceptance, been successful?
- What is the potential for further simplifying or streamlining current HREC approval processes?
- What impacts have South Australian Government policy initiatives over the last two decades had on the state’s HMR sector?
4. Performance analysis

4.1 Defining HMR

For the purpose of the inquiry, the Commission will use the NHMRC definition of research:21

The concept of research is broad and includes the creation of new knowledge and/or the use of existing knowledge in a new and creative way so as to generate new concepts, methodologies, inventions and understandings. This could include synthesis and analysis of previous research to the extent that it is new and creative.

The NHMRC further defines HMR as human research which involves people taking part in surveys and medical or psychological testing/treatment, being observed, researchers collecting and accessing specimens, personal information and other materials. An additional consideration in defining HMR relates to ethical review procedures which provide guidelines on distinguishing health research from service and practice.22

The literature distinguishes health research from practice, the aim of which is to prevent disease or injury and to improve the health of communities through activities such as disease surveillance, program evaluation and outbreak investigation.23

4.2 Measuring HMR activity

Assessing the performance of HMR is considered an important tool in improving the effectiveness and accountability of research funding and agencies.24 However, there is no agreed upon or wholly ‘scientific’ way to evaluate research, and the method of evaluation will depend on the organisation and objectives.25 For example, the Canadian Academy of Health Sciences notes that the objective of research evaluation may include among other reasons, accountability, advocacy or learning purposes, with each implying different organisational goals and requiring different evaluation strategies.26

Existing approaches to measurement and evaluation of HMR activity include bibliometric analysis, retrospective case studies, surveys, peer review; and micro/macroeconomic analysis.27

A research performance analysis may include several different methods to triangulate evaluation findings and the full range of impacts of HMR.28 These methods may be all quantitative, all qualitative, or a combination of both, and be tailored to collect information that supports the evaluation goals.

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21 Australian Code for the Responsible Conduct of Research (2018), The National Health and Medical Research Council, the Australian Research Council and Universities Australia, Canberra.
22 Ibid. p 7.
23 For a detailed discussion, see Otto, J., Holodiny, M., and DeFraites, R, ‘Public Health Practice is not Research’ (2014) 104(4) American Journal of Public Health, 596-602. See also Table A2.1 (Appendix 2) for further guidelines provided by the UK Health Research Authority (2017) on distinguishing health research from service and practice.
27 Ibid, p15. Table A2.2 (Appendix 2) provides a summary of each method as discussed in the report.
Inputs

Inputs into HMR refer to the resources needed to undertake research and development (R&D) activity, including capital, human resources and consumables. Data on the HMR workforce or other input measures are not available at the state level, with the exception of higher education expenditure on research and development (HERD) which is available by field of research at the state level. The Commission hopes to improve this overall position as part of this inquiry.

Table 4.1 presents HERD on HMR in South Australia for the period 2006-16. South Australia’s share of national higher education expenditure on HMR experienced a decline during this period, except for 2014. Expenditure on HMR accounted for the largest share of total HERD in South Australia during this period. Approximately one third of higher education expenditure on R&D was spent on HMR in 2016.

Table 4.1: Higher education expenditure on research and development (HERD) for HMR in South Australia, 2006-16.

<table>
<thead>
<tr>
<th>Year</th>
<th>HERD on HMR for SA $'000</th>
<th>Total HERD for SA $'000</th>
<th>Share of HERD on HMR in SA %</th>
<th>Total HERD on HMR, Australia $'000</th>
<th>SA share of national total HERD on HMR %</th>
</tr>
</thead>
<tbody>
<tr>
<td>2006</td>
<td>126,090</td>
<td>395,085</td>
<td>31.9</td>
<td>1,469,984</td>
<td>8.6</td>
</tr>
<tr>
<td>2008</td>
<td>185,418</td>
<td>505,080</td>
<td>36.7</td>
<td>2,072,060</td>
<td>8.9</td>
</tr>
<tr>
<td>2010</td>
<td>206,567</td>
<td>544,932</td>
<td>37.9</td>
<td>2,327,499</td>
<td>8.9</td>
</tr>
<tr>
<td>2012</td>
<td>236,610</td>
<td>639,915</td>
<td>37.0</td>
<td>2,822,549</td>
<td>8.4</td>
</tr>
<tr>
<td>2014</td>
<td>265,545</td>
<td>724,239</td>
<td>36.7</td>
<td>2,883,654</td>
<td>9.2</td>
</tr>
<tr>
<td>2016</td>
<td>240,324</td>
<td>707,171</td>
<td>34.0</td>
<td>3,086,858</td>
<td>7.8</td>
</tr>
</tbody>
</table>

Source: ABS (2018) cat.8110D005, Research and experimental development, Higher education organisations

The Commission notes that higher education expenditure on R&D captures only a part of the total expenditure on R&D. However, ABS data on R&D are not available for other sectors (business and government expenditure) at the field of research level by jurisdiction.29

Such gaps in available data limit the ability to analyse investments in HMR at the state level. Lack of detailed data on research expenditure was also highlighted in the McKeon Review (2013) as a key issue in the HMR sector. That review found that there was no consistency in definitions and limited ability to identify HMR investments due to a general lack of monitoring of research performed in state and territory hospitals and health networks.30

Outputs

Analysing HMR performance is a complex task made more difficult by data limitations. Given the data constraints, the most common approach in the literature relates to using tangible outputs of the R&D process such as publications and registered health products.31 However, data at the state or institution level are not publicly available.32

In analysing research publications, citations are used as a measure of quality and/or impact. Research output measures require appropriate standardisation, for example, by population or number of workers to enable meaningful comparisons across institutions and jurisdictions.

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29 Business Expenditure on R&D (BERD) and Government Expenditure on R&D (GOVERD) by field of research are available only at the national level.
32 Several research publication database providers such as Clarivate Analytics®, Elsevier® and Thomson Reuters® are available only through subscription.
Figure 4.1 illustrates the distribution of HMR publications and citations by state and place of research for the period 2001 to 2011 as reported in the NSW HMR Strategic Review (2011). Victoria and NSW were clearly ahead of other states in both the number of publications and citations during this period. The Commission notes that this information may not reflect more recent trends but given the absence of readily available data, this provides a useful overview of the distribution of HMR publications.

Figure 4.1: Number of HMR publications and citations by state and place of research, 2001-11.

Source: NSW HMR Strategic Review (2011)

Productivity

Productivity, defined as volume or value of research output per unit of research input, is difficult to measure in HMR due to limited availability of the required data.

Given these constraints, a common approach to measuring research productivity is bibliometric, which measures the number of publications per researcher or institution for a given time period. While there are several well documented limitations of this approach, including accurately accounting for co-authorship, contribution and variations in intensity of publications, the ability to quantify publications makes this a practical tool for measuring research productivity.

Figure 4.2 presents citations per publication in HMR by state between 2001 and 2011. As previously discussed, the lack of publicly available data necessary for analytical purposes has limited the Commission’s ability to obtain more recent data on HMR publications or citations at the state level.
Key issues in evaluating HMR impacts or outcomes include the lack of consistent definitions, data and methodologies that support empirical evidence across the sector. According to a review by the Canadian Academy of Health Sciences, the results of such assessments are “on average, contradictory, and the evidence of health research impact is either highly qualified or mixed”.

Given the absence of a standardised HMR impact assessment framework, funding bodies and research institutes use different definitions and approaches, limiting the ability to make meaningful comparisons across the sector.

For the purpose of the inquiry, the Commission will use the recently developed NHMRC definition of research impact which includes “the verifiable outcomes that research makes to knowledge, health, the economy and/or society, and not the prospective or anticipated effects of the research”. It recognises four specific types of impact: knowledge, health, economic and social.

Even with definitions and a framework in place, there are challenges in assessing the impact of health research, including:

- attribution – of a causal link between observed (or expected) changes and a specific intervention;
- the absence of a counterfactual scenario;
- time lags of research impact; and
- levels of aggregation (individual, research group/grant, institution/department, funding agency, national/jurisdictional) for evaluation.

The Commission would like to understand issues in assessing HMR performance in South Australia, particularly in relation to identifying measures and data sources.

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34 Panel on return on investment in health research (2009), p.47.
36 Panel on return on investment in health research (2009), p.72.
38 The gold standard for evaluation with a comparison is the randomised control trial, but this is not often possible. See for example discussion in the Panel on return on investment in health research (2009), p.72.
Information request 4.1: measurement and data

- What are the limitations of the Commission’s suggested measures?
- What other definitions and data could be used for measurement of inputs, outputs, productivity and impacts in HMR?
5. Key issues

5.1 Factors influencing HMR activity

The terms of reference for the inquiry require that the Commission identify and assess the key factors influencing HMR activity in South Australia. In particular, the Commission would like to understand how the following factors influence HMR performance, especially in relation to scale, productivity and quality.

HMR workforce

A strong and active research workforce is critical for maintaining and strengthening the HMR sector. According to a survey of the HMR workforce, there were 23,411 research staff in Australian universities and medical research institutes in 2009.

However, the lack of up to date HMR workforce data at the jurisdictional level limits the understanding of its size and dynamics in South Australia. HMR activities take place in a range of organisations including universities, research institutes, health services, non-government organisations and the private sector, making it difficult to track and monitor the workforce.

A survey of the HMR workforce conducted by the Australian Society for Medical Research (ASMR) in 2006 found that employment insecurity and lack of funding were causes of considerable anxiety among health researchers. Based on initial consultations, the Commission understands that there is strong international competition for globally recognised researchers, with institutions providing generous attraction packages to secure and retain the best talent.

The McKeon Review (2013) noted that active research participation by health professionals was a key factor in identifying research questions, conducting research and implementing translational activities to improve the health system. It also highlighted the importance of embedding research in the health system to support and facilitate clinician participation in HMR.

While there are no supporting numerical data, anecdotal evidence points to a decline in the number of research-active clinicians in South Australia, which may have important implications for overall HMR performance in the state. The Commission would like to understand the workforce requirements of HMR, the extent to which these are being realised in South Australia and the implications for productivity of HMR.

39 The Australian Society for Medical Research (2016) Australia’s health and medical research workforce: Expert people providing exceptional returns.
42 McKeon Review (2013), p. 15
Access to data

The large volume of data held by the Australian Government and its state and territory counterparts has come to be seen as an underutilised and valuable national resource. This is particularly true for HMR, where access to data sources has become an important analytical tool for researchers. Research conducted using such data has the potential to enhance clinical practice, policy evaluation and the development of new treatments. The use of health and medical data for research is regulated by the Privacy Act 1988 (Cth) at the national level and by state legislation, such as the Health Care Act 2008 (SA) and the Mental Health Act 2009 (SA).

Researchers in different fields of HMR are increasingly making use of ‘data linkage’ techniques. The linking of data sets allows statistically significant connections to be drawn between different sources of information that relate to the same place, event, person or family. This is important for many different types of HMR, including clinical trials, because the linked data draws on information sources at the ‘whole of population’ level. HMR using data linkage is thereby not dependent on relatively small sample sizes.

A number of initiatives have been launched over the last decade to link data resources and make them more available for research, including the Population Health Research Network (PHRN). The PHRN was established by the Australian Government in 2009 and is supported by state and territory governments and the university sector. It includes participation from regional data linkage units, including the SA-NT DataLink, a joint initiative of the South Australian and Northern Territory Governments.

South Australia has recently sought to enhance the way in which public sector data is managed and utilised. The Public Sector (Data Sharing) Act 2016 (SA) provides a statutory foundation for the management of the data held by public sector agencies, and aims to ensure that data is used appropriately as a resource to inform policy making and service.

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44 Menzies Institute for Medical Research, What is Data Linkage, <https://www.menzies.utas.edu.au/research/research-centres/data-linkage-unit/what-is-data-linkage>
45 For additional details on the PHRN, including its relationship with its regional partner linkage units, see <https://www.phrn.org.au/about-us/participants/>
delivery.46 The act includes a number of statutory restrictions on the sharing of some types of data, particularly in relation to prescribed health information. This includes confidential health and medical information collected in the course of a range of medical procedures, such as fertility treatment and organ transplantation.47

Evidence from other jurisdictions suggests that access to data, including data linkage, is a significant factor affecting HMR more broadly. The Commission is therefore interested in understanding whether current arrangements for data access and linkage either support or hinder HMR in South Australia, including any relevant case studies.

Information request 5.2: access to data

- Is the current regulatory environment at the national level conducive to data generation and sharing?
- Is the current regulatory environment at the state level, including the operation of the Public Sector (Data Sharing) Act 2016, conducive to data generation and sharing?
- Is there overlap between national and state legislation?
- What types of data are important to share in HMR?
- What barriers are there to sharing data for HMR?
- What data related bottlenecks constrain HMR and what can be done to remove them?

Please provide relevant supporting examples or case studies, where available.

Infrastructure

Research infrastructure includes a large range of facilities and assets that support high-level HMR, such as scientific equipment, buildings and physical infrastructure, knowledge-based resources, instruments and information and communication technology (ICT). Access to high quality infrastructure is frequently cited as a precondition for enhancing the overall productivity of HMR.48

The costs associated with undertaking HMR are frequently significant, especially if the research is designed to enable the translation or commercialisation of research findings. In addition, the indirect costs of research, including infrastructure costs, are not always covered by the available sources of research funding. Specific infrastructure funding for HMR is relatively constrained, with only some jurisdictions providing access to dedicated funding streams to support HMR infrastructure needs.49

47 See, for additional details, Public Sector (Data Sharing) Regulations 2017 (SA), reg. 2. A number of jurisdictions, including Victoria and NSW, have recently passed similar public sector data sharing legislation. The Australian Government is currently preparing a Bill to facilitate greater sharing of public sector data at the national level and develop enhanced protections in relation to privacy and security. See <https://www.pmc.gov.au/public-data/data-sharing-and-release-reforms>
48 See, for example, Department of Health (WA), Health and Medical Research and Innovation Strategy – Discussion Paper (Perth, 2019).
49 Infrastructure funds maintained by other jurisdictions include the NSW Government’s Medical Research Support Program and the Victorian Government’s Operational Infrastructure Support Program. The South
One of the primary sources of national funding to support research infrastructure is provided through the Australian Government’s National Collaborative Research Infrastructure Strategy (NCRIS). NCRIS was established in 2004 to provide funding to a national network of infrastructure projects. Its aim is to identify and fund, in collaboration with key stakeholders, priority areas for research infrastructure investment.

Funding through NCRIS is allocated on the basis of a restricted and non-competitive grant process, which is determined by priorities identified in the Australian Government’s Research Infrastructure Investment Plan. NCRIS funding is not specific to the HMR sector, but a number of NCRIS funded projects, including the PHRN and the Large Animal Research Imaging Facility, are used in HMR.

The presence of significant research precincts is often seen as an effective way to maximise the effectiveness of a region’s research infrastructure. South Australia has several research and innovation precincts, including Lot 14, the Tonsley Innovation District and the bioscience precinct at Thebarton. Adelaide BioMed City (ABMC) is the state’s largest dedicated health and life sciences precinct, which brings together HMR research conducted under the auspices of its partner organisations: SAHMRI, the University of Adelaide, the University of South Australia, Flinders University and the Central Adelaide Local Health Network (CALHN). ABMC is focused on facilitating collaboration and linking its partners’ strengths in health research, education, clinical care, health translation and commercialisation.

The Commission wants to understand the specific contribution that research infrastructure makes to South Australia’s HMR performance, including the effect of any gaps in the state’s existing infrastructure. The Commission also seeks further evidence on the role of research precincts in facilitating HMR in the state.

**Information request 5.3: infrastructure**

- How well is existing SA public and private HMR infrastructure being utilised?
- Could existing HMR infrastructure be better utilised or shared more effectively to deliver improvements in HMR performance?
- Can the competing demands on infrastructure of delivering health care and conducting research be better managed?
- Are there infrastructure gaps (buildings or equipment) which constrain HMR performance? What are they?
- What role do precincts, neighbourhoods and physical proximity play in promoting collaboration?
- Can SA do more to leverage precincts to improve HMR performance?

Please provide relevant supporting examples or case studies, where available.

**Collaboration**

Some recent studies have suggested that collaboration between researchers and other stakeholders, often working across multiple sites, is likely to enhance the productivity and
effectiveness of HMR. Effective collaboration is also frequently cited as one of the most important factors in fostering transdisciplinary research. While this is increasingly significant in all areas of R&D, it is regarded as particularly important for HMR. The convergence of disciplines like engineering, mathematics and data science with HMR has the potential to illuminate complex problems and challenges, including in genomics, precision medicine and biomedical engineering.

Collaboration and partnerships also have the potential to enable institutions and researchers to find ways of accessing new markets, making the most efficient use of funding opportunities (for example, through specialisation or sharing facilities), and reducing the inefficiencies associated with duplication of research effort.

Efforts aimed at fostering collaboration are often focussed on supporting the effective translation of research findings into practical measures to improve the health of communities and individuals. In South Australia, this is facilitated by Health Translation SA (HTSA), which was established in 2015 as an Advanced Health Research Translation Centre (AHRTC) with accreditation from the NHMRC. Like the seven other accredited health translation centres throughout Australia, it aims to facilitate successful translation by bringing together universities, health researchers and health service providers. Consumer groups and policy makers are also closely involved in HTSA’s translation and collaboration activities.

The Commission would like to understand the role and significance of collaboration in the various stages of the HMR process, including the continuum from basic research to translation, and the factors that drive or inhibit collaboration between researchers and with industry.

Information request 5.4: collaboration

- How important is collaboration to securing research funding and to the achievement of HMR outcomes – both between researchers and between research institutions and industry, nationally or globally?
- Are current levels of collaboration by SA researchers/institutions optimal?
- Has the performance of SA Government departments helped or hindered collaboration in the state’s HMR sector?
- What steps could be taken to enhance collaboration amongst research institutions, including universities, and between research institutions and industry?
- Are there innovative models of collaboration which could be adopted in SA?

Please provide relevant supporting examples or case studies, where available.

Funding

Funding sources for HMR include the Australian and state governments, the private sector and non-government and philanthropic entities. The HMR funding system is fragmented and
complex with a multitude of funding bodies and programs that support different types of research, and stakeholders at different levels.\textsuperscript{53} Figure 5.1 provides an overview of the HMR funding system as discussed in the McKeon Review (2013).

\textit{Figure 5.1: HMR funding and activity flows}

Source: McKeon Review (2013)

\textit{Note: This figure does not include the MRFF, which commenced in 2015.}

The NHMRC is the leading source of HMR funding with a total expenditure of $862 million in 2018. South Australia’s share in 2012 was 7.4 per cent. While this had fallen to 6 per cent in 2018, the share of NHMRC funding for South Australia has historically been either above or in line with SA’s share of GDP, which stood at 5.7 per cent in 2018.

The Australian Government’s funding decisions in relation to the MRFF are guided by the Australian Medical Research Advisory Board. As at 30 September 2019, South Australia has received approximately $17.5 million or 3 per cent of total MRFF funding since commencement of funding in 2016.\textsuperscript{54} In 2019-20, total funding provided through the MRFF will be approximately $392.5 million, compared to total funding under the NHMRC in the 2018 calendar year of approximately $862 million. Funding for the HMR sector through the MRFF is projected to total approximately $4.972 billion over the decade to 2027-28.\textsuperscript{55}

Applications for research funding, including from the NHMRC, and the approval processes that apply to HMR projects are handled separately. The approval process for HMR follows the requirements laid out in the national statement, and entails both ethics approval by a HREC and a site specific assessment (SSA) undertaken by the hosting institution. The latter is designed to ensure that a hosting institution possesses the capacity to undertake the proposed HMR, and forms a central aspect of research governance. Funding can only be used once ethics approval is granted and the SSA has been completed. The Commission notes that the South Australian Government is currently implementing recommendations

\textsuperscript{53} Further details available in McKeon Review (2013) and NSW Health and medical strategic review (2011).

\textsuperscript{54} <https://www.health.gov.au/resources/publications/medical-research-future-fund-mrff-grant-recipients>

from the 2018 Birch Review, some of which address the way in which SA Health ensures effective research governance.

The Commission is interested in broadening its understanding of HMR funding in South Australia, particularly in relation to recent trends in funding success, challenges and opportunities to enhance performance. The Commission is also interested in understanding whether the processes that apply to ethics approval and SSAs have an adverse effect on funding outcomes in South Australia.

Information request 5.5: funding

- Why has SA’s share of Australian Government HMR grant funding been falling?
- What role has the South Australian Government played in assisting public and private researchers to access Australian Government funding?
- What are the key factors which influence SA’s success rate in securing NHMRC and MRFF funding?
- How efficient are processes for applying for and reporting on use of NHMRC and MRFF funds in terms of information requirements, complexity, administrative effort and timeframes?
- What challenges, if any, do SA researchers/institutions face, compared to other jurisdictions, in securing Australian Government research funding?
- Other than the Australian Government, how do universities and research institutes source funding for research?
- What barriers, if any, are there to industry involvement in HMR? How important is industry involvement to success in securing research funding?
- What steps could be taken to facilitate more industry investment in HMR in SA?
- Do the processes for ethics and governance approval have an adverse effect on the ability of South Australian researchers to secure Australian Government funding?

Please provide relevant supporting examples or case studies, where available.

5.2 Translation

HMR can be translated into health, economic and social benefits for individuals, communities and governments. The translational process is complex and often non-linear and is motivated by two separate but related drivers: non-commercial and commercial.\(^{56}\)

The Commission has been asked to recommend action to increase the translational impact of HMR and to identify and assess opportunities for increased commercialisation of HMR in South Australia.

Non-commercial translations provide individual and population health benefits (for example, from limiting the spread of disease). These may have significant indirect economic benefits.

such as cost savings and avoided costs from reduced hospitalisations but may not generate direct financial gains as in the commercial pathway to translation.\footnote{Ibid. p 115.}

**Figure 5.2: Commercialisation process in HMR**

![Commercialisation process in HMR](source)

Commercial drivers of HMR include the economic and financial gains from pharmaceuticals, medical devices and diagnostic tests that are developed.\footnote{Ibid. p 220.} HMR commercialisation is a means of delivering research benefits to the community and creating economic benefits. There are different stakeholders in HMR commercialisation who are engaged at different stages of the process as illustrated in Figure 5.2.

Clinical trials form a key component of the HMR commercialisation pathway and have been identified as a sub-sector within the South Australia health and medical industries strategy.\footnote{Growth State: Health and medical industries discussion paper (2019), Government of South Australia.} Based on data available from the Australia-New Zealand Clinical Trials Register (ANZCTR), South Australia’s share of clinical trials conducted in Australia increased from 13.1 per cent in 2015 to 15.2 per cent in 2018.\footnote{Available from <https://www.anzctr.org.au/>. The data available from the register may not capture all the clinical trials taking place in the country, as there is no mandatory requirement for registration.} Apart from the number of clinical trials data available from the ANZCTR, the Commission has not been able to locate other data on HMR translation at the state level.

Currently there are several national HMR commercialisation initiatives in place, including the Australian Government’s Medical Research Commercialisation Fund (MRCF), NHMRC accredited health translation centres and programs within the Medical Research Future Fund (MRFF). NSW, Victoria, Queensland and WA have specific initiatives aimed at improving HMR commercialisation at the state-level.\footnote{See Appendix 3 for an overview of HMR commercialisation initiatives at the state level.}

In South Australia, the $28 million Research, Commercialisation and Startup Fund (RCSF), launched in February 2019, supports researchers, entrepreneurs and businesses to accelerate commercialisation.\footnote{<https://innovationandskills.sa.gov.au/funds/research-commercialisation-and-startup-fund/>. The SA Government does not have any HMR specific commercialisation initiatives.}

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57 Ibid. p 115.
58 Ibid. p 220.
60 Available from <https://www.anzctr.org.au/>. The data available from the register may not capture all the clinical trials taking place in the country, as there is no mandatory requirement for registration.
61 See Appendix 3 for an overview of HMR commercialisation initiatives at the state level.
The translation of research undertaken in the SA public health system is covered by the government’s Intellectual Property Policy (IPP). The IPP provides a broad policy framework that is binding on all public sector agencies. The central principle underlying the IPP is that the government, as a default position, should always seek to retain ownership of any intellectual property (IP) that has been created under its auspices, including in the public health system. Under the monetary rewards framework that forms part of the IPP, the net returns from any IP generated by SA Health employees must be split equally between the employees and the SA Government.

During the Commission’s inquiry into South Australian Government procurement in 2019, the Commission formed the view that inadequate guidance and policies on managing IP in procurement had led to a reluctance by suppliers to engage with government and contributed to risk averse procurement processes. The government supported the Commission’s recommendation that it develop clearer IP arrangements, recognising that a fair and reasonable approach to IP protection of businesses during tender processes and contracts would drive innovation.

The Commission would like to understand to what extent HMR activity in South Australia results in translation in the state, whether it be commercial or non-commercial, and the drivers and impediments to translation. These may include access to funding, facilities, clinical trials, markets and regulatory arrangements, among others. The Commission is also interested to understand, in light of the recent IP reform, whether state government procurement policies and practices are conducive to translation of HMR.

**Information request 5.6: translation of research**

- Is there potential to enhance translation of SA based research into health care policy and practice in SA and how can this be realised?
- Is there potential to increase the quantity and quality of clinical trials conducted in SA?
- What opportunities are there to increase commercialisation of HMR in SA?
- What barriers, if any, are there to commercialisation of HMR?
- What steps can be taken to remove or reduce these barriers?
- What have been the impacts of current national and state government initiatives to promote domestic commercialisation?
- How is HMR effort split between basic and applied research in SA?
- Does the South Australian Government’s Intellectual Property Policy, including the monetary rewards framework, encourage or hinder the translation of HMR undertaken in the public health system?
- Do the South Australian Government’s procurement policies and practices encourage or inhibit HMR commercialisation?

Please provide relevant supporting examples or case studies, where available.
5.3 Competitive advantage

The Commission has been asked to identify and assess the characteristics of South Australia and its population that may give rise to areas of competitive advantage, compared to other jurisdictions, in HMR and development and identify methods of maximising these opportunities.

A recent discussion paper on South Australia’s health and medical industries, as part of the South Australian Government’s Growth State initiative, concluded that external opportunities for growth are present both locally and globally in research and development activities.63

In 2016 Adelaide was listed as Australia’s most competitive business city by KMPG.64 The South Australian Department for Trade and Investment has cited South Australia’s locational advantages as:

- a skilled and accessible labour pool at competitive rates compared to other capital cities (12 per cent cheaper than New South Wales)65;
- savings of up to 60 per cent in office spaces relative to Sydney66;
- Adelaide is ranked as the 10th most liveable city in the world67;
- tax reform initiatives with reductions in business taxes of over $670m during 2017-202168; and
- lowest cost of living and commute times in mainland Australia.69

Information request 5.7: competitive advantage – location

- Is South Australia perceived as an attractive location globally or nationally for investment in HMR and commercial innovation? If not, why not?

Please provide relevant supporting examples or case studies, where available.

South Australia’s population, size, stability, diversity, age and health profile and other features could create particular advantages or disadvantages for the state as a location for HMR and development.

Information request 5.8: competitive advantage – population

- Are there particular characteristics of South Australia’s population that may create competitive advantage and opportunity in any fields or phases of HMR compared to other jurisdictions?

Please provide relevant supporting examples or case studies, where available.

South Australia’s publicly funded universities and research institutes have identified key areas of strength in regard to HMR.

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63 Department for Trade and Investment, Growth State: Our Plan for Prosperity Health and Medical Industries Discussion Paper, 2019, p.3
64 KPMG, (2016) Competitive Alternatives: KPMG’s guide to international business locations costs.
65 ABS 6302.0 Average Weekly Earnings, May 2017
66 CBRE Research June 2017 Global Prime Office Occupancy Costs
67 The Economist Intelligence Unit (2018) The Global Liveability Index, p.2
68 Investment Attraction South Australia (2017): Financial and Business services: South Australia a better return on your investment, p.6
69 Ibid, p.10
The University of Adelaide reports strengths in reproductive medicine and paediatrics, cardiovascular disease, metabolic disease, cancer – solid tumours, cancer – leukemia, lymphoma, myeloma, health technology assessment, Aboriginal health equity, infectious diseases, medicinal chemistry, and innovative imaging tools.\textsuperscript{70}

Flinders University reports its competitive strengths as a strong relationship with Flinders Medical Centre and SA Health; agility; flagship health and medical institutes – Orama Institute for Mental Health, Wellbeing and Neuroscience; Flinders Health and Medical Research Institute (FHMRI) and the Caring Futures Institute (CRI); collaborations with the health industry; health and medical education; and its rural and regional engagement.\textsuperscript{71}

The University of South Australia reports competitive strengths in biochemistry and cell biology, clinical sciences, Human Movement and Sport Sciences, nursing, nutrition and dietetics, pharmacology and pharmaceutical sciences, medical physiology, public health and health services; and psychology. \textsuperscript{72}

SAHMRI reports key research strengths in Aboriginal health, ageing and aged care, cancer, cardiovascular disease, diabetes, nutrition and gut health, mental health, immunology, neurosciences, other infectious diseases, medical devices, health services research and population health research.\textsuperscript{73}

**Information request 5.9: competitive advantage – areas and phases of research**

- Does South Australia have areas of research excellence of national or global renown? What are they?
- What are South Australia’s competitive strengths and weaknesses in various fields and phases in HMR?

Please provide relevant supporting examples or case studies, where available.

South Australia is home to clinical trials across pharmaceutical, medical technology and digital health sub-sectors.\textsuperscript{74} A rise in South Australia’s share of the Australian clinical trials market between 2015 and 2018\textsuperscript{75} may indicate that SA has a positive environment to attract and conduct clinical trials. Based in Adelaide’s BioMed City, CMAX Clinical Research is among Australia’s most experienced clinical trials units. It has conducted over 550 studies since 1993, including over 100 first-in-human studies.\textsuperscript{76}

In early phase clinical trials, Australia is 28 per cent cheaper than the US before tax incentives, and 60 per cent cheaper after tax incentives.\textsuperscript{77} Recent figures show investigator led clinical trials in Australia can return $5.80 for every $1 invested.\textsuperscript{78} However, the cost for Australian clinical trials is high compared with India and China, where there has been an increase in clinical trials in the last few years.\textsuperscript{79} In trials with lower complexity in design or that require features such as large patient pools, Australia is increasingly rivalled by competitors

\textsuperscript{70} Information provided by the University of Adelaide.  
\textsuperscript{71} Information provided by Flinders University  
\textsuperscript{72} Information provided by the University of South Australia.  
\textsuperscript{73} For more information see; <https://portal.sahmriresearch.org/en/organisations/>  
\textsuperscript{74} Department for Trade and Investment, Growth State: Our Plan for Prosperity Health and Medical Industries Discussion Paper, 2019, p.6  
\textsuperscript{75} ANZCTR, Available from https://www.anzctr.org.au/. The data available from the register may not capture all the clinical trials taking place in the country, as there is no mandatory requirement for registration.  
\textsuperscript{76} Australian Trade and Investment Commission, Clinical Trials, 2018  
\textsuperscript{77} Frost & Sullivan White Paper (2016)Australia: Preferred Destination for Early Phase Clinical Trials  
\textsuperscript{78} Australian Clinical Trials Alliance. Economic evaluation of investigator-initiated clinical trials conducted by networks. Sydney: ACSQHC; 2017. p.4  
\textsuperscript{79} Clinical Trials in Australia: Trends, tendencies and future development, 2013. P.
with better access to larger patient pools and lower cost bases from the Asia Pacific, Eastern Europe or Latin America.80

**Information request 5.10: competitive advantage – clinical trials**

- What type of clinical trials are being undertaken in South Australia?
- What proportion of clinical trials are sponsored by industry and what proportion are investigator driven?
- Does South Australia have any competitive advantages in conducting clinical trials?

Please provide relevant supporting examples or case studies, where available.

According to evidence sourced by the Department of Industry, Innovation and Science, successful innovation precincts encourage increased collaboration between researchers and end users, fostering higher levels of innovation, knowledge transfer, and commercialisation to drive sustainable economic growth and job creation.81 Business collaboration on innovation is associated with a 70 per cent increase in the likelihood of new-to-world innovation and a 32 per cent increase in the likelihood of new-to-Australia innovation.82

South Australia has seen significant investment in health and medical precincts over the last decade, including at Adelaide BioMed City and the Tonsley Innovation District. This investment sought, amongst other things, to promote collaboration between researchers and to attract both talented researchers and research funding to the state. The Commission notes that similar investments have been made in other jurisdictions, albeit on the basis of whole-of-government HMR strategies. With the exception of *Research Focus 2020*, which is a portfolio-specific strategy developed by DHW, the investment in South Australia has not been guided by a whole-of-government strategy (as discussed in section 3.5). The key benefit of such strategies in other jurisdictions is their capacity to enhance existing competitive advantages and mitigate competitive disadvantages.

The Commission wants to understand the impact of investment in HMR facilities and precincts, including on South Australia’s competitiveness as a location for HMR, as well as the value of a whole-of-government HMR strategy.

**Information request 5.11: competitive advantage – collaboration and precincts**

- The size and culture of South Australia and Adelaide is said to make collaboration easier. Does this apply in HMR?
- How competitive is South Australia in attracting leading researchers and talented postgraduates to HMR?
- Do Adelaide’s innovation precincts provide it with a competitive edge in HMR and translation?

Please provide relevant supporting examples or case studies, where available.

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80 MTPConnect (2017) Clinical Trials in Australia: the economic profile and competitive advantage of the sector. p.45
6. Summary of information requests

Information request 3.1: policy environment
- Is the division of policy responsibilities between national and state governments clear?
- What, if any, areas of duplication, gaps or inconsistencies exist?
- Is there alignment between state and national policy and research priorities?
- How should HMR research priorities be determined?
- How efficiently are regulatory arrangements administered? How significant is the compliance burden on researchers/institutions?
- Have recent reforms to ethics approvals processes, such as the introduction of mutual acceptance, been successful?
- What is the potential for further simplifying or streamlining current HREC approval processes?
- What impacts have South Australian Government policy initiatives over the last two decades had on the state’s HMR sector?

Information request 4.1: measurement and data
- What are the limitations of the Commission’s suggested measures?
- What other definitions and data could be used for measurement of inputs, outputs, productivity and impacts in HMR?

Information request 5.1: workforce
- What strategies are being used by institutions to attract talented researchers and postgraduates and how successful have they been?
- Are there barriers to clinicians participating in research? How can any barriers be addressed?
- How many clinician researchers are currently active in SA?
- What is the long-term trend in their number?
- What connections are there between SA Health and university workforces and how do these affect recruitment and retention of HMR researchers?
- How does the current situation in SA compare with other Australian jurisdictions?

Information request 5.2: access to data
- Is the current regulatory environment at the national level conducive to data generation and sharing?
- Is the current regulatory environment at the state level, including the operation of the Public Sector (Data Sharing) Act 2016, conducive to data generation and sharing?
- Is there overlap between national and state legislation?
- What types of data are important to share in HMR?
- What barriers are there to sharing data for HMR?
- What data related bottlenecks constrain HMR and what can be done to remove them?
Information request 5.3: infrastructure

- How well is existing SA public and private HMR infrastructure being utilised?
- Could existing HMR infrastructure be better utilised or shared more effectively to deliver improvements in HMR performance?
- Can the competing demands on infrastructure of delivering health care and conducting research be better managed?
- Are there infrastructure gaps (buildings or equipment) which constrain HMR performance? What are they?
- What role do precincts, neighbourhoods and physical proximity play in promoting collaboration?
- Can SA do more to leverage precincts to improve HMR performance?

Information request 5.4: collaboration

- How important is collaboration to securing research funding and to the achievement of HMR outcomes – both between researchers and between research institutions and industry, nationally or globally?
- Are current levels of collaboration by SA researchers/institutions optimal?
- Has the performance of SA Government departments helped or hindered collaboration in the state’s HMR sector?
- What steps could be taken to enhance collaboration amongst research institutions, including universities, and between research institutions and industry?
- Are there innovative models of collaboration which could be adopted in SA?

Information request 5.5: funding

- Why has SA’s share of Australian Government HMR grant funding been falling?
- What role has the South Australian Government played in assisting public and private researchers to access Australian Government funding?
- What are the key factors which influence SA’s success rate in securing NHMRC and MRFF funding?
- How efficient are processes for applying for and reporting on use of NHMRC and MRFF funds in terms of information requirements, complexity, administrative effort and timeframes?
- What challenges, if any, do SA researchers/institutions face, compared to other jurisdictions, in securing Australian Government research funding?
- Other than the Australian Government, how do universities and research institutes source funding for research?
- What barriers, if any, are there to industry involvement in HMR? How important is industry involvement to success in securing research funding?
- What steps could be taken to facilitate more industry investment in HMR in SA?
- Do the processes for ethics and governance approval have an adverse effect on the ability of South Australian researchers to secure Australian Government funding?
Information request 5.6: translation of research

- Is there potential to enhance translation of SA based research into health care policy and practice in SA and how can this be realised?
- Is there potential to increase the quantity and quality of clinical trials conducted in SA?
- What opportunities are there to increase commercialisation of HMR in SA?
- What barriers, if any, are there to commercialisation of HMR?
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- What have been the impacts of current national and state government initiatives to promote domestic commercialisation?
- How is HMR effort split between basic and applied research in SA?
- Does the South Australian Government’s Intellectual Property Policy, including the monetary rewards framework, encourage or hinder the translation of HMR undertaken in the public health system?
- Do the South Australian Government’s procurement policies and practices encourage or inhibit HMR commercialisation?

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- Is South Australia perceived as an attractive location globally or nationally for investment in HMR and commercial innovation? If not, why not?

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- Are there particular characteristics of South Australia’s population that may create competitive advantage and opportunity in any fields of phases of HMR compared to other jurisdictions?

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- Does South Australia have areas of research excellence of national or global renown? What are they?
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- How competitive is South Australia in attracting leading researchers and talented postgraduates to HMR?
- Do Adelaide’s innovation precincts provide it with a competitive edge in HMR and translation?
7. Appendices

Appendix 1. Relative HMR performance of South Australia

Declining SA share of Australian Government research funding

NHMRC funding to SA for HMR has grown from $18.3m in 2000 to $57m in 2018, but the state’s share of national funding has fallen from 10.9% to 6.6% over this period.

*Figure A1.1: SA value of NHMRC expenditure ($m) vs. share of Australia (%), 2000-2018*

![Graph showing SA value of NHMRC expenditure and share of Australia](source NHMRC)

HERD on medical and health sciences accounts for a third of SA HERD

Higher education expenditure on R&D (HERD) in medical and health sciences was $240m in 2016.

*Figure A1.2: Medical and health sciences share of state higher education R&D expenditure (%)*

![Graph showing HERD share of state higher education R&D expenditure](source ABS 8111.0)
Declining SA share of national HERD on medical and health sciences

While its importance to SA has grown, accounting for 34% of state HERD, SA’s share of national HERD activity has steadily fallen over the last 30 years to 7.8% in 2016.

*Figure A1.3: SA share of Australian total higher education expenditure on R&D in medical and health science, 1996-2016 (%)*

Source: ABS 8111.0

Static SA share on national university teaching and research staff employed in health faculties.

The number of health and medical teaching and research staff at SA’s universities has risen from 472 in 2001 to 876 in 2017. SA’s share of national staff has remained steady over this period at just under 12%.

*Figure A1.4: FTE teaching only or teaching and research staff in Health at higher education institutions by state, 2001-2017 (No.)*

Source: DESE
Declining share of national post graduate enrolments

From 2001 to 2013 SA’s share of national postgraduate enrolments in health and medical fields was between 10% and 12%. This share has fallen from a peak of 11.7% in 2013 to 9.7% in 2018.

*Figure A1.5: South Australia’s share of the Australian total postgraduate student enrolments in Health, 2001-2018*

Source: DESE

Declining share of overseas student enrolments in health in Australian universities

SA’s share of overseas student enrolments in health and medical fields in Australian universities peaked at 11.5% in 2006 but has declined since to 10.1% in 2018.

*Figure A1.6: South Australia’s share of the Australian total overseas student enrolments in Health, 2001-2018*

Source: DESE
Growth in the number of clinical trials in SA and a rising SA share of national clinical trials

The number of registered clinical trials in SA has increased from 180 in 2015 to 313 in 2018. The state’s share of clinical trials registered nationally has also risen over this period from 13.1% to 15.2%.

*Figure A1.7: Number of clinical trials undertaken in South Australia compared with South Australia’s share, 2015-2018*

![Graph showing growth in clinical trials and SA share]

*Source: ANZCTR*

Declining SA share of national pharmaceutical exports

SA exported $80.4m of pharmaceutical products in 2018-19. This accounted for 1.4% of national pharmaceutical exports, compared to 1.7% in 2008-09.

*Figure A1.8: Share of Australia’s total pharmaceutical exports by state, 2008-2019*

![Graph showing share of pharmaceutical exports by state]

*Source: DFAT using ABS 5368.0*

**NB:** Re-exports are goods which are imported into Australia then exported without alteration.
Stable SA share of national medical device exports

SA exported $70.4m of medical device products in 2018-19. SA share of national medical device exports remained constant at 3.9% from 2008-2019.

Figure A1.9: Share of Australia’s total medical device manufacturing exports by state, 2008-2019

Source: DFAT using ABS 5368.0
## Appendix 2. HMR conceptual and measurement issues

Table A2.1: Differentiating research from other activities in the health sector

<table>
<thead>
<tr>
<th>Research</th>
<th>Service Evaluation</th>
<th>Clinical Audit</th>
<th>Surveillance</th>
<th>Usual Practice (in public health)</th>
</tr>
</thead>
<tbody>
<tr>
<td>The attempt to derive generalisable new knowledge including studies that aim to generate hypotheses as well as studies that aim to test them.</td>
<td>Designed and conducted solely to define or judge current care.</td>
<td>Designed and conducted to produce information to inform delivery of best care.</td>
<td>Designed to manage outbreak and help the public by identifying and understanding risks associated.</td>
<td>Designed to investigate outbreak or incident to help in disease control and prevention.</td>
</tr>
<tr>
<td>Quantitative research – designed to test a hypothesis. Qualitative research – identifies/explores themes following established methodology.</td>
<td>Designed to answer: “What standard does this service achieve?”</td>
<td>Designed to answer: “Does this service reach a predetermined standard?”</td>
<td>Designed to answer: “What is the cause of this outbreak?”</td>
<td>Designed to answer: “What is the cause of this outbreak?” and treat.</td>
</tr>
<tr>
<td>Addresses clearly defined questions, aims and objectives.</td>
<td>Measures current service without a reference to a standard.</td>
<td>Measures against a standard.</td>
<td>Systematic, statistical methods to allow timely public health action.</td>
<td>Systematic, statistical methods may be used.</td>
</tr>
<tr>
<td>Quantitative research – may involve evaluating or comparing interventions, particularly new ones. Qualitative research – usually involves studying how interventions and relationships are experienced.</td>
<td>Involves an intervention in use only. The choice of treatment is that of the clinician and patient according to guidance, professional standards and/or patient preference.</td>
<td>Involves an intervention in use only. The choice of treatment is that of the clinician and patient according to guidance, professional standards and/or patient preference.</td>
<td>May involve collecting personal data and samples with the intent to manage the incident.</td>
<td>Any choice of treatment is based on clinical best evidence or professional consensus.</td>
</tr>
<tr>
<td>Usually involves collecting data that are additional to those for routine care but may include data collected routinely May involve treatments, samples or investigations additional to routine care.</td>
<td>Usually involves analysis of existing data but may include administration of interview or questionnaire.</td>
<td>Usually involves analysis of existing data but may include administration of interview or questionnaire.</td>
<td>May involve analysis of existing data or administration of interview or questionnaire to those exposed.</td>
<td>May involve administration of interview or questionnaire to those exposed.</td>
</tr>
<tr>
<td>Quantitative research – study design may involve allocating patients to intervention groups. Qualitative research – uses clearly defined sampling framework underpinned by conceptual or theoretical justifications.</td>
<td>No allocation to intervention: the health professional and patient have chosen intervention before service evaluation.</td>
<td>No allocation to intervention: the health professional and patient have chosen intervention before audit.</td>
<td>Does not involve an intervention.</td>
<td>May involve allocation to control group to assess risk and identify sources of incident but treatment unaffected.</td>
</tr>
<tr>
<td>Normally requires HREC review.</td>
<td>Does not require HREC review.</td>
<td>Does not require HREC review.</td>
<td>Does not require HREC review.</td>
<td>Does not require HREC review.</td>
</tr>
</tbody>
</table>

Table A2.2: Available methods for evaluating HMR

<table>
<thead>
<tr>
<th>Method</th>
<th>Pros</th>
<th>Cons</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bibliometric analysis</td>
<td>* Quantitative: measures volume of output</td>
<td>* Estimates of quality by citations and journal impact factors (JIFs) can be misleading</td>
</tr>
<tr>
<td></td>
<td>* Can be used to indicate quality of output</td>
<td>* Use of JIFs can obscure the impact of individual articles</td>
</tr>
<tr>
<td></td>
<td>* Enables analysis of global trends</td>
<td>* Data are difficult to compare across research fields and disciplines</td>
</tr>
<tr>
<td></td>
<td>* Suited to repeated analyses</td>
<td>* Analysis complicated by the introduction of electronic publications and open and public access journals</td>
</tr>
<tr>
<td></td>
<td>* A number of new bibliometric indicators, such as the H-index and Y-Factor, are being developed (Ball, 2005; Ball, 2006)</td>
<td>* No consideration of the value of ‘grey’ literature</td>
</tr>
<tr>
<td>Case study analysis</td>
<td>* Provides in-depth analysis of the process of discovery</td>
<td>* Selection bias: cases chosen may not be representative</td>
</tr>
<tr>
<td></td>
<td>* Can demonstrate pathways from basic science to application in health services</td>
<td>* Often difficult to track and interpret the history of scientific discovery</td>
</tr>
<tr>
<td></td>
<td>* Information useful for a range of purposes (e.g. reporting to stakeholders, media)</td>
<td>* Problems of recall bias</td>
</tr>
<tr>
<td>Systematic peer review</td>
<td>* Well understood component of research management</td>
<td>* Time consuming for experts</td>
</tr>
<tr>
<td></td>
<td>* Widely accepted by the research community</td>
<td>* Concerns about objectivity and variability of judgements and lack of transparency</td>
</tr>
<tr>
<td>Surveys and consultations</td>
<td>* Can identify outputs and outcomes associated with particular pieces of funding/ research</td>
<td>* Dependent on contact details being available, e.g. for past award holders</td>
</tr>
<tr>
<td>Economic rate of return</td>
<td>* Can be applied to variety of sectors</td>
<td>* Poor response rates can lead to biased responses</td>
</tr>
<tr>
<td>(a) Micro-economic analysis</td>
<td>* Case-based studies provide a rich source of data e.g. HTA contribution to national guidelines</td>
<td></td>
</tr>
<tr>
<td></td>
<td>* Can be used comparatively, e.g. contribution of cost effectiveness studies</td>
<td></td>
</tr>
<tr>
<td>(b) Macro-economic analysis</td>
<td>* Quantitative</td>
<td>* Involves subjective decisions around attribution of what’s involved and therefore what to ‘cost’</td>
</tr>
<tr>
<td></td>
<td>* Provides big picture and context</td>
<td>* Difficult to put financial value on many influences involved</td>
</tr>
<tr>
<td></td>
<td>* Demonstrates likely directions</td>
<td></td>
</tr>
<tr>
<td></td>
<td>* Potentially powerful political tool</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Source: *Medical Research: assessing the benefits to society, a report by the UK Evaluation Forum* (2006), p16
### Table A2.3: NHMRC definition of impact

<table>
<thead>
<tr>
<th>Type of impact</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Knowledge Impact</strong></td>
<td>New knowledge demonstrating the benefits emerging from adoption, adaption or use of new knowledge to inform further research, and/or understanding of what is effective.</td>
</tr>
<tr>
<td></td>
<td>recognition of research publications (e.g. citation metrics, particularly field weighted); data sharing; contribution to registries or biobanks; prizes and conference presentations; uptake of research tools and techniques; evidence of uptake of the research by other disciplines</td>
</tr>
<tr>
<td><strong>Health Impact</strong></td>
<td>Improvements in health through new therapeutics, diagnostics, disease prevention or changes in behaviour; or improvements in disease prevention, diagnosis and treatment, management of health problems, health policy, health systems, and quality of life.</td>
</tr>
<tr>
<td></td>
<td>policy or program adopted; a clinical guideline adopted; international or national practice standards adopted; improved service effectiveness; Phase I, II and III clinical trials underway or completed; improved productivity due to research innovations (e.g. reduced illness, injury); Quality-Adjusted Life Years, Potential Years of Life Lost, Patient Reported Outcome Measures and other relevant indicators; relative stay index for multi-day stay patients; hospital standardised mortality ratio; cost per weighted separation and total case weighted separation reports (including community and government)</td>
</tr>
<tr>
<td><strong>Economic Impact</strong></td>
<td>Improvements in the nation’s economic performance through creation of new industries, jobs or valuable products, or reducing health care costs; improving efficiency in resource use or improving the welfare/well-being of the population within current health system resources. An economic impact may also contribute to social or health impacts, including human capital gains and the value of life and health.</td>
</tr>
<tr>
<td></td>
<td>Health Care System Savings; relative stay index for multi-day stay patients, hospital standardised mortality ratio, cost per weighted separation and total case weighted separation; reduction in Medicare Benefits Schedule/Pharmaceutical Benefits Scheme costs; improved productivity due to research innovations (e.g. reduced illness, injury); improved service effectiveness Product Development; a research contract with an industry partner and an active collaboration; granting of a patent; execution of a licensing agreement with an established company; income from intellectual property; raising funding from venture capital or other commercial sources or from government schemes that required industry co-participation; successful exit from start-up company (public market flotation, merger or acquisition); development of pre-goods manufacturing practice prototype; successful generation or submission of a regulatory standard data set, applications for pre-market approval of a medical device, a new drug or device for registration (e.g. by Food and Drug Administration, European Medicines Agency, Therapeutic Goods Administration); product sales</td>
</tr>
<tr>
<td><strong>Social Impact</strong></td>
<td>Improvements in the health of society, including the well-being of the end user and the community. This may include improved ability to access health care services; to participate socially (including empowerment and participation in decision making) and to quantify improvements in the health of society.</td>
</tr>
<tr>
<td></td>
<td>uptake or demonstrated use of evidence by decision makers/policy makers; qualitative measures demonstrating changes in behaviours, attitudes, improved social equity, inclusion or cohesion; improved environmental or social determinants of health; changes to health risk factors</td>
</tr>
</tbody>
</table>

*Source: NHMRC*[^83]

## Appendix 3. Jurisdictional HMR commercialisation initiatives

<table>
<thead>
<tr>
<th>Jurisdiction</th>
<th>Commercialisation initiative</th>
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</thead>
<tbody>
<tr>
<td><strong>New South Wales</strong></td>
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</tbody>
</table>
|                    | • **The medical devices fund**  
|                    | Established in 2013, the Fund has awarded approximately $55 million for commercialisation activities to date.  
|                    | • **The medical devices commercialisation training program**  
|                    | Initiated through the NSW Office for Health and Medical Research in 2014, this program is expected to provide learning opportunities for up to 200 NSW-based researchers a year over the next four years. |
| **Victoria**       |  
|                    | • **Victorian medical research acceleration fund**  
|                    | Created under Victoria’s HMR strategy 2016-2020, the aim of the Fund is to support early stages of HMR. It provides $3 million per funding round. |
| **Queensland**     |  
|                    | • **Bio-venture fund**  
|                    | The Queensland government committed $25 million in 2010 to support the development and commercialisation of HMR from across the globe.  
|                    | • **Translational research institute (TRI)**  
|                    | Supported by Australian and Queensland governments, TRI is a joint venture between Queensland Health, The University of QLD, QUT and the Mater Hospital.  
|                    | • **QIMR Berghofer medical research institute**  
|                    | A fully integrated biomedical R&D centre, the QIMR Berghofer supports the translation of fundamental basic research from discovery to development, scale up and manufacture, and Phase I and II clinical trials. |
| **Western Australia** |  
|                    | • **Future Health Research and Innovation (FHRI) Fund**  
|                    | The FHRI Fund was established through the 2017 FHRI policy. It includes two funding streams: research; and innovation and commercialisation. $30 million over four years from 2013-14 to 2016-17. |
| **Cross-jurisdictional** |  
|                    | • **The Medical Research Commercialisation Fund (MRCF)**  
|                    | MRCF is a seed fund established in 2007 and is a collaboration between several medical research institutes, Australian and state governments and super funds. Managed by Brandon Capital Partners, it invests exclusively in commercialisation opportunities from member institutes.  
|                    | • **NHMRC Development Grants**  
|                    | Provides funding for 1-3 years to support individual researchers, research teams, or a health and medical research company in partnership with researchers to undertake research at the early proof-of-principle or pre-seed stage.  
|                    | • **UniSeed**  
|                    | Established in 2000, UniSeed is a $60 million venture fund established operating at the Universities of Melbourne, Queensland and New South Wales, with investment capital provided by the three universities and AustralianSuper. It exclusively facilitates the commercialisation of IP generated by the three partner universities.  
|                    | • **UniQuest**  
|                    | UniQuest was established in 1984 as the main commercialisation arm of The University of Queensland. It has developed commercialisation agreements and partnerships with the Mater Medical Research Institute; University of Wollongong; University of Technology, Sydney; James Cook University; University of Tasmania; and Queensland Health. |