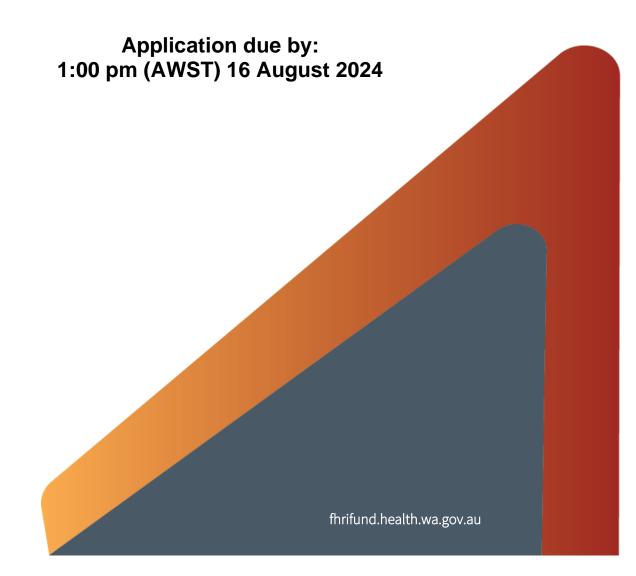


# Major Research and Innovation Application Support

## **Guidelines and Conditions**



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#### 1. Introduction

The Major Research and Innovation Application Support (MRIAS) program is a Program of the Western Australian (WA) Future Health Research and Innovation (FHRI) Fund.

The FHRI Fund provides a secure source of funding to drive health and medical research, innovation and commercialisation, and through these activities improve the health and prosperity of all Western Australians. It also provides an opportunity to diversify the economy, create jobs, improve the sustainability of the health system and position WA as a leader in research and innovation.

This Program contributes to the **FHRI Fund Priority Goal**:

 Provide cash commitments for submission to major competitive co-funding programs, making Western Australian-led applications more competitive and, therefore, increasing the State's share of national and international competitive funding.

The expected outcomes are in alignment with the following objectives of the Western Australian Future Health Research and Innovation Fund Act 2012 (the Act):

- improving the health and wellbeing of Western Australians
- improving Western Australia's economic prosperity
- advancing Western Australia to being, or maintaining Western Australia's position as, a national or international leader in research and innovation activities.

The Program is administered by the Office of Medical Research and Innovation (OMRI), WA Department of Health (Department of Health). Queries may be directed to DOH.OMRI@health.wa.gov.au.

### 2. Purpose

The purpose of the Program is to provide a competitive mechanism to allocate State Government co-funding support to competitive research or innovation applications to national or international grant funding programs.

The aims of the Program are to:

- promote high-quality research and innovation in WA
- enable opportunities for the translation or commercialisation of research or innovation outcomes to improve the health and/or wellbeing of the WA community
- enhance WA's standing as a leader in health and medical research and innovation.

The objectives of the Program are to:

- improve WA success rates for eligible health and medical research and innovation grant funding programs (External Programs)
- increase the competitive grant income brought into, and expended in, WA.

## 3. Program description

The MRIAS Program provides in-principle cash commitments for WA research or innovation applications being submitted to nationally or internationally competitive external grant funding programs (External Programs), that either require State Government cofunding, or favourably view applications that include co-funding.

The MRIAS Program will support applications for research or innovation co-funding that:

- build WA capability and capacity in research or innovation
- · address significant health and medical issues in WA

attract additional competitive grant funding that is expended in WA.

The MRIAS program will accept applications that align with the FHRI Fund's definition of research or innovation.

#### Research is inclusive of:

- Understanding human health, wellbeing and disease, and the biological behavioural, social and environmental factors that contribute to these
- Measuring the magnitude and distribution of a health problem
- Developing solutions, interventions, products and technologies that could contribute to improving human health and wellbeing
- Understanding how interventions, policies and programs aimed at improving human health and wellbeing can be most effectively delivered.

#### Innovation is inclusive of:

- The development, application and/or commercialisation of the outcomes of the grant funding obtained through the External Program, for the purpose of improving human health and wellbeing
- The development and delivery of new or improved products, policies, systems and services and delivery methods that seek to improve people's health.

MRIAS applicants must be planning to submit an application to an eligible External Program.

Eligible external grant funding programs must:

- be nationally or internationally advertised
- be competitively available to all potential applicants (i.e. not limited to particular groups or organisations)
- have well-defined mechanisms for competitive assessment and selection
- require or encourage co-funding
- be for health and medical research and/or innovation activities
- demonstrate that the majority of the work and expenditure will occur in WA.

#### For the purposes of MRIAS, eligible External Programs include:

- Australian Cancer Research Foundation Major Grant
- ARC Linkage Projects
- BioMedTech Horizons Program, MTPConnect
- Brandon BioCatalyst CUREator
- DISR Cooperative Research Centre Projects
- MRFF Cardiovascular Health Mission
- MRFF Clinical Trials Activity Initiative
- MRFF Frontier Health and Medical Research Initiative
- MRFF National Critical Research Infrastructure Initiative Stream 3
- NHMRC Collaborations in Health Services Research
- NHMRC Partnerships Program.

Requests to consider other External Programs not listed above may be made by submitting an MRIAS External Program Eligibility Form along with the MRIAS application.

Applications with the primary purpose of addressing the FHRI Fund Focus areas of Aboriginal, rural and regional health, Burden of diseases, COVID-19 and long-COVID or Mental Health are encouraged.

The Activity Lead will be responsible for ensuring all partners in the proposed research or innovation activity are adequately involved in the development of the application to the External Program.

The Activity Lead must advise OMRI as soon as they are notified of the outcome of their application to the External Program.

The Activity Lead must provide OMRI with a copy of their External Program application prior to submission to the External Program, and if unsuccessful, provide a copy of feedback received from the External Program.

The Activity Lead will be responsible for coordinating the Activity and complying with all reporting requirements, if successful.

The Responsible Entity\* will be accountable for the governance and financial management of any funding awarded.

\* It is acknowledged that the term Administering Institution has traditionally been used by universities and research institutes, however the term Responsible Entity is inclusive of industry and reflects that grant agreements are the responsibility of the contracted entity.

#### 4. Eligibility

To be eligible for this Program all criteria below must be met:

- The Responsible Entity must:
  - have an active Australian Business Number (ABN)
  - have a physical and operational presence in WA.
- The Activity Lead must:
  - be an Australian or New Zealand citizen, a permanent resident of Australia, or have an appropriate work visa in place for the duration of the Activity
  - o be based in WA for a minimum of 80 per cent of the period of the Activity
  - have no overdue reports for any grant funding program administered by OMRI (including FHRI Fund programs) from any year (excludes authorised extensions)
  - ensure that funding has not been awarded for any component of the Activity
  - o have a position or title at the Responsible Entity for the period of the Activity The Activity Lead will be required to declare which of the following applies:
    - (a) employee of the Responsible Entity; or
    - (b) honorary or adjunct title at the Responsible Entity.

In the case of (a), if the Activity Lead is also employed by the WA public health system (may include Clinical Academics) they will register a Conflict of Interest for this grant in accordance with the Department of Health Managing Conflicts of Interest Policy that addresses how the Activity Lead intends to ensure WA Health intellectual property (IP) is protected.

In the case of (b), if the Activity Lead is employed by another entity (the Employer), this entity must have an active ABN, a physical and operational presence in WA and evidence must be provided that either:

- i. an affiliation agreement\* exists between the Responsible Entity and the relevant Employer; or
- ii. the intention is for this Activity to be subcontracted\* to the relevant Employer and there is in-principle agreement between the Responsible Entity and the Employer for this arrangement.
- \* the affiliation/subcontract agreement must clearly define each entity's responsibilities in relation to the Activity, and in accordance with the 'Contractual arrangements' section below, include relevant permissions to use third-party

intellectual property (IP) required to deliver the Activity and address ownership of new IP generated by the Activity.

- The Responsible Entity or other entities that fund or are involved in the Activity must not be part of an industry that produces products or services that may contribute to poor physical health or mental wellbeing of the community
- The grant funding must not constitute the entire financial base of the Responsible Entity i.e. the Responsible Entity must have other external sources of income
- The Responsible Entity must ensure applications meet all eligibility criteria set out in these guidelines and in the intended External Program guidelines
- Applications must be submitted in accordance with the 'Application instructions' section of this document
- An application may be deemed ineligible and excluded from further consideration if OMRI identifies that:
  - it does not meet all eligibility criteria as set out in these or the External Program guidelines
  - the proposed Activity duplicates activity previously or currently being undertaken
  - it is not undertaking an innovation or research activity e.g. is a 'business as usual activity', such as quality improvement
  - o it includes any incomplete, false or misleading information
  - o it was submitted after the advertised closing date and time.
- Grant offers may be withdrawn if it is determined that eligibility criteria are not met
- OMRI reserves the right to request further information and make final decisions regarding eligibility
- Decisions made in relation to previous grant programs will not be regarded as precedents and will not be considered when assessing eligibility for this grant program.

## 5. Program funding

The cash amount requested in the MRIAS application can be up to \$1 million (excluding GST) per application, paid over a period of up to 6 years.

The requested amount cannot exceed the total amount of the cash amount requested from the External Program and other partner cash contributions (combined). In-kind contributions are excluded from this amount.

The amount requested from MRIAS, partners and the External Program must allow for expenditure in WA to be at least double the MRIAS funding amount requested.

Funding will not be disbursed until evidence is provided to OMRI that the External Program application has been successful, and an appropriate funding agreement has been executed.

Requested FTE, salary level, costs and duration must reasonably reflect the proposed Activity and be directly attributable to the delivery of the proposed Activity.

Funding will only be made available for the scope of work described in the Application Form, or any modifications to the scope of work approved in writing by OMRI. The Department of Health will not underwrite any costs beyond the funding awarded through the Program.

The intention is that funding will be spent within WA unless goods and services expenditure items are not available in WA and/or it is beneficial to WA if goods or services are procured from outside WA.

All budget items must be adequately described and justified as consideration is given to budgets during the assessment process.

Budgets must be calculated accurately, as requests for additional funding will not be considered.

In-principle support and subsequent funding is offered subject to budget availability, which could be varied in the event of unforeseen circumstances.

Any unexpended funds related to the MRIAS funding must be returned to the Department of Health. Any over-expenditure is the responsibility of the Responsible Entity and no claim may be made against the Department of Health.

#### Letter of commitment

Successful applicants to the MRIAS program will be provided with a letter outlining the inprinciple cash commitment and a letter of support to accompany their application to the External Program.

If the Letter of Support is required to be provided on a specific format or template by the External Program, the Activity Lead will provide this for completion by the OMRI. If the External Program does not mandate a specific format or template, the Activity Lead will provide guidance to the Department of Health regarding the information to be included in the letter, preferably in a template with standardised wording.

#### 6. Application instructions

The instructions below must be followed when making a submission:

- The Application Form available from the <u>FHRI Fund website</u> must be submitted by 1:00 pm (AWST) Friday 16 August 2024
- The application must be completed in Arial font 11 point or larger
- Electronic signatures are acceptable if approval to use the electronic signature has been obtained from that person
- The application is to be emailed to <u>DOH.OMRI@health.wa.gov.au</u> as a <u>single</u>
   Adobe Acrobat PDF or Microsoft Word file, not exceeding 5 MBs, including CVs and
   bibliographic references (if applicable). The application document and email subject
   line must be titled as follows:

Activity Lead SURNAME, First name – MRIAS Round 1 e.g. SMITH, Alex – MRIAS Round 1

 Applications must be complete, include requested certifications and be submitted by the closing date/time. Consideration must be given to the time needed to comply with internal deadlines.

Acknowledgement of receipt of the Application Form will be provided via email to the Responsible Entity and Activity Lead within 5 working days of the closing date.

Applications including commercially sensitive information should be marked as commercial-in-confidence, noting that the 'Activity summary' section in the Application Form may be used for publicity purposes.

Queries regarding the application process should be directed by email to DOH.OMRI@health.wa.gov.au.

#### 7. Selection process

#### Assessment process

Commitments of in-principle co-funding will be made through a competitive, merit-based process, and will only be made for high-quality proposals.

Applications will be assessed by the OMRI for eligibility to both the MRIAS and the External Program prior to assessment, and those not meeting the eligibility requirements will not continue to the assessment stage.

A copy of the External Program's assessment criteria must be submitted with the Application Form.

All eligible applications will be referred for assessment and scoring by a review panel comprising of experienced researchers and innovators, subject matter experts and consumer representatives.

Conflicts of interest that may arise in the assessment and selection process will be treated in accordance with the Department of Health Managing Conflicts of Interest Policy.

The assessment will be based on the criteria and % weightings set out in the table below and will include an assessment of the MRIAS application against the External Program's assessment criteria.

It is expected that applicants will use the MRIAS panel's feedback to further develop their External Program application prior to submission to the External Program.

Assessment Criteria	%
Competitiveness for External Program funding  The MRIAS applications competitiveness against the External Program's assessment criteria.	50
Significance of the Activity for WA	
<ul> <li>the significance of the issue or opportunity for WA (relevance/scale)</li> <li>how the proposed Activity will address the issue or opportunity</li> <li>potential to build WA capability and capacity in research and/or innovation</li> <li>the expected benefits to the WA community (e.g. reduced inequities, improved health outcomes, economic, social and environmental benefits)</li> <li>potential for translation and implementation of findings into policy, practice and/or the development of new processes, products and/or services, and commercialisation, if applicable.</li> </ul>	
Alignment with FHRI Fund Focus Areas	
<ul> <li>The primary purpose of the application addresses the FHRI Fund Focus Areas of:         <ul> <li>Aboriginal and/or regional WA health issues</li> <li>Burden of diseases in WA</li> <li>Living with COVID-19 and Long COVID</li> <li>Mental health.</li> </ul> </li> <li>Scoring of this criterion will be either a 'yes' or 'no', with the answer 'yes' equalling 10% and 'no' equalling 0%</li> </ul>	
Consumer Involvement	
<ul> <li>evidence of appropriate levels of effective consumer involvement (people with a lived experience of a health issue e.g. patients, carers, community members) throughout the design and development of the proposed activity</li> <li>plan for ongoing engagement in the activity, including how lived experience perspectives will inform the activity through formal and informal processes as per the Consumer Involvement section in this document.</li> </ul>	

#### Selection of recipients

Based on the review panel's assessments, the Department of Health will determine and approve the awarding of in-principle co-funding.

Subject to the External Program application being successful, grants will be provided in accordance with the Department of Health financial and procurement processes and delegation authorities.

OMRI reserves the right to offer lower funding rates than requested and/or request modification to the Activity on a case-by-case basis.

#### 8. Consumer involvement

In line with the National Health and Medical Research Council (NHMRC) definition, consumers are people who have lived experience of a health issue. They include patients and potential patients, carers, and people who use health care services. Consumers can also be people who represent the views and interests of a consumer organisation, a community, or a wider constituency.

There is increasing recognition of the benefits of involving consumers in research and innovation. Effective consumer involvement can ensure research and innovation is relevant to the WA community and improves translation into policy and practice.

Health consumers should be engaged during the development of funding applications and embedded in the proposed Activity by being provided with a detailed description of their role and contribution and, where appropriate, included as a team member.

Consumer involvement should incorporate:

- clearly defined relationships with health consumers or community groups who have 'lived experience' of the issue the Activity addresses
- demonstrated understanding of the benefits derived from involving people with a lived experience
- inclusion of consumers in the Activity where appropriate
- plans to involve consumers in the Activity throughout the delivery timeline
- budget strategy with funds allocated to support, implement and acknowledge consumer involvement (e.g. training opportunities, honoraria and payments, additional time to support involvement activities, administration support and consultations and events associated with involvement activities).

Guidance on consumer involvement can be found at the <u>Consumer and Community Involvement Program</u> website and the <u>NHMRC Statement on Consumer and Community Involvement in Health and Medical Research 2016.</u>

It is encouraged that all team members complete the free online 30 minute <u>Consumer and Community Involvement in Health Research</u> course (or equivalent) and for the Activity Lead to complete the free online 30 minute <u>Consumer & Community Involvement and Grant Writing</u> course.

## 9. Contractual arrangements

#### Agreement

Grants will be offered in accordance with either:

the External Program funder's multi-institutional/collaboration agreement or equivalent

- a Department of Health Grant Funding Agreement if the Responsible Entity is external to the WA public health system, or
- a Memorandum of Understanding (MOU) if the Responsible Entity is within the WA public health system.

The Responsible Entity must ensure that appropriate agreements are in place with the Activity Lead, team members and participating entities.

The Department of Health reserves the right to withdraw an offer of award to a Responsible Entity if the Grant Funding Agreement and/or Grant Funding Agreement Terms and Conditions, or MOU, cannot be agreed between the parties.

#### Insurance

A Responsible Entity external to the WA public health system will be required to provide evidence of insurance as a condition of the Grant Funding Agreement (or equivalent), which may include:

- Public Liability (mandatory for all grants)
- Professional Indemnity (mandatory if the Responsible Entity is conducting a clinical trial, provides any form of medical treatment or advice, training, or will provide any tailored design, advice or specification services)
- Property for the Responsible Entity's replacement value of assets (mandatory for building, plant, machinery, equipment)
- Workers Compensation (mandatory if the Responsible Entity has employees or is paying salaries, noting this includes payments to working Directors)
- Product Liability (mandatory if the Responsible Entity manufactures, supplies, sells, services or repairs a product)
- Motor Vehicle if the Responsible Entity owns vehicles
- Clinical Trials if the Responsible Entity undertakes clinical trials (note this insurance may include Professional Indemnity)
- Cyber Liability if the Activity involves confidential data, e.g. identifiable patient information.

OMRI recommends that you seek advice from your insurance advisors to confirm the level and type of insurance that is required for the Activity.

The Responsible Entity is responsible for ensuring participating entities have appropriate insurance.

Note: Any Activity that requires site governance approval will also be required to provide evidence of appropriate insurance during the governance process, which may vary depending on the site.

#### Payment instalments

The payment schedule will be developed to accommodate the funding requirements of the External Program funder.

If ethics and governance approvals are required for the Activity, then the Responsible Entity may only release MRAS funding to the Activity Lead once all approvals for the Activity have been obtained and lodged with the Responsible Entity.

The Department of Health reserves the right to suspend payment of funding instalments where Activity viability has become uncertain.

#### Termination of funds

Funds shall revert to, or be recoverable by, the Department of Health in instances where:

- eligibility requirements are no longer met, unless a request for variation to address this is approved by OMRI
- the External Program grant is terminated
- the Activity is terminated by OMRI as a result of insufficient progress being made at the time of Progress Reports or any interim Progress Report, or it has been otherwise determined by either the Responsible Entity or OMRI that the Activity is no longer viable
- full or partial funding for the Activity is obtained from another source
- funds are used for purposes other than those for which they were awarded
- funds were spent on activities that require data sharing, ethics and/or governance approvals and such approvals were not obtained before undertaking the activities
- funds are not fully expended at the conclusion of the Activity (including any extensions approved by OMRI)
- it is determined that misleading or fraudulent information has been provided
- the Responsible Entity does not enter into formal agreements with respect to this Activity, which includes Intellectual Property ownership, where appropriate
- other entities fund or are involved in the Activity that are part of an industry that
  produces products or services that may contribute to poor physical health or mental
  wellbeing of the community.

#### Additional funding sources

Additional sources of funding are permitted, and encouraged, provided the additional funding supports activities that complement, but do not duplicate, the Activity for which grant funding under this Program is awarded.

#### Requests for variation

Requests for variations to the Grant Funding Agreement or MOU, such as Activity description, Activity Lead or Responsible Entity, must be directed to OMRI. Approval of the variation will be at the discretion of the Department of Health. If variations are not approved this could result in termination of the grant with associated funding reverting to, or being recoverable by, the Department of Health, where for example eligibility or viability of the Activity is affected.

## 10. Approvals

#### Research ethics and research governance

The Responsible Entity, and any participating entity, will be responsible for obtaining and lodging all relevant research ethics and governance approvals that are required for undertaking funded activities, and ensuring these are maintained as required for the duration of the Activity.

Research ethics approvals must be obtained from relevant ethics committees (human and/or animal). Research governance authorisation (also known as site specific assessment or access request review) must be obtained from each relevant institution/site conducting the Activity or providing access to data, participants or tissue samples.

For information on research ethics and governance submission requirements for the WA public health system please refer to the following websites: Research Ethics; Research Governance; Multi-centre Research.

#### Use of data collections

An Activity that requires access to and use of WA Department of Health data collections requires review and approval for data release in accordance with the <u>Health Services Act</u> <u>2016</u> and the <u>Health Services (Information) Regulations 2017</u>. This is in addition to research ethics and governance approvals and will include a feasibility assessment to determine whether the data requested is appropriate for the purposes of the study and approval for use of the data from the data custodian.

Preliminary cost and time estimates can be obtained by contacting <a href="DataServ@health.wa.gov.au">DataServ@health.wa.gov.au</a>. Cost estimates should be included in the proposed budget and an estimate of time for release of the data should be incorporated into the milestones in the Application Form.

For further information please review the <u>Data Linkage Services</u> website. Should the application for funding be successful, we recommend you immediately begin the data request and approval process.

#### 11. Reporting

The Activity Lead and Responsible Entity are responsible for meeting reporting requirements over the duration of the Activity and at its conclusion.

OMRI acknowledges that the External Program may have its own reporting requirements. Where feasible and appropriate, reports prepared for the External Program funder may be accepted by OMRI as meeting the MRIAS financial and activity reporting requirements.

Where required, report template forms will be provided by OMRI, which must be used if the External Program reporting requirements do not address MRIAS reporting requirements.

A copy of all reports provided to the External Program funder, either as a requirement of the External Program or for any other reason, must be forwarded to OMRI.

OMRI reserves the right to request a progress report at any point.

#### Community Stakeholder Brief

In order to provide feedback to consumers, a one-page *Community Stakeholder Brief* which includes an outline of the Activity, its outcomes, and next steps is to be provided to all participating consumers and a copy submitted to OMRI with the Final Activity Report.

## 12. Publicising, acknowledgements and publications

All details and information regarding MRIAS applications will be kept confidential until outcomes of the External Program application have been announced.

Acknowledging there is an embargo period for successful applicants, MRIAS applicants must contact the OMRI as soon as they are advised by the External Program that they have been successful.

The Minister for Medical Research and/or the Department of Health will publicly announce recipients, including the title of the Activity. All other parties must withhold announcement/media coverage until after OMRI advises this has occurred.

The Department of Health will work with the Responsible Entity to determine announcement dates, noting that the External Program publicity conditions, if any, take precedence.

Acknowledgement of FHRI Fund support must be made in publications, conference presentations, public discussion, press statements etc. A copy of any published material or media must be provided to Us.

In order to maximise knowledge exchange, funding recipients must comply with the NHMRC 'Publication and dissemination of research: a guide supporting the Australian Code for the Responsible Conduct of Research', which can be downloaded from the <u>Australian Code for the Responsible Conduct of Research</u> page, and the <u>NHMRC Open Access Policy</u>.

### 13. Confidentiality

Activity title, Activity Lead, funding amount, Responsible Entity, plain language summaries and sections indicated on applications or reports may be used for publicity purposes.

All other information provided in applications and reports will be maintained confidentially by OMRI, review panels, evaluation panels and the FHRI Fund Advisory Council. If requests are received by OMRI to make public any aspect of the Activity, other than the aspects listed above, the authorisation of the Responsible Entity will be sought, notwithstanding information requested under the <u>Freedom of Information Act 1992 (WA)</u> or information pertaining to the receipt of State Government financial assistance tabled in the Parliament of Western Australia.

#### 14. Evaluation

OMRI undertakes evaluations of Funding Programs, which will include unsuccessful applications. All parties in the application, including team members and consumer representatives, are required to contribute to the evaluation.

## 15. Complaints

Responsible Entities or Activity Leads who feel that their interests have been adversely affected by an action taken by OMRI in administering the Program may lodge a complaint. Complaints can only be considered when they refer to the administrative process and not to the funding decision. Complaints must be submitted via email (marked Confidential) to: Deputy Director General (OfficeoftheDDG@health.wa.gov.au)



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