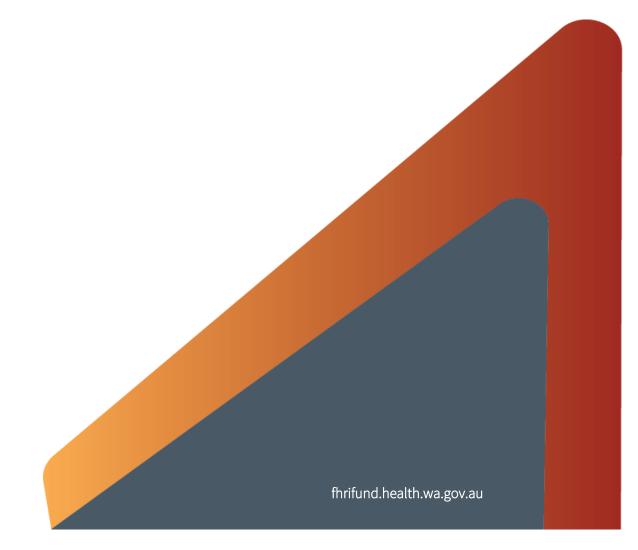


# FHRI Fund Consumer and Community Involvement Support

# **Guidelines and Conditions**

# **Applications close:**

1:00 pm (AWST) Wednesday 18 December 2024



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#### 1. Introduction

The FHRI Fund Consumer and Community Involvement Support program (the Program) is a funding program of the Western Australian (WA) <u>Future Health Research and Innovation (FHRI) Fund.</u>

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 Goals:

- enhance clinical trial capacity and expertise to improve the quality of clinical trials in WA and make the State more attractive to funders of clinical trials (grant funding and commercial sponsors)
- enhance health and medical research literacy, skills and experience of consumers so that they engage more in research
- establish innovation Programs and Initiatives to support topical and/or early-stage ideas and enable opportunities for these innovative ideas to secure follow-on funding from commercial/other funders.

The expected outcomes are in alignment with the following objectives of the <u>Western</u> Australian Future Health Research and Innovation Fund Act 2012:

- improving the health and wellbeing of Western Australians
- 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 support consumer and community involvement (CCI) in research and innovation activity ideation, development and writing of grant applications and ongoing involvement in FHRI Fund and nationally supported research and innovation activities.

The aims of the Program are to:

- improve the quality of research and innovation activities funded by the FHRI Fund and their translatable outcomes by inclusion of improved CCI
- increase CCI capacity in WA for research and innovation activities contributing to WA being able to continue its position as a national leader in CCI.

The objectives of the Program are to:

- facilitate community involvement and engagement in research and innovation
- empower consumers and community to inform research and innovation priorities and methodologies
- increase the likelihood of translatable research and innovation outcomes.

# 3. Program description

Consumers are defined as people who have lived experience of a health issue. They include patients, 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, community, or a wider constituency.

Effective consumer involvement ensures research and innovation is relevant to the WA community and improves translation into policy and practice.

Further guidance on consumer involvement can be found at the WA Health Translation Network Consumer and Community Involvement Program website and in the NHMRC Statement on Consumer and Community Involvement in Health and Medical Research 2016.

Applications to the Program can be made for the following stages of CCI support:

#### Option A:

 incorporating CCI activities to inform research and/or innovation priorities and ideas for future research and/or innovation activities.

#### Option B:

- incorporating CCI activities to develop and write a planned FHRI Fund or national research or innovation grant application
- incorporating CCI activities into an existing FHRI Fund or national research or innovation activity where CCI activity is not already funded.

The Program encourages applications with the primary purpose of addressing one of the following FHRI Fund Strategy Focus Areas:

- A (Aboriginal, rural and remote health)
- B (Burden of diseases)
- C (living with COVID-19 and Long COVID)
- M (Mental health).

Funding will be awarded through a competitive and merit-based process.

The Activity Lead will be responsible for coordinating the Activity and ensuring its timely execution.

The Activity Lead may nominate a CCI Lead to undertake the CCI activities, who is culturally appropriate, as required. The CCI Lead will work under the direction of the Activity Lead.

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 for this grant, 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 of the following criteria apply:

- 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
  - physically reside 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 the Office of Medical Research and Innovation (OMRI) (including FHRI Fund programs) from any year (excludes authorised extensions)
- ensure that funding has not been awarded for any component of the Activity.
- 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 <u>register</u> a Conflict of Interest for this grant in accordance with the Department of Health <u>Managing Conflicts of Interest Policy</u> 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 as set out in these guidelines.
- Applications must be submitted in accordance with the 'Application instructions' section of this document.
- An Activity Lead may submit more than one application to the Program, providing that there is no overlap in the Activity.
- An application may be deemed ineligible and excluded from further consideration if OMRI identifies that:
  - o it does not meet all eligibility criteria as set out in these guidelines
  - the proposed Activity duplicates activity previously or currently being undertaken
  - 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

Funding amounts up to \$25,000 excluding GST are available to successful applications to finance the Activity to be completed within a 12-month period.

Funding is available for the following:

#### • Option A:

 incorporating CCI activities to inform research and/or innovation priorities and ideas for future research and/or innovation activities.

#### • Option B:

- incorporating CCI activities to develop and write a planned FHRI Fund or national research or innovation grant application
- o incorporating CCI activities into an existing FHRI Fund or national research or innovation activity where CCI activity is not already funded.

Funding is not intended to support research and innovation activities supported through State-based funding sources, other than the FHRI Fund.

Requested costs must reasonably reflect the proposed Activity and be directly attributable to the delivery of the proposed Activity.

Funding will be in accordance with the following:

#### Costs:

- must only include CCI Lead payments, expenses associated with hosting CCI events, honorariums, consumer payments, other supplies and catering for CCI activities and travel directly related to the Activity
- for travel will not be approved unless strongly justified as being essential to the undertaking of the Activity and must not include costs related to conference attendance.

#### Overhead charges:

 may be requested up to a maximum of 10% of the total budget, noting that WA public health system Responsible Entities cannot claim standard overhead charges in accordance with the Financial Management Manual s522 (grant funding administered by the OMRI is exempt).

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 should 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.

Funding is offered subject to budget availability, which could be varied in the event of unforeseen circumstances.

# 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) Wednesday 18 December 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 –CCISupport e.g. SMITH, Alex – CCISupport.

 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

Funding will be awarded on merit, based on a process of assessment and selection.

Depending on the number of applications received, a review panel may conduct a shortlisting assessment stage to determine the eligible applications that are most aligned with the aims and objectives of the Program.

All eligible applications, or only those selected if a shortlisting assessment stage is undertaken, will be referred for full assessment and scoring by a review panel comprising of consumer representatives, health and medical research and innovation experts and the Department of Health CCI coordinator.

This assessment will be based on the criteria and % weightings set out in the table below.

Conflicts of interest that may arise will be treated in accordance with the WA health system Managing Conflicts of Interest Policy.

Assessment Criteria	%
Significance of the Activity	20
<ul> <li>Option A (CCI activities for ideation and prioritisation)</li> <li>planned FHRI Fund, NHMRC or MRFF grant applications relevant to this Activity.</li> </ul>	
<ul> <li>Option B (CCI activities for grant application development or for existing activity)</li> <li>the significance of the proposed issue to the community according to the community</li> </ul>	
the expected benefits to the WA community (e.g. reduce inequities, improved health outcomes, economic, social, and environmental benefits).	

Activity plan  Appropriate involvement of consumers and/or community members to achieve the Activity objectives including:  • the proposed CCI methodologies  • proposed locations where the Activity will be undertaken  • an achievable timeline.	50
Activity Lead and team track record and potential     Capacity of the team to conduct the Activity relative to opportunity.     Experience and expertise of the Activity Lead, CCI Lead and the team to conduct CCI activities.	
Budget Appropriate allocation of funds to support the Activity.	

#### Selection of recipients

Based on the assessment and recommendations of the review panel(s), the Department of Health will determine and approve the awarding of grants 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. Contractual arrangements

Grants to entities external to the WA public health system are offered in accordance with the Department of Health Grant Funding Agreement (and its Terms and Conditions) which is a legal agreement between the Department of Health (Us) and the Responsible Entity (You).

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 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, 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 recommend that you seek advice from your insurance advisors to confirm what level and type is required for the Activity.

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

Note that 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.

#### Intellectual Property

Intellectual Property (IP) that arises out of the Activity will vest with the Responsible Entity (You). However, consideration will be given to the provisions of the <u>Western Australian Government Intellectual Property Policy 2023</u> (or any future iterations of this), and that IP rights should be allocated to optimise the economic, social or environmental benefits for WA from the use, commercialisation and disposal of the IP. For information, the IP clause that will apply to this Program is:

- 1. The ownership of any Intellectual Property generated by undertaking the Activity shall vest in You.
- 2. The ownership of any background or pre-existing Intellectual Property and associated Moral Rights, used or incorporated in the Activity that is presently vested in a Party shall remain vested in that Party, unless otherwise agreed.
- 3. Each Party will be entirely and solely responsible for the use in the Activity of any Intellectual Property and associated Moral Rights it has provided to undertake the Activity which belongs to, or is licensed from, any other party, and indemnifies the other Party against all claims by a third party arising out of use of that Intellectual Property and associated Moral Rights.
- 4. Subject to the confidentiality provisions of the Agreement, You hereby grant to Us, a non-exclusive, irrevocable, perpetual, royalty-free licence to use (excluding the ability to sub-licence or grant further licences) any of the Intellectual Property generated in the Activity, and which falls within the scope of WA Health's normal activities. This includes, but is not necessarily limited to, activities related to healthcare provision, teaching, training and research. This license does not automatically extend to any potential or eventual commercial development of the Intellectual Property, and any commercial products that might directly or indirectly result from the Activity Intellectual Property. However, where You believe that there is the potential for commercialisation of the Intellectual Property developed in the course of the Activity, both Parties shall negotiate in good faith the appropriate legal and beneficial interests, rights and access to the Intellectual Property by Us.
- 5. You indemnify and will keep indemnified Us and all Our respective officers, employees and agents from and against all costs, losses, expenses, actions, suits, demands, claims, damages and other liabilities resulting from Your failure to comply with this agreement, or otherwise resulting from the actual or alleged infringement of the Intellectual Property rights or associated Moral Rights of any third party by You.
- 6. Your obligations under this Agreement are continuing and survive expiration or termination of the Agreement.

Where relevant, agreements between the Activity Lead, team members and participating entities must include relevant permissions to use third-party IP required to deliver the Activity and have Freedom to Operate for the Activity. When a team includes a member(s)

from the WA public health system as a participant in the Activity (i.e. the WA public health entity is not the Responsible Entity), the IP agreement must be authorised at an appropriate level by the relevant WA public health system entity.

Any questions regarding such IP matters should, in the first instance, be directed to OMRI (DOH.OMRI@health.wa.gov.au).

#### Requests for variation

Requests for variations to the Grant Funding Agreement, 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.

# 9. Funding conditions

#### Payment instalments

Funding will be provided in instalments to the Responsible Entity as follows:

- One instalment subject to execution of a Grant Funding Agreement\*.
- Subsequent instalments (if applicable) will be subject to satisfactory progress being achieved against the Activity milestones, as demonstrated in Progress Reports.
- \* Within the WA public health system, payment will be made to the Responsible Entity via a General Ledger Journal (GLJ) transfer progressively upon receipt of evidence of expenditure.

If ethics and governance approvals are required (refer to 'Approvals' section of this document), then the Responsible Entity may only release the first instalment to the Activity Lead once all approvals for the Activity have been obtained and lodged with the Responsible Entity.

#### 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.

#### 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 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 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, noting the date funds revert to, or are recoverable from, would be the date you are notified by the funding source
- funds are used for purposes other than those for which they were awarded
- 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
- the Activity Lead is no longer employed by the Responsible Entity unless a transfer of Responsible Entity has been approved by OMRI.

# 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 Data Linkage Services 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.

All reports are to be completed on templates provided by OMRI.

#### **Progress Activity Report**

Progress Reports outlining the progress against the milestones listed in the Activity plan may be required as stipulated in the Grant Funding Agreement.

OMRI reserves the right to request a Progress Report at any point.

OMRI reserves the right to suspend or withdraw funding where insufficient progress has been made.

#### Final Activity Report

A Final Report detailing the Activity and outcomes must be submitted to OMRI at the conclusion of the Activity. Failure to submit the Final Report at this time may render the Activity Lead ineligible for further funding from the FHRI Fund and OMRI until the Final Report is received.

#### Financial Report

A financial acquittal statement outlining the expenditure of funds must be submitted to OMRI at the conclusion of the Activity. Acquittal statements must be certified by an authorised finance officer (or equivalent) of the Responsible Entity.

OMRI reserves the right to request interim Financial Reports at any stage during the Activity.

Any unexpended funds must be returned to the Department of Health. Any overexpenditure is the responsibility of the Responsible Entity, and no claim may be made against the Department of Health.

#### 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

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.

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).



This document can be made available in alternative formats on request for a person with a disability.

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