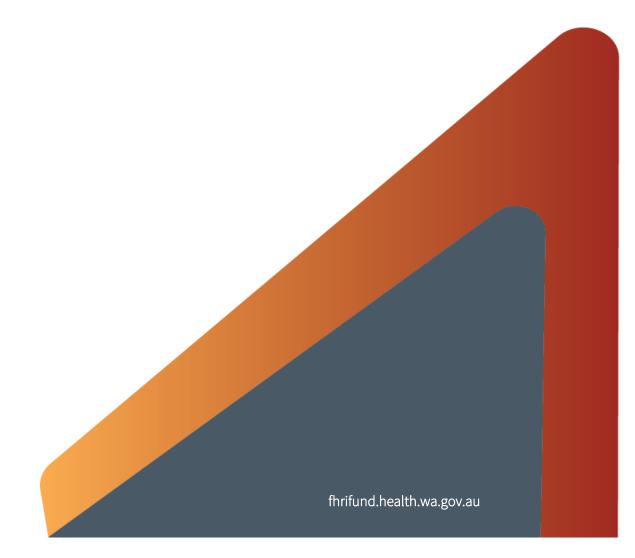


FHRI Fund Enabling Scheme 2024-25

Guidelines and Conditions

Applications close:

1:00 pm (AWST) Tuesday 4 March 2025



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1. Introduction

The FHRI Fund Enabling Scheme (the Program) is a funding 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.

The Program contributes to the FHRI Fund Priority Goal:

 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).

and Strategy objective:

• Theme 3: Platforms: Support new or existing infrastructure to elevate WA as an international leader in research and innovation.

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

 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 increase the scale and excellence of health and medical research and innovation in WA by supporting accessible local infrastructure.

The aim of the Program is to:

 support state-of-the-art facilities and equipment, that are available to the broader WA health and medical research and/or innovation sector (the sector) that will facilitate a strong foundation for research and innovation developments, translation, commercialisation, and economic growth in WA.

The objectives of the Program are to partner with entities to:

- increase the availability and use of research and innovation infrastructure (e.g. facilities or equipment)
- enable collaboration within the WA research and innovation community (academia, industry, government, non-government organisations)
- support greater research and innovation outputs, translation or commercial outcomes
- build a sustainable foundation for supporting research and innovation excellence that makes WA a place of choice
- promote the attraction and retention of high-quality researchers and innovators in WA, including through the creation of employment opportunities.

3. Program description

The Program is available to all eligible WA entities that undertake or support health and medical research and/or innovation¹ activities for the WA sector. Entities may include universities, research or innovation institutions, public or private health service providers or hospitals, non-government organisations, private entities, or consortia that operate research and/or innovation infrastructure that is accessible to the sector.

Co-funding is available for:

- upgrades to existing laboratories or facilities (i.e. construction and accreditation) used solely for health and medical research and/or innovation purposes that will facilitate broader sector access (if applicable)
- upgrades or replacement of major equipment and/or digital infrastructure (i.e. computing and data services) used solely for health and medical research and/or innovation purposes, and its commissioning
- purchase and installation of major equipment and/or digital infrastructure used solely for health and medical research and/or innovation purposes, and its testing and commissioning, to increase the 'industry offering' of the facility.

For the purposes of this Program, digital infrastructure includes:

- data management platforms for sharing data, storage, and long-term management
- data synthesis, analysis and visualisation software tools to integrate into virtual research and innovation environments
- cloud storage and computing
- artificial intelligence
- quantum computing and devices
- cybersecurity
- digital capabilities that will result in an equitable, accessible, and connected ecosystem that incorporates regional, remote and First Nations researchers
- Internet of things (IoT)
- trust and identity services, frameworks, and persistent identifiers (PIDs).

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

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

* 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:
 - provide health and medical research and/or innovation services in WA
 - have an active Australian Business Number (ABN) with a minimum 3-year trading history for the registered ABN
 - have a physical and operational presence in WA

¹ This document refers to research and innovation however, entities may undertake or support health and medical research, health and medical innovation or both.

- not be in receipt of National Collaborative Research Infrastructure Strategy (NCRIS) funding.
- 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 OMRI (including FHRI Fund programs) from any year (excludes authorised extensions)
 - ensure that grant funding administered by OMRI (including FHRI Fund programs) 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> (WA Health staff access only) 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.
- Evidence of matched funding must be provided in the application.
- 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 receiving Department of Health or FHRI Fund funding for the same outputs and/or outcomes
 - 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 between \$500,000 and \$1,250,000 excluding GST are available to successful applications over a period of up to 3-years.

Funding is for up to 50 per cent of eligible Activity costs and requires the applicant to at least match the contribution amount in cash. Applications may include requests for a combination of Activities.

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.

Funds can only be spent outside WA for the purchase of equipment to bring to WA, or where a small portion of funding is required for operational expenses to support the WA-based infrastructure.

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.

Co-funding sources must be included in the Budget section of the Application Form.

The funding is not intended to support the following activities:

- expenses that are primarily focussed on routine maintenance of existing infrastructure
- retrospective costs for activities that have already begun
- salary and training costs
- minor equipment such as ICT devices
- operational costs of the infrastructure
- business as usual operational expenditure and routine professional services
- land and lease costs
- any amount paid on account of GST
- costs related to preparing the grant application, preparing any project reports and preparing any project variation requests
- costs related to building routine websites, sales and promotional activities, marketing or communications campaigns
- regulatory and intellectual property fees and charges associated with registering domestic or international patents or other intellectual property enforcement expenses
- service contracts or ongoing subscriptions.

6. Application instructions

The instructions below must be followed when making a submission:

- The Application Form must be submitted via the Department of Health Grant Management System by 1:00 pm (AWST) Tuesday 4 March 2025.
- 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.

Instructions for the Grant Management System are located at https://fhrifund.health.wa.gov.au/Funding/GMS-link-page.

Please note that the Grant Management System Application Form is not yet published. The application questions are provided in the Application Form in word document format so that you can commence preparing your application.

The Grant Management System Application Form will be available online closer to the Application due date.

Acknowledgement of receipt of the Application Form will be provided via email to the Responsible Entity, Activity Lead and Team Members after submission in the Grant Management System.

Queries related to the Guidelines and Conditions can be directed to DOH.OMRI@health.wa.gov.au with the subject line beginning with 'Query – FHRIFES2024-25'.

Queries regarding the application process can be directed to DOH.GMS@health.wa.gov.au with the subject line beginning with 'GMS Application Assistance – FHRIFES2024-25.

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 health and medical research and/or innovation and commercialisation experts, WA Government health and infrastructure planning experts, and consumer representative(s).

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

Applications will be assessed based on the criteria and % weightings set out in the table below:

Assessment Criteria	%
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Landa de Callanda	
 Impact of the Activity Potential for 'state-of-the-art' equipment and/or facility that contributes to the competitiveness of the sector. Meets an identified need/demand. The impact and interaction with existing initiatives currently operating in the same area. Plan to make the facility/equipment broadly accessible. Potential to facilitate research and/or innovation developments, translation commercialisation in WA. Potential to facilitate national or international partnerships. Potential to create employment opportunities and attract and retain high-quality researchers and innovators to WA. Potential economic, social, health and environmental benefits to WA of the Activity. 	25
 List of all locations where the Activity will be undertaken, approvals and agreements that will be required before the Activity can proceed Plan to ensure availability and broad access to the infrastructure for the sector Suitable implementation plan and milestones and timeframes that captures required approvals and agreements, and a risk management plan. Sustainability plan for ongoing facility/equipment operation and upgrades. 	25
 Ability to Deliver the Activity The capacity and capability (track-record, expertise, and industry knowledge) of the Activity Lead and Team members to deliver the proposal. Whether the resources, total funding sought and provided through the grant, partners, participants, and other funding sources is sufficient to undertake the initiative. 	25
 Partnerships and collaborations Extent and relevance of partnerships and collaborations with other entities to maximise access, realise efficiency gains and maximise benefit of the facility and/or equipment to the sector. How consumer involvement has informed the need for the Activity and its implementation. 	

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. 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 recommended 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

Grants 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 recommends that you seek advice from your insurance advisors to confirm what level and type of insurance 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</u> <u>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. You will negotiate in good faith with Us to provide, in a fair and reasonable manner for both parties, any product to which this grant funding has significantly contributed, to the WA (public) Health system, or agreed components of this, either free of charge, or at the cost of production, for a mutually acceptable period of time after its production, providing that this in no manner compromises the attraction of additional funding, and/or the commercialisation by You of the product.
- 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.

10. Funding conditions

Payment instalments

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

- The first instalment will be subject to execution of a Grant Funding Agreement.
- Subsequent instalments, if applicable, will be subject to provision of satisfactory 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.

Partial payment or suspension of funds

The Department of Health reserves the right to:

- provide funding instalments in parts, based on Activity to date and risk assessment of future Activity
- suspend payment of funding instalments or part instalments where Activity viability has become uncertain.

Additional funding sources

Additional sources of funding are required to cover at least 50 per cent of the proposed cost. Funding sources may be from the Responsible Entity and/or third-party entities and may include grant income, where appropriate.

The co-contribution must be cash. In-kind contributions and discounts are encouraged but are separate to the cash co-contribution.

In all cases the responsibility for provision of co-funding lies with the Responsible Entity.

Termination of funds

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

- eligibility requirements are no longer met
- the Activity is terminated by OMRI as a result of insufficient progress being made, or it has been otherwise determined by either the Responsible Entity or OMRI that the Activity is no longer viable
- funds are used for purposes other than those for which they were awarded
- funds were spent on activities that require 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, 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 50 per cent co-funding component is withdrawn or no longer viable during the Activity timeframe.

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 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.

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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