GOVERNMENT OF WESTERN AUSTRALIA

Western Australian Future Health Research & Innovation Fund

Innovation Seed Fund 2024-25

Guidelines and Conditions

Applications close:
1:00 pm (AWST) Thursday 5 December 2024

fhrifund.health.wa.gov.au

Contents

1. Introduction

The Innovation Seed Fund 2024-25 (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.

This Program contributes to the FHRI Fund Priority Goals:

- 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 *Western Australian Future Health Research and Innovation Fund Act 2012*:

- improving the health and wellbeing of Western Australians
- improving the financial sustainability of Western Australia's health system
- 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 this Program is to provide the opportunity for WA innovators to develop and commercialise their innovations, create high-level health sector jobs and enhance the production/manufacturing capacity of the State.

The aims of the Program are to:

- increase the number of new health and medical innovation start-up companies in WA
- improve the success of WA innovation initiatives in accessing additional funding/investment to assist in taking the innovations to market.

The objectives of the Program are to:

- advance the innovation maturity level of the funded innovations
- encourage non-government funding/investment for the progression of more advanced innovations.

3. Program description

This Program aims to support the validation of inventive concepts, the feasibility testing of proposed solutions, and the advancement of developed solutions towards the path of commercialisation within the following categories:

Category 1 – Devices, diagnostic and platforms including digital

The innovation is a device or technology that will diagnose, prevent, treat and/or monitor a health condition that impacts the people of Western Australia. This includes novel equipment, digital tools, and medical implants that aim to improve the safety, effectiveness, access, timeliness and/or cost as compared with existing practice.

Category 2 – Therapeutics and vaccines

The innovation is a drug, compound or medical biologic that will detect, prevent or treat a health condition that impacts the people of Western Australia. This includes novel medicines, vaccines, immune modulators and other medical products derived from chemical or biological material that aim to improve safety, quality, access or patient outcomes as compared with existing practice.

The funding is intended to support key de-risking activities that advance the innovation to a maturity level where the innovation is better positioned to attract funding/investment from traditional innovation funding sources (such as commercialisation funds, venture capital investors or through equity raising) to commence, or progress, the commercialisation process.

Funding will be available for early to intermediate stage start-ups, emerging spin-outs or small to medium enterprises.

Funding will be provided to innovation proposals that demonstrate potential to develop and commercialise novel (new) processes, products and/or services that may have major impact on the health and/or wellbeing of the WA community. The innovation may result in incremental or transformative/disruptive change.

As such, this funding is to support activities that would be undertaken at Innovation Maturity Levels (IMLs) 3 to 7 as outlined in Appendix 1.

The Program is directed towards Activities that fall within the health and medical innovation and commercialisation stream of the FHRI Fund.

Funding cannot be used to support Activities that are deemed to be research, unless these are an integral part of the innovation Activity and are feasible to be undertaken within the timeframe of the Activity. It should also be noted that this Program will not support 'business as usual' activities, such as quality improvement.

Selection of recipients will be through a competitive and merit-based two-stage process, with the submission of initial Expressions of Interest (EOI), followed by Full Proposals from invited applicants following an assessment process.

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.

* *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 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 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 proposed innovation Activity to be undertaken must be within the range of IML 3 to IML 7 (as outlined in Appendix 1).
- For IML 7 activities that are funded through the Program, it must be demonstrated that funding/investment from non-government sources, that at least matches that received through the Program, has been secured. This could be through previous, or new, funding/investments.
- Any rights (for example Intellectual Property rights) to develop or implement the innovation must be vested with the innovation team, or otherwise not be vested in another entity in a manner which would preclude the ability of the innovation team to deliver the innovation (Freedom to Operate).
- 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:
  - it does not meet all eligibility criteria as set out in these guidelines
  - the proposed Activity duplicates activity previously or currently being undertaken
  - it is not an innovation, e.g. is a 'business as usual' activity, such as quality improvement

- it includes any incomplete, false or misleading information
- 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.
- To be eligible to submit a Full Proposal you must have received an invitation from OMRI to progress to the Full Proposal stage following the EOI stage.

5. Program funding

Funding amounts between $50,000 and $750,000 excluding GST are available to successful applicants to finance the Activity as per the table below:

Activity Innovation Maturity Level (IML)	Funding available	Maximum Activity duration
IML 3	$50,000 to $100,000	Up to 12 months
IML 4-6	$250,000 to $500,000	Up to 24 months
IML 7	$500,000 to $750,000	Up to 24 months*

** subject to meeting the eligibility criterion regarding matched funding/investment*

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 be in accordance with the following:

- Salary costs:
  - may include Award/Agreement increases and salary increments as appropriate
  - may include leave entitlements that accrue and are taken during the period the salary is being paid by the grant funding (noting annual leave is accrued at a rate of 7.69% and long service leave at a rate of 2.5% of the base salary paid by grant funding).
  - may not include leave entitlements accrued outside this period, parental leave, sabbatical, severance and termination payments
  - may include superannuation, payroll tax and workers compensation as on-costs up to a maximum of 30%, noting that WA public health system salaries can only include superannuation as a salary on-cost
  - are not to provide salary for the Activity Lead. An exemption to this rule may be requested, where it is deemed that this salary is crucial to the success of the Activity. Adequate justification must be provided. Determination of exemptions will be made on a case-by-case basis, at the discretion of OMRI.
- Non-salary costs:
  - may include expenses such as essential services, supplies, equipment and consumer involvement
  - 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
  - may be requested for equipment, however, the total value of all equipment items must not exceed 10% of the budget request or $15,000, whichever is the lesser amount, and quotes for each item must be attached to the application.

- 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 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 cannot be used to support activities that are deemed to be research, unless these are an integral part of the innovation Activity and are feasible to be undertaken within the timeframe of the grant.

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:

Expression of Interest (EOI) Form

- The EOI Form available from the FHRI Fund website must be submitted by **1:00 pm (AWST) Thursday 5 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 DOH.OMRI@health.wa.gov.au as a **single** 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 – ISF EOI 2024-25
  e.g. SMITH, Alex – ISF EOI 2024-25
- 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.

Full Proposal Form

- Full Proposal application instructions will be provided to Activity Leads in the Full Proposal invitation email sent by OMRI.
- Full Proposal Forms will only be accepted if Activity Leads have received an invitation to progress to the Full Proposal stage.
- The Full Proposal Form provided by OMRI must be submitted by the requested date/time.

Acknowledgement of receipt of the EOI Form and Full Proposal 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

Eligibility will be reviewed by the Office of Medical Research and Innovation (OMRI).

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

This will be through a two-stage process, with the submission of initial Expression of Interest (EOI) Forms, followed by Full Proposals from invited applicants.

The review panels will include experienced innovators, health and medical innovation 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.

The two-stage process is described below:

Stage 1 – Expressions of Interest

The purpose of this stage is for EOIs to be sought and assessed by a review panel to determine those that will be invited to apply to the Full Proposal stage.

The review panel will consider the following:

1. Whether the intended outcome of the Activity is an innovation, i.e. will result in an innovative solution, as opposed to being research or quality improvement.
2. The significance of the problem and the innovation's potential to address this.
3. The potential for the solution to be commercialised.
4. The contribution of the grant funding to progression of the solution and the potential benefits of the solution (value-for-money).

Stage 2 – Full Proposal

The purpose of this stage is to assess applications to determine if they are considered 'fundable' and determine an overall panel ranking of these.

Assessment of Full Proposals will be based on the criteria and % weightings set out in the table below.

Assessment Criteria	**%**
Significance of the problem • The problem that the innovation addresses. • The relevance and scale of the problem in WA. • The importance of addressing the problem in WA, and at a national and global level.	**15**
Proposed innovation • The proposed innovation and how it is novel (new). • The justification for the selected maturity level of the innovation Activity, which must be within the range of IML 3 to IML 7, and how this is appropriate for the funding requested and the Activity duration proposed (refer to Appendix 1).	**15**

• The expected IML at the end of the Activity and justification for this. • The differentiation between the proposed innovation and any existing or emerging competing processes, products and/or services. • The technical merit (proof of concept) of the innovation, including key data that support the innovation.	
Activity Plan • The Activity objectives, ensuring these are specific, measurable, attainable, relevant and time-bound. • The methodology that will be followed and how achievement of the Activity objectives will be demonstrated. • The contribution the grant funding will make to progression of the solution along the innovation pipeline, in the context of other funding that may be required for the proposed Activity. • How the Activity will improve the commercial potential of the innovation (e.g. product acquisition, licencing agreement) and drive investor/partner interest to get the innovation to market. • The achievability of the proposed milestones and timeframe. • The proposed budget to undertake the Activity and justification for budget items, including any proposed salary components.	**15**
Capacity, capability and resources • The knowledge, expertise and experience of the Activity Lead and Team Members. • The contribution of the Activity Lead and each Team Member to the proposed Activity. • Any collaborations with WA health service providers (public and/or private) and WA industry. • Access to technical resources, infrastructure, equipment and facilities and additional support personnel, if necessary.	**10**
Intellectual Property • Any existing IP that will contribute to the Activity (e.g. patent filings) and freedom to operate with this (e.g. through IP ownership or having a licence to use). • The anticipated strategy for the protection and management of IP that is developed through the Activity and beyond.	**10**
Consumer involvement • How consumers (people with lived experience of a health issue, including patients and potential patients, carers and people who use health care services) have been involved in the development of the proposed Activity. • The plan for ongoing consumer engagement in the Activity, including their roles and how their lived experience perspectives will inform the Activity through formal and informal processes. Refer to the 'Consumer involvement' section of this document.	**10**
Anticipated commercialisation strategy • The anticipated commercialisation pathway for the innovation from its current stage to market, including possible timeframes for each stage and go/no-go decision points. • The anticipated funding strategy to take the innovation to market. • The anticipated model for the generation of financial returns through commercialisation of the innovation. • Potential investors and/or natural partners/acquirers of the innovation.	**10**
Value proposition • The potential impact of the proposed innovation on the problem in WA. • The impact that the innovation will have on the health and/or wellbeing of the WA community. • The economic, social and environmental benefits of the innovation to WA.	**15**

• The potential commercial value of the innovation, including market size and scalability, at the WA, national and global level. • The advantage of the innovation over any competing processes, products and/or services. • The drivers for clinicians, patients, community and/or industry to adopt the innovation.	

Selection of recipients

Based on the assessments 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 Consumer and Community Involvement Program website and the NHMRC Statement on Consumer and Community Involvement in Health and Medical Research 2016.

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

9. 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 recommends 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 *Western Australian Government Intellectual Property Policy 2023* (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 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.

Partial payment or suspension of funds

The Department of Health reserves the right to:

- provide funding instalments in parts, based on milestone achievement and risk assessment of future milestones
- suspend payment of funding instalments or part 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 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, 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 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, 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.

11. Approvals

Research ethics and research governance

Funding cannot be used to support Activities that are deemed to be research, unless these are an integral part of the innovation Activity and are feasible to be undertaken within the timeframe of the Activity.

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 *Health Services Act 2016* and the *Health Services (Information) Regulations 2017*. 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 DataServ@health.wa.gov.au. 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.

12. 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 over-expenditure 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.

13. 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 Australian Code for the Responsible Conduct of Research page, and the NHMRC Open Access Policy.

14. 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 *Freedom of Information Act 1992 (WA)* or information pertaining to the receipt of State Government financial assistance tabled in the Parliament of Western Australia.

15. 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.

16. 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).

Appendix 1 – Innovation Maturity Level (IML)

Funding amounts and duration are based on the applicable IML as per the table below:

Activity Innovation Maturity Level (IML)	Funding available	Maximum Activity duration
IML 3	$50,000 to $100,000	Up to 12 months
IML 4-6	$250,000 to $500,000	Up to 24 months
IML 7	$500,000 to $750,000	Up to 24 months*

** subject to meeting the eligibility criterion regarding matched funding/investment.*

Category 1: Devices, diagnostics and platforms including digital

	IML 1	IML 2	IML 3	IML 4	IML 5	IML 6	IML 7	IML 8	IML 9
	Need	**Idea**	**Proof of Concept**	**Proof of Feasibility**	**Proof of Value**	**Preliminary Validation**	**Confirmatory Validation**	**Approval and Launch**	**Uptake**
Description	Identification of problem or unmet need	Potential solution described, evaluated and selected (where applicable, in comparison with any existing, inferior, solution)	Key concepts validated and value proposition tested	Feasibility of solution demonstrated, which aligns with stakeholder and/or potential user feedback and/or expectations	Solution developed to a stage where it is recognised to have value by stakeholders and/or potential users	Production of prototype, minimum viable product, or equivalent, and collection of relevant data. As required, is attractive to further developmental investment.	The solution is definitively demonstrated to be effective and to be of value to stakeholders and/or users. The solution is ready to be taken to market (or equivalent).	Institutional and regulatory approval received (as required) and solution launched	The solution is implemented/used by stakeholders and/or users

Adapted from the Innovation Maturity Levels (IML) of the MTPConnect *BioMedTech Horizons* program, which is based on the Consortia for Improving Medicine with Innovation & Technology's *Navigating the HealthTech Innovation Cycle*.

Category 2: Therapeutics and vaccines

Please note the descriptions provided for each IML below are only indicative. Justification for the selected IML is required in the application.

	IML 1	IML 2	IML 3	IML 4	IML 5	IML 6	IML 7	IML 8	IML 9
	Need	**Idea**	**Early Proof of Concept**	**Proof of Feasibility/ Hit discovery**	**Early preclinical / Hit-to-lead**	**Preclinical testing / Lead optimisation**	**Clinical development**	**Approval and Launch**	**Uptake**
Indicative Description	Identification of problem or unmet need	Hypothesis formation or target identification, key disease-linked biological insight or a molecule linked with a disease-causing pathway.	Early data to support a hypothesis. This may include in vitro, in vivo and in silico target validation studies, genetic or pathway studies.	Proof that a target/pathway is tractable. This may include high throughput screening / antibody development, protein production, assay development, and hit confirmation.	Activities may include potency, selectivity, in vitro and in vivo studies, mechanism of action.	Lead Optimisation activities, pharmacokinetics/ pharmacodynamics. This may include lead-to-candidate and toxicology studies.	Contribution to early-phase clinical trials and formal enabling activities.	Institutional and regulatory approval received (as required) and solution launched.	The solution is implemented/used by stakeholders and/or users.

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