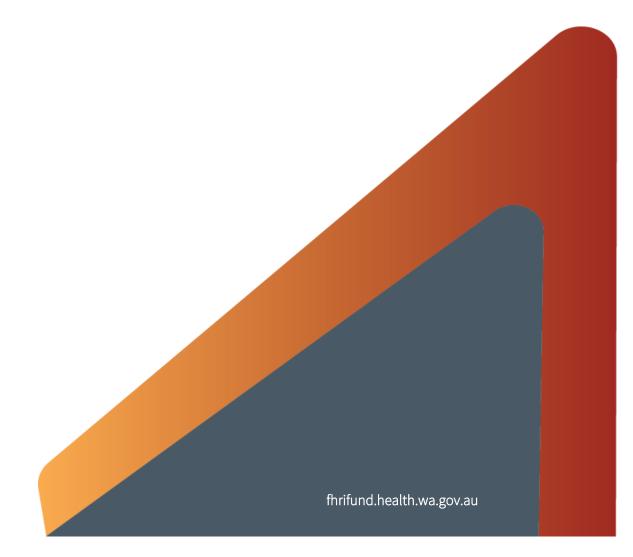


Innovation Seed Fund 2025-26

Guidelines and Conditions

Expression of Interest Applications close: 1:00 pm (AWST) Thursday 22 January 2026



Contents

| 1. | Introduction | 3 |
|-----|--|----|
| 2. | Purpose | 3 |
| 3. | Program description | 4 |
| 4. | Eligibility | 5 |
| 5. | Program funding | 6 |
| 6. | Application instructions | 8 |
| 7. | Selection process | 10 |
| 8. | Consumer involvement | 12 |
| 9. | Contractual arrangements | 12 |
| 10. | Funding conditions | 14 |
| 11. | Approvals | 15 |
| 12. | Reporting | 15 |
| 13. | Publicising, acknowledgements and publications | 16 |
| 14. | Confidentiality | 16 |
| 15. | Evaluation | 16 |
| 16. | Complaints | 17 |
| App | pendix 1 – Innovation Maturity Level (IML) | 18 |

1. Introduction

The Innovation Seed Fund 2025-26 (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 following FHRI Fund Strategic Themes and Priorities:

Strategic Theme 2: Accelerate and Translate. Endeavour to build a thriving innovation pipeline through early support of high-potential innovation. Lift discipline and capability through partnerships with private investors and ultimately accelerate the translation of ideas into practical real-world application.

- Priority 4: Underwrite innovation: Support high-potential, early-stage health innovations that carry commercial and translational promise. Funding will be structured to absorb early risk and provide clear stage-gated progression toward impact.
- **Priority 5: Activate the innovation community:** Engage WA's researchers, entrepreneurs, and startups through competitive programs that promote bold thinking and real-world application. These initiatives will build momentum, visibility, and a stronger culture of innovation.
- **Priority 6: Build investment partnerships:** Form long-term partnerships with investors who bring both capital and commercial capability with a shared commitment to WA-led ventures. These relationships will amplify FHRI Fund investments and accelerate the path to market.

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
- improving Western Australia's economic prosperity.

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 support WA innovators to develop and commercialise their health and medical innovations through start-up companies operating in WA, creating high-value jobs and enhancing the biomedical support and manufacturing capacity of the State.

The aims of the Program are to:

- promote the establishment and development of start-up companies in WA
- strengthen their investment readiness
- enable WA innovators to be more competitive in securing additional investment or applying for funding to bring their health and medical innovations to market.

The objectives of the Program are to:

 increase establishment, retention and success of start-up companies operating in WA who are developing health and medical innovations

- accelerate the growth of WA-based start-up companies and advance their strategy towards commercialisation and scale
- increase the success of WA innovators in accessing additional investment or funding.

3. Program description

The Program will provide grants 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 streams:

Stream 1 - Devices, diagnostic and digital

The innovation is a device or technology that will prevent, diagnose, treat and/or monitor a health condition that impacts the people of Western Australia. This includes but is not limited to novel equipment, digital tools, and medical implants that aim to improve the safety, effectiveness, access, timeliness and/or cost as compared with existing practice.

Stream 2 - Therapeutics and vaccines

The innovation is a drug, compound or medical biologic that will prevent, detect, or treat a health condition that impacts the people of Western Australia. This includes but is not limited to 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.

Funding will be available to industry (e.g. start-ups, spin-outs or small to medium enterprises), as well as health service providers, universities and medical research institutes engaged in health and medical innovation who intend to commercialise their innovations through spin-outs.

Funding will be provided to innovation proposals that demonstrate strong potential to develop and commercialise novel processes, products and/or services and have major impact on the health and/or wellbeing of the WA community.

For the purposes of the FHRI Fund, an 'innovation' is an invention or development of novel (new and original) ways of achieving tangible outcomes, that address identified problems by creating new opportunities or addressing unmet needs, through solutions that deliver more effective and/or efficient methods, processes, products and/or services that have positive health and medical impact and/or value.

The funding is intended to support key de-risking activities that advance the innovation to a maturity level where the proponent is better positioned to attract funding/investment from traditional innovation funding sources such as commercialisation funds, venture capital and private investors to progress the commercialisation process.

As such, this funding is to support activities that would be undertaken at Innovation Maturity Levels (IMLs) 3 to 6 as outlined in Appendix 1.

Funding cannot be used to support Activity that are deemed to be <u>research</u>, 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 EOI 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, 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:
 - o must have an active Australian Business Number (ABN)
 - o must 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)
 - o ensure that funding has not been awarded for any component of the Activity
 - o have a position or title at the Responsible Entity for the period of the Activity The Activity Lead will be required to declare which of the following applies:
 - (a) employee of the Responsible Entity or Director of the company that is 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 6 (as outlined in Appendix 1).
- 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 funding.
- 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
 - o the proposed Activity duplicates activity previously or currently being undertaken
 - o it is not an innovation, e.g. is a 'business as usual' activity, such as quality improvement
 - o it includes any incomplete, false or misleading information
 - o it was submitted after the advertised closing date and time.
- Grant offers may be withdrawn if it is determined that eligibility criteria are not met.
- OMRI reserves the right to request further information and make final decisions regarding eligibility.
- Decisions made in relation to previous grant programs will not be regarded as precedents and will not be considered when assessing eligibility for this grant program.
- To be eligible to submit a Full Proposal the Activity Lead must have received an invitation from OMRI to progress to the Full Proposal stage following the EOI stage.

5. Program funding

Funding amounts are available to successful applicants to finance an Activity as follows:

- up to \$750,000 ex GST for Stream 1 (devices, diagnostic and digital)
- up to \$1,500,000 ex GST for Stream 2 (therapeutics and vaccines)

The maximum Activity duration is 24 months.

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:
 - o may include Award/Agreement increases and salary increments as appropriate
 - o may include leave entitlements that <u>accrue and are taken</u> during the period the salary is being paid by the grant funding as a base salary cost (noting annual leave is accrued at a rate of 7.69% of the base salary paid by grant funding and long service leave at a rate of 2.5% of the base salary paid by grant funding)
 - cannot include leave entitlements accrued outside the period the salary is being paid by the grant funding, parental leave, sabbatical, severance and termination payments
 - o can only include superannuation, payroll tax and workers compensation as salary on-costs up to a maximum of 30%, noting that salaries paid by a WA public health system entity can only include superannuation as a salary on-

- cost (this includes WA public health system invoices for salaries paid by the Responsible Entity)
- o cannot include salary or remuneration 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:

- o can only include expenses such as essential services, supplies, equipment unique to the Activity and consumer involvement
- o for travel will not be approved unless strongly justified as being essential to the undertaking of the Activity and expenditure must not include costs related to dissemination of outcomes, such as conference attendance and publications
- o may be requested for equipment and specialised computing requirements that are unique to the Activity and cannot include service, maintenance and repair costs. 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
- o cannot include personal computers/devices and IT equipment, related peripherals or software for communicating, writing and undertaking simple analyses
- o cannot include entertainment costs (as defined by the ATO) unless incurred in support of participants of a clinical trial
- o cannot include administrative costs such as stationery, photocopying, postage and communications (such as telephone or internet).
- Overhead charges (indirect/infrastructure costs):
 - o may be requested up to a maximum of 10% of the total Activity (direct) costs, noting that WA public health system Responsible Entities cannot claim overhead charges or charge overheads on invoices paid by the Responsible Entity for grant expenditure 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 <u>research</u>, 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

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 any internal Responsible Entity deadlines.

Acknowledgement of receipt of the Application Form will be provided via email to the Responsible Entity, Activity Lead and Team Members.

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 related to these Guidelines and Conditions can be directed to DOH.OMRI@health.wa.gov.au with the subject line beginning with 'Query – ISF 2025-26'.

The instructions below must be followed when making a submission:

Expression of Interest (EOI) application

The EOI application must contain the following documents and items:

- Completed EOI Form, available on the Department of Health electronic Grant Management System.
- Pitch deck: a concise presentation (maximum of 15 PowerPoint slides, submitted in PDF format) outlining key aspects of the innovation, including:
 - o problem being addressed and market size
 - o proposed innovation/solution how it works
 - o value proposition
 - o clinical or scientific evidence
 - o competitors
 - Intellectual Property (IP) position and strategy
 - o regulatory position and strategy
 - business model and commercialisation strategy
 - o Innovation Maturity Level (IML) and development plan
 - o team
 - o summary.
- Short video pitch of maximum 3 minutes, outlining key aspects of the innovation, including:
 - o problem being addressed and market size
 - o proposed innovation/solution how it works
 - o value proposition
 - o clinical or scientific evidence
 - o competitors
 - Intellectual Property (IP) position and strategy
 - o regulatory position and strategy
 - o business model and commercialisation strategy
 - o Innovation Maturity Level (IML) and development plan
 - o team.

Additional documents not listed in the EOI requirements will not be considered during the panel review process.

The EOI application including required documents must be submitted via the Department of Health Grant Management System by 1:00 pm (AWST) Thursday 22 January 2026.

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

Queries regarding the application process can be directed to DOH.GMS@health.wa.gov.au with the subject line beginning with 'GMS Application Assistance – ISF 2025-26 EOI'.

Full Proposal application

Full Proposal applications will only be accepted if Activity Leads have received an invitation to progress to the Full Proposal stage after selection from the EOI stage.

The Full Proposal application must contain the following documents:

- Completed Full Proposal Form.
- Pitch deck: a concise presentation (maximum of 15 PowerPoint slides, submitted in PDF format) outlining key aspects of the innovation, including:
 - o problem being addressed and market size
 - o proposed innovation/solution how it works
 - o value proposition
 - o clinical or scientific evidence
 - o competitors
 - Intellectual Property (IP) position and strategy
 - regulatory position and strategy
 - business model and commercialisation strategy
 - Innovation Maturity Level (IML) and development plan
 - o team
 - o summary.
- Short video pitch of maximum 3 minutes, outlining key aspects of the innovation, including:
 - problem being addressed and market size
 - o proposed innovation/solution how it works
 - o value proposition
 - o clinical or scientific evidence
 - o competitors
 - o Intellectual Property (IP) position and strategy
 - o regulatory position and strategy
 - o business model and commercialisation strategy
 - o Innovation Maturity Level (IML) and development plan
 - o team.
- Team member CVs highlighting relevant qualifications and achievements. Each CV must be no longer than 3 pages, using Arial font size 11 or larger.

Additional documents not listed in the Full Proposal requirements will not be considered during the panel review process.

Further application instructions will be provided to Activity Leads who are invited to submit a Full Proposal application.

Where deemed necessary, Full Proposal applicants may be required to pitch to the relevant review panel and respond to questions from the panel.

7. Selection process

Assessment process

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

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

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

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:

EOI Stage

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 EOI assessment criteria:

- 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 potential for the innovation to be commercialised and the proposed approach for development and commercialisation.
- 3. The potential impact that the innovation will have on the health and/or wellbeing of the WA community.
- 4. The contribution the grant funding will make towards progression of the innovation towards commercialisation (value for money).

Applicants successful in the EOI stage, who are invited to submit a Full Proposal, will receive feedback from the EOI review panel to assist in the further development of their Full Proposal application. Applicants unsuccessful in the EOI stage will receive general feedback.

Full Proposal Stage

The purpose of this stage is to assess applications to determine if they are considered 'fundable'.

Full applications should build on the initial detail provided as part of the EOI stage but also take into consideration the specific feedback provided as part of the EOI process. 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. | | | | | |
| 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 6, and how this is appropriate for the funding requested and the Activity duration proposed (refer to Appendix 1 for the IML descriptors). | | | | | |

- The expected IML at the end of the Activity and justification for this.
- The technical merit of the innovation, including key data that supports the innovation.
- How engagement with stakeholders that could include but is not limited to health consumers with 'lived experience' of the health issue, clinicians or companies has influenced the design, development and commercialisation strategy of the proposed innovation.

Value proposition

15

- The potential impact of the proposed innovation on the problem in WA.
- The competitive landscape and the competitive advantage of the proposed innovation against any existing or emerging competing processes, products and/or services.
- The potential commercial value of the innovation, including market size and scalability, at the WA, national and global levels.
- The drivers for relevant stakeholders to adopt the innovation.

Activity Plan

20

- The Activity objectives, ensuring these are specific, measurable, attainable, relevant and time-bound.
- The methodology that will be followed, including key experiments or trial design, power analysis, study population and study end points, and how achievement of the Activity objectives will be demonstrated.
- 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.
- Justification of how the proposed Activity is different from business-as-usual activities
 or cannot be readily funded from existing sources of funding (e.g. investment, public
 markets or existing funds).

Capacity, capability and resources

10

- 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.
- Access to existing and potential other funding and/or investment sources that will complement the funding requested for this Activity.

Intellectual Property strategy

10

- The anticipated strategy for the protection and management of IP that is developed through the Activity and beyond. This may include formal IP rights, as well as alternative protection measures where more appropriate.
- Any existing IP that will contribute to the Activity (e.g. patent filings) and freedom to operate with this IP (e.g. through ownership or licensing arrangements, including expiry dates).
- Any other parties involved in the IP that are relevant to the Activity.

Anticipated commercialisation strategy

20

- The anticipated stages to progress the innovation from its current IML to market, including milestones and estimated timeframes for each stage, and with commercial relevant go/no-go decision points indicated that make the innovation more investable.
- The anticipated funding and/or investment 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.

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.

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

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 appropriate 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 <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. 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.

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.

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 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
- 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
- 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 Activity end date (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 <u>research</u>, 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 <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 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 Activity Reports may be required as stipulated in the Grant Funding Agreement.

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

OMRI reserves the right to suspend or withdraw funding where insufficient progress has been made or where it has been determined that the Activity is no longer viable.

Final Activity Report

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

Financial Report

A *Financial Report* outlining the expenditure of funds may be required as part of a *Progress Report* and must be submitted to OMRI at the conclusion of the Activity. *Financial Reports* must be certified by an authorised finance officer (or equivalent) of the Responsible Entity.

OMRI reserves the right to request a *Financial Report* 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.

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 <u>Australian Code for the Responsible Conduct of Research</u> page, and the <u>NHMRC Open Access Policy</u>.

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 <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.

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, Infrastructure, Medical Research, and Innovation (ODDG.IMRI@health.wa.gov.au).

Appendix 1 – Innovation Maturity Level (IML)

Stream 1: Devices, diagnostics and 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. | solution described, | 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*.

Stream 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. |



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

© Department of Health 2025

Copyright to this material is vested in the State of Western Australia unless otherwise indicated. Apart from any fair dealing for the purposes of private study, research, criticism or review, as permitted under the provisions of the *Copyright Act 1968*, no part may be reproduced or re-used for any purposes whatsoever without written permission of the State of Western Australia.