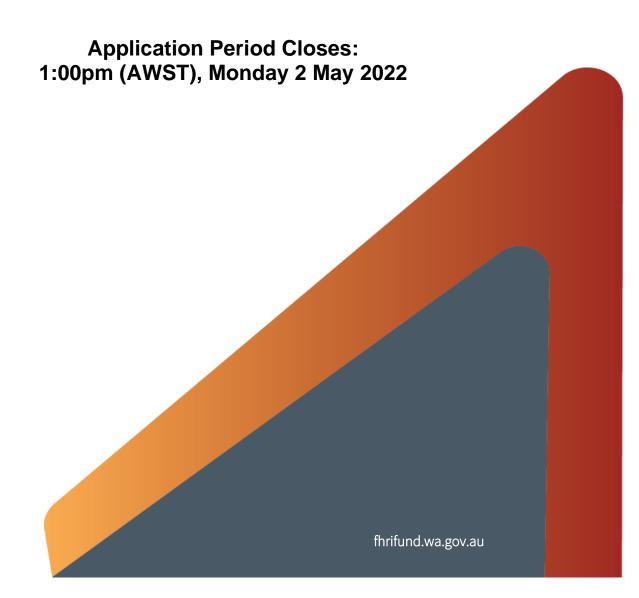


Innovation Seed Fund 2022

Guidelines and Conditions



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1. Introduction

The Innovation Seed Fund (the Seed Fund) is a Program of the Western Australian (WA) Future Health Research and Innovation (FHRI) Fund.

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

This Program contributes to the <u>FHRI Fund 2021/22 to 2023/24 Priority</u>: Establish an innovation seed fund to support early stage ideas and enable these innovative ideas to secure follow-on funding from commercial/other funders.

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

- improving the health and wellbeing of Western Australians
- improving the financial sustainability of Western Australia's health system
- improving Western Australia's economic prosperity.

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

2. Purpose

The purpose of the Seed Fund 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 Seed Fund is directed towards activities that fall within the <u>health and medical</u> innovation and commercialisation stream of the FHRI Fund.

The Seed Fund has been designed to bridge the gap in access to early stage funding in WA and to 'prime' the commercialisation pipeline, providing the opportunity for start-ups to be more competitive in securing follow-on funding and developing into sustainable businesses.

Funding will be targeted towards **early stage start-ups** for activities that could significantly de-risk, or validate, innovations with commercial potential, and make them more attractive to further investment.

Funding will be provided on a competitive basis 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.

The objectives of the Seed Fund are to:

- Increase the number of new health and medical innovation start-up companies in WA.
- Advance the innovation maturity level of the majority of funded innovations.
- Improve the success of WA innovation initiatives in accessing additional funding to assist in taking the innovation to market.

3. Program description

Seed Fund grants are made available through a competitive and merit-based process.

Funding amounts of between \$250,000 to \$500,000 are available to successful applicants to finance an innovation activity to be completed within no longer than a two-year period.

The Seed Fund is aimed at innovations with demonstrated technical merit, having at least evidence of proof of concept.

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

As such this funding is to support activities that would be undertaken during proof of feasibility, proof of value or preliminary validation stages of the innovation development life cycle, i.e. Innovation Maturity Level 4 to 6 as outlined in Appendix 1.

Activities that aim to demonstrate the validity of the innovation at advanced stages in an operational environment, such as clinical trials, are considered to be at a maturity level beyond the scope of the Seed Fund.

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.

Seed Fund applicants must describe:

- The significant problem that the innovation addresses.
- The proposed innovation to address the problem.
- The benefits of the innovation.
- Activities that will be undertaken to develop the innovation.
- The anticipated pathway to commercialisation.

Applications can be made by individuals or teams, with the support of a Responsible Entity. Where there is a team involved in the innovation activity, one person from the team must be nominated as the Innovation Lead.

The Innovation Lead will be responsible for coordinating the innovation activity, ensuring its timely execution, and complying with all reporting requirements.

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

4. Eligibility

To be eligible for this Program all of the following criteria apply:

- Applications must be submitted through a Responsible Entity which:
 - has an active Australian Business Number (ABN)
 - has a physical and operational presence in WA.
- The funding must not constitute the entire financial base of the Responsible Entity.
- The Innovation Lead applicant must:
 - o be an Australian citizen or permanent resident in Australia
 - o reside in WA for the period of the grant
 - be employed by the Responsible Entity for the period of the grant For the purposes of this Program, 'employment' includes the following:

 (a) employee of the Responsible Entity

- (b) honorary position at the Responsible Entity
- (c) adjunct status at the Responsible Entity that has an affiliation agreement with the employing entity.

Where (c) applies, the Responsible Entity is required to clearly identify the employing entity.

- have no outstanding reports for any RIO or FHRI Fund grant funding programs from any years (excluding authorised extensions).
- The maturity level of the innovation, at its current stage of development, must be at least IML 3 but no further advanced than 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).
- Applications must be submitted in accordance with Section 6 (<u>Application Instructions</u>).

RIO reserves the right to request further information and make final decisions regarding eligibility.

5. Program funding

Funding from \$250,000 up to \$500,000, to be expended over a maximum of two years, is available for an innovation activity.

Funding will be in accordance with the following:

- Salary costs:
 - Salaries must be directly attributable to the delivery of the activity outcomes.
 - Salaries of up to \$150,000 per annum, including on-costs, may be requested for each individual, with this limit adjusted to a pro rata amount for fractional Full Time Equivalent (FTE).
 - o Salary on-costs may be requested to up to 30%.
 - However, WA public health system applicants must claim salary on-costs in accordance with the WA Health Financial Management Manual s521 'Internal Salary Recoup (within WA Health entities)' table.
 - Salary funding can be used for leave entitlements that accrue during the innovation activity. However, severance and termination payments and leave entitlements accrued outside this period must not be paid through this funding.
- Innovation activity costs:
 - Activity costs may include funding for essential services, equipment, consumables, and other additional expenses directly related to the innovation activity.
 - Travel costs will not be approved unless these are strongly justified as being essential to the undertaking of the activity.
- Overhead charges:
 - Overhead charges (also referred to as indirect/infrastructure costs, e.g. utilities) may be requested up to 10% of the total budget.
 - However, WA public health system applicants cannot claim standard overhead charges, as per the Financial Management Manual s522 (RIO is an exempt organisation).

Requested FTE, salary level and activity costs must reasonably reflect the proposed innovation activity.

The intention is that funding will be spent within WA unless goods and services expenditure items are not available in WA.

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

Applicants should calculate budgets accurately, as requests for additional funding will not be considered.

RIO reserves the right to negotiate reductions in the amount of the funding awarded on a case-by-case basis.

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

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

6. Application instructions

The instructions below must be followed when making a submission:

- The Application Form available from the FHRI Fund website must be utilised.
- The Application Form must be typed in Arial font 11 point or larger.
- Applications must be submitted through the Responsible Entity grant administration (or equivalent operations/finance) office and applicants are responsible for complying with any internal deadlines for this.
- Electronic signatures are acceptable. The onus is on the applicant to ensure approval to use an electronic signature has been obtained.
- The application is to be emailed to RIO.DOH@health.wa.gov.au by the Responsible Entity as a **single** Adobe Acrobat PDF or Microsoft Word file, not exceeding 2MBs, including the CV of the Innovation Lead, and cited information (if applicable). The application email subject line should be titled as follows:

Innovation Lead SURNAME, First name – Innovation Seed Fund e.g. SMITH, Alex – Innovation Seed Fund.

• Applications must be complete, include requested certifications and submitted by the closing date/time.

Acknowledgment of receipt of applications will be provided by RIO via email to the Responsible Entity and applicant within five working days of the closing date.

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

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

7. Selection process

Assessment process

Funding will be awarded on merit, based on a process of assessment and selection. The assessment process will be conducted by a review panel comprising one or more of each of the following:

- experts in health and medical innovation
- experts in health and medical entrepreneurship and commercialisation
- persons with appropriate WA health and medical knowledge/experience
- consumer representatives.

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

Applications must meet the eligibility requirements and will be assessed based on the criteria set out in the table below.

Assessment criteria

The review panel will consider the assessment criteria outlined below.

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 and its maturity level

- The proposed innovation and how it is novel (new).
- The current maturity level of the innovation, which must be at least IML 3 but no further advanced than IML 6 (refer to Appendix 1).
- 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 validate the innovation.

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.
- 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.

Proposed activity

- The activity that will be undertaken, including objectives, methodology and realistic measures of outcomes.
- How the activity will contribute to validation or de-risking of the innovation.
- How the activity will improve the commercial potential of the innovation 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.

Capacity, capability and resources

- The knowledge, expertise and experience of the Innovation Lead and Team Members.
- The contribution of the Innovation Lead and each Team Member.
- Any collaborations with WA health service providers and WA industry.
- Access to technical resources, infrastructure, equipment and facilities and additional support personnel, if necessary.

Intellectual Property

• Any existing patent filings, including stage and priority dates.

- Names of the key inventors and the IP ownership structure.
- The IP strategy for protection of the innovation and any potential new IP during and beyond the funding period.

Consumer involvement

- How consumers (e.g. patients, carers, community members) have been involved in the development of the innovation to date, including the development of the activity proposal.
- The plan for ongoing consumer engagement in the activity, including their roles and how their lived experience perspectives will inform the activity delivery (refer to Section 8).

Anticipated commercialisation pathway and 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.

Selection of recipients

Based on the review panel assessments, 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.

RIO reserves the right to negotiate lower funding rates than requested, the timing of the funding awarded or to request modification to the proposed innovation activity on a case-by-case basis.

8. Consumer involvement

In line with the National Health and Medical Research Council's (NHMRC) definition, consumers are people who have lived experience of a health issue. They include patients, their friends, families, carers and members of the general public. 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 the research and innovation process. Effective consumer involvement can ensure research and innovation is relevant to the WA community and improves the uptake of findings.

Applicants should engage with health consumers during the development of funding applications and embed them in the proposed activity by including them in the innovation team where appropriate and providing a detailed description of their role and contribution.

Consumer involvement should incorporate:

- Clearly defined relationships with health consumers or community groups who have 'lived experience' of the issue the innovation addresses.
- Demonstrated understanding of the benefits derived from involving people with lived experience.
- Inclusion of consumers in the innovation team where appropriate.
- Plans to involve consumers in the innovation activity throughout the delivery timeline.
- Budget being allocated to support, implement and acknowledge consumer involvement (e.g. stakeholder training opportunities, honoraria and payments, additional time to support involvement activities, administrative support and consultations and events associated with involvement activities).

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> <u>Involvement in Health and Medical Research 2016</u>.

9. Contractual arrangements

Grant Funding Agreement

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 constitutes a legal agreement between the Department of Health and the Responsible Entity. For entities within the WA public health system, a Memorandum of Understanding (MOU) will be entered into.

Where research is a component of the innovation activity, this must be conducted in accordance with the <u>Australian Code for the Responsible Conduct of Research 2018</u>, and must have any required ethics and governance approvals.

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

Insurance

Responsible Entities external to the WA public health system will be required to demonstrate appropriate types and levels of insurance, as a condition of the Grant Funding Agreement.

Note that recipients who require site governance approval will also be required to demonstrate appropriate levels of insurance during this process, which may vary depending on the site.

Intellectual property

Intellectual Property (IP) that arises out of the activity will generally be vested with the applicants. However, consideration will be given to the provisions of the <u>Western Australian Government Intellectual Property Policy 2015</u>, 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.

The Responsible Entity must ensure that appropriate agreements specifying IP ownership are in place with the team members and participating entities. This includes relevant permissions to use third-party intellectual property 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. is not the Responsible Entity), the IP agreement must be authorised at an appropriate level by the relevant WA public health system entity.

The Responsible Entity must also establish appropriate sub-agreements with any third-party entities to specify IP ownership, or protect IP developed.

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

Requests for variation

Requests for variations to the Grant Funding Agreement or MOU, such as activity timing and duration, Responsible Entity, Innovation Lead, must be directed to RIO. Approval of the variation will be at the discretion of the Department of Health and require endorsement by the Responsible Entity. 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. Variation requests must be submitted at least 30 days prior to the end of the Agreement.

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 or MOU.
- Further instalments, if applicable based on activity duration, will be subject to satisfactory progress being achieved against the activity milestones, demonstrated in a Progress Report.

If approvals are required before the activity can commence (refer <u>Section 11 Approvals</u>), then the Responsible Entity must not release the first instalment funding until these approvals have been obtained and lodged with the Responsible Entity.

Seeking alternative funding sources

Applicants are permitted, and encouraged, to seek additional sources of funding during the innovation activity providing, this complements, but does not duplicate, the activity for which the funding was 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 RIO
- the activity is terminated by RIO as a result of insufficient progress being made at the time of progress reports, or it has been otherwise determined by either the funding recipient or RIO that the activity is no longer viable
- the recipient is successful in obtaining funding for the activity from another source
- funds are used for purposes other than those for which they were awarded
- funds are 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 RIO)
- the recipient is found to have provided misleading or fraudulent information.

11. Approvals

Ethics and governance approvals

The Responsible Entity, and any other participating entities, will be responsible for obtaining any ethics and governance approvals that might be required for undertaking funded activities, before those activities are commenced.

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

12. Reporting

The Innovation Lead is responsible for meeting reporting requirements over the duration of the activity and at its conclusion.

All reports are to be completed on template forms provided by RIO.

Progress Reports

A report outlining the progress against the milestones listed in the activity plan is required at least annually.

RIO reserves the right to request additional progress activity reports at any point.

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

Final Report and Community Stakeholder Brief

A Final Report detailing the activity and outcomes is to be submitted to RIO at the conclusion of the activity. Failure to submit the Final Report at this time may render all innovation team members ineligible for further funding from the FHRI Fund and RIO, until the Final Report is received.

In addition, in order to provide feedback to stakeholders, 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 consumer groups (including Aboriginal communities) and a copy submitted to RIO.

Financial Acquittal Statement

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

RIO reserves the right to request interim acquittal statements 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 can be made against the Department of Health.

13. Acknowledgements

The Minister for Medical Research and/or the Department of Health will publicly announce recipients of funding, including the title of the activity. All other parties must withhold announcements/media coverage until after this has occurred. The embargo on publicity will be in effect until RIO advises it has been lifted.

Acknowledgment of FHRI Fund support should be made as opportunities arise in publications, conference presentations, public discussion, press statements etc, as appropriate. The preferred citation is: "This work is/was supported by the Western Australian Future Health Research and Innovation Fund, which is an initiative of the WA State Government".

14. Complaints

Applicants who feel that their interests have been adversely affected by an action taken by RIO 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:

Executive Director, Clinical Leadership and Reform CLR.CED@health.wa.gov.au

15. Confidentiality

Plain language summaries and funding recipient statements provided in applications or reports may be used for publicity purposes, as stated on the relevant templates.

All other information provided in applications and reports will be maintained confidentially by RIO and review panels. If requests are received by RIO to make public any aspect of the activity, other than the plain language summaries or statements, the authorisation of the Responsible Entity will be sought.

Applicants are advised that the Department of Health is subject to the *Freedom of Information Act 1992 (WA)*. This provides a general right of access to records held by State Government agencies. In addition, information pertaining to the receipt of State Government financial assistance may be tabled in the Parliament of Western Australia.

16. Publications

Where applicable, funding recipients are requested to forward copies of publications resulting from the funded activity to RIO. In order to maximise knowledge exchange, funding recipients are asked to comply with the NHMRC's '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.

17. Evaluation

RIO will undertake evaluations of the Innovation Seed Fund Program, and the Responsible Entity, Innovation Lead, Team Members, consumers and participating entities will be required to contribute to this.

Appendix 1 – Innovation Maturity Level

The following has been 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*.

The maturity level of the innovation, at its current stage of development, must be at least IML 3 but no further advanced than IML 6. The proposed innovation activities to be undertaken with an Innovation Seed Fund grant must align with the highlighted IML 4, 5 or 6.

	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



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