

WA Cohort Studies – Operational Support Program 2025 (WACS-OSP)

Guidelines and Conditions

Applications due by:

1:00 pm (AWST) Thursday 3 April 2025

fhrifund.health.wa.gov.au

Contents

1.	Introduction	3
2.	Purpose	3
3.	Program description	4
4.	Eligibility	4
5.	Program funding	5
6.	Program conditions	6
7.	Application instructions	6
8.	Selection process	7
9.	Contractual arrangements	9
10.	Funding conditions	10
11.	Approvals	11
12.	Reporting	12
13.	Publicising, acknowledgements and publications	12
14.	Confidentiality	12
15.	Evaluation	13
16.	Complaints	13
App	pendix A: Eligible Funding Sources	14

1. Introduction

The WA Cohort Studies – Operational Support Program 2025 (the Program) is a funding program of the Western Australian (WA) <u>Future Health Research and Innovation (FHRI)</u> 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:

- support the development of early- and mid-career researchers, helping them to achieve an independent and self-sustaining career
- enhance health and medical research literacy, skills and experience of consumers so that they engage more in research
- enhance clinical trial capacity and expertise to improve the quality of clinical trials in WA and make the State more attractive to funders of clinical trials (grant funding and commercial sponsors)
- target high-performing researchers in WA to maintain and/or advance the State's position as a leader in health and medical research.

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
- advancing Western Australia to being, or maintaining Western Australia's position as, a national or international leader in research and innovation activities.

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

2. Purpose

The purpose of the Program is to provide operational funding to eligible cohort studies based on demonstrable competitive excellence. The Program intends to enable cohort studies to continue contributing to the delivery of improved clinical outcomes, changes to health policy and translational health outcomes.

The aims of the Program are to:

- ensure ongoing operations of WA cohort studies so that they can continue to contribute to the delivery of clinical outcomes, changes to health policy and translational health outcomes
- continue cohort studies' engagement with researchers and availability of data and biospecimen collections to inform research activities
- encourage new partnerships between WA cohort studies and researchers to undertake research and the ability for researchers to leverage competitive grant income
- support students, early and mid-career researcher's careers in health and medical research.

The objectives of the Program are to:

• support activities that are essential to operating cohort studies, with a focus on enabling WA cohort studies to collaborate with each other to realise efficiencies

 support activities and infrastructure essential to operating cohort studies, which are not typically covered by research grants.

3. Program description

The Program will provide funding to WA based cohort studies to support their ongoing operational costs for the 2025-26 financial year. For the purposes of the Program, a cohort study will be defined as an ongoing study where:

- participants are followed over time with continuous or repeated monitoring of risk factors or health outcomes (for at least five years)
- participants are recruited and then followed based on a common characteristic, such as an occupation or demographic similarity (for at least five years).

Funding provided through the Program is not intended to meet the full operational funding gap for eligible cohort studies. It is expected that the studies will use the Program funding as leverage to obtain additional funding from other sources.

The Activity Lead is the authorised representative of the cohort study.

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

Funding will be awarded based on demonstrable competitive excellence, recency and relevance.

* 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, the following criteria apply:

- The Responsible Entity must:
 - have an active Australian Business Number (ABN)
 - have a physical and operational presence in WA
 - be affiliated with a WA university, WA research institution, WA public health service provider¹ or a WA public-private partnership (PPP) provider², who is responsible for the financial activities of the cohort study.
- 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)
 - have a position at the Responsible Entity for the period of the Activity
 - be an authorised representative of the cohort study.

¹ WA public health service provider means a health service provider established by an order made under section 32(1)(b) of the *Health Services Act 2016*, such as the Child and Adolescent Health Service, East Metropolitan Health Service, North Metropolitan Health Service, South Metropolitan Health Service, WA Country Health Service and PathWest.

² Public-private partnership (PPP) provider refers to private hospitals with an agreement with the state government to provide public health services, for example, Joondalup Health Campus and St John of God Midland Public Hospital.

- The cohort study must:
 - o be physically based in WA
 - have ongoing core operational staff
 - have at least one active study that has or is recalling the cohort to collect samples or data (i.e. does not include projects utilising existing samples or data) by researchers not directly involved in the collection and maintenance of the cohort study
 - have received at least \$1,000,000 in eligible research grants received over the previous three calendar years, as defined in the Selection Process section
 - have existing standard operating procedures for data capture and biospecimen collection
 - have expenses to provide data and/or samples to researchers for research (not limited to any one field of study)
 - have an existing scientific advisory committee and consumer and community advisory group.
- The Responsible Entity, cohort study and 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 or the cohort study i.e. the Responsible Entity and cohort study (if different) 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 application may be deemed eligible 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
 - o 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 being met.
- OMRI reserves the right to request further information and make final decisions regarding eligibility.
- Decisions made in relation to previous grant programs will not be regarded as precedents and will not be considered when assessing eligibility for this grant program.

5. Program funding

Eligible cohort studies will receive grant funding proportional to its research grants received, PhD dollar value and total number of new projects received over the previous three calendar years (i.e. 2022, 2023 and 2024), in comparison to other eligible cohort studies.

This method ensures cohort studies are recognised for activities that are directly supporting current research and building research capability in WA.

Funding amounts up to \$500,000 excluding GST, are available to finance the Activity over a 12-month period.

Funding from the WACS-OSP will be used by eligible cohort studies to fund services and infrastructure that support activities which are not funded by research grants. A comprehensive list of included expenditure items is included in the Program conditions section.

Funding may not be used to fund research projects or major capital works.

The Department of Health will not underwrite any costs beyond the funding awarded through this 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.

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

6. Program conditions

Included expenditure items

Recipients may use their WACS-OSP grant on the following items, which must be associated with the cohort studies activities during the period of the grant:

- salaries of core personnel associated with the management of the study
- salaries of core personnel associated with cohort assessment/retention and data and bio-specimen collection
- core costs associated with cohort assessment/retention, including consumer consultation
- collection of new data and bio-specimens
- management, storage and curation of previously collected data and bio-specimens
- purchase or upgrade of software (including user licenses) and IT hardware
- research management, including facilitating agreements with external researchers
- general administrative services for the cohort study
- collaborative activities with other WA cohort studies with the aim of increasing efficiencies and access for researchers.

Excluded expenditure items

The following are excluded expenditure items:

- travel
- research projects
- major capital works
- non-research purposes such as for diagnostic, therapeutic, forensic, audit, public health surveillance, or marketing authorisation purposes.

7. Application instructions

The instructions below must be followed when making a submission:

- The Application Form and the Assessment of Research Excellence spreadsheet available from the <u>FHRI Fund website</u> must be submitted by 1:00 pm (AWST) Thursday 3 April 2025.
- 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 Form and Assessment of Research Excellence spreadsheet are to be sent in a single email to <u>DOH.OMRI@health.wa.gov.au</u>. The Application Form is to be a single Adobe Acrobat PDF or Microsoft Word file, not exceeding 5 MBs, including CVs and bibliographic references (if applicable), and the Assessment of Research Excellence spreadsheet is to be a single Microsoft Excel workbook.

The application document and email subject line must be titled as follows:

Activity Lead SURNAME, First name – WACSOSP2025

e.g. SMITH, Alex - WACSOSP2025

 Applications must be complete, include requested certifications and be submitted by the closing date/time. Consideration must be given to the time needed to comply with internal deadlines.

Acknowledgement of receipt of the application will be provided via email to the Responsible Entity and Activity Lead within 5 working days of the closing date.

Queries regarding the application process should be directed by email to DOH.OMRI@health.wa.gov.au with the subject line beginning with 'Query – WACSOSP2025.

8. Selection process

Assessment process

Funding will be awarded on demonstrable research excellence, based on a funding formula.

This formula will calculate the relative research excellence of eligible cohort studies in comparison to each other and will be based on eligible research grants received, number of PhD students and the number of new projects supported by the study in the previous three calendar years.

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

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

Assessment Criteria

Eligible research grants received

- Equivalent to the grant amount received by the researcher who is utilising the cohort study
- Minimum threshold of \$1,000,000 over the previous three calendar years.

PhD students supported

• Equivalent to \$30,000 per student per year

Total number of new projects supported

Equivalent to \$10,000 per new project

Eligible research grants received

Eligible research grants received includes research grant and fellowship income which has been received in the previous three calendar years (2022, 2023 and 2024) for health and medical research (excluding grants from the WA Department of Health and the FHRI Fund).

Eligible research grants received includes a grant which is:

- from a funding source where the grant or fellowship has undergone a competitive review process:
 - a competitive review process must allow for any applicant to apply, must not give preference to the type of institution nor its geographical location, have publicly available selection criteria against which all applications are assessed and have publicly available guidance stating how assessments are conducted
 - has been awarded following scientific peer review, committee or panel review or corporate board review.
- received by researchers whose research project is based on utilising samples and/or associated data from the cohort study
- for health and medical research. For the purposes of this Program, health and medical research is inclusive of:
 - o research to understand human health, wellbeing and disease, and the biological, behavioural, social, and environmental factors that contribute to these
 - o research to measure the magnitude and distribution of a health problem
 - research to develop solutions, interventions, products, and technologies that could contribute to improving human health and wellbeing
 - o research to understand how interventions, policies and programs aimed at improving human health and wellbeing can be most effectively delivered.

Funding sources deemed eligible for the purposes of the Program are listed in Appendix A: Eligible funding sources.

If a funding source is not listed in Appendix A: Eligible funding sources, eligibility of the funding source for the Program purposes will need to be assessed and the *Application Form Funding Source Assessment* section must be provided.

It is incumbent on the Applicant to complete the statements of compliance and provide all necessary documentation to ensure all eligible grants are claimed and the minimum research grants threshold is met.

OMRI has the final determination regarding eligibility of research grants claimed.

For the purposes of this program, eligible research grants received does not include:

- projects funded because of a direct approach from a funding body or from donations
- grants for quality assurance, clinical audit, needs analysis or literature review
- grants for equipment, travel, infrastructure, or training/education.

Research grants received that applies to multiple cohort studies

If a research grant being claimed for the Program is based on or uses samples and/or associated data from more than one cohort study that is applying to this Program, applicants must determine which cohort study will count the research grants received in their application.

If there is agreement between cohort studies to split grants received for the Program purposes, *Application Form – Split Grant Details* section must be provided as evidence of that agreement by all parties. A copy of this must be included in the application for each relevant split grant.

OMRI reserves the right to request external audits of submitted grant claims at any time.

PhD dollar value equivalent

The number of PhD students over the previous three calendar years, conducting research that is based on or uses samples and/or data from a cohort:

 This includes the number of PhD students over the previous three calendar years (2022, 2023 and 2024):

- The number of PhD students are determined by whether they are collecting and/or analysing biospecimens or undertaking research on cohort data during the allocated three calendar years (not when they commenced).
- The PhD full time equivalent status is not included in the calculation of eligible students.
- The number of students will be accounted for by allocating a dollar amount per PhD student. This amount is \$30,000 per year per (for both full time and part-time) PhD student.

Total number of new projects dollar value equivalent

The number of new projects accessing biospecimens or data from the cohort study represents the relevance and ongoing contribution made by the cohort study to support research:

- This comprises the number of new projects that have been approved to access data and/or bio-specimens from a cohort study via an appropriate review process.
 Appropriate review processes include an ethics committee approval or scientific review committee approval
- New projects that have commenced accessing data and/or bio-specimens in the previous three calendar years (2022, 2023 and 2024) will be allocated \$10,000 per project.

Selection of recipients

Based on the application of the funding formula, 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.

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, where applicable.

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 of specification services)
- Property for the Responsible Entity's replacement value of assets (mandatory for building, plant, machinery, equipment)

- Workers Compensation (mandatory if the Responsible Entity has employees or is paying salaries, noting this includes payments to working Directors)
- Product Liability (mandatory if the Responsible Entity manufactures, supplies, sells, services or repairs a product)
- Motor Vehicle if the Responsible Entity owns vehicles
- Clinical Trials if the Responsible Entity undertakes clinical trials (note this insurance may include Professional Indemnity)
- Cyber Liability if the Activity involves confidential data, e.g. identifiable patient information.

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

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

Note 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.

Requests for variation

Requests for variations to the Grant Funding Agreement, such as 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 a single instalment* to the Responsible Entity subject to execution of a Grant Funding Agreement.

* Within the WA public health system, payment will be made to the Responsible Entity via a General Ledger Journal (GLJ) transfer progressively upon receipt of evidence of expenditure.

Partial payment or suspension of funds

The Department of Health reserves the right to:

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

Additional funding sources

Additional sources of funding are 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 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

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 <u>Data Linkage Services</u> website. Should the application for funding be successful, we recommend you immediately begin the data request and approval process.

12. Reporting

The Responsible Entity and the Activity Lead, on the behalf of the cohort study (if different) are responsible for meeting reporting requirements over the duration of the Activity and its conclusion.

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

Final Activity Report

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

Financial Report

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

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

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

13. Publicising, acknowledgements and publications

The Minister for Medical Research and/or the Department of Health will publicly announce recipients. 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 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 (OfficeoftheDDG@health.wa.gov.au).



Appendix A: Eligible Funding Sources

The eligible funding sources for WACS-OSP have been determined in line with the Australian Government <u>Higher Education Research Data Collection (HERDC)</u> specifications for 2023. These are divided into the four following categories.

- Category 1: Australian competitive grant research and development (R & D) income
 Consists only of net receipted income received from Australian funding bodies for
 those R&D schemes and programs that have been self-assessed as Australian
 competitive grant R&D income. For example, income from the National Health and
 Medical Research Council.
- <u>Category 2: other public sector R & D income</u>
 Consists of R&D income received from the Australian public sector that is not eligible for inclusion as Category 1 income. For example, income received from Commonwealth, State or Local governments.
- Category 3: industry and other R & D income
 Category 3 consists of R&D income received from the private sector, philanthropic and international sources that are not eligible under Category 1 or 2.
- Category 4: Cooperative Research Centre R & D income
 R&D income from a Cooperative Research Centre (CRC), when defined within the
 Commonwealth Agreement as a 'Participant', and signatory to the CRC's
 Commonwealth Agreement or Participant's Agreement. Category 4 also includes
 income received from CRC Projects, which support short-term collaborative
 research projects.

If Applicants wish to claim grants from funding sources that are not included within the HERDC specifications, OMRI will assess the eligibility of the funding source for WACS-OSP, using Section 11 of the Application Form.

It is incumbent on the Applicant to complete Section 11 and provide all the necessary documentation; otherwise, the grant may be classed as ineligible and excluded from the total eligible grants claimed.



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

© Department of Health 2024

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.