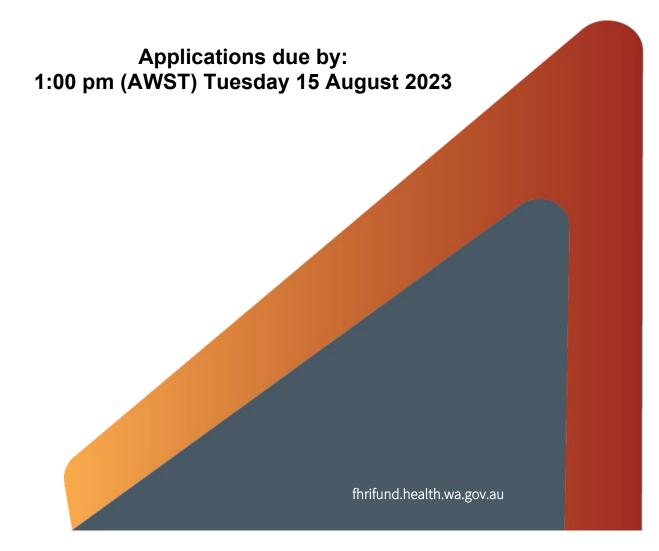


Western Australia (WA) Cohort Studies-Operational Support Program (WACS-OSP)

Guidelines and Conditions



Contents

1.	Introduction	3
2.	Purpose	3
3.	Program description	4
4.	Eligibility	4
5.	Program funding	5
6.	Program conditions	5
7.	Application instructions	6
8.	Assessment process	6
9.	Contractual arrangements	8
10.	Funding conditions	8
11.	Reporting	9
12.	Publicising, acknowledgements and publications	9
13.	Confidentiality	9
14.	Evaluation	10
15.	Complaints	10

1. Introduction

The WA Cohort Studies-Operational Support Program (WACS-OSP) is a Program of the Western Australian (WA) <u>Future Health Research and Innovation (FHRI) Fund</u>.

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

- 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 this Program is to provide a source of operational funding to eligible cohort studies based on demonstrable competitive excellence.

The aims of the Program are to:

- provide operational funding required for cohort studies to continue to contribute to the delivery of clinical outcomes, changes to health policy and translational health outcomes
- provide continuity so that cohort studies can continue advancing their biospecimen and data collections for the intended term
- quantify the return on investment in cohort platform research to demonstrate value to the health and medical research and innovation ecosystem
- 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.

3. Program description

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).

The WACS-OSP provides funding for the 1 July 2023 to 30 June 2024 period.

It is noted that funding provided through the WACS-OSP is unlikely to meet the full operational funding gap for all eligible cohort studies and there is an expectation that these studies will use WACS-OSP funding as leverage to obtain other funding and to provide time to achieve efficiency improvements and cost savings.

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 through a competitive and merit-based process.

* 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 must:
 - have an active Australian Business Number (ABN)
 - o have a physical and operational presence in WA
 - be affiliated with a WA university, WA research institution, WA public health service provider or a WA public-private partnership provider who is responsible for the financial activities of the cohort study.
- The cohort study must:
 - receive income from other sources i.e. the WACS-OSP grant funding must not constitute the entire financial base of the cohort study
 - 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 grant income over the previous three calendar years, as defined in Section 8
 - 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
 - have a consumer and community advisory group.
- Applications must be submitted in accordance with the 'Application instructions' section of this document.

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

5. Program funding

Each eligible cohort study will receive a grant that is proportional to its research grant income, PhD dollar value and total number of new projects received over the previous three calendar years (i.e. 2020, 2021 and 2022), in comparison to other eligible cohort studies. Therefore, cohort studies will receive operational funding support that is proportional to the high-quality research studies they enable and the number of PhD students that are supported. This method ensures cohort studies are not rewarded for sample collection that does not address a specific research question.

An initial limit of \$500,000 per application has been set to ensure support can be provided across all eligible cohort studies, however the OMRI reserves the right to revise this limit.

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. Funding through 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. For example: facilities, Information Technology (IT) services, core personnel salaries, infrastructure such as freezers, administrative services, sample storage and curation, and research management. 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 cohort study
- salaries of core personnel associated with the cohort assessment and data and biospecimen collection
- core costs associated with cohort assessment/retention, data and bio-specimen collection costs (other than core personnel salary) and consumer consultation
- research management, curation and storage of previously collected data and biospecimen and the purchase of equipment, for example storage freezers
- purchase or upgrade of software (including user licenses) and IT hardware
- facilitating agreements with researchers
- general administrative services for the cohort study.

Excluded expenditure items

The following are excluded expenditure items:

- travel
- 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 available from the <u>FHRI Fund website</u> must be submitted by 1:00 pm (AWST) Tuesday 15 August 2023.
- The application must be completed in Arial font 11 point or larger.
- 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 <u>DOH.OMRI@health.wa.gov.au</u> as a <u>single</u> Adobe Acrobat PDF or Microsoft Word file, not exceeding 5 MB. The application and email subject line must be titled as follows:

Applicant SURNAME, First name – WACS-OSP e.g., SMITH, Alex – WACS-OSP

 Applications must be complete, include requested certifications and be submitted by the closing date and time. Applicants are responsible for complying with internal deadlines.

Acknowledgement of receipt of application will be provided via email to the Responsible Entity and cohort study's nominated representative 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.

8. Assessment process

A formula will be implemented to calculate the relative research excellence of eligible cohort studies in comparison to each other and will be based on research grant income, number of PhD students and the number of new projects supported by the cohort study in the previous three 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

- 1. Research grant income Equivalent to the grant amount received by the researcher who is utilising the cohort study
- 2. PhD students supported Equivalent to \$30,000 per student per year
- 3. Total number of new projects supported Equivalent to \$10,000 per new project

Eligible research grant income

Eligible research grant income includes research grant income which has been received in the previous three consecutive calendar years (2020-2022) for health and medical research (excluding grants from the WA Department of Health or FHRI Fund).

Eligible research grant income includes a grant which is:

- from a funding source where the grant has a competitive review process. For example, appropriate governance review is performed such as 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 WACS-OSP 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 WACS-OSP purposes will need to be assessed and *Application Form Section 10 – Funding Source Assessment* must be provided.

It is incumbent on the Applicant to complete the statements of compliance and provide all necessary documentation to ensure all grant income is included and the minimum research grant income requirements are met.

The OMRI has the final determination regarding eligibility status of grants.

For the purposes of this program, competitive research grant income does not include:

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

Research grant income that applies to multiple cohort studies

If a research grant being claimed for the WACS-OSP is based on or uses samples and/or associated data from more than one cohort study that is applying to this Program, then Applicants from the relevant cohort studies must determine which of the cohort studies will count the research grant income in their application.

If there is agreement between cohort studies to split grant income for the WACS-OSP purposes, *Application Form Section 9 – Split Grant Details* must be provided as evidence of that agreement. A copy of *Section 9* must be included in the application for each relevant split grant.

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

PhD dollar value equivalent

The number of PhD students conducting research that is based on or uses samples and/or data from a cohort study represents the support provided by cohort studies to support research career development and retention of researchers in WA.

 This includes the number of PhD students over the previous three calendar years (2020-22).

- 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 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 includes 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. For example, an ethics committee approval or scientific review committee approval.
- New projects that have commenced in the previous three calendar years (2020-2022) will be allocated \$10,000 per project.

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.

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). Within the WA public health system, a Memorandum of Understanding (MOU) will be entered.

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

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.

Requests for variation

Requests for variations to the Grant Funding Agreement or MOU 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.

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 or MOU.

Additional funding sources

Applicants are permitted, and encouraged, to seek additional sources of funding to support the operations of the cohort study.

Termination of funds

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

- eligibility requirements are no longer met, unless a request for variation to address this is approved by OMRI
- funds are not fully expended at the conclusion of the grant (including any extensions approved by the OMRI)
- funds are used for purposes other than those for which they were awarded
- it is determined that misleading or fraudulent information has been provided.

11. Reporting

The cohort study and Responsible Entity are responsible for meeting reporting requirements.

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

Final Activity Report

A final report detailing the outcomes of the funding is to be submitted to OMRI at the conclusion of the funding period. This report should demonstrate how the funding has contributed to operational support and the intended outcomes of the program.

Financial Report

A financial acquittal statement outlining the expenditure of funds must be submitted to OMRI at the conclusion of the funding period. 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 funding period.

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

12. Publicising, acknowledgements and publications

The Minister for Medical Research and/or the Department of Health will publicly announce recipients. 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 as appropriate. The preferred citation is: "This work is/has been supported by the WA Future Health Research and Innovation Fund".

13. Confidentiality

Plain language summaries and sections indicated on applications or reports may be used for publicity purposes.

All other information provided in applications and reports will be maintained confidentially by OMRI, review panels, evaluation panels and the FHRI Fund Advisory Council. If requests are received by OMRI to make public any aspect of the Activity, other than the aspects listed above, the authorisation of the Responsible Entity will be sought, notwithstanding information requested under the *Freedom of Information Act 1992 (WA)*

or information pertaining to the receipt of State Government financial assistance tabled in the Parliament of Western Australia.

14. Evaluation

The OMRI undertakes evaluations of Funding Programs, which will include unsuccessful applications. All parties in the application are required to contribute to the evaluation.

15. Complaints

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

If Applicants wish to claim grants from funding sources that are not on the lists below, eligibility of the funding source for the WACS-OSP purposes will need to be assessed and Application Form Section 11 must be provided. It is incumbent on the Applicant to complete the statements of compliance and provide all necessary documentation; otherwise, the grant will not be included, and this may affect overall eligibility if the minimum grant income requirement is not met.

The following funding sources are deemed eligible for the WACS-OSP:

1. Australian Competitive Grants Register (ACGR)

Grants for medical or health research from funding sources on the 2018 Australian Competitive Grants Register (ACGR) are eligible and may be found at: 2018 acgr listing final.pdf

Note: the ACGR will not be updated beyond 2018.

- 2. Department of Health approved funding sources:
 - A Foundation Building Strength for Nemaline Myopathy, USA
 - Action Duchenne, UK
 - Arthritis Australia
 - Association Française contre les Myopathies AFM
 - Asthma Australia National Research Program Grants
 - Asthma Foundation of Western Australia
 - Australian Paediatric Endocrine Group (APEG) Novo Nordisk
 - Australian Primary Health Care Research Institute (APHCRI) Foundation Grants
 - Autism Speaks, USA
 - Avner Pancreatic Cancer Foundation Limited Accelerator Grant
 - Bill & Melinda Gates Foundation (Requests for Proposals RFPs stream only)
 - Brain Foundation McArdle Disease Award (Research Gifts)
 - BrightFocus Foundation
 - British Heart Foundation
 - Canadian Institutes of Health Research
 - Cancer Australia Project Grant
 - Cancer Council NSW STREP Grants
 - Cancer Council WA Epidemiology Initiative
 - Cancer Council WA Research Project Grants
 - Cancer Council WA STREP Funding Scheme
 - Cancer Research Trust Postdoctoral Fellowships
 - Cancer Research Trust Collaborative Cancer Grant
 - Cooperative Research Centres (if specific project was an identifiable part of the original application; each will be reviewed on a case-by-case basis)
 - Cure Brain Cancer Foundation Innovation Grant
 - Cystic Fibrosis Foundation, USA
 - Department of Health and Ageing Dementia and Aged Care Services Fund -Research and Innovation Funding Round

- Duchenne Ireland
- Dutch Duchenne Parent Project Small Project Grant
- Exercise and Sports Science Australia (ESSA) Clinical Exercise Physiology Research Grant
- Healthway Priority Driven Research
- HeartKids Australia Grants-in Aid
- Howard Hughes Medical Institute International Research Scholars Program (America)
- International Olympic Committee Anti-Doping Research Fund
- International Rett Syndrome Foundation
- Juvenile Diabetes Research Foundation (JDRF) International, USA
- Juvenile Diabetes Research Foundation (JDRF), UK
- Michael J Fox Foundation (MJFF), USA
- Muscular Dystrophy Association (USMDA), USA
- National Breast Cancer Foundation Pilot Study
- National Institute of Health Research (NIHR), UK Health Technology Assessment (HTA) Programme
- National Institutes of Health, USA
- National Stroke Foundation Seed Grant
- Parent Project Muscular Dystrophy, USA Exploratory Award
- Pfizer Australia Paediatric Endocrine Research grant
- Ramaciotti Foundations
- Red Nose Foundation Project Grant
- Retina Australia
- Slater and Gordon Research Grant
- The Ophthalmic Research Institute of Australia (ORIA) Research Grants
- US Department of Defense/Congressionally Directed Medical Research Schemes/Peer Reviewed Cancer Research Program/Discovery Award
- Victorian Neurotrauma Initiative (VNI)
- The ISAZ-Waltham Collaborative Research Award in Human Animal Interactions
- Wellcome Trust, UK
- World Health Organization

Please note funding sources which have been deemed ineligible include:

- Cancer Council WA Capacity Building and Collaboration Grant
- Cancer Council WA Research Fellowship
- Healthway Research Fellowship
- Healthway Starter Grant

These grants may only be submitted for assessment if the funding scheme criteria have been modified since 2020 and now meet the WACS-OSP eligibility criteria.



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

© Department of Health 2023

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.