

Australian Government

Department of Industry, Science and Resources Department of Health and Aged Care





Grant Opportunity Guidelines

Medical Research Future Fund

Medical Research Future Fund – National Critical Research Infrastructure Initiative

2023 Innovative Trials Grant Opportunity Guidelines

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Closing date and time:	5.00pm AEST on 10 July 2024
Commonwealth policy entity:	Australian Government Department of Health and Aged Care
Administering entity	Department of Industry, Science and Resources
Enquiries:	If you have any questions, contact us on 13 28 46 or NCRI@industry.gov.au.
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Medical Research Future Fund (MRFF) National Critical Research Infrastructure Initiative: 2023 Innovative Trials Grant Opportunity process

The Medical Research Future Fund is designed to achieve Australian Government objectives

This grant opportunity is part of the above grant program, which contributes to the Department of Health and Aged Care's Outcome 1. The Department of Health and Aged Care works with stakeholders to plan and design the grant program according to the *Commonwealth Grants Rules and Guidelines*.

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The grant opportunity opens

We publish the grant guidelines on business.gov.au and GrantConnect.

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You complete and submit a grant application

You complete the application form, addressing all the eligibility and assessment criteria in order for your application to be considered.

$\mathbf{\Psi}$

We assess all grant applications

We review the applications against eligibility criteria and notify you if you are not eligible.

We assess eligible applications against the assessment criteria and compare it to other eligible

applications, if applicable.

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We make grant recommendations

We provide advice to the decision maker on the merits of each application.

$\mathbf{\Psi}$

Grant decisions are made

The decision maker decides which applications are successful.

$\mathbf{\Psi}$

We notify you of the outcome

We advise you of the outcome of your application. We may not notify unsuccessful applicants until grant agreements have been executed with successful applicants.

$\mathbf{\Psi}$

We enter into a grant agreement

We will enter into a grant agreement with you if successful. The type of grant agreement is based on the nature of the grant and will be proportional to the risks involved.

$\mathbf{\Psi}$

Delivery of grant

You undertake the grant activity as set out in your grant agreement. We manage the grant by working with you, monitoring your progress and making payments.

$\mathbf{\Psi}$

Evaluation of the Grant Opportunity

We evaluate the specific grant activity as a whole. We base this on information you provide to us and that we collect from various sources.



1. About the Medical Research Future Fund

1.1. Medical Research Future Fund (MRFF)

The MRFF, established under the *Medical Research Future Fund Act 2015* (MRFF Act), provides grants of financial assistance to support health and medical research and innovation to improve the health and wellbeing of Australians. It operates as an endowment fund with the capital preserved in perpetuity. The MRFF reached maturity at \$20 billion in July 2020. The MRFF provides a long-term sustainable source of funding for endeavours that aim to improve health outcomes, quality of life and health system sustainability.

This MRFF investment is guided by the *Australian Medical Research and Innovation Strategy* 2021-2026 (the Strategy) and related set of *Australian Medical Research and Innovation Priorities* 2022-2024 (the Priorities), developed by the independent and expert Australian Medical Research Advisory Board following extensive national public consultation.

1.2. About the National Critical Research Infrastructure Initiative

The National Critical Research Infrastructure Initiative (the Initiative) forms part of the Fund. The Australian Government has announced a total of \$650 million over 10 years from 2022-23 for the Initiative.

This initiative provides funding to establish and extend infrastructure (facilities, equipment, systems and services) of critical importance that will be used to conduct world-class health and medical research. Funding will be provided through the following Streams:

- innovation enablers
- digitisation of health care
- co-investment partnerships
- mRNA technology enablers.

Further information on the rationale of the Initiative is available on the Department of Health and Aged Care website.

The MRFF Monitoring, Evaluation and Learning Strategy (the Evaluation Strategy) provides an overarching framework for assessing the performance of the MRFF and is publicly available on the <u>MRFF website</u>. Applicants to this grant opportunity are expected to describe how their proposed project aligns with the objectives and outcomes of the National Critical Research Infrastructure Initiative and the Measures of Success as described in the Evaluation Strategy. These will be key assessment criteria for funding. Projects funded from this grant opportunity will be monitored and evaluated against the Evaluation Strategy.

For further details see sections 5 and 6.

There will be other grant opportunities as part of this Initiative and we will publish the <u>opening and</u> <u>closing dates</u> and any other relevant information on business.gov.au and GrantConnect.

We administer the MRFF according to the Commonwealth Grants Rules and Guidelines (CGRGs)¹.

¹ <u>https://www.finance.gov.au/sites/default/files/commonwealth-grants-rules-and-guidelines.pdf</u>



1.3. About the 2023 Innovative Trials Grant Opportunity

These guidelines contain information for the 2023 Innovative Trials Grant Opportunity. This grant opportunity was announced as part of the MRFF under the National Critical Research Infrastructure Initiative (the Initiative).

Research infrastructure is a crucial enabler of research. To help ensure Australian researchers find innovative solutions to complex health problems in areas of unmet need, there is a need to support the establishment and extension of infrastructure (i.e. facilities, equipment, systems and services) of critical importance that will be used to conduct world-class health and medical research. In particular, the 'innovation enablers' stream of the Initiative promotes the development and implementation of new research methodologies/applications by supporting development and/or expansion of research enablers such as biobanks, tissue repositories, novel platforms, and secure health data environments to create valuable research resources.

For the purpose of this grant opportunity, 'unmet medical need' arises where individuals are living with a serious health condition, where there are limited satisfactory options for prevention, diagnosis or treatment to support improved health outcomes.

Traditional randomised controlled trials are the gold-standard approach to generate evidence regarding the benefits and harms of potential medical therapies. However, they can be slow, expensive to perform, inefficient and limited in the questions they address and external validity². The use of alternative innovative trial methodologies has increased in recent years as they may allow for more cost effective, generalisable, and high-quality real world clinical evidence over conventional trial designs.

Additionally, in 2021, the Centre for Evidence-Based Healthcare at Bond University was commissioned to evaluate the MRFF Clinical Trials Activity initiative and MRFF investments in clinical trials. The 'Evaluation of the MRFF Clinical Trials Activity' report³ was published following analysis of national and international clinical trials registries data, survey of clinical trial grantees in Australia and national and international stakeholders. As part of the report's findings, opportunities for improvement were identified from stakeholders, such as encouraging more efficient or innovative trial designs. As such, the 2023 Innovative Trials grant opportunity focuses on promoting development and implementation of 'adaptive platform' and 'registry based' trials which are thought to offer more efficient evaluation of interventions.

Adaptive platform trials offer the ability to study multiple interventions in a disease or condition in a perpetual manner, with the flexibility to drop/add treatments to be tested⁴. The focus of an adaptive platform trial is a disease or condition, rather than a particular intervention, therefore the overarching design can be created before any specific experimental arms are defined. Adaptive Platform Trials provide the innovation needed to combat current and emerging health challenges. As such, there is an opportunity to bolster Australia's national capacity and capability to conduct adaptive clinical trials by supporting the establishment of critical long lasting adaptive trial infrastructure. Funding for adaptive platform trial 'central infrastructure' projects will therefore be

⁴ The Adaptive Platform Trials Coalition. Adaptive platform trials: definition, design, conduct and reporting considerations. Nat Rev Drug Discov 18, 797–807 (2019). 3



² Bothwell, L. E., Greene, J. A., Podolsky, S. H. & Jones, D. S. Assessing the gold standard — lessons from the history of RCTs. *N. Engl. J. Med.* **374**, 2175–2181 (2016).

³ <u>https://www.health.gov.au/resources/publications/evaluation-of-the-medical-research-future-fund-clinical-trials-activity</u>

provided under Stream 1 of this grant opportunity through three topics that support building the sequential components of adaptive platform trial 'central infrastructure'. This comprises initial design, through to establishment of a new adaptive platform trial, and then to expanding an existing adaptive platform trial to answer new questions.

Registry-based randomised controlled trials are another alternative approach to traditional randomised controlled trials, which integrate conventional trial methodologies with registry systems and leverage clinical registries⁵ to facilitate high-quality clinical trials at lower cost^{6,7}. Registrybased randomised controlled trials are generally considered under the broader umbrella of pragmatic trials and incorporate major elements of conventional randomised controlled trials. They are, for example, well suited for testing hypotheses involving already-available clinical interventions for which there are uncertainties about the optimal combination, sequence, or duration of standard-of-care treatment, or where multiple standard-of-care options exist³.

Advantages of registry-based randomised controlled trials include more efficient identification and recruitment of patients and increased likelihood to produce results that are generalisable to the wider population⁸ due to the inclusion of real-world patients. There is an opportunity to leverage the use of nationally available registry datasets and systems for research. For example, the importance of maximising the impact of clinical quality registries in achieving better health outcomes is recognised by the National Strategy for Clinical Quality Registries and Virtual Registries 2020-2030⁹. Stream 2 of this grant opportunity was therefore developed to support harnessing the potential of registries to conduct cost-efficient clinical trials at a national level. Funding under this Stream will be provided for projects that aim to embed a registry-based randomised controlled trial into a pre-existing clinical registry in order to promote the establishment and conduct of more efficient clinical trials as well as promote capacity and capability development in the clinical trials workforce.

Although there is a call to use innovative trial methodologies including adaptive platform trials and registry-based randomised controlled trials more widely, the magnitude of efficiency gains and factors that influence efficiency have not yet been quantified. There is yet little quantitative evidence that shows whether and by how much they are more cost effective. To bridge this gap, funding will be provided under Stream 3 of this grant opportunity for projects that aim to generate definitive evidence of the efficiency and cost effectiveness of innovative trial designs over conventional trial designs. This evidence can then be translated into practice by triallists as well as funders to drive innovation and optimisation of clinical trial methodology to maximise outcomes.

⁹ https://www.health.gov.au/sites/default/files/2023-04/a-national-strategy-for-clinical-quality-registries-and-virtual-registries-2020-2030_0.pdf



⁵ https://clinicaltrialsalliance.org.au/wp-content/uploads/2022/10/Medical-Journal-of-Australia-2022-Ahern-Realising-the-potential-leveraging-clinical-quality-registries-for-real.pdf

⁶ Karanatsios, B., Prang, KH., Verbunt, E. et al. Defining key design elements of registry-based randomised controlled trials: a scoping review. Trials 21, 552 (2020).

⁷ James S, Rao SV, Granger CB. Registry-based randomized clinical trials--a new clinical trial paradigm. Nat Rev Cardiol. 2015 May;12(5):312-6.

⁸ Prang, KH., Karanatsios, B., Zhang, A. et al. "Nothing to lose and the possibility of gaining": a qualitative study on the feasibility and acceptability of registry-based randomised controlled trials among cancer patients and clinicians. Trials 24, 92 (2023).

The objective and intended outcome of this grant opportunity are aligned with the following *Australian Medical Research and Innovation Priorities 2022-2024*:

- Research Infrastructure and Capability
- Health and Medical Researcher Capacity and Capability.

Consistent with the MRFF Act, the objective of this grant opportunity is to provide grants of financial assistance to support Australian medical research and medical innovation projects that:

Stream 1 (<u>Incubator and Targeted Call for Research</u>): address an area of unmet medical need by promoting the development and implementation of adaptive platform trials. Research proposals in this stream must focus on one of the following Topics:

- Topic A (Incubator): conducting inception projects that build evidence and capability to demonstrate the feasibility of establishing a national adaptive platform trial that would allow for rapid assessment of pharmacological and/or non-pharmacological interventions in an area of unmet need
- **Topic B** (<u>Targeted Call for Research</u>): establishing a new national adaptive platform trial that addresses an area of unmet need, including set up of central infrastructure and conduct of initial launch domains
- **Topic C** (<u>Targeted Call for Research</u>): expanding an existing adaptive platform trial by adding new domains that address an area of unmet need.

Stream 2 (<u>Targeted Call for Research</u>): conduct a registry-based randomised controlled trial in an area of unmet medical need by embedding a registry-based randomised controlled trial into a preexisting clinical registry.

Stream 3 (<u>Targeted Call for Research</u>): generate evidence of the efficiency and cost effectiveness of innovative trial designs over conventional trial designs for:

- Topic A (<u>Targeted Call for Research</u>): adaptive platform trials
- Topic B (<u>Targeted Call for Research</u>): registry-based randomised controlled trials.

Projects which leverage existing research infrastructure projects such as those funded by the Australian Government through the National Collaborative Research Infrastructure Strategy (NCRIS) will be highly regarded (see Appendix A).

Applicants to all streams should consider the breadth and diversity of the study population including considering priority populations to ensure the needs of the consumers and end-users are met in the long-term.

To be competitive for funding, applicants must propose to conduct research that delivers against the above objective/s and those of the Initiative. Applicants are encouraged to propose novel and/or innovative research and describe how the outcomes of the research will be translated into health benefits for Australians.

Additional information for Stream 1

Applicants to Stream 1 (all topics) should include (as relevant) consideration of:

- the incidence and impact of the disease that the adaptive platform trial is proposed to serve
- whether the outcomes of the proposed trial can be established in a clinically meaningful manner so that useful adaptation can be implemented
- clinical consensus on prioritisation of research questions and choice of initial/subsequent interventions within the adaptive platform trial



- statistical simulations necessary to guide the trial design and understand the operating characteristics of the platform
- plans for digital infrastructure and data management
- assessment of trial feasibility, including site participation and feedback
- trial management and governance structures
- evaluation of the impact of the trial on the area of unmet medical need that is being addressed
- how equitable access to the trial will be provided to a range of researchers relevant to the discipline.

Applicants should also include consideration of strategies for the ongoing viability of the proposed platform beyond the life of the grant.

Applications that involve research that spans across various settings within health services (e.g. community-based care, hospitals, general practices); or that is coordinated across networks (e.g. Primary Health Practice Based Research Networks, Local Health Networks) and thus able to provide immediate benefit to patients are encouraged.

Applications that include building capacity on-shore (i.e. in Australia) are strongly encouraged. If applicants request funding for a component of their research to be undertaken overseas (e.g. for statistical or other support services), applicants are required to demonstrate how training of Australia-based statisticians, data managers and/or trialists (as appropriate) in those services will be embedded in the project.

Eligible overseas activities expenditure is generally limited to 10 per cent of total eligible project expenditure and must be clearly outlined and justified within the grant application. For information on travel and overseas expenditure refer to section 4.6.

Additional information for Stream 2

Applicants should demonstrate that the proposed registry-based randomised controlled trial will support research that is addressing an area of unmet medical need and that the proposed registry to be used is well-established and fit for purpose. Funding should not be used to implement significant changes or upgrades to the registry.

Additional information for Stream 3

Successful applicants will be required to work with the Department of Health and Aged Care to build evidence of the value, efficiency and cost effectiveness of innovative trial methodologies (either adaptive platform trials for Topic A or registry-based randomised controlled trials for Topic B) in generating evidence compared to traditional trial methodologies.

The intended outcome of the research funded by this grant opportunity is to improve the health and wellbeing of Australians by enhancing Australia's research infrastructure to promote new research approaches that will address health challenges by generating new knowledge and improving health outcomes.

This document sets out:

- the eligibility and assessment criteria
- how we consider and assess grant applications
- how we notify applicants and enter into grant agreements with grantees
- how we monitor and evaluate grantees' performance



responsibilities and expectations in relation to the opportunity.

The Department of Industry, Science and Resources (the department/we) is responsible for administering this grant opportunity on behalf of the Department of Health and Aged Care.

We have defined key terms used in these guidelines in the glossary at Section 13.

You should read this document carefully before you fill out an application.

Impact of COVID-19

The MRFF acknowledges the potential impacts of COVID-19 on the health and medical research sector, including the ability of researchers to submit applications and undertake research. You will be asked to consider these impacts in your risk management plan. This information will be taken into account in the assessment of your application (refer section 5).

1.4. Encouraging Partnerships

Applicants are encouraged to seek strategic partnerships with organisations whose decisions and actions affect Australians' health, health policy and health care delivery in ways that improve the health of Australians. Organisations that are capable of implementing policy and service delivery and would normally not be able to access funding through most MRFF funding mechanisms are highly valued as partners.

Partnerships and co-investment are encouraged in order to maximise impact of investment, provide opportunities for more mature sites/agencies to build the capacity of emerging sites/agencies, reduce duplication of activities, and reduce potential respondent administrative burden on participating communities. Partnerships are also encouraged to ensure the proposed research is of relevance to consumers and delivery of services, and to support translation of research outcomes into practice.

Partner organisations include:

- those working in federal, state, territory or local government in the health portfolio or in other areas affecting health, such as economic policy, urban planning, education or transport
- those working in the private sector such as employers, private health insurance providers or private hospitals
- those commercial entities with an interest in this area, for example pharmaceutical companies
- non-government organisations and charities
- community organisations such as consumer groups
- healthcare providers
- professional groups.

Partnerships with an overseas partner organisation are acceptable, provided the objectives of the grant opportunity are fully met. However, you cannot use the grant to cover retrospective costs or to support research projects undertaken outside of Australia (although funding can be sought to support the Australian-based components of multinational clinical trials).

While partnerships are encouraged, they may not necessarily be relevant for all projects. Where relevant, partner funding contributions will contribute to the assessment of project impact and overall value and risk, but are not a requirement (see section 5).



2. Grant amount and grant period

For this grant opportunity, up to \$23.7 million is available over two years from 2024-25:

- Stream 1 (Incubator and Targeted Call for Research):
 - \$9.37 million in 2024-25
 - \$7.83 million in 2025-26
- Stream 2 (<u>Targeted Call for Research</u>):
 - \$3.0 million in 2024-25
 - \$1.5 million in 2025-26
- Stream 3 (<u>Targeted Call for Research</u>):
 - \$1.0 million in 2024-25
 - \$1.0 million in 2025-26

Grant funds will be provided according to the funding profile indicated above; however, grant funds can be expended across the life of the project. See section 4.3.

Each stream and topic will be funded separately, as follows:

- Stream 1 Topic A, the top 4 applications will be funded
- Stream 1 Topic B, the top 2 applications will be funded
- Stream 1 Topic C, the top 2 applications will be funded
- Stream 2, applications will be funded based on rank until the total funding available for the stream has been reached
- Stream 3, the top ranked application for each topic will be funded.

For this grant opportunity, an application may be submitted to <u>one</u> of the above three streams only. Applicants must specify the stream and (where applicable) topic to which they are applying in their application. For clarity, applicants can apply for more than one stream with different applications, but can only submit one application per stream.

The types of grants that are available under this grant opportunity are:

- Targeted Call for Research grants
- Incubator grants.

Applicants are encouraged to design a research project that best addresses the objectives and intended outcomes of the grant opportunity and propose an appropriate budget.

2.1. Grants available

The grant amount will be up to 100 per cent of eligible project costs (grant percentage).

The amounts available for a single grant are as follows:

- Stream 1, Topic A (Incubator): There is no minimum grant amount and the maximum amount available for a single grant is \$0.3 million.
- Stream 1, Topic B (<u>Targeted Call for Research</u>): There is no minimum grant amount and the maximum amount available for a single grant is \$5.0 million.
- Stream 1, Topic C (<u>Targeted Call for Research</u>): There is no minimum grant amount and the maximum amount available for a single grant is \$3.0 million.



- **Stream 2** (Targeted Call for Research): There is no minimum grant amount and the maximum amount available for a single grant is \$1.5 million.
- Stream 3, Topic A (Targeted Call for Research): There is no minimum grant amount and the maximum amount available for a single grant is \$1.0 million.
- Stream 3, Topic B (<u>Targeted Call for Research</u>): There is no minimum grant amount and the maximum amount available for a single grant is \$1.0 million.

2.2. Project period

You must complete your project within 5 years of the project start date.

For Stream 1 Topic A, projects must be completed within 12 months of the project start date.

The Program Delegate may approve an extension of time under certain circumstances.

3. Eligibility criteria

We cannot consider your application if you do not satisfy all eligibility criteria. Applicants should note that they are required to provide additional information in their application to address the eligibility criteria for this grant opportunity. See sections 3.2, 6.1 and 6.2.1.

3.1. Who is eligible?

To be eligible you must:

- have an Australian Business Number (ABN)
- be incorporated in Australia

and in accordance with s24 of the <u>MRFF Act 2015¹⁰</u>, be one of the following entities:

- a medical research institute
- a university
- a corporate Commonwealth entity
- a corporation (including businesses and not for profits).

Joint applications are encouraged, provided you have a lead organisation who is the main driver of the project and is eligible to apply. For further information on joint applications, refer to section 6.2.

We cannot waive the eligibility criteria under any circumstances.

3.2. Chief Investigators

All members of the research team must be listed on the application form as Chief Investigators (CIs). Applicants must nominate a Chief Investigator A (CIA) who will take the lead role in conducting the project and report on the outcomes of the project as specified in the grant agreement.

To facilitate collaborative research teams with the required capacity and capability to undertake the proposed research, up to 15 CIs may be included as members of the research team. If you include more than 15 CIs, your application will be considered ineligible.

¹⁰ <u>https://www.legislation.gov.au/Details/C2015A00116</u>



A person must not be named as a CI on more than one application submitted per stream of this grant opportunity (i.e. a person may be named as a CI on a maximum of one application per stream). If a CI is named on more than one application submitted to a stream of this grant opportunity, both/all applications will be considered ineligible.

To be considered for funding, 20% or more of all Chief Investigators must be early to mid-career researchers. For the purposes of this grant opportunity, an early to mid-career researcher is defined as an individual who is within ten years post-PhD (i.e. within ten years of their PhD award date). Applicants must meet this criterion at the closing date for applications to the grant opportunity, and applicants must nominate a lead organisation who holds evidence of the PhD award dates for all Chief Investigators as specified in section 6.2.1.

See also section 6.1.

3.3. Additional eligibility requirements

We can only accept applications where you can provide:

- evidence from your board (or chief executive officer or equivalent if there is no board) that the project is supported, and that you can complete the project and meet the costs of the project not covered by grant funding
- letters of support from each project partner.

3.4. Who is not eligible?

You are not eligible to apply if you are:

- an individual
- partnership
- unincorporated association
- any organisation not included in section 3.1
- trust (however, an incorporated trustee may apply on behalf of a trust)
- a non-corporate Commonwealth entity
- an organisation, or your project partner is an organisation, included on the National Redress Scheme's website on the list of 'Institutions that have not joined or signified their intent to join the Scheme' (www.nationalredress.gov.au)
- an employer of 100 or more employees that has <u>not complied</u> with the Workplace Gender Equality Act 2012.

4. What the grant money can be used for

4.1. Eligible activities

To be eligible your project must:

- be aimed at the objectives in Section 1.3
- include one or more of the following eligible activities:
 - minor capital works
 - development/installation of research equipment



- employment of personnel
- other direct research costs.

We may also approve other activities.

4.2. Eligible locations

We will consider activities based in any geographical location in Australia. You may request funding for a component of the research to be undertaken overseas if the equipment/resources required for that component are not available in Australia and the component is critical to the successful completion of the research project. However, the expectation is the majority of the research activities and funding expenditure will occur in Australia.

4.3. Eligible expenditure

You can only spend grant funds on eligible expenditure you have incurred on an agreed project as defined in your grant agreement.

- For guidance on eligible expenditure, see Appendix A.
- For guidance on ineligible expenditure, see Appendix B.

If your application is successful, we may ask you to verify project costs that you provided in your application. You may need to provide evidence such as quotes for major costs.

Not all expenditure on your project may be eligible for grant funding. The Program Delegate (who is an Australian Government official who has been authorised to make decisions) makes the final decision on what is eligible expenditure and may give additional guidance on eligible expenditure if required.

To be eligible, expenditure must:

- be a direct cost of the project
- be incurred by you for required project audit activities.

You must incur the project expenditure between the project start and end dates (Activity Start and Completion Dates) for it to be eligible unless stated otherwise.

You must not commence your project until you execute a grant agreement with the Commonwealth.

5. The assessment criteria

You must address all assessment criteria in your application. We will assess your application based on the weighting given to each technical criterion and against the non-weighted (non-technical) assessment criterion.

The application form requests information that directly relates to the assessment criteria below. The amount of detail and supporting evidence you provide in your application should be relative to the project size, complexity and grant amount requested. You should provide evidence to support your responses to each criterion. Size limits apply to all responses.

We will only award funding to applications that score satisfactorily against all criteria.



5.1. The assessment criteria for Stream 1 (topic A) (Incubator)

5.1.1. Assessment Criterion 1- Project Impact (40% weighting)

Project Impact is the extent to which the project's research outputs will contribute to meaningful advances in health outcomes, practice and/or policy, consistent with the objectives and outcomes described in section 1.3. The assessment of Project Impact will also consider the project's contribution to the objective of the Initiative as described in section 1.2 and your statement against the <u>MRFF Measures of Success</u>.

In your response to this criterion, you should ensure that you:

- articulate the need for a novel solution to a critical and/or intractable health issue that is
 informed by the findings of a national and/or international landscape analysis and will be of
 value to the community, health service providers, and health system managers
- demonstrate how the project will establish an evidence base for further research that focuses on implementing the proposed solution
- demonstrate the involvement of consumers (including people with relevant lived experience and their carers), the community, health providers and/or other end users (e.g. health professionals, health services, and coordination mechanisms such as Primary Health Networks) in the project and how their needs, priorities, views and values have informed the research question and its conceptualisation, development and planned translation and implementation
- demonstrate the involvement of academic, industry, state/territory, and/or other partners in the project and how their needs and views have informed its conceptualisation, development and planned translation and implementation.

Further instructions are in section 6.1.

5.1.2. Assessment Criterion 2 – Project Methodology (30% weighting)

Project Methodology is a description of the design and conduct of the proposed research in the form of a project plan. The assessment of Project Methodology will consider the scientific quality and feasibility of the project plan and its ability to deliver on the project's intended outcomes. Projects are expected to be original and build on (rather than duplicate) research that has already been undertaken.

In your response to this criterion, you should ensure you clearly articulate:

- the research question and how you will utilise novel approaches, methodologies, instrumentation, and/or interventions to address it
- how the project will establish partnerships across the health and research sector that have the potential to transform the delivery of health solutions
- how consumers will be involved in the proposed research, including their contributions throughout the life of the project
- arrangements for project governance and oversight to support its successful delivery
- appropriate milestones, performance indicators and timeframes.

Grantees will be required to report on project progress at 12 month intervals. Further instructions are in section 6.1.



5.1.3. Assessment Criterion 3 - Capacity, Capability and Resources to Deliver the Project (30% weighting)

Capacity, Capability and Resources is the relevant skills, knowledge, experience and resources the research team and any partners are contributing to the project. The assessment of Capacity, Capability and Resources will consider the overall composition of the research team, the contribution of individual researchers to the project, and the involvement of partners in the successful delivery of the project.

In your response to this criterion, you should ensure that you demonstrate:

- the research team has the capability, skills, leadership and expertise to successfully deliver the project
- the research team includes individuals that bring diverse experiences and expertise (e.g. across disciplines, genders, cultures, lived experience relevant to the research question, career stages and research sectors)
- the research team has the skills, experience and capacity to involve and support consumers (including those with lived experience) in the proposed research, and ensure that this is done appropriately and effectively
- the commitment of partners to the project and how any cash or in-kind contributions will support its successful delivery.

Each Chief Investigator should provide an example from the last five years of how their research has contributed to meaningful advances in health outcomes, practice and/or policy through the translation or implementation of research findings.

Further instructions are in section 6.1.

5.1.4. Assessment Criterion 4 - Overall Value and Risk of the Project (nonweighted)

Overall Value and Risk is the extent to which the project's research outputs will meaningfully contribute to the objective/s and intended outcomes of the grant opportunity, the Initiative, and the MRFF more broadly. Your response to this criterion will consist of your Measures of Success statement, proposed budget, and risk management plan submitted with your application.

The assessment of Overall Value and Risk will consider:

- the relative contribution of the outcomes or results you have identified in your Measures of Success statement to the intended outcomes of the grant opportunity, the goal and aims of the Initiative, and the MRFF
- the appropriateness of the requested budget (including the value and type of any cash or inkind contributions) to support successful delivery of the project, including whether it is sufficiently detailed and justified and represents value with money
- the appropriateness of the risk management plan, including strategies for identifying, documenting, monitoring and reporting on key risks to the completion of the project.

Further instructions are in section 6.1.

5.2. The assessment criteria for Stream 1 (topics B and C), Stream 2 and Stream 3 (Targeted Call for Research)

5.2.1. Assessment Criterion 1 – Project Impact (40% weighting)

Project Impact is the extent to which the project's research outputs will contribute to meaningful advances in health outcomes, practice and/or policy, consistent with the objectives and outcomes



described in section 1.3. The assessment of Project Impact will also consider the project's contribution to the objective of the Initiative as described in section 1.2 and your statement against the <u>MRFF Measures of Success</u>.

In your response to this criterion, you should ensure that you:

- describe how the project builds upon existing knowledge to progress the area of research and how the research outcomes will contribute to meaningful advances in health outcomes, practice and/or policy in Australia
- demonstrate the involvement of consumers (including people with relevant lived experience and their carers), the community, health providers and/or other end users (e.g. health professionals, health services, and coordination mechanisms such as Primary Health Networks) in the project and how their needs, priorities, views and values have informed the research question and its conceptualisation, development and planned translation and implementation
- demonstrate the involvement of academic, industry, state/territory, and/or other partners in the project and how their needs and views have informed its conceptualisation, development and planned translation and implementation.

In addition, applications that specifically focus on the health of priority populations (defined as Aboriginal and/or Torres Strait Islander people, older people experiencing diseases of ageing, people with rare or currently untreatable diseases/conditions, people in remote/rural communities, people with a disability, individuals from culturally and linguistically diverse communities, LGBTIQ+ people, youth), should:

- describe how the anticipated outputs will contribute to meaningful advances in health outcomes, practice and/or policy for the priority population
- demonstrate how the proposed research focuses on interventions that will be acceptable (e.g. culturally appropriate) to the priority population
- demonstrate leadership by, and involvement of, the priority population in the project, and how their needs, views and values have informed its conceptualisation, development and planned implementation.

Further instructions are in section 6.1.

5.2.2. Assessment Criterion 2 - Project Methodology (30% weighting)

Project Methodology is a description of the design and conduct of the proposed research in the form of a project plan. The assessment of Project Methodology will consider the scientific quality and feasibility of the project plan and its ability to deliver on the project's intended outcomes. Projects are expected to be original and build on (rather than duplicate) research that has already been undertaken.

In your response to this criterion, you should ensure you clearly articulate:

- the research question and the proposed approach for addressing it, including (as appropriate) tools and techniques, participants (e.g. diversity of participants), interventions, controls, statistical approaches, and strategies for data collection and use
- how consumers will be involved in the proposed research, including their contributions throughout the life of the project
- arrangements for project governance and oversight to support its successful delivery
- appropriate milestones, performance indicators and timeframes.

In addition, applications that specifically focus on the health of priority populations, should also articulate how the proposed methodology includes strong and meaningful leadership and involvement of the priority population, including its people, communities and organisations.



If your project plan includes the conduct of a clinical trial, your response should also:

- provide details of the trial design
- specify and justify recruitment targets (including targets for ensuring diversity, e.g. by gender) and sample sizes
- articulate how the clinical trial design will support advancement of robust clinical trial methodologies and/or protocols
- describe how consumers have been involved in the trial design (e.g. its conception, protocol and schedule, participant information, consent forms or videos).

Grantees will be required to report on project progress at 12 month intervals.

Further instructions are in section 6.1.

5.2.3. Assessment Criterion 3 - Capacity, Capability and Resources to Deliver the Project (30% weighting)

Capacity, Capability and Resources is the relevant skills, knowledge, experience and resources the research team and any partners are contributing to the project. The assessment of Capacity, Capability and Resources will consider the overall composition of the research team, the contribution of individual researchers to the project, and the involvement of partners in the successful delivery of the project.

In your response to this criterion, you should ensure that you demonstrate:

- the research team has an appropriate mix of skills (scientific, project management, etc) to undertake the proposed research
- the research team includes individuals that bring diverse experiences and expertise (e.g. across disciplines, genders, cultures, lived experience relevant to the research question, career stages and research sectors)
- the research team has the skills, experience and capacity to involve and support consumers (including those with lived experience) in the proposed research, and ensure that this is done appropriately and effectively
- the commitment of partners to the project and how any cash or in-kind contributions will support its successful delivery.

In addition, applications that specifically focus on the health of priority populations, should demonstrate that the research team includes leadership by the priority population, and that the research team has experience in delivering research that has positively impacted health policies and programs of relevance to the priority population.

Each Chief Investigator should provide an example from the last five years of how their research has contributed to meaningful advances in health outcomes, practice and/or policy through the translation or implementation of research findings.

Further instructions are in section 6.1.

5.2.4. Assessment Criterion 4 - Overall Value and Risk of the Project (nonweighted)

Overall Value and Risk is the extent to which the project's research outputs will meaningfully contribute to the objective/s and intended outcomes of the grant opportunity, the Initiative, and the MRFF more broadly. Your response to this criterion will consist of your Measures of Success statement, proposed budget, and risk management plan submitted with your application.

The assessment of Overall Value and Risk will consider:



- the relative contribution of the outcomes or results you have identified in your Measures of Success statement to the intended outcomes of the grant opportunity, the goal and aims of the Initiative, and the MRFF
- the appropriateness of the requested budget (including the value and type of any cash or inkind contributions) to support successful delivery of the project, including whether it is sufficiently detailed and justified and represents value with relevant money
- the appropriateness of the risk management plan, including strategies for identifying, documenting, monitoring and reporting on key risks to the completion of the project.

5.3. Further instructions are in section 6.1. Consumer and community involvement

The Statement on Consumer and Community Involvement in Health and Medical Research (the Statement) has been developed because of the important contribution consumers make to health and medical research. The Statement's purpose is to guide research institutions, researchers, consumers and community members in the active involvement of consumers and community members in all aspects of health and medical research. NHMRC and the Consumers Health Forum of Australia Ltd worked in partnership with consumers and researchers to develop the Statement. Further information on the Statement is available on <u>NHMRC's website</u>.

Researchers are actively encouraged to involve consumers at all stages and levels of their proposed research, including in defining the research question and through the life of the proposed research and its translation.

6. How to apply

Before applying, you should read and understand these guidelines, the sample <u>application form</u> and the sample <u>grant agreement</u> published on business.gov.au and GrantConnect.

You can only submit an application during a funding round.

To apply, you must:

- complete the online program application form via business.gov.au
- provide all the information requested
- address all eligibility and assessment criteria
- include all necessary attachments.

You will receive confirmation when you submit your application. You should retain a copy of your application for your own records.

You are responsible for making sure your application is complete and accurate. Giving false or misleading information is a serious offence under the *Criminal Code Act 1995* (Cth). If we consider that you have provided false or misleading information we may not progress your application. If you find an error in your application after submitting it, you should call us immediately on 13 28 46.

If we find an error or information that is missing, we may ask for clarification or additional information from you that will not change the nature of your application. However, we can refuse to accept any additional information from you that would change your submission after the application closing time.

If you need further guidance around the application process, or if you are unable to submit an application online, <u>contact us</u> at business.gov.au or by calling 13 28 46.



6.1. Attachments to the application

Provide the following documents with your application:

- a detailed project plan, including your project methodology and a project feasibility analysis (maximum 12 pages excluding appendices)
- a list of all Chief Investigators using the template on <u>business.gov.au</u> who have shared authority and responsibility for leading and directing the design, conduct and reporting of the proposed project outlined in this application, including the early to mid-career researcher (EMCR) status and affiliations of each person listed
- a detailed and itemised project budget, including but not limited to disaggregation by project component and Financial Year (FY), and your related fee card
- a statement of how your project will contribute to the Measures of Success for the MRFF as described in the MRFF Evaluation, Monitoring and Learning Strategy (see <u>www.health.gov.au/mrff</u>) in a table format with the following headings: MRFF Measure of Success; How the project will contribute towards the measure of success; Description of outcome or result against which the contribution will be evaluated (maximum one page)
- a detailed risk management plan, and any supporting documentation, describing how you
 propose to monitor, manage and report identified risks including risks that may arise during
 your project (maximum two pages)
- details of intellectual property arrangements as an attachment if this is not included within the written content of the application
- evidence of support from the board, CEO or equivalent
- trust deed (where applicable)
- letters of support (where applicable).

You must attach supporting documentation to the application form in line with the instructions provided within the form. You should only attach requested documents. We will not consider information in attachments that we do not request.

6.2. Joint applications

We encourage organisations to join together as a group to deliver a project. In these circumstances, you must appoint a lead organisation. Only the lead organisation can submit the application form and enter into the grant agreement with the Commonwealth. The application should identify all other members of the proposed group and include a letter of support from each of the project partners. Each letter of support should include:

- details of the project partner
- an overview of how the project partner will work with the lead organisation and any other project partners in the group to successfully complete the project
- an outline of the relevant experience and/or expertise the project partner will bring to the group
- the roles/responsibilities the project partner will undertake, and the resources it will contribute (if any)
- details of a nominated management level contact officer.

You must have a formal arrangement in place with all parties.



6.2.1. Lead Organisations and Chief Investigator A

Applicants must nominate a lead organisation who meets the eligibility criteria, holds evidence of the PhD award dates for all Chief Investigators, and will submit the application. The lead organisation must enter into the grant agreement and nominate a project lead (Chief Investigator A) who will conduct the project and report on the outcomes of the project as specified in the grant agreement.

6.3. Timing of the grant opportunity process

You can only submit an application between the published opening and closing dates. We cannot accept late applications.

Table 1: Expected timing for this grant opportunity

Activity	Timeframe
Assessment of applications	14 weeks
Approval of outcomes of selection process	8 weeks
Negotiations and award of grant agreements	4 weeks
Notification to unsuccessful applicants	2 weeks
Earliest start date of project	Date of execution of your grant agreement
End date of grant activity	Incubator grants - within 1 year of project start date (Stream 1 Topic A)
	Targeted Call for Research grants - within 5 years of project start date

7. The grant selection process

We first review your application against the eligibility criteria. If eligible, we will then assess it against the assessment criteria. Only eligible applications will proceed to the assessment stage.

We refer your application to an independent committee of experts (the Committee). For the 2023 Innovative Trials Grant Opportunity, the Committee will comprise national and international experts.

The Committee will undertake the assessment in accordance with the CGRGs and consider your application on its merits, based on:

- how well it meets the criteria
- whether it provides value with relevant money.

When assessing the merits of your application against the three technical (weighted) assessment criteria, the Committee will use the rating scale at Appendix C. Rating of the non-technical (Overall Value and Risk of your project) assessment criterion will be done in accordance with the Rating Scale at Appendix D.

To be awarded MRFF funding, applications must receive a rating of 5 or higher against each of the weighted technical assessment criteria (Criteria 1, 2 and 3), and a rating of 'Good' or 'Excellent' for the non-weighted assessment criterion.



When assessing whether the application represents value with relevant money, the Committee will have regard to:

- the overall objective/s to be achieved
- the value of the grant sought
- extent to which the application matches identified MRFF priorities
- the extent to which the application demonstrates that funding will assist to meeting the proposal outcomes/ objectives.

The Committee will provide the Program Delegate with a report of the assessment outcomes.

If the selection process identifies unintentional errors in your application, we may contact you to correct or clarify the errors, but you cannot make any material alteration or addition.

7.1. Who will approve grants?

The Program Delegate decides which grants to approve taking into account the recommendations of the committee, the availability of grant funds and the geographical spread of projects across Australia.

The Program Delegate's decision is final in all matters, including:

- the grant approval
- the grant funding to be awarded
- any conditions attached to the offer of funding.

We cannot review decisions about the merits of your application.

The Program Delegate will not approve funding if there is insufficient program funds available across relevant financial years for the grant opportunity.

8. Notification of application outcomes

We will advise you of the outcome of your application in writing. If you are successful, we will advise you of any specific conditions attached to the grant, including the timing of any public communications you make regarding being awarded a grant. If you are unsuccessful, we will give you an opportunity to discuss the outcome with us.

9. Successful grant applications

9.1. The grant agreement

You must enter into a legally binding grant agreement with the Commonwealth. A sample <u>grant</u> <u>agreement</u> is available on business.gov.au and GrantConnect.

We must execute a grant agreement with you before we can make any payments. Execute means both you and the Program Delegate have signed the agreement. We are not responsible for any expenditure you incur until a grant agreement is executed. You must not start any project activities until a grant agreement is executed.

The approval of your grant may have specific conditions determined by the assessment process or other considerations made by the Program Delegate. We will identify these in the offer of grant funding.



If you enter an agreement under this grant opportunity, you cannot receive other grants for the same activities from other Commonwealth, State or Territory granting programs.

The Commonwealth may recover grant funds if there is a breach of the grant agreement.

We will use a standard grant agreement.

You will have 30 days from the date of a written offer to execute this grant agreement with the Commonwealth. During this time, we will work with you to finalise details.

The offer may lapse if both parties do not sign the grant agreement within this time. Under certain circumstances, we may extend this period. We base the approval of your grant on the information you provide in your application. We will review any required changes to these details to ensure they do not impact the project as approved by the Program Delegate.

9.2. Grant agreement variations

We recognise that unexpected events may affect project progress. In these circumstances, you can request a variation to your grant agreement, including:

- changing project milestones
- extending the timeframe for completing the project
- changing project activities.

The program does not allow for:

an increase of grant funds.

If you want to propose changes to the grant agreement, you must put them in writing before the project end date (Activity Completion Date). We can provide you with a variation request template.

If a delay in the project causes milestone achievement and payment dates to move to a different financial year, you will need a variation to the grant agreement. We can only move funds between financial years if there is enough program funding in the relevant year to allow for the revised payment schedule. If we cannot move the funds, you may lose some grant funding.

You should not assume that a variation request will be successful. We will consider your request based on factors such as:

- how it affects the project outcome
- consistency with the program policy objective, grant opportunity guidelines and any relevant policies of the department
- changes to the timing of grant payments
- availability of program funds.

9.3. Project specific legislation, policies and industry standards

You must comply with all relevant laws and regulations in undertaking your project. You must also comply with the specific legislation/policies/industry standards that follow. It is a condition of the grant funding that you meet these requirements. We will include these requirements in your grant agreement.

Wherever the government funds research activities, the following special regulatory requirements may apply:



- MRFF Act 2015¹¹
- Working with Vulnerable People registration
- State/Territory legislation in relation to working with children
- Ethics and research practices:
 - the NHMRC/ARC/UA <u>Australian Code for the Responsible Conduct of Research</u> (2018) and successor documents
 - the NHMRC/ARC/UA National Statement on Ethical Conduct in Human Research (2023)
 - the <u>Australian Code for the care and use of animals for scientific purposes</u> (2013) endorsed by the NHMRC, the ARC, the Commonwealth Scientific and Industrial Research Organisation and UA.

If there is any conflict or inconsistency between a successor document and its predecessor, then the successor document prevails.

9.3.1. Child safety requirements

You must comply with all relevant legislation relating to the employment or engagement of anyone working on the project that may interact with children, including all necessary working with children checks.

You must implement the National Principles for Child Safe Organisations endorsed by the Commonwealth and available at: <u>National Principles | Child Safe Organisations</u> (humanrights.gov.au)

You will need to complete a risk assessment to identify the level of responsibility for children and the level of risk of harm or abuse, and put appropriate strategies in place to manage those risks. You must update this risk assessment at least annually.

You will also need to establish a training and compliance regime to ensure personnel are aware of, and comply with, the risk assessment requirements, relevant legislation including mandatory reporting requirements and the National Principles for Child Safe Organisations.

You will be required to provide an annual statement of compliance with these requirements in relation to working with children.

9.4. Intellectual property rights

Applicants must provide details of intellectual property (IP) arrangements in their applications. This includes both the use of IP in the project and the proposed ownership rights to IP generated by the project as well as strategies for protecting Australia's interests. Where IP is likely to be generated by the project, successful applicants are required to conclude protocols or contracts with their collaborating partners on the management of IP issues. These agreements should be in accordance with laws and regulations in Australia.

9.5. Dissemination of research outcomes

You must ensure appropriate safeguards are in place to protect patient privacy, intellectual property and commercially confidential information.

¹¹ <u>https://www.legislation.gov.au/Details/C2015A00116</u>



Except where publication may compromise your obligations with respect to patient privacy, intellectual property and/or commercially confidential information, grantees are required to:

- if a clinical trial, submit the clinical trial protocol to an open access repository within six months of HREC approval, or publish a protocol manuscript as soon as practicable
- within 12 months of completion of the grant activity, disseminate the research findings through:
 - ensuring that research findings are available in an open access repository
 - content specific forums
 - submission to peer-reviewed journals.
- make lay summaries available to research participants, concurrently with sharing and dissemination of research results.

Grantees are encouraged to publish de-identified research data following completion of the grant in an open access repository and in accordance with best practice.

9.6. How we pay the grant

The grant agreement will state the:

- maximum grant amount we will pay
- proportion of eligible expenditure covered by the grant (grant percentage)
- any in-kind contributions you will make
- any financial contribution provided by you or a third party.

We will not exceed the maximum grant amount under any circumstances. If you incur extra costs, you must meet them yourself.

We will make payments according to an agreed schedule set out in the grant agreement. Payments are subject to satisfactory progress on the project.

9.7. Grants Payments and GST

If you are registered for the Goods and Services Tax (GST), where applicable we will add GST to your grant payment and provide you with a recipient created tax invoice. You are required to notify us if your GST registration status changes. GST does not apply to grant payments to government related entities¹².

Grants are assessable income for taxation purposes, unless exempted by a taxation law. We recommend you seek independent professional advice on your taxation obligations or seek assistance from the <u>Australian Taxation Office</u>. We do not provide advice on tax.

10. Announcement of grants

We will publish non-sensitive details of successful projects on GrantConnect. We are required to do this by the CGRGs unless otherwise prohibited by law. We may also publish this information on business.gov.au. This information may include:

name of your organisation

¹² See Australian Taxation Office ruling GSTR 2012/2 available at ato.gov.au



- title of the project
- description of the project and its aims
- amount of grant funding awarded and grant duration
- Australian Business Number
- business location
- your organisation's industry sector.

11. How we monitor your grant activity

11.1. Keeping us informed

You should let us know if anything is likely to affect your organisation or impact successful delivery of your project/s.

We need to know of any key changes to your organisation or its business activities, particularly if they affect your ability to complete your project, carry on business and pay debts due.

You must also inform us of any changes to your:

- name
- addresses
- nominated contact details
- bank account details.

If you become aware of a breach of terms and conditions under the grant agreement you must contact us immediately.

You must notify us of events relating to your project and provide an opportunity for the Minister or their representative to attend.

11.2. Reporting

You must submit reports in line with the grant agreement. We will provide the requirements for these reports as appendices in the grant agreement. We will remind you of your reporting obligations before a report is due. We will expect you to report on:

- progress against agreed project milestones and MRFF Measures of Success
- risks arising during the project
- project expenditure, including expenditure of grant funds
- information about your project that supports evaluation of the MRFF.

The amount of detail you provide in your reports should be relative to the project size, complexity and grant amount.

We will monitor the progress of your project by assessing reports you submit and may conduct site visits to confirm details of your reports if necessary. Occasionally we may need to re-examine claims, seek further information or request an independent audit of claims and payments.

11.2.1. Progress reports

Progress reports must:



- include evidence to demonstrate progress against the outcome/s and result/s identified in your Measures of Success statement (see section 6.1)
- include details of your progress towards completion of agreed project activities, including any risks arising and how they are being managed to ensure planned project outcomes are met
- show the total expenditure incurred to date
- be submitted by the report due date
- include information about your project that supports evaluation of the MRFF.

We will only make grant payments when we receive satisfactory progress reports.

You must discuss any project or milestone reporting delays with us as soon as you become aware of them.

11.2.2. End of project report

When you complete the project, you must submit an end of project report.

End of project reports must:

- include evidence to demonstrate achievement of the outcome/s and result/s identified in your Measures of Success statement (see section 6.1)
- include the agreed evidence as specified in the grant agreement (including, but not limited to, evidence of project impact)
- identify the total expenditure incurred for the project
- include information about your project that supports evaluation of the MRFF
- include a declaration that the grant money was spent in accordance with the grant agreement and to report on any underspends of the grant money
- be submitted by the report due date.

11.2.3. Ad-hoc reports

We may ask you for ad-hoc reports on your project. This may be to provide an update on progress, or any significant delays or difficulties in completing the project, or to support evaluation of the MRFF.

11.3. Independent audits

We may ask you to provide an independent audit report. An audit report would verify that you spent the grant in accordance with the grant agreement. The audit report requires you to prepare a statement of grant income and expenditure. The report template is available on business.gov.au and GrantConnect.

11.4. Compliance visits

We may visit you during or at the completion of your project to review your compliance with the grant agreement. We may also inspect the records you are required to keep under the grant agreement. For large or complex projects, we may visit you after you finish your project. We will provide you with reasonable notice of any compliance visit.



11.5. Evaluation

The Department of Health and Aged Care will evaluate the grant to measure how well the outcomes and objectives have been achieved. We may use information from your application and project reports for this purpose, and for the purpose of the evaluation of MRFF more broadly. We may also interview you, or ask you for more information to help us understand how the grant impacted you and to evaluate how effective the program was in achieving its outcomes.

We may contact you up to two years after you finish your project for more information to assist with this evaluation, or the evaluation of MRFF more broadly.

11.6. Grant acknowledgement

If you make a public statement about a project funded under the grant opportunity, including in a brochure or publication, you must acknowledge the grant by using the following:

'This project received grant funding from the Australian Government.'

If you erect signage in relation to the project, the signage must contain an acknowledgement of the grant.

12. Probity

We will make sure that the grant opportunity process is fair, according to the published guidelines, incorporates appropriate safeguards against fraud, unlawful activities and other inappropriate conduct and is consistent with the CGRGs.

12.1. Conflicts of interest

Any conflicts of interest could affect the performance of the grant opportunity or program. There may be a conflict of interest, or perceived conflict of interest, if our staff, any member of a committee or advisor and/or you or any of your personnel:

- has a professional, commercial or personal relationship with a party who is able to influence the application selection process, such as an Australian Government officer or member of an external panel
- has a relationship with or interest in, an organisation, which is likely to interfere with or restrict the applicants from carrying out the proposed activities fairly and independently, or
- has a relationship with, or interest in, an organisation from which they will receive personal gain because the organisation receives a grant under the grant program/ grant opportunity.

As part of your application, we will ask you to declare any perceived or existing conflicts of interests or confirm that, to the best of your knowledge, there is no conflict of interest.

If you later identify an actual, apparent, or perceived conflict of interest, you must inform us in writing immediately.

Conflicts of interest for Australian Government staff are handled as set out in the Australian <u>Public</u> <u>Service Code of Conduct (Section 13(7))¹³</u> of the <u>Public Service Act 1999</u> (Cth)¹⁴. Committee

¹⁴ https://www.legislation.gov.au/Details/C2017C00270



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¹³ https://www.legislation.gov.au/Details/C2017C00270/Html/Text#_Toc491767030

members and other officials including the decision maker must also declare any conflicts of interest.

We publish our conflict of interest policy on the department's website¹⁵.

12.2. How we use your information

Unless the information you provide to us is:

- confidential information as per 12.2.1, or
- personal information as per 12.2.3,

we may share the information with other government agencies for a relevant Commonwealth purpose such as:

- to improve the effective administration, monitoring and evaluation of Australian Government programs
- for research
- to announce the awarding of grants.

12.2.1. How we handle your confidential information

We will treat the information you give us as sensitive and therefore confidential if it meets all of the following conditions:

- you clearly identify the information as confidential and explain why we should treat it as confidential
- the information is commercially sensitive
- disclosing the information would cause unreasonable harm to you or someone else
- you provide the information with an understanding that it will stay confidential.

12.2.2. When we may disclose confidential information

We may disclose confidential information:

- to the committee and our Commonwealth employees and contractors, to help us manage the program effectively
- to the Auditor-General, Ombudsman or Privacy Commissioner
- to the responsible Minister or Assistant Minister
- to a House or a Committee of the Australian Parliament.

We may also disclose confidential information if:

- we are required or authorised by law to disclose it
- you agree to the information being disclosed, or
- someone other than us has made the confidential information public.

¹⁵ https://www.industry.gov.au/sites/g/files/net3906/f/July%202018/document/pdf/conflict-of-interest-and-insider-trading-policy.pdf



12.2.3. How we use your personal information

We must treat your personal information according to the Australian Privacy Principles (APPs) and the *Privacy Act 1988* (Cth). This includes letting you know:

- what personal information we collect
- why we collect your personal information
- to whom we give your personal information.

We may give the personal information we collect from you to our employees and contractors, the committee, and other Commonwealth employees and contractors, so we can:

- manage the program
- research, assess, monitor and analyse our programs and activities.

We, or the Minister, may:

- announce the names of successful applicants to the public
- publish personal information on the department's websites.

You may read our <u>Privacy Policy</u>¹⁶ on the department's website for more information on:

- what is personal information
- how we collect, use, disclose and store your personal information
- how you can access and correct your personal information.

12.2.4. Freedom of information

All documents in the possession of the Australian Government, including those about the program, are subject to the *Freedom of Information Act 1982* (Cth) (FOI Act).

The purpose of the FOI Act is to give members of the public rights of access to information held by the Australian Government and its entities. Under the FOI Act, members of the public can seek access to documents held by the Australian Government. This right of access is limited only by the exceptions and exemptions necessary to protect essential public interests and private and business affairs of persons in respect of whom the information relates.

If someone requests a document under the FOI Act, we will release it (though we may need to consult with you and/or other parties first) unless it meets one of the exemptions set out in the FOI Act.

12.3. Enquiries and feedback

For further information or clarification, you can contact us on 13 28 46 or by <u>web chat</u> or through our <u>online enquiry form</u> on business.gov.au.

We may publish answers to your questions on our website as Frequently Asked Questions.

Our <u>Customer Service Charter</u> is available at business.gov.au. We use customer satisfaction surveys to improve our business operations and service.

If you have a complaint, call us on 13 28 46. We will refer your complaint to the appropriate manager.

¹⁶ https://www.industry.gov.au/data-and-publications/privacy-policy



If you are not satisfied with the way we handle your complaint, you can contact:

General Manager – Business Grants Hub Department of Industry, Science and Resources GPO Box 2013 CANBERRA ACT 2601

You can also contact the <u>Commonwealth Ombudsman¹⁷</u> with your complaint (call 1300 362 072). There is no fee for making a complaint, and the Ombudsman may conduct an independent investigation.

¹⁷ http://www.ombudsman.gov.au/



13. Glossary

Term	Definition
Administering entity	When an entity that is not responsible for the policy, is responsible for the administration of part or all of the grant application processes
Application form	The document or computerised submission system that applicants use to apply for funding under the grant opportunity.
Assessment criteria	Are the specified principles or standards, against which applications will be judged. These criteria are also used to assess the merits of proposals and, in the case of a competitive grant opportunity, to determine application rankings.
Chief Investigator	A member of the research team.
Chief Investigator A	The member of the research team that takes the lead role in conducting the project and reporting on the outcomes of the project as specified in the grant agreement.
Commencement date	The expected start date for the grant activity.
Committee	The body established by the Department to consider and assess eligible applications and make recommendations for funding under the program.
Commonwealth Grants Rules and Guidelines (CGRGs)	Establish the overarching Commonwealth grants policy framework and articulate the expectations for all non- corporate Commonwealth entities in relation to grants administration. Under this overarching framework, non- corporate Commonwealth entities undertake grants administration based on the mandatory requirements and key principles of grants administration
Completion date	The expected date by which the grant activity must be completed and the grant spent.
Date of effect	Can be the date on which a grant agreement is signed or a specified starting date.
Decision maker	The person who makes a decision to award a grant.
Department	The Department of Industry, Science, and Resources.
Early to mid-career researcher	An individual who is within ten years post-PhD (i.e. within ten years of their PhD award date), including career disruptions.



Term	Definition
Eligibility criteria	Refer to the mandatory criteria which must be met to qualify for a grant. Assessment criteria may apply in addition to eligibility criteria
Eligible activities	The activities undertaken by a grantee in relation to a project that are eligible for funding support as set out in 4.1.
Eligible application	An application or proposal for services or grant funding for which the Program Delegate has determined is eligible for assessment in accordance with these guidelines.
Eligible expenditure	The expenditure incurred by a grantee on a project and which is eligible for funding support as set out in 4.2 and Appendix A.
Fee card	The rationale or method by which any proposed budget items have been derived when estimating expenditure.
Footprint	The footprint is the outline of the total area of the lot or site surrounded by the exterior walls of a building or portion of a building, exclusive of courtyards.
Grant activity/activities	Refers to the project/tasks/services that the grantee is required to undertake.
Grant agreement	Sets out the relationship between the parties to the agreement, and specifies the details of the grant.
GrantConnect	Is the Australian Government's whole-of-government grants information system, which centralises the publication and reporting of Commonwealth grants in accordance with the CGRGs.
Grantee	The individual/organisation which has been selected to receive a grant.
Grant funding or grant funds	The funding made available by the Australian Government to grantees under the program.
Grant opportunity	Refers to the specific grant round or process where a Commonwealth grant is made available to potential grantees. A grant opportunity is aimed at achieving government policy outcomes under a Portfolio Budget Statement Program.
Minister	The Australian Government Minister for Health and Aged Care.



Term	Definition
Minor Capital Works	Minor/general repair, maintenance and/or upgrade projects that directly contribute to project outcomes and objectives. These works must not change the footprint of current premises.
Personal information	Has the same meaning as in the <i>Privacy Act 1988</i> (Cth) which is: Information or an opinion about an identified individual, or an individual who is reasonably identifiable:
	 a. whether the information or opinion is true or not; and b. whether the information or opinion is recorded in a material form or not.
PhD award date	The date an individual's Doctor of Philosophy (Phd) thesis is passed (not the date of conferral).
Program Delegate	An Australian Government official in the Department of Health and Aged Care with responsibility for the grant opportunity.
Project	A project described in an application for grant funding under this grant opportunity.
Quote	 A quote must contain the following information: organisation's ABN Description of infrastructure works Itemised materials and costs Potential timeframe; and Indicates GST inclusive and exclusive amounts including GST exempt items if applicable.



Term	Definition
Value with relevant Money	Value with relevant money in this document refers to 'value with relevant money' which is a judgement based on the Grant Proposal representing an efficient, effective, economical and ethical use of public resources and determined from a variety of considerations.
	When administering a grant opportunity, the relevant financial and non-financial costs and benefits of each proposal are considered including, but not limited to:
	 the quality of the project proposal and activities;
	 fitness for purpose of the proposal in contributing to government objectives;
	 that the absence of a grant is likely to prevent the grantee and government's outcomes being achieved; and
	 the potential grantee's relevant experience and performance history.



Appendix A. Eligible expenditure

This section provides additional guidance on the eligibility of expenditure referred to in Section 4.3.

Applicants are encouraged to utilise existing research infrastructure to support their research wherever possible to reduce duplication and achieve the best return on project funding, and grant funds can be requested to support access to existing research facilities and infrastructure.

Applicants are encouraged to consider utilising research infrastructure projects such as those funded by the Australian Government through the National Collaborative Research Infrastructure Strategy (NCRIS). The NCRIS projects encompass a variety of infrastructure relevant to health research such as the Translating Health Discovery (THD) project and the Population Health Research Network (PHRN) project. Further information including access and pricing is available at www.education.gov.au/national-collaborative-research-infrastructure-strategy-ncris.

Your approach to accessing research facilities or infrastructure may impact our assessment of the suitability and value for money of the requested budget.

How we verify eligible expenditure

If your application is successful, we may ask you to verify project costs that you provided in your application when we negotiate your grant agreement. You may need to provide evidence such as quotes for major costs.

The grant agreement will include details of the evidence you may need to provide when you achieve certain milestones in your project. This may include evidence related to eligible expenditure.

If requested, you will need to provide the agreed evidence along with your progress reports.

You must keep payment records of all eligible expenditure, and be able to explain how the costs relate to the agreed project activities. At any time, we may ask you to provide records of the expenditure you have paid. If you do not provide these records when requested, the expense may not qualify as eligible expenditure.

At the end of the project, you will be required to provide an independent financial audit of all eligible expenditure from the project.

Equipment

You may purchase equipment, provided you can demonstrate it is critical to meeting project objectives and outcome.

Applicants can request funding to pay for equipment costing over \$10,000 that is essential to the research. The total equipment requested cannot exceed \$80,000.

Applicants must clearly outline the total value of all items of equipment for each year, why the equipment is required for the proposed research and why the equipment cannot be provided by the institution.

The applicant must be prepared to meet all service and repair costs in relation to equipment funded.

Funds will not be provided for the purchase of computers except where these are an integral component of a piece of laboratory equipment or are of a nature essential for work in the research



field, for example, a computer which is dedicated to data collection from a mass spectrometer, or used for the manipulation of extensively large datasets (i.e. requiring special hardware).

Labour expenditure

Eligible labour expenditure for the grant covers the direct labour costs of employees you directly employ on the core elements of the project. We consider a person an employee when you pay them a regular salary or wage, out of which you make regular tax instalment deductions.

We consider costs for technical, administrative and project management activities eligible labour expenditure, provided there are direct, demonstrated and monitored links to project objectives and outcomes.

We consider labour expenditure for leadership or administrative staff (such as CEOs, CFOs, accountants and lawyers) as eligible expenditure, provided there are direct, demonstrated and monitored links to project objectives and outcomes. However, we limit these costs to 10 per cent of the total amount of eligible labour expenditure claimed. Where a case exists for labour expenditure of leadership or administrative staff to exceed this, approval must be sought from the Program Delegate.

Eligible salary expenditure includes an employee's total remuneration package as stated on their Pay As You Go (PAYG) Annual Payment Summary submitted to the ATO. We consider salary-sacrificed superannuation contributions as part of an employee's salary package if the amount is more than what the Superannuation Guarantee requires.

The maximum salary for an employee, director or shareholder, including packaged components that you can claim through the grant is \$175,000 per financial year. Requests can be made to the Program Delegate to exceed this amount on a case by case basis, where justified, and at the discretion of the Program Delegate.

For periods of the project that do not make a full financial year, you must reduce the maximum salary amount you claim proportionally.

You can only claim eligible salary costs when an employee is working directly on agreed project activities during the agreed project (Activity) period.

Commonwealth funded positions can be considered eligible to count towards an in-kind contribution. However, the Commonwealth funded position cannot also draw a salary from funds awarded through this grant opportunity for the same activity.

Labour on-costs

You may include eligible salary costs such as employer paid superannuation, payroll tax, workers compensation insurance, and leave entitlements (including paid maternity leave, sick leave, long service leave and recreation leave). These costs must be reasonable and be separately identified in the project budget.

You should calculate eligible salary costs using the formula below:



Eligible salary costs	=	Annual salary package	×	Weeks spent on project	×	percentage of time spent on project
			_	52 weeks	-	

You cannot calculate labour costs by estimating the employee's worth. If you have not exchanged money (either by cash or bank transactions) we will not consider the cost eligible.

Evidence you will need to provide can include:

- details of all personnel working on the project, including name, title, function, time spent on the project and salary
- ATO payment summaries, pay slips and employment contracts.

Contract expenditure

Eligible contract expenditure is the cost of any agreed project activities that you contract others to do. These can include contracting:

- another organisation
- an individual who is not an employee, but engaged under a separate contract.

All contractors must have a written contract prior to starting any project work—for example, a formal agreement, letter or purchase order which specifies:

- the nature of the work they perform
- the applicable fees, charges and other costs payable.

Invoices from contractors must contain:

- a detailed description of the nature of the work
- the hours and hourly rates involved
- any specific plant expenses paid.

Invoices must directly relate to the agreed project, and the work must qualify as an eligible expense. The costs must also be reasonable and appropriate for the activities performed.

We will require evidence of contractor expenditure that may include:

- an exchange of letters (including email) setting out the terms and conditions of the proposed contract work
- purchase orders
- supply agreements
- invoices and payment documents.

You must ensure all project contractors keep a record of the costs of their work on the project. We may require you to provide a contractor's records of their costs of doing project work. If you cannot provide these records, the relevant contract expense may not qualify as eligible expenditure.

Travel and overseas expenditure

Eligible travel and overseas expenditure may include:



- domestic travel limited to the reasonable cost of accommodation and transportation required to conduct agreed project and collaboration activities in Australia
- domestic travel for third parties (i.e. certifiers, tradesman), where the travel is essential to the successful completion of the grant activity
- overseas travel, where it is formally documented and agreed by the Delegate, as essential to the conduct of the project, in advance of the travel being taken and is limited to the reasonable cost of accommodation and transportation.
- applicants may request funding for a component of the research to be undertaken overseas if the equipment/resources required for that component are not available in Australia and the component is critical to the successful completion of the research project. However, the expectation is the majority of the research activities and funding expenditure will occur in Australia.

Eligible air transportation is limited to the economy class fare for each sector travelled; where noneconomy class air transport is used:

- only the equivalent of an economy fare for that sector is eligible expenditure
- the grantee will require evidence showing what an economy air fare costs at the time of travel
- grant funding only up to the economy air fare cost at the time of travel amount can be used.

When considering an application for overseas travel, the Delegate will undertake a Value for Money assessment to determine whether the cost of overseas expenditure is eligible. This may depend on:

- the proportion of total grant funding that you will spend on overseas expenditure
- the proportion of the service providers total fee that will be spent on overseas expenditure
- how the overseas expenditure is likely to aid the project in meeting the program objectives.

Eligible overseas activities expenditure is generally limited to 10 per cent of total eligible project expenditure. Where the amount exceeds 10 per cent, Program Delegate approval must be sought.

Other eligible expenditure

Other eligible expenditures include costs directly related to the project activity that are not already being supported through any other sources, or where other Commonwealth, state or territory governments do not have primary responsibility, including:

- staff training that directly supports the achievement of project outcomes
- financial auditing of project expenditure
- costs you incur in order to obtain planning, environmental or other regulatory approvals during the project (Activity) period. However, associated fees paid to the Commonwealth, state, territory and local governments are not eligible
- insurances which are specifically required to cover the grant activity
- accessing intellectual property (IP) expertise and supporting the protection of IP

Other specific expenditures may be eligible as determined by the Program Delegate.

Evidence you need to supply can include supplier contracts, purchase orders, invoices and supplier confirmation of payments.



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Appendix B. Ineligible expenditure

This section provides guidance on what we consider ineligible expenditure.

The Program Delegate may impose limitations or exclude expenditure, or further include some ineligible expenditure listed in these guidelines in a grant agreement or otherwise by notice to you.

Examples of ineligible expenditure include:

- major capital works projects such as the purchase or construction of new/expanded facilities; works requiring a construction project manager; works that alone or together (where multiple projects are proposed in one application) extend beyond minor/general repair, maintenance and/or upgrade projects
- maintenance or upgrades on buildings or structures owned and/or operated by state/territory governments
- activities, equipment or supplies that are already being supported through other sources or where other Commonwealth, state or territory governments have primary responsibility
- reimbursement of activities that have commenced prior to the execution of a grant agreement
- research activity undertaken outside of Australia, although funding can be sought to support the Australian-based components of multi-national research activity
- costs incurred prior to the agreed project (Activity) start date
- retrospective costs
- any in-kind contributions
- financing costs, including interest
- debt financing
- costs related to obtaining resources used on the project, including interest on loans, job advertising and recruiting, and contract negotiations
- non-project related staff training and development costs
- costs related to preparing the grant application, preparing any project reports (except costs of independent audit reports we require) and preparing any project variation requests
- conference attendance, and associated travel (except in pre-approved circumstances where the research outputs of the activity are to be presented)
- travel or overseas costs that exceed 10% of total project costs except where otherwise approved by the Program Delegate (see above)
- health insurance, travel insurance, foreign currency, airport and related travel taxes, passports and visas
- entertainment and hospitality costs
- personal subscriptions (e.g. personal journal subscriptions)
- personal membership of professional organisations and groups
- airline club membership
- communications costs (mobiles, telephone calls)
- institutional overheads and administrative costs.



This list is not exhaustive and applies only to the expenditure of the grant funds. Other costs may be ineligible where we decide that they do not directly support the achievement of the planned outcomes for the project or that they are contrary to the objective of the grant opportunity.

You must ensure you have adequate funds to meet the costs of any ineligible expenditure associated with the project.



Appendix C. Assessment scoring scale

When assessing the merits of your application against the assessment criteria, the Committee will use the following ten-point scale (10 highest, 1 lowest).

Score	Rating Scale
10	Excellent Quality – response to this criterion significantly exceeds expectations. Evidence confirms consistent superior performance against this criterion in all areas. Claims are fully substantiated.
9	Outstanding Quality - response to this criterion exceeds expectations in most key areas and addressed to a very high standard in others. Most claims are fully substantiated with others very well substantiated.
8	Very Good Quality - response to this criterion meets expectations to a very high standard in all areas. All claims are well substantiated.
7	Good Quality – response to this criterion meets expectations to a high standard in all areas. Claims are well substantiated in key areas.
6	Fair Quality – response to this criterion addresses all areas well. Claims are well substantiated in most areas. Some minor shortcomings.
5	Acceptable Quality – response addresses most key areas to a consistent acceptable standard with no major shortcomings. Most claims are adequately substantiated. Some proposals may be questionable.
4	Marginal Quality – response is marginal and does not fully meet expectations. Some claims unsubstantiated; others only adequately substantiated or lack sufficient detail. Some proposals may be unworkable.
3	Poor Quality – response poorly addresses some areas or fails to address some areas. Claims largely unsubstantiated. A number of proposals may be unworkable.
2	Very Poor Quality – response inadequately deals with most or all areas. Claims almost totally unsubstantiated. A number of proposals may be unworkable.
1	Unacceptable Quality – response does not meet expectations. Criteria not addressed or insufficient or no information to assess the criterion. Claims unsubstantiated, no evidence and unworkable.



Appendix D. Rating scale for assessment criterion 4: Overall Value and Risk

Rating	Descriptor
Excellent	 The application provides excellent overall value The identified outcome/s or result/s against which the project's contribution to the MRFF measures of success will be evaluated are clearly articulated and well aligned with the overall goals of the MRFF, the initiative and the grant opportunity The proposed budget is detailed, aligns very well with the scope and scale of the proposed project, and is sufficient to undertake all components of work. The applicant's risk management plan is well considered and appropriate to the project. The stated approach to the management, monitoring and reporting of risks is clearly articulated within their application. Any risks arising through the assessment are tolerable and well mitigated, and not likely to adversely impact on the achievement of stated objectives of the
Good	 project. The application provides good overall value. The outcome/s or result/s against which the project's contribution to the MRFF measures of success will be evaluated are articulated reasonably clearly and are somewhat aligned with the overall goals of the MRFF, the initiative and the grant opportunity The proposed budget, with some minor shortcomings, is substantiated and will
	 meet the scope and scale of the proposed project. The applicants risk management plan is appropriate to the project, with some minor shortcomings. The stated approach to the management, monitoring and reporting of risk is articulated within their application, with claims supported across key areas. Any risks arising through the assessment are tolerable and unlikely to adversely impact on the achievement of stated objectives of the project, although some risks may require additional mitigations and/or monitoring to ensure the delivery of project outcomes.
Marginal	 The application provides marginal overall value. The outcome/s or result/s against which the project's contribution to the MRFF measures of success will be evaluated are not clearly articulated and do not align with the overall goals of the MRFF, the initiative and the grant opportunity The proposed budget is higher than expected for a project of the same scale and scope, with some line items questionable.



•	The applicant's risk management plan lacks detail in some areas, there are some gaps in risk identification or analysis or some mitigation and management strategies appear questionable.
•	Some risks arising through the assessment may require additional mitigation and/or monitoring to ensure that they are managed in a way that doesn't impact on the delivery of some project outcomes.

