Australian Government
National Health and Medical Research Council

Medical Research
Future Fund

Medical Research Future Fund – Coronavirus Research Response

2020 Respiratory Medicine Clinical Trials Research on COVID-19 Grant Opportunity Guidelines

Opening date:	**23 March 2020**
Application closing date and time:	**5pm ACT local time** on **Monday 6 April 2020**
Commonwealth policy entity:	**Australian Government Department of Health**
Administering entity:	**National Health and Medical Research Council**
Enquiries:	Applicants requiring further assistance should direct enquiries to their Administering Institution's Research Administration Officer. Research Administration Officers can contact NHMRC's Research Help Centre for further advice: Phone: 1800 500 983 Email: help@nhmrc.gov.au Questions should be submitted no later than **1:00pm ACT Local Time on Friday 3 April 2020.**
Date guidelines released:	**Monday 23 March 2020**
Type of grant opportunity:	**Targeted competitive**

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Medical Research Future Fund (MRFF) Coronavirus Research Response: 2020 Respiratory Medicine Clinical Trials Research on COVID-19 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's Outcome 1. The Department of Health 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 GrantConnect.

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You complete and submit a grant application

Your institution's Research Administration Office (RAO) completes the application form on the NHMRC's Granting System (Sapphire) on behalf of your Administering Institution. Your application must address all of the eligibility and assessment criteria to be considered for a grant.

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We assess all grant applications

We review all applications against eligibility criteria. Then a peer review panel assesses eligible applications against the technical assessment criteria (weighted) and against the non-technical criterion value and risk (non-weighted).

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We make grant recommendations

We provide advice to the decision maker on the recommendations of the peer review panel.

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Grant decisions are made

The decision maker decides which applications are successful.

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We notify you of the outcome

We advise you of the outcome of your application via NHMRC's Granting System (Sapphire).

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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.

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Delivery of grant

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

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Evaluation of the Grant Opportunity

We evaluate your specific grant activity, the Initiative as a whole, and the MRFF. 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. At maturity, the MRFF will reach $20 billion. 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 2016-2021* (the Strategy) and related set of *Australian Medical Research and Innovation Priorities 2016–2018* (the Priorities), developed by the independent and expert Australian Medical Research Advisory Board following extensive national public consultation.

In 2019-20 Budget, the Government announced its continued commitment to supporting lifesaving medical research with a $5 billion 10-year investment plan from the MRFF. It will place Australia at the leading edge of research in areas like genomics and will support the search for cures and treatments, including for rare cancers. The plan is underpinned by four key themes – patients, researchers, translation and missions.

1.2 About the Coronavirus Research Response

The Australian Government has committed $2.4 billion to a Coronavirus (COVID-19) National Health Plan to support our health system to manage the outbreak of novel coronavirus in Australia. The package provides support across primary care, aged care, hospitals and research, and includes $30 million over two years from the MRFF for a Coronavirus Research Response comprising vaccine, anti-viral and respiratory medicine research. These research priorities are in line with the priorities agreed at the recent Coronavirus Research Roundtable.

The Coronavirus Research Response will enable Australian researchers to drive innovation and contribute to global efforts to control the COVID-19 outbreak. This measure will use the considerable expertise of Australia's world-class health and medical researchers, which is critical for ensuring preparedness and the safety of all Australians and the global community.

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

1.3 About the 2020 Respiratory Medicine Clinical Trials Research on COVID-19 Grant Opportunity

These guidelines contain information for the 2020 Respiratory Medicine Clinical Trials Research on COVID-19 Grant Opportunity.

The global outbreak of the respiratory illness caused by novel coronavirus (COVID-19) was declared a pandemic by the World Health Organisation on 11 March 2020, reflecting the incidence and spread of hundreds of thousands of documented cases on every continent except Antarctica[1].

[1] https://www.who.int/dg/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---11-march-2020

Symptoms of COVID-19 can be mild; however, in severe cases the illness can result in pneumonia, severe acute respiratory syndrome, and death[2]. The potential for the COVID-19 pandemic to overwhelm health care systems has serious implications for patient outcomes. Treatments to alleviate the respiratory effects of COVID-19 are crucial to saving the lives of affected individuals, especially high-risk patients including the elderly, people with compromised immune systems and people with chronic illnesses. They are also needed to alleviate the burden on clinical care, and to ensure that supplies and services such as outpatient facilities, emergency departments, hospitals and acute and intensive care units can be provided to those who need them.

The objective of the 2020 Respiratory Medicine Clinical Trials Research on COVID-19 Grant Opportunity is to use clinical trials to accelerate the implementation of treatments for severe acute respiratory distress in patients infected with COVID-19.

Applications to this grant opportunity must propose a clinical trial that accelerates the implementation of treatments for severe acute respiratory distress in patients infected with COVID-19 in order to support the response to the COVID-19 outbreak in Australia. Applicants should note that the research funded by this grant opportunity is not intended to be used for development of vaccines or anti-viral therapies for COVID-19. These issues are the subject of separate MRFF grant opportunities.

Given the rapidly evolving nature of the COVID-19 outbreak, applicants must propose clinical trials that will support the rapid implementation of new treatments for COVID-19, including demonstration of access to relevant clinical trial networks, patient cohorts and other critical resources to allow for rapid progression of the product into clinical practice. Applicants must provide evidence of the feasibility of quickly implementing their proposed intervention, including the target population, potential timeframes, workforce adaption, overall project costs, and how it will be made available to the Australian public (e.g. via existing reimbursement pathways).

The intended outcome of the research funded under this priority is to use clinical trials to accelerate the implementation of safe and effective treatments for severe acute respiratory distress in patients infected with COVID-19. This includes the identification of plausible pathways to clinical practice within 12 months of commencement.

To be competitive for funding, applicants must propose a clinical trial that delivers against the above objective. If applicants propose a clinical trial that is not relevant to the desired outcome they will be considered against the assessment criteria and found to be uncompetitive. Administering Institutions are requested to ensure they only submit applications that address the desired outcomes.

Applicants may wish to consider leveraging existing or complementary research funding opportunities from Government and non-Government sources as part of their application.

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, and
- responsibilities and expectations in relation to the opportunity.

The NHMRC is responsible for administering this grant opportunity on behalf of the Department of Health.

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[2] https://www.health.gov.au/news/health-alerts/novel-coronavirus-2019-ncov-health-alert/what-you-need-to-know-about-coronavirus-covid-19

You should read this document carefully before you fill out an application. We have defined key terms used in these guidelines in the glossary at section 13.

1.4 Encouraging Partnerships

Applicants are encouraged to seek strategic partnerships involving 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.

They include organisations such as:

- 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 respiratory medicine clinical trials research for COVID-19, such as biotechnology and pharmaceutical companies
- non-government organisations and charities
- community organisations such as consumer groups
- healthcare providers, and/or
- 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).

2. Grant amount and grant period

2.1 Grants available

For this grant opportunity, up to $5 million of funding through the Medical Research Future Fund is available in 2019-20.

There is no maximum grant amount but grants cannot exceed the amount of available funds.

Table 1. Funding profile ($ million – GST exclusive)

$5 million from the Medical Research Future Fund is available over one year from 2019-20.

2019-20
5

2.2 Project period

The project must be completed by 30 June 2021.

3. Eligibility criteria

We cannot consider your application if you do not satisfy all eligibility criteria.

3.1 Who is eligible?

To be eligible you must:

- be an NHMRC approved Administering Institution
- have an Australian Business Number (ABN)
- be incorporated in Australia

and in accordance with s20 and s24 of the Medical Research Future Fund Act 2015[3], be one of the following entities:

- a medical research institute
- a university
- a corporate Commonwealth entity
- a corporation (including businesses and not for profits)
- a state or territory government, or
- a state of territory government entity.

Joint applications are encouraged, provided you have a lead organisation who is the main driver of the project and is eligible to apply.

We cannot waive the eligibility criteria under any circumstances.

3.2 Additional eligibility requirements

You are ineligible for funding under this grant opportunity if you have participated in the development of these grant guidelines.

Your application may also be ineligible and excluded from further consideration if it contravenes other requirements as set out in these Grant Guidelines. Examples include, but are not limited to:

- the application is not certified and submitted via NHMRC's Granting System (Sapphire) by the RAO of an NHMRC approved Administering Institution by the advertised closing date and time
- a person is named as a Chief Investigator (CI) on more than one application submitted to this grant opportunity
- the Grant Proposal does not comply with formatting requirements and page limits

[3] https://www.legislation.gov.au/Details/C2015A00116

- the proposed research duplicates research previously or currently being undertaken. We may compare the research proposed in grant applications with grants previously or currently funded by the MRFF, NHMRC or other agencies (e.g. Australian Research Council) and published research (see also section 7.2)
- the application fails to accurately declare the source, duration and level of funding already held by the research team for research in the particular area of the application
- the application includes any incomplete, false or misleading information
- its aims are inconsistent with the object of the MRFF Act to improve the health and wellbeing of Australians
- persons named on the application are the subject of a decision by the NHMRC Chief Executive Officer or Delegate that any application they make to NHMRC, for specified funding opportunities, will be excluded from consideration for a period of time, whether or not they meet the eligibility requirements. Such decisions will generally reflect action taken by NHMRC in response to research misconduct allegations or findings, or a Probity Event. See the NHMRC Policy on Misconduct related to NHMRC Funding.

If a decision to exclude an application from further consideration is made, we will provide the decision and the reason(s) for the decision to the Administering Institution's RAO in writing. The Administering Institution's RAO is responsible for advising applicants of the decision in writing.

3.3 Chief Investigators

Applicants must nominate a Chief Investigator A (CIA) who will take the lead role in submitting the application, conducting the research, and reporting as required under the grant agreement.

A person must not be named as a Chief Investigator (CI) on more than one application submitted to this grant opportunity. Up to 10 CIs may be included as members of the research team.

It is generally required that, at the time of application submission, the CIA is an Australian citizen or is a permanent resident in Australia (see also section 6.4*)*. The research proposal must involve CIA being based in Australia for the duration of the grant.

Researchers who are not Australian citizens or permanent residents in Australia are eligible to apply as a Chief Investigator B to J.

See also section 6 – *How to apply*.

4. What the grant money can be used for

4.1 Eligible activities

To be eligible, activities in your Grant Proposal must clearly demonstrate their criticality in meeting objectives of the 2020 Respiratory Medicine Clinical Trials Research on COVID-19 Grant Opportunity under Section 1.3. You can only spend grant funds to pursue the research activities described in your Grant Proposal. You can use the grant to pay costs that arise directly from these activities. The following categories must be used in your proposed budget:

- Equipment
- Personnel (personnel support packages)
- Other Direct Research Costs (DRCs).

Rules apply to each category of expenditure. Applicants are required to justify the budget requested for each year of the proposed research. Your budget, including your justification of the proposed expenditure, will be part of the value and risk assessment. Refer sections 5.4 and 6.4.

4.2 Equipment

You 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. Individual items of equipment costing less than $10,000 must be requested within DRCs (see below).

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.

For each item of equipment requested, a written quotation must be received and held with the RAO of the Administering Institution, to be available to the Australian Government on request.

The Administering Institution 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 used for the manipulation of extensively large datasets (i.e. requiring special hardware).

4.3 Personnel

Salary contributions for research staff (Chief Investigators, Professional Research Persons and Technical Support Staff) are provided as Personnel Support Packages (PSPs). The level of PSP requested in an application must match the roles and responsibilities of the position and the percentage of the PSP requested must reflect the required time commitment. Applicants must fully justify all requests for PSPs.

Personnel Support Packages – for funding commencing in 2020		
Level	**Description**	**$ per annum**
PSP1	Technical support - non-graduate personnel Note: A PSP1 at 50% may be claimed for postgraduate students supported on NHMRC research grants	56,772
PSP2	Junior graduate research assistant; or junior graduate nurse, midwife or allied health professional; or junior data manager/data analyst	70,890
PSP3	Experienced graduate research assistant/junior postdoctoral research officer; or experienced graduate nurse, midwife or allied health professional; or experienced data manager/analyst	77,950

Personnel Support Packages – for funding commencing in 2020		
Level	**Description**	**$ per annum**
PSP4	Experienced postdoctoral researcher or clinician without specialist qualifications (i.e., a researcher who may be considered as a named investigator on the research application)	92,070
PSP5	Senior experienced postdoctoral researcher (i.e., a researcher who would normally be considered as a named investigator on the research application and is more than 10 years post-doctorate.	99,129

Chief Investigators

CIs, including the CIA, may draw a salary if they are based in Australia for at least 80% of the funding period. CIs based overseas are not able to draw a salary, but salary support is available for research support staff based overseas (see section 4.1). Requested salaries must be based on Personnel Support Packages (PSPs).

Applicants can receive up to 100% salary across NHMRC and MRFF grants. Multiple partial salaries can be drawn up to 100%, if allowed in the grant guidelines for the respective grant opportunity.

Associate Investigators

An Associate Investigator (AI) is an individual who provides intellectual input to the research and whose participation reasonably warrants recognition. AIs are ineligible to draw a salary from this grant opportunity grant. There are no restrictions on individuals who may be named as an AI.

4.4 Other Direct Research Costs

For the purposes of this grant opportunity, other Direct Research Costs (DRCs) are costs that are integral to achieving the approved research objectives of a grant where the recipient is selected on merit against a set of criteria. Such costs must directly address the research objectives of the grant, relate to the approved research plan and require the associated budget to have been properly justified. Direct research costs may include the following:

- personnel costs related to contract staff and limited external persons (not for Chief Investigators or additional personnel). The basis for costing must be included.
- clinical services that are over and above standard care
- Medicare costs (out of pocket medical expenses)
- reimbursement of reasonable costs associated with randomised control trials (RCT)
- reasonable imaging and diagnostic costs (MRI, PET, CT, ultrasound, genotyping, biochemical analysis)
- equipment costing less than $10,000 that is unique to the project and is essential for the project to proceed
- purchases of services directly required for the successful conduct of the project (including services from institutional facilities)

- specialised computing requirements that are essential to meeting project specific needs.

Publication costs cannot be requested in your application but may be listed as a direct research cost in your financial acquittal.

The above list is not comprehensive. Where a research cost is not included in the above list you should refer to the definition in the first paragraph of this sub-section. If you are still unsure clarification should be sought from NHMRC. Direct research costs will be critically scrutinised during the assessment of applications and during on-site compliance monitoring visits.

4.5 Accessing existing research infrastructure

Applicants are encouraged to utilise existing research infrastructure to support their research wherever possible so as to reduce duplication and achieve the best return on project funding, and DRCs can be requested to support access to 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 of the requested budget. For information on how to include research facilities within your application refer to section 6.4.

4.6 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 within your grant application and formally approved by the relevant Faculty Research Committee, or where subsequently requested, documented and agreed by the Delegate) as being essential to the conduct of the project, ahead of the travel being taken, will be limited to the reasonable cost of accommodation and transportation.

Eligible air transportation is limited to the economy class fare for each sector travelled. Where non-economy class air transport is used:

- only the equivalent of an economy fare for that sector is eligible expenditure
- the grantee will be required to provide evidence showing what an economy air fare cost was 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.

4.7 What the grant money cannot be used for

Indirect costs of research

You cannot use the grant to pay the indirect costs of research.

Indirect costs of research are Institution overhead costs that benefit and support research. They can include the operations and maintenance of buildings, provision of facilities and libraries, hazardous waste disposal, regulatory and research compliance and administration of research services. Although they are necessary for the conduct of research, and may be incurred in the course of research, they are costs that do not directly address the approved research objectives of a grant.

Costs that cannot be paid with the grant include, but are not limited to:

- airline club memberships
- computers, computer networks, peripherals and software for communicating, writing and undertaking simple analyses
- communications costs (mobiles, telephone calls)
- conference attendance, and associated travel
- entertainment and hospitality costs
- ethics approval costs
- furniture
- health insurance, travel insurance, foreign currency, airport and related travel taxes, passports and visas
- institutional overheads and administrative costs
- non-project related staff training and development
- overseas travel (except as provided for in section 4.6 - *Travel and overseas expenditure*)
- patent costs
- personal membership of professional organisations and groups
- personal subscriptions (e.g. private journal subscriptions)
- physical space and all associated administrative, laboratory and office services
- purchase of reprints
- research infrastructure: facilities necessary for the research endeavour that a responsible Institution would be expected to supply as a prerequisite to its engagement in research.

Other ineligible expenditure

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). 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. Refer to section 4.6.

A grant cannot be provided to you if you receive funding from another government source for the same purpose. You can apply for grants under any Commonwealth program but, if your applications are successful, you must choose either the grant from this Program or the other Commonwealth grant.

Where you have submitted the same application to NHMRC and MRFF grant opportunities and have received an offer of funding from one of these sources, NHMRC and the Department of Health reserve the right to withhold any further offer of funding for the application.

Where it appears that an applicant has submitted similar applications for research funding and has been successful with more than one application, the applicant is required to provide us with a written report clearly identifying the difference between the research aims of the two research activities. If we do not consider the two research activities to be sufficiently different, an offer of funding for one of the applications may be withheld, or you will be required to decline or relinquish one of the grants.

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) Overall Value and Risk of the project 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 Assessment Criterion 1 - Project impact (30% weighting)

You are required to address this criterion within your Grant Proposal. Project impact is the potential to increase knowledge of important topics that achieve the outcomes of the grant opportunity. You should demonstrate this by providing details of how your research proposal will be directly relevant to the objectives and desired outcomes of this grant opportunity, specifically:

- Clinical trials that support the rapid implementation of respiratory medicines for COVID-19.
- In your application you should ensure you consider the following questions:
    - How has the potential impact on health outcomes been justified?
    - Have you systematically reviewed the scientific literature?
    - How has the identified research informed the research question?
    - Do the points of difference between identified studies and the proposed research provide a strong justification for the proposed research?
- High-quality evidence of the efficacy of new health treatments for COVID-19
- Engagement of health service delivery partners (e.g. commercial) that will support implementation of study findings into practice, as quickly as possible
- Describe how you will achieve an outcome (i.e. a plausible pathway to clinical practice) within 12 months of commencing

- The extent to which your research includes new and innovative approaches, or brings new perspectives to existing approaches

Please commence addressing this criterion by substantiating that the research addresses respiratory medicine clinical trials research on COVID-19.

Further instructions are in section 6.4.

5.2 Assessment Criterion 2 - Project methodology (40% weighting)

In responding to this criterion you should demonstrate your proposed methodology, encompassing the strengths and weaknesses of the study design and the scientific quality and feasibility of the proposal. You are required to provide information on appropriate milestones, performance indicators and timeframes.

You are required to demonstrate access to relevant clinical trial networks, patient cohorts and other critical resources to allow for rapid progression of your product to clinical practice. Applicants must also provide evidence of the feasibility of quickly implementing the proposed intervention, including the target population, potential timeframes, workforce adaption, overall project costs, and how it will be made available to the Australian public (e.g. via existing reimbursement pathways).

You should also consider the following questions in relation to the scientific quality of your research proposal:

- Is there a clear research question? Does the clinical trial measure health outcomes? Or validated surrogates for health outcomes?
- Is the methodology described in sufficient detail? Are the participants, intervention/exposure and comparators/controls clearly specified? Are data collection, management and statistical analysis described?
- Is the methodology appropriate for the research question? What are the strengths and weaknesses of the study design? Have any major pitfalls been overlooked?
- Is the research design feasible? Are the required expertise, tools and techniques established? Are targets for the recruitment of participants realistic? Will the study have sufficient sample size to be able to identify meaningful effect differences?
- Does the proposal include milestones, performance indicators and timeframes? Grantees will be required to report against the milestones, performance indicators and timeframes at specified intervals.
-

Further instructions are in section 6.4.

5.3 Assessment Criterion 3 - Capacity, capability and resources to deliver the project (30% weighting)

This criterion is used to assess whether the research team named in your application has the appropriate mix of research skills and experience to undertake the research project. In demonstrating Capacity, Capability and Resources you should not provide information about your Administering Institution. You should provide:

- Information on each CI's research achievements, as a 'snapshot' file drawn from their CVs in NHMRC's Granting System (Sapphire), including:
    - Career Disruption (during the last 5 years)

    - Relative to Opportunity (during the last 5 years)
    - Publications (during the last 5 years)
    - NHMRC grants, and MRFF grants administered by NHMRC (during the last 5 years).
    - Other Research Funding (during the last 5 years)
  - Each CI should provide an example from within the last 5 years of how their research has impacted policies or programs, through the translation or implementation of the research findings.
  - Details of Capacity and Capability relative to opportunity, which you provide within the Grant Proposal:
    - Team capacity and capability relevant to this application
    - Chief Investigator capability and capacity, including each CI's top 5 publications and 'Relative to opportunity' considerations and career disruption (where relevant).

Your application must clearly demonstrate that:

- the CIs have an appropriate mix of research skills and experience to successfully undertake this research project
- the CIs have expertise sufficient to anticipate and solve potential obstacles (e.g. higher than anticipated non-compliance rates or new competing therapies) to the successful completion of the proposal
- the CI team has expertise in all aspects of the Proposal, including the methodological and scientific underpinnings (e.g. statistics, bioinformatics and health economics)
- the CI team's previous research outputs demonstrate their capability to undertake the research project
- the CIs have previously delivered high quality research outputs in this area of research
- the team has previously demonstrated a high level of research productivity
- the listed team reflects the contribution of early- and mid-career researcher/s to the research project.

Further instructions are in section 6.4.

Relative to Opportunity

For this grant opportunity, the policy is that assessment processes will accurately assess an applicant's track record and associated productivity relative to stage of career, including consideration as to whether productivity and contribution are commensurate with the opportunities available to the applicant. In alignment with NHMRC's Principles of Peer Review, particularly the principles of fairness and transparency, the following additional principles further support this objective:

- Research opportunity: Researchers' outputs and outcomes should reflect their opportunities to advance their career and the research they conduct
- Fair access: Researchers should have access to funding support available through NHMRC grant programs consistent with their experience and career stage
- Career diversity: Researchers with career paths that include time spent outside of academia should not be disadvantaged. We recognise that time spent in sectors such as industry may enhance research outcomes for both individuals and teams.

The above principles frame our approach to the assessment of a researcher's track record during expert review of grant applications. We expect that those who provide expert assessment during peer review will give clear and explicit attention to these principles to identify the highest quality research and researchers to be funded. We recognise that life circumstances can be very varied and therefore it is not possible to implement a formulaic approach to applying Relative to Opportunity and Career Disruption considerations during peer review.

Circumstances considered may include:

- amount of time spent as an active researcher
- available resources, including situations where research is being conducted in remote or isolated communities
- building relationships of trust with Aboriginal and Torres Strait Islander communities over long periods and subsequent impact on track record and productivity
- clinical, administrative or teaching workload
- relocation of an applicant and his/her research laboratory or clinical practice setting or other similar circumstances that impact upon research productivity
- for Aboriginal and Torres Strait Islander applicants, community obligations, including 'sorry business'
- restrictions on publication of research undertaken in other sectors
- the typical performance of researchers in the research field in question
- research outputs and productivity noting time employed in other sectors. For example, there might be a reduction in publications when employed in sectors such as industry
- carer responsibilities (that do not come under the Career Disruption below).

Career Disruption

A career disruption involves a prolonged interruption to an applicant's capacity to work, due to pregnancy, major illness/injury or carer responsibilities.

Interruptions must involve either a continuous absence from work for periods of 90 calendar days or more and/or a long-term partial return to work that has been formalised with the applicant's employer.

The period of career disruption may be used to determine an applicant's eligibility for a grant opportunity or to allow additional track record information to be considered during assessment. See also *Relative to Opportunity* above.

5.4 Assessment Criterion 4. Overall Value and Risk of the Project (non-weighted)

Your application should demonstrate the overall value and risk of the project, including that you have robust risk identification and management processes.

You should provide:

- Your proposed budget and justification.
- A risk management plan.

Our assessment will also take into consideration:

- the suitability of your proposed budget to complete all project activities
- how well the requested budget has been detailed and justified

- how soundly your risk management approach is demonstrated
- any risks identified as part of the assessment of your application
- the appropriateness of the submitted risk management plan in documenting key risks to the completion of the research proposal, including your plan to manage those identified risks, and
- how you propose to monitor and report risks (both those identified in your submitted risk management plan and those which may arise during your project).

Refer section 6.4 and to the *Rating Scale for Overall Value and Risk* for further information.

5.5 Health research involving Aboriginal and Torres Strait Islander peoples

We are committed to improving the health outcomes of Aboriginal and Torres Strait Islander peoples and encourage applications that address Aboriginal and Torres Strait Islander health.

NHMRC has established certain requirements and processes designed to ensure that research into Aboriginal and Torres Strait Islander health is of the highest scientific merit and is beneficial and acceptable to Aboriginal and Torres Strait Islander peoples and communities.

To qualify as Aboriginal and Torres Strait Islander health research, at least 20% of the research effort and/or capacity building must relate to Aboriginal and Torres Strait Islander health.

Qualifying applications must address Indigenous research excellence, as follows:

- Community engagement - the proposal demonstrates how the research and potential outcomes are a priority for Aboriginal and Torres Strait Islander communities with relevant community engagement by individuals, communities and/or organisations in conceptualisation, development and approval, data collection and management, analysis, report writing and dissemination of results.
- Benefit - the potential health benefit of the project is demonstrated by addressing an important public health issue for Aboriginal and Torres Strait Islander peoples. This benefit can have a single focus or affect several areas, such as knowledge, finance and policy or quality of life. The benefit may be direct and immediate or it can be, indirect, gradual and considered.
- Sustainability and transferability - the proposal demonstrates how the results of the project have the potential to lead to achievable and effective contributions to health gain for Aboriginal and Torres Strait Islander peoples, beyond the life of the project. This may be through sustainability in the project setting and/or transferability to other settings such as evidence-based practice and/or policy. In considering this issue the proposal should address the relationship between costs and benefits.
- Building capability - the proposal demonstrates how Aboriginal and Torres Strait Islander peoples, communities and researchers will develop relevant capabilities through partnerships and participation in the project.

Your response to these criteria will be taken into account when assessing your application against the Assessment Criteria relevant to this proposal (refer to the *Assessment Criteria Scoring Matrix* for further information).

Further instructions on addressing Indigenous research excellence are in section 6.4.

5.6 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. 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 NHMRC's website.

Researchers are encouraged to consider the benefits of actively engaging consumers in their proposed research.

6. How to apply

GrantConnect (www.grants.gov.au) is the authoritative source of information on this grant opportunity. Any alterations or addenda to these Guidelines will be published on GrantConnect.

Applications must be submitted electronically using NHMRC's online Granting System (Sapphire). Electronic submission requires Administering Institutions and Chief Investigators on an application to register for an account.

Applicants who are not registered in NHMRC's Granting System (Sapphire) can submit a new user request via the system login page. Sapphire Tutorials and FAQs can be found here:

Tutorials: https://healthandmedicalresearch.gov.au/tutorials.html#

FAQ: https://healthandmedicalresearch.gov.au/help.html

Contact your RAO or the NHMRC Research Help Centre for further assistance.

Your application will consist of:

- a Profile Report containing information drawn from each Chief Investigator's Profile in NHMRC's Granting System (Sapphire)
- an Application Report containing information that you entered directly into the Application Form in NHMRC's Granting System (Sapphire)
- a Grant Proposal. You will upload this PDF file into NHMRC's Granting System (Sapphire). Refer to section 6.4.
- a Declaration of Applicant Interests. You will upload this PDF file into NHMRC's Granting System (Sapphire). Refer to section 12.1
- letter/s from research facilities (where relevant). These PDF files will be uploaded into NHMRC's Granting System (Sapphire). Refer to section 6.4.

Detailed instructions on completing your application are in section 6.4 below. Your Administering Institution is required to certify your application as correct and complete prior to submitting it to NHMRC.

Applicants should construct applications with the knowledge that the full application may be provided to Australian and international expert assessors.

All information submitted must be complete, current and accurate at the time of submission. Under section 136.1 of the *Commonwealth Criminal Code Act 1995*, it is an offence to provide false or misleading information to a Commonwealth body in an application for a benefit.

Examples of false or misleading information in an application include, but are not limited to:

- providing a dishonest statement regarding time commitments to the research

- providing incomplete or inaccurate facts regarding other sources of funding
- providing a fictitious record of your achievements
- falsifying claims in publication records (such as describing a paper as accepted for publication when it has only been submitted).

If we believe that omissions or inclusion of misleading information are intentional we may refer the matter for investigation and take action under the Grant Guidelines, the funding agreement or, for this grant opportunity, the *NHMRC Policy on Misconduct related to NHMRC Funding*.

6.1 Joint (consortia) applications

In some cases, the institution that will administer your application may differ from the institution in which you will actually conduct the proposed research. For example, many universities administer research being conducted in an affiliated teaching hospital. You are required to list participating institutions in your application and specify the percentage of the research effort being undertaken in the departments within these institutions.

Prior to submission your Administering Institution's RAO is required to assure us that arrangements for the management of the grant have been agreed between all institutions associated with the application.

6.2 Timing of the grant opportunity process

Applications must be submitted to NHMRC by the closing date below. Late applications will not be accepted.

Requests for application extensions will be considered on a case by case basis and must be submitted by email to help@nhmrc.gov.au on or before the scheme close date and time. Requests will only be considered for:

- unforeseen circumstances, e.g. natural calamities such as bushfires, floods or hurricanes, or
- exceptional circumstances that affect multiple researchers, e.g. power and/or internet network outages, or
- where an applicant, or a member of their immediate family[4], is incapacitated due to an unforeseen medical emergency, such as life-threatening injury, accident or death.

Extensions, if granted, will be for a maximum of seven calendar days. This is to ensure that subsequent peer review processes and approval of funding recommendations are not delayed.

Requests for extension submitted after the scheme close date and time will not be considered.

The expected completion date of your research must be nominated in your application.

Activity	**Timeframe**
Applications open	Monday 23 March 2020
Applications close	5pm ACT local time on 6 April 2020
Assessment of applications	April 2020
Approval of outcomes of selection process	May 2020

[4] Immediate family comprises a spouse, child, parent or sibling. It includes de facto, step and adoptive relations (e.g. de facto, step or adopted children).

Activity	Timeframe
Announcement of outcomes	May 2020
Notification to unsuccessful applicants	On announcement
Acceptance of grant offer	Within one week of formal offers
Activity commences	June 2020*
End date	June 2021

***to avoid delays in commencement of research, applicants are encouraged to seek ethics approval as soon as their proposal is drafted, not wait for funding to be announced.**

6.3 Questions during the application process

Applicants requiring further assistance should direct enquiries to their Administering Institution's Research Administration Officer. Research Administration Officers can contact NHMRC's Research Help Centre for further advice:

Phone: 1800 500 983

Email: help@nhmrc.gov.au

Any alterations or addenda to these Guidelines will be published on GrantConnect.

6.4 Completing the grant application

Using NHMRC's Granting System (Sapphire)

Applications must be submitted electronically using NHMRC's online Granting System (Sapphire). Electronic submission requires Administering Institutions and Chief Investigators on an application to register for an account.

Sapphire Tutorials and FAQs can be found here:

Tutorials: https://healthandmedicalresearch.gov.au/tutorials.html#

FAQ: https://healthandmedicalresearch.gov.au/help.html

If you have any technical difficulties, please contact your RAO or NHMRC's Research Help Centre on

1800 500 983 or by email to help@nhmrc.gov.au

Starting your application in NHMRC's Granting System - Sapphire

Applicants must create a new application for this grant opportunity in NHMRC's Granting System (Sapphire). The following advice is provided to assist you to complete specific sections of the application.

Project Synopsis

A Synopsis of your application is required in the NHMRC Granting System (Sapphire) Application Form. This information will inform the selection of assessors with suitable expertise to review your application, and for communication with various audiences regarding how the grants selected for funding will achieve the outcomes sought from this grant opportunity.

Applicants proposing clinical research including clinical trials should ensure that the Synopsis is written in plain English, incorporates Participant, Intervention, Comparator and Outcome) and concludes by stating why the research is important.

Direct Research Costs

Enter details of the proposed research budget into NHMRC's Granting System (Sapphire) keeping in mind the level and duration of funding available for grants under this grant opportunity. Details on permitted uses of funds and setting of budgets can be found in the section 4.

Requests for Equipment, Personnel Support Packages and Other Direct Research Costs must be included in your budget.. For each item requested you must enter:

- the item type
- the name/description of the item
- the total value of the item requested for each year
- a justification for the particular item requested.

Applicants may request funding for services from research facilities required to undertake the Grant Proposal. These services may include, but are not limited to, biospecimens or data from biobanks, pathology services, clinical registries, the Australian Twin Registry, Cell Bank Australia, the Trans-Tasman Radio Oncology Group or clinical trial services.

Provide details of the costs of using the services of research facilities as DRCs in NHMRC's Granting System (Sapphire) and ensure they are fully justified. Applicants should consult with research facilities to ensure that the services they require can be provided and that the charges included in the research budget reflects their charges. Letters from research facilities confirming their collaboration must be uploaded into NHMRC's Granting System (Sapphire).

The total annual amount requested across all DRC line items for each year of a grant will be available at the 'summary' tab of the application form.

CV/Profile requirements

Instructions for entering CV information in NHMRC's Granting System (Sapphire) are provided in the System (Sapphire)relevant user guides. System (Sapphire)All mandatory sections of your Chief Investigators' profiles must be completed.

It is important that CIs update their Profile and CV in NHMRC's Granting System (Sapphire) prior to certification of the application by your RAO. Changes made to your CV after applicant certification will not appear in the submitted application.

The following components of your Chief Investigators' CVs will be incorporated into your application:

Career Disruption (during the last 5 years)

For guidance on what constitutes a career disruption refer to section 5 *(Career Disruption)*. If applicable, you (or members of your CI Team) should use this opportunity to declare any career disruptions that may be relevant to your career history.

If you have had an extended career disruption within the last five years, it is advised that you briefly explain this in your application and nominate additional research achievements for the most recent year/s without a career disruption.

For example, if in the last five years you have taken six months of maternity/carers leave and then returned to work at 0.5 Full Time Equivalent (FTE) for three years before resuming at a full-time level, you will have worked an equivalent of three years FTE over the past five years. You should therefore add any publications or other components of your Track Record that you want peer reviewers to consider predating five years by two years.

Please select the nature of the career disruption from the drop down menu.

- *Impact*

Provide a brief explanation on the impact the career disruption/s has had on your research and research achievements and associated productivity relative to stage of career. Applicants should not describe the nature of the career description in this field. Note that this information will be provided to peer reviewers. Maximum of 2000 characters including spaces and line breaks.

- *Additional research outputs*

Provide details of additional research outputs (those that occurred in the relevant preceding years) that you want the reviewers to consider when assessing your application. If applicable, indicate any national or international conferences where you were invited to give a major presentation, or other significant invitations (e.g., to join an editorial board of a major journal, or write a major review), and were not able to do so because of considerations associated with the career disruption. Maximum of 2000 characters including spaces and line breaks.

- *Dates*

You are required to nominate the periods in the last five years where you have had a disruption (approximate dates). Entries will be listed in reverse chronological order.

Applicants that have circumstances impacting their track record may also include their additional research outputs as part of their overall track record in the last 5 years under the CI Track Record of the Grant Proposal.

Relative to Opportunity (during the last 5 years)

If applicable, you (or members of your CI Team) should use this section to provide details on any relative to opportunity considerations and the effect they have had on your research and research achievements. See section 5.

Publications (during the last 5 years)

Publication information must be uploaded using a tab delimited file using Microsoft Excel® or by exporting your EndNote® Library as an .xml file. Applicants should verify that publication information has been correctly uploaded by requesting a CV Snapshot. Further details on how to upload publications are provided in the tutorials and FAQs for NHMRC's Granting System (Sapphire).

Your publications will be grouped together by the type of publication. They will also automatically be given an Identification Number (ID). Do not use the ID number or sequence number created in the 'Snapshot Reports' to refer to specific publications in other sections of your application.

NHMRC grants and MRFF grants administered by NHMRC (during the last 5 years)

Provide sufficient details about the funding to make clear what the funding was intended for, what you achieved and your role within these grants.

Other Research Funding (during the last 5 years)

Provide sufficient details about the funding to make clear what the funding was intended for, what you achieved and your role within these grants.

The Grant Proposal

You will upload your Grant Proposal into NHMRC's Granting System (Sapphire) as a PDF file. A pre-formatted Microsoft Word template for the Grant Proposal can be downloaded from the grant opportunity webpage on GrantConnect.

Applicants must use this template to complete their Grant Proposal. Mandatory naming, size and formatting requirements apply.

Formatting Requirements for the Grant Proposal	
File format	The Grant Proposal must be saved and uploaded in Portable Document Format (PDF)
File size	The PDF file MUST NOT exceed 2MB in size
File name	The PDF file must be named as follows: *APP ID_CIA Surname_ program name_document type.pdf* e.g. APP1234567_Smith_MRFF 2020 Respiratory Medicine Clinical Trials on COVID-19_Grant Proposal.pdf
Page size	A4
Page limits	Page limits are specified for each component of the Grant Proposal.
Font	NHMRC recommends a minimum of 12 point Times New Roman. Applicants must ensure the font is readable.
Header	Application ID and CIA surname must be included in the header. The document title must be included in the header and have the following format: *MRFF grant opportunity name and year of application* – Grant Proposal e.g. MRFF 2020 Respiratory Medicine Clinical Trials on COVID-19 2020 - Grant Proposal
Line spacing	Single
Language	English
Web links	Web links are not permitted except in citations of materials only available online. The full URL must be provided and the style must allow identification from a printed version of the application.

Applications that fail to comply with the formatting requirements or the specified page limits may be excluded from consideration. Applicants and RAOs are advised to retain a copy of the PDF file. If

printing the PDF file for the purposes of checking formatting and page length, ensure that page scaling is set to 'None' in the print settings.

Your Grant Proposal must include the following components, and no other components:

	Component	Page Limit
A	Project Impact	2 pages
B	Project methodology	2 pages
C	Milestones and Performance Indicators	1 page
D	Capacity, capability and resources to deliver the project	
	1. Team capacity and capability relevant to this application	1 page
	2. Chief Investigator capability and capacity	1/2 page per CI
E	Value and Risk of your project	
	1. Risk Management Plan	1 page
F	References	1/2 page

A brief description of each component is provided below.

A. Project impact (maximum two A4 pages)

This section should be used to address Assessment Criterion 1 - Impact of the expected outcomes to the objectives of this grant opportunity. Applicants are requested to commence this section (i.e. the top of the first page) by substantiating that the research project proposed meets the objectives as described in section 1.3. Applicants should provide details of how their engagement with partners including funding will leverage other complementary funding sources and the amount of those contributions.

B. Project methodology (maximum two A4 pages)

This section should be used to address Assessment Criterion 2 - Project methodology. Please provide sufficient background information to justify the research being proposed, identify the aims and approach to be taken and provide sufficient information on the research plan for assessors to assess scientific validity, research quality and feasibility. Provide details to demonstrate your access to critical resources that will support respiratory medicines clinical trials research for COVID-19. This section may include background, defined aims and outcomes.

C. Milestones and Performance Indicators (maximum one A4 page)

Please provide a table of milestones and performance indicators and corresponding dates. The approach should be specific to the proposed research project and provide for effective monitoring of progress. Applicants to the Respiratory Medicines Clinical Trials Research on COVID-19 grant opportunity are encouraged to include milestones such as (as applicable) receipt of ethics approval for first trial site and all trial sites, enrolment of first participant, recruitment numbers per month, reporting to Human Research Ethics Committees (HREC) sites, budget targets, placement of data in a repository, close out and publication.

D. Capacity, capability and resources to deliver the project

1. Team Quality and Capability relevant to this application (maximum one A4 page)

You should provide a summary of the research team's overall quality and capability including:

- the expertise and productivity of team members relevant to the proposed project
- the team's influence in this specific field of research
- how the team will work together on this project
- how junior members are contributing to the capabilities of the team.

Information about Associate Investigators must not be included as contributing to team quality and capability.

2. Chief Investigator Capability and Achievement (maximum half an A4 page per CI)

Chief Investigators should use this section to highlight their research achievements. Each Chief Investigator should provide information on:

- the top 5 publications in the last 5 years
- overall Track Record in the last 5 years, and
- an example from the last 5 years on the impact of previous research.

Top 5 Publications in the last 5 years

Applicants are asked to list their top 5 publications in the last 5 years, taking into account career disruption. Provide reasons for your choice of publications.

When considering how to address this criterion please note that, in accordance with the San Francisco Declaration on Research Assessment, NHMRC has eliminated the use of Journal Impact Factors and 'Excellence in Research Australia' metrics in the assessment of applications.

Overall Track Record in the last 5 years

Chief Investigators can use this section to identify aspects of their track record that are in addition to their publication record. This includes any relative to opportunity considerations you wish to raise. The last 5 years of publications and research support are included in the CV section, so consider choosing other information you think demonstrates that you can deliver on your role and responsibilities in this research proposal (i.e. designing, implementing and interpreting studies similar to that proposed). The following may be relevant:

- Career summary (e.g. qualifications, employment and appointments)
- Collaborations
- Community engagement and involvement
- Contribution to the field, including the translation of research into health
- Commercial outcomes and patents, including whether licensed (when, to whom and whether current) (see NHMRC's Guide to Evaluating Industry-Relevant Experience)
- International standing, including invitations to speak and committees
- Peer review (e.g. for granting bodies, journals/editorial roles)
- Professional activities (e.g. committees, conference organisation/participation)

- Supervision and mentoring.

Example of the impact of previous research in the last 5 years

Applicants are asked to provide an example of the impact of their previous research in the last five years, taking into account career disruption. Some examples of research impact may include:

- Development of new knowledge within an internationally recognised field of research.
- Improvement to health in the Australian population and/or Australia's Indigenous people.
- Improvement to health systems, services, policy, programs or clinical practice.
- Development of a service delivery or system change, prevention or intervention program, device, therapeutic or change in clinical practice.
- Change in policy that has impacted social well-being, equality or social inclusion or impacted the social well-being of the end-user, public and community.

E. Overall Value and Risk of your project

This Assessment Criterion is used to determine how well your project presents as an investment in the achievement of MRFF priorities, as well as that the application represents an efficient, effective, economical and ethical use of public resources. Your project should also thoroughly consider the risks associated in all aspects of the delivery of your project, and the impact of these risks. Your response to the criteria must consist of the following:

1. A Risk Management Plan (maximum one A4 page)

With reference to Assessment Criterion 4, please provide a Risk Management Plan (RMP) that addresses key risks in relation to your research project and how you propose to address, manage, mitigate, monitor and report those risks. Risk themes for consideration in developing your risk management plan are provided in the below table (the list is not exhaustive).

Risk Themes	Types of Risk
People	People capability Recruitment Project management Stakeholders Safety
Information	Intervention or procedures for gathering research data Data integrity / accuracy Data disclosure / unauthorised access
Governance	Accountability Assurance processes Litigation Reporting
Delivery	Scientific design /Research integrity Budget / financial Innovation Resources Project failure Performance measures Poor practice / incorrect analysis

Regulatory	Legislation Ethics Policy

STEP 1: Provide a tabulated list of the key risks in the following format:

Risk theme	Risk	How risk is mitigated / managed

STEP 2: You must also explain how you propose to monitor and report risks (both those identified in your submitted risk management plan and those which may arise during your project):

- describe your proposed approach for monitoring risks (e.g. timing of review, what risk ratings you propose to use in monitoring, whose responsibility)
- describe how you plan to report on risks (e.g. what you will report, what process, to who and at what point)

The RMP (incorporating **STEPS 1 and 2**) must be no longer than one A4 page in length.

F. References (maximum half an A4 page)

Provide a list of all references cited in the application using a recognised citation style. Only include references to cited work.

Submitting the application

Once all Profile details, application form details and PDF documents have been entered/uploaded into NHMRC's Granting System (Sapphire), the application can be certified and submitted.

Applications are first certified by the CIA, then by the Administering Institution. Please review the application to ensure it is accurate and complete and meets all eligibility requirements.

The CIA must provide the RAO with evidence that the application is complete. This written evidence should be retained by the Administering Institution and must be provided to us on request. The following assurances, acknowledgements and undertakings are required of the CIA prior to submitting an application:

- All required information has been provided and is complete, current and correct
- All eligibility and other application requirements have been met
- All personnel contributing to the research activity have familiarised themselves with the *Australian Code for the Responsible Conduct of Research*, the *National Statement of the Ethical Conduct of Human Research*, the *Australian Code for the Care and Use of Animals for Scientific Purposes* and other relevant NHMRC policies concerning the conduct of research, and agree to conduct themselves in accordance with those policies

- All personnel named in the application have provided written agreement to be named, to participate in the manner described in the application and to the use of their personal information as described in the *NHMRC Privacy Policy*
- All Chief Investigators have provided written agreement for the final application to be certified
- That the application may be excluded from consideration if found to be in breach of any requirements, in accordance with section 3.

and if funded,

- the research will be carried out in strict accordance with the Grant Guidelines and the funding agreement, and
- the research may be used to inform evaluations of the grant opportunity and the Program.

The following assurances, acknowledgements and undertakings are required of the Administering Institution prior to submitting an application:

- reasonable efforts have been made to ensure the application is complete and correct and complies with all eligibility and other application requirements detailed in the Grant Guidelines
- where the CIA is not an Australian citizen or permanent resident, they will have the requisite work visa in place at the time of accepting the successful grant and will be based in Australia for the duration of the funding period
- the appropriate facilities and salary support will be available for the funding period.
- approval of the Research Activity by relevant institutional committees and approval bodies, particularly in relation to ethics and biosafety, will be sought and obtained prior to the commencement of the research, or the parts of the research that require their approval
- arrangements for the management of the grant have been agreed between all institutions associated with the application
- the application is being submitted with the full authority of, and on behalf of, the Administering Institution, noting that under section 136.1 of *the Commonwealth Criminal Code Act 1995*, it is an offence to provide false or misleading information to a Commonwealth body in an application for a benefit. This includes submission of an application by those not authorised by the Institution to submit applications for funding to NHMRC
- written evidence of consent has been obtained from all CIs and AIs and provided to the RAO.

Administering Institutions must ensure that the RAO role is authorised to certify and submit applications. Once an application has been submitted and the application period has closed, the application is considered final and no changes may be made.

7. The grant selection process

7.1 Assessment of grant applications

NHMRC will assess the eligibility of your application at any stage following the close of applications. NHMRC may request further information in order to assess whether the eligibility requirements have

been met. Administering Institutions will be notified in writing of ineligible applications and are responsible for advising applicants.

If eligible, we will then assess your application on its merits, based on:

- how well it meets the assessment criteria
- whether it provides value with relevant money.[5]

Scoring of the technical (not-value for money) assessment criteria will be done in accordance with the Assessment Criteria Scoring Matrix provided with these guidelines. Rating of the non-technical (Value and Risk of your project Assessment Criterion will be done in accordance with the Rating Scale for Assessment Criterion: Overall Value and Risk of your project provided with these guidelines.

To be awarded MRFF funding applications must receive a rating of 4 or higher against each of the weighted technical assessment criteria (Criterion 1, 2 and 3), and a rating of 'Good' or 'Excellent' for the non-weighted assessment criterion.

When assessing the extent to which the application represents value with relevant money, we will have regard to:

- potential contribution to the achievement of outcomes of this grant opportunity and the MRFF, relative to the value of the grant amount sought, and
- the extent to which the evidence in the application demonstrates that it will contribute to meeting the outcomes/objectives.

7.2 Who will assess applications?

Applications will undergo rigorous peer review, whereby they are subject to scrutiny and evaluation by independent experts in the field(s) of the application; innovative research design; and/or research requiring multidisciplinary and novel methodology approaches. Assessors are required to declare material personal interests (financial or non-financial) and material personal associations in accordance with NHMRC policy on the declaration and management of conflicts of interest.

When developing your application, you should take into account the nature of peer review: assessors may draw as appropriate from the research literature and from their breadth of knowledge in the relevant discipline(s) and field(s). Issues not relevant to the assessment criteria are not to be considered.

Australian and/or international expert assessors will be selected taking into account the discipline(s) and field(s) of the research and other research keywords entered in NHMRC's Granting System (Sapphire). *Applicants should construct applications with the knowledge that the full application may be provided to Australian and international expert assessors.*

Expert assessors will be selected taking into account the discipline(s) and field(s) of the research and other research keywords entered in NHMRC's Granting System (Sapphire). Expert assessors will score your application against the technical assessment criteria (criteria one to three) and the non-technical assessment criteria. NHMRC may collate the scores against the technical assessment criteria provided by assessors to identify applications to be considered for funding and less meritorious

[5] See glossary for an explanation of 'value for money'.

applications to be removed from further consideration. A grant review panel may meet to discuss the applications and finalise assessment scores.

NHMRC may seek additional advice on any grant application.

NHMRC will forward the outcomes of the assessment process to the Department of Health. NHMRC may also provide copies of all application information to the Department of Health.

Applicants must not make contact about their application with anyone who is directly engaged with its peer review such as a member of the grant review panel. Doing so may constitute a breach of the *Australian Code for the Responsible Conduct of Research 2018* and result in the application being excluded from consideration.

7.3 Who will approve grants?

NHMRC will provide the outcomes of the assessment process to the Department of Health in the form of a ranked list. This information will consist of a weighted combined score against the technical assessment criteria and separate rating against the non-technical criteria. To be awarded MRFF funding applications must receive a score of 4 or higher against each of the weighted technical Assessment criteria (Criterion 1, 2 and 3) and a rating of 'Good' or 'Excellent' for the non-weighted assessment criterion Overall Value and Risk.

The Minister or his delegate (the Delegate) will approve grants drawing on the outcomes of NHMRC's assessment process. The Delegate may take into consideration applicant interests declared pursuant to section 12.1.

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

- the approval of the grant
- the grant funding amount to be awarded
- the terms and conditions of the grant.

The Delegate must not approve funding if it reasonably considers the program funding available across financial years will not accommodate the funding offer, and/or the application does not represent value for money.

Refer also section 12.6.

8. Notification of application outcomes

You will be advised of the outcome of your application by NHMRC via NHMRC's Granting System (Sapphire). If you are successful, you will also be advised about any specific conditions attached to the grant, including the timing of any public communications you make regarding being awarded a grant.

All applicants will be provided with feedback on the outcome of the application consisting of individual scores and an overall score against the technical assessment criteria, and a rating against the non-technical assessment criterion.

9. Successful grant applications

Successful applicants will be expected to contribute to peer review processes for future MRFF grant processes which require peer review assessment.

A grant cannot be provided to you if you receive funding from another government source for the same purpose. You can apply for grants under any Commonwealth program but, if your applications are successful, you must choose either the grant from this Program or the other Commonwealth grant.

Where you have submitted the same application to other grant opportunities and have received an offer of funding from one of these sources, the Administering Entity and the Department of Health reserve the right to withhold any further offer of funding for the application.

Where it appears that an applicant has submitted similar applications for research/project funding and has been successful with more than one application, the applicant is required to provide a written report clearly identifying the difference between the research/project aims of the two research activities. If the two research activities are not sufficiently different, an offer of funding for one of the applications may be withheld, or you will be required to decline or relinquish one of the grants.

9.1 The grant agreement

You must enter into a legally binding grant agreement with the Commonwealth. A sample grant agreement is available on the Administering Entity's website 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 Minister or their 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.

The offer may lapse if both parties do not sign the grant agreement within a specified time period. 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 Minister or the Delegate.

Where a grantee fails to meet the obligations of the grant agreement, the Commonwealth may suspend grant payments and take action to recover grant funds.

Your Administering Institution should not make financial commitments until a grant agreement and schedule has been executed by the Commonwealth and your Administering institution continues to meet its undertakings, including:

- where the CIA is not an Australian citizen or permanent resident, they will have the requisite work visa in place at the time of accepting the successful grant and be based in Australia for the duration of the funding period
- the appropriate facilities and salary support are available for the funding period
- approval of the Research Activity by relevant institutional committees and approval bodies, particularly in relation to ethics and biosafety, will be sought and obtained prior to the commencement of the research, or the parts of the research that require their approval, and
- arrangements for the management of the grant have been agreed between all institutions associated with the research.

If the above undertakings are not being met your RAO must notify NHMRC. Payment of the grant may be suspended until NHMRC and the Department of Health has considered a request from your RAO to vary the grant conditions.

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 but within the maximum year period as specified in your proposal, and
- 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. We can provide you with advice on how to make your request.

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, and
- 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 any specific legislation/policies/industry standards within the grant funding agreement, such as:

- The MRFF Act [1]
- Working with Vulnerable People registration
- State/Territory legislation in relation to working with children
- Ethics and research practices.

9.4 How we pay the grant

The grant agreement will state the:

- grant amount approved by the Commonwealth
- the proportion of the approved grant amount that will be paid in each calendar year during the term of the grant.

Expenditure against approved activities will be monitored over the duration of the funding period. Grant funding will be dependent on meeting any conditions and agreed milestones.

Timing of grant payments will be detailed in the schedule to the funding agreement. Your Administering Institution is responsible for paying any extra eligible expenses that are incurred.

9.5 Grant payments and GST

All amounts referred to in these Grant Guidelines are exclusive of GST, unless stated otherwise. Administering Institutions are responsible for all financial and taxation implications associated with receiving funds.

Payments will depend on satisfactory progress being made against milestones and performance indicators. The Commonwealth will review your progress reports to confirm that the milestones and performance indicators have been achieved. Where milestones and performance indicators have not been achieved grant payments may be suspended.

10. Announcement of grants

If successful, your grant will be listed on the GrantConnect website 21 days after the date of effect[6] as required by Section 5.3 of the *Commonwealth Grants Rules and Guidelines*. The following information may also be published in a manner that allows it to be searched and viewed in a variety of ways:

- Application identity number
- Chief Investigator name/s
- Administering Institution
- Scientific title
- Broad Research Area
- Funding partners (if relevant)
- Approved grant amount and duration, and
- The plain English summary (or a part thereof).

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[1] https://www.legislation.gov.au/Details/C2015A00116

[6] See glossary

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.

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, and
- 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

Your Administering Institution is required to report to NHMRC on the progress of the grant and the use of grant funds. Where an institution fails to submit reports (financial or otherwise) as required, the Commonwealth may take action under the provisions of the funding agreement. Failure to report within timeframes may affect eligibility to receive future funding.

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
- risks arising during your project
- project expenditure, including expenditure of grant funds, and
- contributions of participants directly related to the project.

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.

11.3 Progress reports

Progress reports must:

- include details of your progress towards completion of agreed project activities, including any risks arising and how these are being managed to ensure project outcomes
- show the total eligible expenditure incurred to date

- include evidence of expenditure
- be submitted by the report due date (you can submit reports ahead of time if you have completed relevant project activities), and
- 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.

11.4 End of project report

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

End of project reports must:

- include the agreed evidence as specified in the grant agreement (including, but not limited to, evidence of project impact)
- identify the total eligible expenditure incurred for the project
- 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, and
- include information about your project that supports evaluation of the MRFF.

11.5 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.

11.6 Annual Financial Reports

Annual financial reports are required in a form prescribed by the Commonwealth. At the completion of the grant, a financial acquittal is also required.

11.7 Registration of clinical trials

Clinical trials supported through MRFF grant opportunities must be registered in the Australian New Zealand Clinical Trials Registry (ANZCTR) prior to commencement of the clinical phase. Information on how to register your clinical trial is available at www.anzctr.org.au.

11.8 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.

11.9 Compliance visits

We may visit you during the project period, 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.

11.10 Dissemination of research outcomes

Administering Institutions and Chief Investigators must ensure appropriate safeguards are in place to protect patient privacy, intellectual property and commercially confidential information.

Except where publication may compromise the Administering Institution's 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, and
  - 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 activity in an open access repository and in accordance with best practice.

11.11 Evaluation

We will evaluate the grant to measure how well the outcomes and objectives have been achieved. Your grant agreement requires you to provide information to help with this evaluation. 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.

11.12 Grant acknowledgement

If you make a public statement about a project funded under the program, 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.

Your declaration of applicant interests will take the form of a single PDF file that complies with the *Formatting requirements for the Grant Proposal* specified in section 6.4.

The declaration should be uploaded into NHMRC's Granting System (Sapphire).

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 Public Service Code of Conduct (Section 13(7))* of *the Public Service Act 1999* (Cth). Committee members and other officials including the decision maker must also declare any conflicts of interest.

12.2 Privacy: confidentiality and protection of personal information

NHMRC is the Administering Entity for this grant opportunity. NHMRC will receive and assess applications. NHMRC will forward all application material and assessment scores to the Department of Health.

The Privacy Act 1988 (Privacy Act) requires entities bound by *the Australian Privacy Principles to have a privacy policy*. NHMRC's *Privacy Policy* is available on our website at: www.nhmrc.gov.au/privacy. Our privacy policy outlines the personal information handling practices at the NHMRC.

NHMRC may disclose your personal information to assessors from overseas countries, where there is a need, and in accordance with *the Privacy Act* and the NHMRC's *Privacy Policy*. NHMRC's Granting System (Sapphire) will prompt you with a notice that seeks your consent to overseas disclosures.

Applicants are required by the grant agreement to comply with the *Privacy Act 1988*, including *the Australian Privacy Principles*, and impose the same privacy obligations on any subcontractors engaged by the applicant to assist with the activity.

NHMRC may share information provided to it by applicants with other Commonwealth agencies for any purposes including government administration, research or service delivery and according to Australian laws, including the *Public Service Act 1999*, *Public Service Regulations 1999*, *Public Governance, Performance and Accountability Act 2013*, *Crimes Act 1914*, and the *Criminal Code Act 1995*.

12.3 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, or
- 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.

12.4 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.

All Freedom of Information requests must be referred to the Freedom of Information Coordinator in writing.

By mail: Freedom of Information Coordinator

National Health and Medical Research Council

GPO Box 1421

CANBERRA ACT 2601

By email: foi@nhmrc.gov.au

12.5 Enquiries and feedback

All applicants will be provided with feedback on the outcome of the application consisting of individual scores and an overall score against the assessment criteria.

12.6 Complaints in relation to funding outcomes

Applicants or grantees seeking to lodge a formal complaint about NHMRC's assessment process should do so via the Administering Institution's RAO, in writing, within 28 days of the relevant decision or action.

Each complaint should be directed to the Complaints Team at: complaints@nhmrc.gov.au. NHMRC will provide a written response to all complaints.

If you do not agree with the way NHMRC has handled your complaint, you may complain to the Commonwealth Ombudsman. The Ombudsman will not usually look into a complaint unless the matter has first been raised directly with NHMRC.

The Commonwealth Ombudsman can be contacted on:

Phone (Toll free): 1300 362 072
Email: ombudsman@ombudsman.gov.au
Website: 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 of all of the grant administration processes.
Application form	The document or computerised submission system that applicants use to apply for funding under the program/grant opportunity.
Assessment criteria	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.
Assessment Criterion 4 - Value and Risk Rating Scale	A document accompanying the Grant Guidelines that provides example benchmarks against Assessment Criteria 4 – *Value and Risk* to assist reviewers when scoring applications.
Commencement date	The expected start date for the grant activity.
Commonwealth entity	A Department of State, or a Parliamentary Department, or a listed entity or a body corporate established by a law of the Commonwealth. See subsections 10(1) and (2) of the PGPA Act.
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 that the grant activity must be completed and the grant spent by.

Term	Definition
Date of effect	Can be the date on which a grant agreement is signed or a specified starting date. Where there is no grant agreement, entities must publish information on individual grants as soon as practicable.
Decision maker	The person who makes a decision to award a grant.
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 section 4.
Eligible application	An application or proposal for services or grant funding under the program that 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 section 4.
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.
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.
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.
Minister	The Australian Government Minister for Health.

Term	Definition
Personal information	Has the same meaning as in the *Privacy Act 1988* (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.
Program Delegate	An Australian Government official in the Department of Health or the NHMRC with responsibility for the grant opportunity.
Project	A project described in an application for grant funding under this grant opportunity.
Selection process	The method used to select potential grantees. This process may involve comparative assessment of applications or the assessment of applications against the eligibility criteria and/or the assessment criteria.
Value with money	Value with 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.