Australian Government
National Health and Medical Research Council

Medical Research Future Fund

Medical Research Future Fund – European Joint Programme on Rare Diseases

2022 MRFF Joint Transnational Call Grant Opportunity Guidelines

Opening date:	**1 December 2022**
Application closing date and time:	**5pm ACT local time** on **15 February 2023**
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 Eligible Organisation'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 **Wednesday 9 February 2023**.
Date guidelines released:	**20 December 2021**
Type of grant opportunity:	**Targeted competitive**

Contents

Medical Research Future Fund (MRFF) European Joint Programme on Rare Diseases (EJP RD) 2022 MRFF Joint Transnational Call Grant Opportunity process

The Medical Research Future Fund - European Joint Programme on Rare Diseases (EJP RD) 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 Joint Call Secretariat opens the call along with Partner Organisations

Topics selected for co-funding are advertised for joint submissions by Australian researchers and committed partners through the European Joint Programme on Rare Diseases (EJP RD) website.

NHMRC publishes the notification via alerts to Research Administration Officers (RAO) or equivalent, the NHMRC Tracker and as a Forecast Opportunity on GrantConnect.

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You complete and submit a pre-proposal to the EJP RD

You complete the form using the templates provided on the EJP RD website and submit it via their electronic submission system.

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Pre-proposals are assessed

The Joint Call Secretariat (JCS) and Call Steering Committee (CSC) members review all pre-proposals against the eligibility criteria.

Pre-proposals are then assigned to Scientific Evaluation Committee (SEC) members, who evaluate and rank the pre-proposals. The top ranked pre-proposals are invited to submit a full application to the EJP RD.

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You complete and submit an application to the EJP RD

You complete the application form using the templates provided on the EJP RD website and submit it via their electronic submission system.

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Applications to the EJP RD are assessed

Your application is assigned to external scientific reviewers to undertake in-depth assessments. You will have an opportunity to respond to the external scientific reviewers' written comments through a rebuttal.

The SEC then assesses eligible applications against the assessment criteria and ranks the applications.

The CSC makes a final recommendation on the applications it considers fundable, based on the final ranking list provided by the SEC.

The JCS notifies the Project Lead/Coordinator if their application is considered fundable.

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Your organisation registers to become an MRFF Eligible Organisation

If your organisation is not already an MRFF Eligible Organisation (i.e. approved to submit MRFF grant applications and receive MRFF funding through NHMRC), your organisation should check its eligibility and then submit an MRFF Eligible Organisation certification form. The form is available on the

NHMRC website. A list of existing, already approved Eligible Organisations is also available on NHMRC's website.

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The MRFF grant opportunity opens

We publish the grant guidelines on GrantConnect.

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You complete and submit an MRFF grant application

You complete the application form for the MRFF grant opportunity in the NHMRC's Granting System (Sapphire). Your application must address all of the eligibility criteria to be considered for a grant. Your Eligible Organisation's Research Administration Officer (RAO) then certifies and submits the application form.

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We review all MRFF grant applications

We review all applications against the eligibility criteria and also review the proposed budget.

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We make grant recommendations

We provide advice to the decision maker.

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Grant decisions are made

The decision maker decides which MRFF grant applications are successful.

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We notify you of the outcome

We advise you of the outcome of your MRFF grant application via Sapphire.

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We enter into a grant agreement

We will enter into a grant agreement with the Eligible Organisation through which you applied, if your grant application is 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 through the relevant Eligible Organisation. We monitor your progress and make 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. The MRFF reached maturity at $20 billion in July 2020. The MRFF provides a long-term sustainable source of funding for endeavours that aim to improve health outcomes, quality of life and health system sustainability.

This MRFF investment is guided by the *Australian Medical Research and Innovation Strategy 2016-2021* (the Strategy) and related set of *Australian Medical Research and Innovation Priorities 2020-2022* (the Priorities), developed by the independent and expert Australian Medical Research Advisory Board following extensive national public consultation.

In the 2019-20 Budget, the Government announced its continued commitment to supporting lifesaving medical research with a $5 billion 10-year investment plan for 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 Emerging Priorities and Consumer Driven Research Initiative

The Emerging Priorities and Consumer Driven Research Initiative (the Initiative) forms part of the MRFF. The Australian Government has announced a total of $633.0 million over 10 years from 2018-19 for the Initiative.

This initiative aims to enable or support:

- high quality biomedical, clinical, health services and/or population health research that improves patient care
- translation of new discoveries into clinical practice
- new diagnoses, treatments and cures for those suffering from rare and debilitating conditions
- joint collaboration of consumers and researchers in undertaking research in emerging priority areas, and
- many Australians with debilitating conditions.

Further information on the rationale of the Emerging Priorities and Consumer Driven Research Initiative is available on the Department of Health website.

The MRFF Monitoring, Evaluation and Learning Strategy (the Evaluation Strategy) provides an overarching framework for assessing the performance of the MRFF and is publicly available on the MRFF website.

Applications considered fundable by the Call Steering Committee (CSC) are expected in their MRFF application to describe how their proposed project aligns with the Measures of Success as described in the Evaluation Strategy. Projects funded from this grant opportunity will be monitored against the Evaluation Strategy.

For further details see sections 5 and 6.

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

1.3 About the 2022 MRFF Joint Transnational Call Grant Opportunity

The European Joint Programme on Rare Diseases (EJP RD) brings over 130 institutions from 35 countries together to create a comprehensive, sustainable ecosystem allowing a virtuous circle between research, care and medical innovation.

As part of the EJP RD, international organisations have joined forces to carry out a joint call for proposals for transnational cooperative research projects in the field of rare diseases. The list of participating funding organisations is listed on the EJP RD website.

The joint call is published at the same time by the funding organisations in the respective countries and coordinated centrally by a Joint Call Secretariat (JCS). The JCS is based at the Institut of Health Carlos III (ISCIII, Spain). The respective national guidelines apply to the actual implementation of the national sub-projects.

These guidelines contain information for the 2022 MRFF Joint Transnational Call Grant Opportunity.

The objective and intended outcome of this grant opportunity are aligned with the following *Australian Medical Research and Innovation Priorities 2020-2022*:

- Digital health intelligence
- Consumer-driven research.

Consistent with the *Medical Research Future Fund Act 2015*, the objectives of this grant opportunity are to provide grants of financial assistance to support Australian medical research and medical innovation projects that develop new analytic tools and pathways to accelerate diagnosis and diagnostic monitoring (including undiagnosed cases) of rare diseases.

Research proposals should focus on least one of the following:

- Phenotype-driven diagnosis: integration across different ontologies, integration of shared pathways, digital phenotyping, development of artificial intelligence approaches/applications to extract health related data in aid of diagnosis
- Prognostic markers/biomarkers investigations for early diagnosis and monitoring
- Methodologies for solving cases that are currently difficult to analyse due to different underlying mechanisms (e.g. mosaicism, genomic (non-coding) alterations, gene regulation, complex inheritance), including new genomics/functional genomics technologies, multi-omics, mathematics, biostatistics, bioinformatics and artificial intelligence approaches
- Functional strategies to globally stratify variants of unknown significance (VUS) for clinical use, setting up of (in vitro) systems to distinguish between VUS and pathogenic variants (e.g. confirming disruption of splicing for deep intronic variants, loss of protein function, and gain of toxic protein function)
- Development of pathway models to enable diagnosis, especially for newly discovered diseases that may share underlying molecular mechanisms with already known diseases.

To be competitive for funding, applicants must propose to conduct research that delivers against the above objective.

The intended outcome of the research funded by this grant opportunity is to improve the health and wellbeing of Australians by improving diagnosis and providing better treatment options for those with a rare disease.

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.

Impact of COVID-19

The MRFF acknowledges the potential impacts of COVID-19 on the health and medical research sector, including the ability of researchers to submit applications and undertake research. You will be asked to consider these impacts in your risk management plan (refer section 6.4).

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. Partnerships are also encouraged to ensure the proposed research is of relevance to consumers and delivery of services, and to support translation of research outcomes into practice.

Partner organisations include:

- medical research institutes, i.e. organisations that have conducting medical research as a primary purpose, and which are also registered with the Australian Charities and Not-for-Profits Commission
- universities
- corporate Commonwealth entities, i.e. Commonwealth entities that are bodies corporate
- corporations, i.e. Australian public companies, Australian private companies and other incorporated entities
- 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
- non-government organisations and charities
- community organisations such as consumer groups
- healthcare providers, and/or
- professional groups.

In some instances, a body of a type listed above may be eligible to apply for MRFF funding in its own right, for example in the case of commercial entities or non-government organisations that are corporations. The above list recognises the desirability of entering into partnerships as a means of advancing the outcomes of the MRFF and is not intended to imply that the types of bodies listed are ineligible to seek MRFF funding.

While partnerships are encouraged, they may not necessarily be relevant for all projects.

2. Grant amount and grant period

2.1 Grants available

The Australian Government has announced a total of $633.0 million for the Emerging Priorities and Consumer Driven Research Initiative. For this grant opportunity, up to $1.0 million of funding is available in 2022-23 to support the Australian component of the research.

The MRFF will only fund the Australian components of the project. The MRFF will not fund any components of the project that are undertaken by collaborative partners; these must be funded by other participating funding countries.

Grant funds will be provided to the Eligible Organisation according to the funding profile indicated in Table 1; however, grant funds can be expended across the life of the project (project period). See below and section 2.2.

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

There is no minimum grant amount, and the maximum amount available for a single grant is $300,000.

Table 1. Funding profile over the grant period ($ million - GST exclusive)

2022-23	2023-24	2024-25
1.0	Nil	Nil

2.2 Project period

The maximum project period is three years.

3. Eligibility criteria

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

3.1 Who is eligible?

To be eligible:

- the CSC must have made a recommendation that your application is considered fundable.
- you must submit your application via an NHMRC approved MRFF Eligible Organisation.

  Information on becoming an MRFF Eligible Organisations can be found at https://www.nhmrc.gov.au/funding/manahe-your-funding/mrff-eligible-organisations.
  This eligibility criterion derives from provisions set out in section 24 of the MRFF Act and cannot be waived.

3.2 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.

To facilitate collaborative research teams with the required capacity and capability to undertake the proposed research, up to 15 CIs may be included as members of the Australian-based 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 the 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 CI but cannot be listed as CIA.

See also section 6.

3.3 Additional eligibility requirements

Your application may 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 Sapphire by the RAO of an approved MRFF Eligible Organisation by the advertised closing date and time
- 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 sections 4.7 and 7.2)
- 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 Eligible Organisation's RAO in writing. The Eligible Organisation's RAO is responsible for advising applicants of the decision in writing.

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 the objectives of the 2022 MRFF Joint Transnational Call Grant Opportunity under Section 1.3. You can only spend grant funds to pursue the research activities described in your application to the Joint 2022 Transnational Call Grant Opportunity.

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 review process (refer Section 7).

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 organisation.

For each item of equipment requested, a written quotation must be received and held with the Eligible Organisation submitting the application, to be available to the Australian Government on request.

The Eligible Organisation 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 (CIs and Professional Research Persons) 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.

Table 2. Personnel Support Packages

Personnel Support Packages – for funding commencing in 2022*		
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	58,373
PSP2	Junior graduate research assistant; or junior graduate nurse, midwife or allied health professional; or junior data manager/data analyst	72,888

Personnel Support Packages – for funding commencing in 2022*		
Level	**Description**	**$ per annum**
PSP3	Experienced graduate research assistant/junior postdoctoral research officer; or experienced graduate nurse, midwife or allied health professional; or experienced data manager/analyst	80,148
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)	94,666
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.	101,924

*The indicated PSPs are for funding commencing in 2021-2022; amounts may change for grants commencing in 2022-23.

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 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. Up to 10 AIs may be named in an application.

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. DRCs may include the following:

- personnel costs related to contract staff and limited external persons (not for Chief Investigators or additional personnel). The basis for the 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 organisational 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 section. If you are still unsure, clarification should be sought from NHMRC. DRCs 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. 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 https://www.dese.gov.au/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 information on 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, tradesperson), 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 with 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

The MRFF will only fund Australian components of the project. The MRFF will not fund any components of the project that are undertaken by collaborative partners; these must be funded by other participating funding countries.

Indirect costs of research

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

Indirect costs of research are Organisation 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
- organisational overheads and administrative costs
- non-project related staff training and development
- overseas travel (except as provided for in section 4.6)
- 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 Organisation 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 withdrawn at the discretion of the Minister or their delegate, or you will be required to decline or relinquish one of the grants. See section 9.

5. The assessment criteria

The SEC will assess all eligible pre-proposals and full applications to the EJP RD based on the assessment criteria as outlined in the Call text available on the EJP RD website. There are no additional assessment criteria for applications submitted to this grant opportunity. Applications will be assessed against the eligibility criteria only (see section 3).

The requested budget for the Australian component of eligible applications will be reviewed by the Office of NHMRC as described in section 7.

6. How to apply

This section describes the process for submitting an MRFF grant application via Sapphire. To submit an MRFF grant application, your application must be eligible as described in section 3.

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 Sapphire. Electronic submission requires the Eligible Organisation and Chief Investigators on an application to register for an account.

If an organisation wishing to apply is not yet an approved MRFF Eligible Organisation, the organisation must complete an Eligible Organisation certification form and receive approval before the organisation will receive a Sapphire account. Information about becoming an MRFF Eligible Organisation and a list of already approved MRFF Eligible Organisations is available on the NHMRC website. If your organisation does not meet the eligibility criteria, your organisation may wish to partner with an MRFF Eligible Organisation to receive funding. See section 3.1.

Applicants who are not registered in 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 MRFF grant application will consist of:

- the original application submitted to the JCS
- a copy of the letter from the JCS advising that the application is considered fundable
- a detailed description of the Australian component of the budget
- a risk management plan
- a Measures of Success Statement
- Letters of support from Partner Organisations.

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

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 organisation that will administer your application may differ from the organisation 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 organisations in your application and specify the percentage of the research effort being undertaken in the departments within these organisations.

Prior to submission your Eligible Organisation's RAO is required to assure us that arrangements for the management of the grant have been agreed between all organisations 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 close date and time. Requests will only be considered for:

- unforeseen circumstances, e.g. natural calamities such as bushfires, floods or cyclones, 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[1], 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 assessment 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 and must not extend beyond the grant period.

If the organisation you wish to apply through is not yet an approved Eligible Organisation, it is important that the organisation submits their Eligible Organisation certification form as soon as possible, so there is enough time for the certification form to be reviewed, and if approved, enough time for Eligible Organisation set up in Sapphire before the application close date.

Table 3. Expected timing for this grant opportunity

Activity	Timeframe
MRFF grant applications open	1 December 2022
MRFF grant applications close	5pm ACT local time on 15 February 2023
Review of MRFF grant applications	March 2023
Approval of outcomes	April 2023
Announcement of outcomes	April 2023
Notification to unsuccessful applicants	On announcement
Acceptance of grant offer	Within one month of formal offers
Activity commences	Within a reasonable time frame following execution of the grant agreement
End date	Within 3 years of execution of the grant agreement.

6.3 Questions during the application process

Questions about the review of applications by the SEC should be directed to the contacts listed in the 2022 MRFF Joint Transnational Call documents published on the EJP RD website.

Applicants requiring further assistance should direct enquiries to their Eligible Organisation's Research Administration Officer. Research Administration Officers can contact NHMRC's Research Help Centre for further advice regarding the MRFF aspect of the 2022 MRFF Joint Transnational Call Grant Opportunity:

[1] 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).

Phone: 1800 500 983

Email: help@nhmrc.gov.au

NHMRC will not respond to any enquiries submitted after the date and time indicated on the cover page of these grant guidelines.

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

6.4 Completing the grant application

Using Sapphire

Applications must be submitted electronically using Sapphire. Electronic submission requires approved Eligible Organisations 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 Sapphire

Applicants must create a new application for this grant opportunity in Sapphire.

The application should contain all the required information to be eligible for review.

The 2022 MRFF Joint Transnational Call application

You will upload your 2022 MRFF Joint Transnational Call application into Sapphire as a PDF file.

Table 4. Formatting Requirements for the 2022 MRFF Joint Transnational Call application

Formatting Requirements for the application	
File format	The application 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: *CIA Surname_ grant opportunity name_document type.pdf* e.g. Smith_2022 MRFF Joint Transnational Call application.pdf
Page size	A4
Header	Application ID and CIA surname must be included in the header
Language	English

Applications that fail to comply with the formatting requirements or the specified page limits may be excluded from consideration. Applicants and Eligible Organisations 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.

Letter from the Joint Call Secretariat

A letter from the JCS advising the outcome of your application to the EJP RD must be included as part of your MRFF grant application. You will upload the letter into Sapphire as a PDF file. The file name must be named as follows:
CIA Surname_ 2022 MRFF Joint Transnational Call_document type.pdf

Direct Research Costs

Enter details of the proposed research budget into 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 section 4. All components of your budget requests are to be included in 'Direct Research Costs'.

Requests for Equipment, PSPs and DRCs must be included in your budget. For each item 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 within 'Other Research Costs' in 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 Sapphire in 'Third Party Research Facilities'.

Risk Management Plan (maximum two A4 pages)

Please provide a Risk Management Plan that addresses key risks in relation to your research project and how you propose to address, manage, mitigate, monitor and report those risks including risks related to COVID-19 restrictions. 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 risk management plan (incorporating **STEPS 1 and 2**) must be no longer than two A4 pages in length. You will upload your letter into Sapphire as a PDF file. The file name must be named as follows: *CIA Surname_ 2022 MRFF Joint Transnational Call_document type.pdf*

Measures of Success statement (maximum one A4 page)

This statement will be used to evaluate the extent to which your project will contribute to the Measures of Success for the MRFF as described in the Evaluation Strategy, taking into consideration the objectives and outcomes of the EPCDR Initiative in progress reports. Your response must provide a tabulated description of how the research activities will contribute to one or more of the Measures of Success described in the Evaluation Strategy and appropriate outcome/s or result/s against which your progress will be evaluated in the following format:

Measure of success	How the project will contribute towards the measure of success	Description of outcome or result against which the contribution will be evaluated

The statement must be no longer than one A4 page in length. Grantees will be required to report against the outcome/s or result/s at twelve month intervals. You will upload your letter into Sapphire as a PDF file. The file name must be named as follows:

CIA Surname_ 2022 MRFF Joint Transnational Call_document type.pdf

Submitting the application

Prior to submitting the application the CIA and RAO must ensure that:

- all CIs have provided written agreement to the CIA for the final application to be certified
- all personnel have provided written agreement to their being named in the application, to participate in the manner described in the application and to the use of their personal information as described in the *NHMRC Privacy Policy*.

Once all PDF documents and the budget have been entered/uploaded into Sapphire, the application can be certified and submitted.

Certification is required of both the CIA and Eligible Organisation. 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 Eligible Organisation 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
- 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, 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 Eligible Organisation 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 organisational 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 organisations associated with the application
- the application is being submitted with the full authority of, and on behalf of, the Eligible Organisation, 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 Eligible Organisation to submit applications for funding to NHMRC.

The Eligible Organisation's RAO must 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.

Letters of support from Partner Organisations

Information on any partner organisation(s) contributing to your proposal must be entered into the 'Partner Organisations' section within the application form in Sapphire. Provide the name and address of the partner organisation and the details of an authorised officer within the organisation. The authorised officer must be a person occupying a position with responsibility for the Partner's participation in the research who has the authorisation to expend the partner's money or resources.

A letter of support should be uploaded for each partner organisation listed in section 6.4. The letter must be on the partner organisation's letterhead and be signed by the authorised officer (see above). Please note that applicants should not sign the letter of support unless they are a representative of the partner organisation and have the authorisation to expend the partner's money or resources.

Each letter of support should be no more than two A4 pages in length and must include:

- application number and title
- a brief description of the partner organisation
- the authorised officer's role within the organisation
- the organisation's lead researcher for the study (name, position held and a brief background)
- information on the financial and/or in-kind support for the proposed research that are the responsibility of the partner organisation
- consent for the Australian Government to identify the partner organisation in media releases, on websites and in future grant opportunity documentation
- a weblink to the partner organisation's most recent annual report - the full URL must be provided and the style must allow identification from a printed version of the application.

Letters of support should comply with the formatting requirements for the Grant Proposal (see section 6.4) with exceptions to provide for the use of organisational letterheads and a weblink to the

annual report. It is important that the title of the file is in the following format: *CIA Surname_grant opportunity name_LoS_organisation name (or acronym).pdf*

7. The grant selection process

7.1 Assessment of grant applications

All applications to this grant opportunity must have been previously submitted and assessed by the SEC through a competitive grant process managed by the JCS. For further details on the eligibility requirements and assessment criteria for that process please visit the EJP RD website.

Under this grant opportunity, NHMRC will assess the eligibility of your MRFF grant 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. Eligible Organisations will be notified in writing of ineligible applications and are responsible for advising applicants.

- If eligible, we will then review your application on its merits, based on whether it provides value with relevant money.[2]
- When assessing the extent to which the application represents value with relevant money, we will have regard to the potential contribution to the achievement of outcomes of this grant opportunity and the MRFF, relative to the value of the grant amount sought.

7.2 Who will assess applications?

NHMRC will undertake administrative review processes to ensure relevant applications meet MRFF-specific eligibility requirements and budgetary limits. NHMRC internally reviews the budget requested to fund the Australian-based part of the project, considering the extent to which applications represent value for money.

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 assessment such as a member of the grant assessment committee. 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 review process to the Department of Health.

The Minister or their Delegate (the Delegate) will approve grants drawing on the outcomes of NHMRC's review process.

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

- the approval of the grant
- the grant funding amount to be awarded

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

- 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 with 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 Grant Management System. 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.

9. Successful grant applications

Successful applicants are expected to contribute to assessment processes for future MRFF grant opportunities which require expert 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 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/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 withdrawn at the discretion of the Minister or their delegate, or you will be required to decline or relinquish one of the grants.

9.1 The grant agreement

Your Eligible Organisation must enter into a legally binding grant agreement with the Commonwealth. A sample grant agreement is available on the NHMRC's website.

We must execute a grant agreement with the Eligible Organisation before we can make any payments. Execute means both the Eligible Organisation 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 the Eligible Organisation enters 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.

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 Eligible Organisation should not make financial commitments until a grant agreement and schedule has been executed by the Commonwealth and your Eligible Organisation 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 organisational 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 organisations associated with the research.

If the above undertakings are not being met your Eligible Organisation must notify NHMRC. Payment of the grant may be suspended until NHMRC and the Department of Health has considered a request from your Eligible Organisation 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
- 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 schedule to 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 financial year during the term of the grant.

Your Eligible Organisation is responsible for paying any extra eligible expenses that are incurred.

All amounts referred to in these grant guidelines are exclusive of GST, unless stated otherwise. Eligible Organisations 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.

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.

10. Announcement of grants

If successful, your grant will be listed on the GrantConnect website 21 days after the date of effect[3] 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
- Eligible Organisation

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

[3] See glossary

- Scientific title
- Broad Research Area
- Funding Partners (if relevant), and
- Approved grant amount and duration..

11. How we monitor your grant activity

11.1 Keeping us informed

Your Eligible Organisation's RAO 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.

Your RAO 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.

Your Eligible Organisation 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 Eligible Organisation is required to report to NHMRC on the progress of the grant and the use of grant funds. Where an organisation 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 and MRFF Measures of Success
- risks arising during your project
- project expenditure, including expenditure of grant funds, and
- information about your project that supports evaluation of the MRFF.

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

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

11.3 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
- a description of the overall progress on the joint project with international collaborative partners
- include evidence to demonstrate progress against the outcome/s and result/s identified in your Measures of Success statement (see section 6.4)
- show the total 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 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.

11.5 End of project report

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

End of project reports must:

- include evidence of completion of agreed project activities as specified in the grant agreement (including, but not limited to, evidence of project impact)
- include evidence to support achievement of the outcome/s and result/s identified in your Measures of Success statement (see section 6.4)
- identify the total 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.

11.6 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.

11.7 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

Eligible Organisations 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 Eligible Organisation'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 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.

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 review 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.

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
- 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
    - 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 Complaints in relation to funding outcomes

Applicants or grantees seeking to lodge a formal complaint about NHMRC's review process should do so via the Eligible Organisation'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

Complaints regarding the assessment process managed by the EJP RD must be directed to the JCS. See the EJP RD website for details.

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.
Call Steering Committee (CSC)	The steering group is composed of a single representative from each country/region funding organisation that joins the JTC2022. The CSC will supervise the progress of the call and the evaluation of proposals. The CSC will make the final funding recommendation to the national/regional funding organisations on the proposals to be funded, based on the final ranking list provided by the SEC. All decisions concerning the call procedures will be taken by the CSC
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 by which the grant activity must be completed and the grant spent.
Date of effect	Can be the date on which a grant agreement is signed or a specified starting date. 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.

Term	Definition
European Joint Programme on Rare Diseases (EJP RD) website	www.ejprarediseases.org
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.
Eligible Organisation	An organisation that meets the eligibility requirements for receiving and administering MRFF funding and has been approved as an MRFF Eligible Organisation by NHMRC.
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	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.
Joint Call Secretariat (JCS)	The National Institute of Health Carlos III (ISCIII), Spain are administering the Call on behalf of the Partner Organisations.
Minister	The Australian Government Minister for Health and Aged Care.

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.
Research Administration Officer	The officer nominated by an Eligible Organisation as its contact person for the purpose of grant applications and grant agreements.
Scientific Evaluation Committee (SEC)	A panel of internationally recognised, independent, scientific experts responsible for the evaluation of submitted proposals. SEC members must sign a confidentiality form and a statement to confirm that they do not have any conflicts of interest
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.
Sapphire	NHMRC's online granting system.

Term	Definition
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.