Medical Research Future Fund - Clinical Trials Activity

Rare Cancers, Rare Diseases and Unmet Need Grant Opportunity

Opening date: Monday 25 June 2018
Closing date for minimum data: 5pm AEST on Wednesday 1 August 2018
Application closing date and time: 5pm AEST on Wednesday 15 August 2018
Commonwealth policy entity: Australian Government Department of Health
Co-Sponsoring Entity: National Health and Medical Research Council
Enquiries: If you have any questions, please contact NHMRC’s Research Help Centre:

P: 1800 500 983 (+61 2 6217 9451 for international callers)
E: help@nhmrc.gov.au

Date guidelines released: 25 June 2018
Type of grant opportunity: Restricted competitive
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1. Rare Cancers, Rare Diseases and Unmet Need Grant Opportunity

The Australian Government approves funding from the Medical Research Future Fund for this Grant Program

The Program was announced on Wednesday 24 January 2018 as part of disbursements under the Medical Research Future Fund (MRFF).

The MRFF Clinical Trials Activity: Rare Cancers, Rare Diseases and Unmet Need Program is designed to achieve Australian Government objectives.

The grant opportunity is part of the Australian Government Department of Health Portfolio Budget Statement Outcome 1. The Department works with stakeholders to plan and design the grant opportunity.

Associated with this grant opportunity is the call for applications to support brain cancer clinical trials through the Government’s Australian Brain Cancer Mission.

The National Health and Medical Research Council (NHMRC) develops the grant guidelines

NHMRC plans and designs the grant opportunity according to the Commonwealth Grants Rules and Guidelines in consultation with the Department of Health.

The call for applications opens

NHMRC publishes the grant guidelines and advertises on GrantConnect.

You complete a grant application using NHMRC’s Research Grants Management System (RGMS)

Your institution’s Research Administration Office (RAO) will submit the application to NHMRC on behalf of your Administering Institution.

NHMRC assesses all grant applications

NHMRC assesses the applications against eligibility criteria and notifies you if you are not eligible. NHMRC then assesses your application against the assessment criteria. The proposed budget is scrutinised to ensure value for money.
Grant recommendations are made
NHMRC advises the Minister or their delegate of the outcome of its assessment of applications and makes recommendations on applications to receive funding.

NHMRC advises Cancer Australia of the outcome of its assessment of applications for the Australian Brain Cancer Mission. Cancer Australia makes recommendations to the Minister or their delegate on applications to receive funding.

Grant decisions are made
The Commonwealth decides which grant applications are successful.

NHMRC or Cancer Australia notify you of the outcome
NHMRC advises you of the outcome of your application via RGMS.

Cancer Australia advises you of the outcome of your application to the Australian Brain Cancer Mission via email.

NHMRC or Cancer Australia makes a grant offer to your research institution on behalf of the Department of Health
Your Administering Institution’s Authorised Officer will accept the grant offer on behalf of your Administering Institution.

Delivery of grant
You undertake the grant activity as set out in your Research Proposal and provide progress reports every twelve months against Milestones and Performance Indicators. The grant will be managed by monitoring your progress and making payments.

Evaluation of the Program
The Department of Health evaluates the grant opportunity and the Program. This evaluation is based on information you provide and that is collected from various sources.
1.1 About the Grant Program

1.1.1 MRFF Rare Cancers, Rare Diseases and Unmet Need Grant Program

The Medical Research Future Fund (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 in improving 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.

The independent and expert Australian Medical Research Advisory Board’s Australian Medical Research and Innovation Strategy 2016–2021 and related Australian Medical Research and Innovation Priorities 2016–2018 were developed following extensive stakeholder consultation. The priorities identified by the Advisory Board were utilised to make decisions on the provision of financial assistance from the MRFF.

The MRFF Lifting Clinical Trials and Registries Capacity Grant Program was announced in the 2017 Budget and was one of the first disbursements from the MRFF. This Program is now known as the MRFF Clinical Trials Activity: Rare Cancers, Rare Diseases and Unmet Need Grant Program.

The expected outcomes of this Program are:

- New opportunities for clinical trial participation and associated benefits from accessing the latest research
- Attention given to under-researched health priorities and conditions, such as rare cancers and rare diseases.
- Deployment of innovative trial designs and recruitment strategies
- Purposeful health service engagement to improve the translation of research into practice and improve outcomes for patients
- New health treatments, drugs and devices to improve health and wellbeing
- Reinforcement of Australia’s position as a preferred destination for clinical trials.

Further information on the rationale of the Program is available on the Department’s website. The Program is being undertaken according to the Commonwealth Grants Rules and Guidelines (CGRGs).

1.1.2 Australian Brain Cancer Mission

On the 29 October 2017, the Minister for Health announced the Australian Brain Cancer Mission (the Mission). The $105 million Mission aims to double the survival rates and improve the quality of life for patients with brain cancer over the next 10 years, with the longer term aim of defeating the disease.
The Australian Government will contribute up to $55 million under the Medical Research Future Fund (MRFF) and seeks matching contributions from philanthropy, other governments, industry and the private sector.

Implementation of the Australian Brain Cancer Mission is being managed by Cancer Australia and one of the early strategic activities is the support of new and expanded clinical trials and international collaborations.

In 2018, Cancer Australia and its Mission co-investors – Carrie’s Beanies 4 Brain Cancer and the Mark Hughes Foundation – will use this grant opportunity to fund clinical trials in brain cancer under the Australian Brain Cancer Mission. To be considered for funding from the Australian Brain Cancer Mission applicants must ensure that they indicate this within NHMRC’s Research Grant Management System (RGMS). Refer to section 7.3.3 Minimum Data for further information.

1.2 About this opportunity to apply for a Grant

These guidelines contain information on this opportunity to apply for funding under the Program. This document sets out:

- the purpose of the grant opportunity
- the eligibility and assessment criteria
- how grant applications are assessed and evaluated
- responsibilities and expectations in relation to the opportunity.

You must read this document before completing an application. For clarity, the term ‘grant guideline’ has the same meaning as ‘funding rules’.

1.3 Objectives of the grant opportunity

1.3.1 Rare Cancers, Rare Diseases and Unmet Need

This competitive grant opportunity will provide support for publicly funded clinical trials that address areas of health burden and unmet need, such as rare cancers and rare diseases.

Applications to this grant opportunity must propose a clinical trial that addresses an ‘unmet medical need’ by improving the health outcomes for members of the Australian community living with serious health conditions, whose diagnosis or treatment is not adequately addressed by existing options.

Rare cancers and rare diseases are specific, life threatening or chronically debilitating health conditions that affect fewer than 1 in 2,000 people in the population\(^1\). There are limited effective treatment options for many rare cancers and diseases, and the combined health burden is significant.

\(^1\) This widely cited definition of a rare disease has been agreed and adopted by the 28 member countries of the European Union.
The grant opportunity aims to increase clinical trial activity in Australia by supporting new, high quality research. Novel and innovative clinical trial methodologies are encouraged, such as the application of precision medicine to take individual genetic variation into account in disease treatment.

Applications proposing participation in international multi-centre clinical trials or utilising the capabilities of established clinical quality registries\(^2\) are also encouraged.

1.3.2 Supporting new and expanded clinical trials in Brain Cancer

The competitive grant opportunity funded through the Australian Brain Cancer Mission will support new and expanded clinical trials and international collaborations in brain cancer.

Specifically through this funding, the Australian Brain Cancer Mission is seeking to fund new or expanded innovative clinical trials in brain cancer that could involve international collaborations. The clinical trials should:

- be for children, adolescents and young adults, or adults with malignant brain cancer* and
- support increased and equitable access and participation.

The clinical trials may be in areas of:

- Diagnosis
- Treatment
  - Discovery and Development, or Clinical Application of Localized Therapies, Systemic Therapies, or Combinations of Localised and Systemic Therapies, including the assessment of new biological end points.

- Cancer Control, Survivorship & Outcomes
  - Patient Care, Survivorship, or End-of-Life Care

*Brain cancer is defined as cancers arising in the brain (code C71) in the International Statistical Classification of Diseases and Related Health Problems, Tenth Revision (ICD-10)

Brain cancer is the sixth leading cause of cancer burden and brain cancers carry high rates of morbidity and mortality. The young are disproportionately affected by brain cancer, being the leading cause of cancer-related deaths for those under 25 years of age.

The objective of this grant opportunity through the Mission is to support increased and equitable access and participation in clinical trials for people with brain cancer.

1.4 Outcomes sought from this grant opportunity

The desired outcomes from this grant opportunity are:

- improved health outcomes for members of the Australian community living with serious health conditions for which there are limited effective treatment options by

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\(^2\) A clinical outcome feedback loop is the defining feature of clinical quality registries, refer www.safetyandquality.gov.au/our-work/information-strategy/clinical-quality-registries/
providing study findings (health outcomes or validated surrogate health outcomes) within 12 months of the grant period concluding.

- completed clinical trials that provide high-quality evidence of the efficacy of new health treatments, drugs and devices utilising, where appropriate, the research capabilities of existing clinical quality registries.
- clinical trials that test the effectiveness of interventions for which a commercial return is unlikely to be achieved due to low patient numbers or where it is not possible to obtain an enforceable intellectual property right.
- expanded clinical trials activity in Australia by supporting new controlled clinical trials or alternatively, where justified, innovative and adaptive trial designs and precision medicine trials that take individual genetic variation into account in disease treatment. Clinical trials should not have commenced recruitment; however new treatment arms of established Australian and International trials will also be considered.

To be competitive for funding, applicants must propose to conduct a single clinical trial that delivers against all the above outcomes. Grantees will be required to report against milestones, performance indicators and timeframes at twelve month intervals.

Examples of research that is not considered relevant to the desired outcomes include, but are not limited to:

- extensions of funding for ongoing clinical trials: as the Program and the grant opportunity aim to support new clinical trials where recruitment has not yet commenced.

2. Grant amount

The Australian Government has announced a total of up to $33 million from the MRFF for this grant opportunity. Grants of up to five years duration will be considered with funding anticipated to commence in January 2019.

It is anticipated that up to twenty grants will be funded across a range of health care conditions.

Additional funding of up to $3.5 million is available to support meritorious applications that address the aims of the Australian Brain Cancer Mission.

In making funding decisions, the Australian Government reserves the right to preferentially fund high quality applications addressing rare cancers and rare diseases. The Australian Government may also take research investments in related areas (e.g. the Australian Brain Cancer Mission, the Low Survival Cancers and Disease (LSCD) grant opportunity, other research programs and the number and/or proportion of funds awarded in specific cancers or diseases under this grant opportunity) into account in its funding decisions.

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1 For the purposes of this grant opportunity an adaptive design is defined as a design that allows adaptations to trial and/or statistical procedures of the trial after its initiation without undermining the validity and integrity of the trial.
3. Grant eligibility criteria

To be eligible for consideration applications must satisfy all the requirements set out in these Grant Guidelines. An application may be considered ineligible and excluded from further consideration if:

- it contravenes an eligibility rule or other requirement as set out in these Grant Guidelines. Examples include, but are not limited to:
  - Minimum data describing your application is not entered into RGMS by the specified date
  - The application is not certified and submitted via RGMS 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
  - The Grant Proposal does not comply with formatting requirements and page limits
  - The proposed research duplicates research previously or currently being undertaken. NHMRC may compare the research proposed in grant applications with grants previously or currently funded by the Medical Research Future Fund, NHMRC or other agencies (e.g. Australian Research Council) and published research (see also section 4.2)
  - 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

- it, or persons named on the application, contravenes an applicable law or code

- persons named on the application are the subject of a decision by the 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 Probit Event. See the NHMRC Policy on Misconduct related to NHMRC Funding.

If a decision to exclude an application from further consideration is made, NHMRC will provide its 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.

3.1 Who is eligible to apply for a grant?

Applications will only be accepted from NHMRC approved Administering Institutions. A list of NHMRC approved Administering Institutions is available at: www.nhmrc.gov.au/grants-funding-administering-grants.
In addition to being, or having an affiliation with, an Administering Institution, to be eligible for a grant under the MRFF Act an organisation must be one of the following bodies:

- a medical research institute
- a university
- a corporate Commonwealth entity
- a corporation
- a state or territory government, or
- a state or territory government entity.

4. Eligible grant activities

4.1 What can the grant money be used for?

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 in order to demonstrate value for money. Poorly justified items may be reduced or removed from the budget.

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

4.1.2 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.

<table>
<thead>
<tr>
<th>Level</th>
<th>Description</th>
<th>$ per annum</th>
</tr>
</thead>
<tbody>
<tr>
<td>PSP1</td>
<td>Technical support - non-graduate personnel</td>
<td>55,933</td>
</tr>
<tr>
<td>PSP2</td>
<td>Junior graduate research assistant; or junior graduate nurse, midwife or allied health professional; or junior data manager/data analyst</td>
<td>69,842</td>
</tr>
<tr>
<td>PSP3</td>
<td>Experienced graduate research assistant/junior postdoctoral research officer; or experienced graduate nurse, midwife or allied health professional; or experienced data manager/analyst</td>
<td>76,798</td>
</tr>
<tr>
<td>PSP4</td>
<td>Experienced postdoctoral researcher (i.e., a researcher who may be considered as a named investigator on the research application and/or approaching the NHMRC Career Development Fellowship scheme or equivalent), or clinician without specialist qualifications</td>
<td>90,709</td>
</tr>
<tr>
<td>PSP5</td>
<td>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-doctoral and/or would be expected to have applied for or held an NHMRC Career Development Fellowship (formerly Career Development Award) or equivalent)</td>
<td>97,664</td>
</tr>
</tbody>
</table>

4.1.3 Other Direct Research Costs (DRCs)

For the purposes of this grant opportunity, 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.
• materials required to conduct the research – laboratory supplies, consumables, printed materials, microfilms, purchase costs of animals
• survey or field expenses that have been fully justified in the application
• Medicare costs (out of pocket medical expenses)
• reimbursement of reasonable costs associated with randomised control trials (RCT)
• reasonable medical diagnosis 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)
• costs of animal agistment and animals purchased that are a direct requirement of the research project
• 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. Direct research costs will be critically scrutinised during the assessment of applications and during on-site compliance monitoring visits.

4.2 What the grant money cannot be used for

You cannot use the grant to cover retrospective costs or to support clinical trials 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 clinical trial.

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 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 NHMRC with a written report clearly identifying the difference between the research aims of the two research activities. If NHMRC does not consider the two research activities to be sufficiently different, the applicant will be required to decline or relinquish one of the grants.
4.3 Eligible and ineligible expenditure

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
- conference attendance, and associated travel
- communications costs (mobiles, telephone calls)
- entertainment and hospitality costs
- institutional overheads and administrative costs
- overseas travel (except where formally approved and documented by the relevant Faculty Research Committee (or equivalent) prior to the travel being undertaken.)
- health insurance, travel insurance, foreign currency, airport and related travel taxes, passports and visas
- patent costs
- personal subscriptions (e.g. private journal subscriptions)
- purchase of reprints
- personal membership of professional organisations and groups
- *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. This includes:
  - animal house facilities
  - computers, computer networks, peripherals and software for communicating, writing and undertaking simple analyses
  - ethics approval costs
  - furniture
  - non-project related staff training and development
  - physical space and all associated administrative, laboratory and office services.

5. Infrastructure support for Independent Medical Research Institutes

The Department may, at its sole discretion, provide infrastructure support to Administering Institutions that are also NHMRC-approved independent medical research institutes (IMRIs). This support will contribute to infrastructure costs associated with the competitively awarded
MRFF research grants managed by NHMRC-approved IMRIs. This support is similar to that provided to NHMRC-approved IMRIs under the Independent Research Institute Infrastructure Support Scheme (IRIISS).

Infrastructure support, where provided, is only to be used to support the following types of overhead infrastructure, where that infrastructure is used to support a health and medical research activity:

- a) non-capital aspects of facilities such as libraries, laboratories, computing centres, animal houses, herbaria and experimental farms
- b) the purchase, installation, maintenance and hire and lease of equipment
- c) salaries of research support staff (including research assistants, accounting and administrative staff and technicians) employed to provide general support for a research activity, and
- d) the salary of a research assistant supporting a number of research projects, but not the salary of a research assistant dedicated to a particular project.

Items not regarded as elements of research infrastructure and which cannot be funded are:

- a) capital works e.g. the construction of buildings
- b) rental of accommodation
- c) salaries or stipends of researchers (salaries of staff supporting specific research at the institute level), and
- d) travel costs directly associated with individual projects with the exception of travel costs to allow participation in international consortia.

6. The grant selection process

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.

NHMRC will undertake a peer review assessment of your application against the criteria set out below. Your application will be scored against each assessment criterion and the requested budget critically scrutinised to determine whether it provides value for money. The overall score assigned to each application will be used to prepare a ranked list.

7. The assessment criteria

You will need to address the following assessment criteria. Guidance on how your application will be scored against each criterion is contained in the Category Descriptors.

The assessment criteria are weighted as indicated below. If the grant opportunity is oversubscribed a proportion of applications may be excluded from further consideration based on an assessment against criterion 1. Significance of the grant outcomes.
1. Significance of the grant outcomes (40%)

Significance is the potential to increase knowledge of important topics that achieve the outcomes of the grant opportunity. Significance will be assessed in terms of, but not limited to, the following considerations:

- Is the proposed clinical trial directly relevant to the desired outcomes of this grant opportunity, specifically:
  - improved health outcomes for members of the Australian community living with serious health conditions or brain cancer for which there are limited effective treatment options by providing study findings (health outcomes or validated surrogate health outcomes) within 12 months of the grant period concluding.
  - completed clinical trials that provide high-quality evidence of the efficacy of new health treatments, drugs and devices utilising, where appropriate, the research capabilities of existing clinical quality registries.
  - clinical trials that test the effectiveness of interventions for which a commercial return is unlikely to be achieved due to low patient numbers or where it is not possible to obtain an enforceable intellectual property right.
  - expanded clinical trials activity in Australia by supporting new controlled clinical trials or alternatively, where justified, innovative and adaptive trial designs and precision medicine trials that take individual genetic variation into account in disease treatment. Clinical trials should not have commenced recruitment; however new treatment arms of established trials will also be considered.
  - How has the potential impact on health outcomes been justified? Has the applicant systematically reviewed the research literature? How has the identified research (which should include clinical trials but may include other study designs including preclinical and biomedical 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?

- Does the research question meet the needs of research end-users, consumers or community members?

You are required to address this criterion within your Research Proposal. Please commence addressing this criterion by substantiating, and providing evidence to demonstrate, that the clinical trial addresses a health condition, or brain cancer, with limited effective treatment options. Where the condition is rare (i.e. affects less than 1 in 2000 of the Australian population) this should be clearly stated and substantiated by referencing a publically available dataset or equivalent.

Further instructions are in section 7.3.7 – The Grant Proposal.

2. Scientific Quality of the Proposal (40%)

Assessment of scientific quality encompasses the strengths and weaknesses of the study design and the feasibility of the proposal. Scientific quality will be assessed in terms of, but is not limited to, the following considerations:

- 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 clinical trial appropriate for the research question? What are the strengths and weaknesses of the study design? Have any major pitfalls been overlooked?

• Is the clinical trial 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?

• Were research end-users, including consumers or community members, engaged during the development of the research plan? Will they be involved in the conduct of the clinical trial? Will they be informed of the outcomes?

• Does the proposal include milestones, performance indicators and timeframes? (note: Grantees will be required to report against the milestones, performance indicators and timeframes at twelve month intervals).

You are required to address this criterion within your Research Proposal. Further instructions are in section 7.3.7 – The Grant Proposal.

3. Team Quality and Capability relevant to this proposal (20%)

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 clinical trial. Team Quality and Capability will be assessed in terms of, but not limited to, the following considerations:

• Do the Chief Investigators provide an appropriate mix of research skills and experience to successfully undertake this clinical trial?

• Is the Chief Investigators’ 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?

• Does the team have expertise in all aspects of the Proposal? Does the expertise include the methodological and scientific underpinnings (e.g. statistics, bioinformatics and health economics) of the Proposal?

• Do the team’s previous research outputs demonstrate their capability to undertake the clinical trial?

• Have the Chief Investigators previously delivered high quality research outputs in this area of research?

• Has the team demonstrated a high level of research productivity?

• Does the listed team reflect the contribution of early- and mid-career researcher/s to the clinical trial?

To address this criterion you must identify the researchers in the team that will undertake the clinical trial and provide evidence of their relevant skills and experience.

This criterion will be assessed ‘relative to opportunity’ taking into consideration any career disruptions.
Relative to Opportunity

For this grant opportunity, the policy is that assessment processes should 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. 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
- career disruption (see below)
- clinical, administrative or teaching workload
- Aboriginal and Torres Strait Islander community obligations, including ‘sorry business’
- relocation of an applicant and his/her research laboratory or clinical practice setting or other similar circumstances that impact upon research productivity
- restrictions on publication of research undertaken in other sectors
- the typical performance of researchers in the research field in question.

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 28 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.

Chief Investigators

A person must not be named as a Chief Investigator (CI) on more than one application.

You 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 funding agreement. Up to 10 Chief Investigators 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 7.3.9). The research proposal must involve CIA being based in Australia for the duration of the grant. A CIA is eligible to draw a Personnel Support Package from the grant.

Researchers who are not Australian citizens or permanent residents in Australia are eligible to apply as a Chief Investigator B to F, and if they are based in Australia for the duration of the grant then they are eligible to draw a salary from the grant. Chief Investigators based overseas are not eligible to draw a salary from the grant.

Each Chief Investigator may provide information on ‘relative to opportunity’ considerations and career disruption.
**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. Information about Associate Investigators is not to be included when describing Team Quality and Capability (see below).

Criterion 3 is to be addressed as follows:

1. Information on each Chief Investigator’s research achievements will be drawn from their Profile/CV in RGMS into a ‘snapshot’ file that forms part of your application:
   - CV-CD: Career Disruption (during the last 5 years)
   - CV-RO: Relative to Opportunity (during the last 5 years)
   - CV-Pub: Publications
   - CV-ORF: Other Research Funding
   - CV-RF: NHMRC Research Funding.

2. In your Grant Proposal you are required to provide information on:
   - Team Quality and capabilities relative to the Research Proposal
   - Chief Investigator capabilities and achievements
   - ‘Relative to opportunity’ considerations and career disruption.

Further instructions are in section 7.3.7 – *The Grant Proposal*.

**Criteria for Aboriginal and/or Torres Strait Islander Health Applications**

If at least 20% of the research effort relates to Aboriginal and Torres Strait Islander health your application will also be assessed against the **NHMRC Indigenous Research Excellence Criteria**:

- **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.

Further instructions on addressing the NHMRC Indigenous Research Excellence Criteria are in section 7.3.7 – The Grant Proposal.

7.1 Overview of application process

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 Research Grants Management System (RGMS). Electronic submission requires Administering Institutions and Chief Investigators on an application to register for an account.

Applicants who are not registered in RGMS can submit a new user request via the system login page. Refer to the Training Program for detailed user instructions, or contact your RAO or the NHMRC Research Help Centre for further assistance.

Applicants can apply as Chief Investigator (CIA-CIJ) on one application only. Your application will consist of:
• ‘snapshot’ files containing information drawn from each Chief Investigator’s Profile and Curriculum vitae in RGMS
• ‘snapshot’ files containing information about your proposed research you entered directly into the Application Form, and
• A Grant Proposal and a Declaration of Interests. These two (2) PDF files will be uploaded into RGMS.

Detailed instructions on completing your application are in section 7.3 below. Your Administering Institution is required to certify your application as correct and complete prior to submitting it to NHMRC.

All information submitted to NHMRC 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 NHMRC believes that omissions or inclusion of misleading information are intentional it 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.

7.2 Application process timing

Minimum data describing your application must be submitted to NHMRC by the due date shown below. Applications that fail to satisfy this requirement will not be accepted.

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

The expected commencement date for the funded research is 1 September 2018, subject to execution of the grant agreement and schedule. The expected completion date of your research must be nominated in your application and be prior to 31 December 2023.

Table 1: Expected timing for this grant opportunity

<table>
<thead>
<tr>
<th>Activity</th>
<th>Timeframe</th>
</tr>
</thead>
<tbody>
<tr>
<td>Applications open</td>
<td>Monday 25 June 2018</td>
</tr>
<tr>
<td>Minimum data due</td>
<td>5pm AEST on Wednesday 1 August 2018</td>
</tr>
<tr>
<td>Applications close</td>
<td>5pm AEST on Wednesday 15 August 2018</td>
</tr>
<tr>
<td>Assessment of applications</td>
<td>Approximately 13 weeks</td>
</tr>
<tr>
<td>Approval of outcomes of selection process</td>
<td>4 weeks</td>
</tr>
<tr>
<td>Announcement of outcomes</td>
<td>November-December 2018</td>
</tr>
<tr>
<td>Notification to unsuccessful applicants</td>
<td>On announcement</td>
</tr>
<tr>
<td>Acceptance of grant offer</td>
<td>Within 3 months of formal offers</td>
</tr>
<tr>
<td>Activity commences</td>
<td>January 2019</td>
</tr>
<tr>
<td>End date</td>
<td>31 December 2023</td>
</tr>
</tbody>
</table>

7.3 Completing the grant application

7.3.1 Using NHMRC’s Research Grants Management System (RGMS)


If you have any technical difficulties please contact NHMRC’s Research Help Centre on 1800 500 983 (+61 2 6217 9451 for international callers) or by email to help@nhmrc.gov.au
7.3.2 Starting Your Application in RGMS

Applicants must create a new application for this grant opportunity in RGMS. All components of Part A and Part B of the Application Form must be completed. The following specific advice is provided to assist you to complete your application.

7.3.3 Minimum data

You must submit minimum data in the RGMS by the applicable due date. Minimum data for this grant opportunity is:

- General – Application Information
  - Administering Institution
  - Application Title
  - Aboriginal/Torres Strait Islander Research (yes/no)
  - Synopsis (see section 7.3.4 below)*
  - Plain English Summary*

- A-RC: Research Classification

- B-AI: Application Information
  - Applications to the Australian Brain Cancer Mission

Applicants who wish to be considered for funding from the Australian Brain Cancer Mission must indicate this in section B-AI: Application Information of the application form in RGMS.

*Synopsis and Plain English Summary can be altered after the minimum data period, if required. Using placeholder text such as “text”, “synopsis” or “xx” etc. is not acceptable as minimum data and will be deemed ineligible.

Please note you will also need to complete the RAO Edit Access and Privacy Agreement in order to save your minimum data. Your RAO is not required to certify the minimum data. Applications should only be certified once complete and ready for submission.

7.3.4 Synopsis

A Synopsis of your application is required in the RGMS Application Form as part of the minimum data requirements. The Synopsis should be written in plain English using the Participant-Intervention-Comparator-Outcome (PICO) format and conclude by stating why the clinical trial is important. 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.

7.3.5 Proposed budget

Part B of the Application Form includes the proposed budget. Enter details of the proposed research budget into RGMS 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
Requests for Personnel Support Packages should be included in ‘A-RT: Research Team and Commitment’ in RGMS.

Requests for DRCs and Equipment must be included in ‘B-PB: Proposed Budget – DRC and Equipment’. 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 Research 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 trials services.

Provide details of the costs of using the services of research facilities as DRCs in RGMS 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 RGMS.

The total annual amount requested across all DRC line items for each year of a grant will be automatically rounded to the nearest $5,000 by the application form. The final rounded number is available at the ‘summary’ tab of the application form.

7.3.6 CV/Profile requirements

Instructions for entering CV information in RGMS are provided in the RGMS User Guide – Introduction to RGMS on the NHMRC website. All mandatory sections of your Chief Investigators’ RGMS profiles must be completed. The following components of your Chief Investigators’ CVs will be incorporated into your application:

**CV-CD: Career Disruption (during the last 5 years)**

For guidance on what constitutes a career disruption refer to section 7. 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.

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.

If the career disruption is of a highly sensitive nature and you (or members of your CI Team) do not wish to include this information in RGMS, details may be submitted separately to NHMRC. Applicants wishing to submit details of a sensitive career disruption separately should:
a. indicate in the relevant Chief Investigator Capability and Achievement section of the Grant Proposal that they wish to make a claim under the career disruption provisions and that it is of a sensitive or private nature

b. include details of the outputs that relate to the career disruption period claimed in the Chief Investigator Capability and Achievement section of the Grant Proposal. One extra page may be used only for the purpose of providing details of additional research outputs (those that occurred in the relevant preceding years) that you want the reviewers to consider when assessing your application

c. provide details of the nature of the career disruption in a separate PDF document to NHMRC in-confidence to email address: career.disruptions@nhmrc.gov.au (link sends e-mail), marked ‘For the attention of the MRFF Rare Cancers, Rare Disease and Unmet Need grant opportunity’ by the application closing date. Provide as much information as possible to explain your situation and ensure your application ID number is included in the PDF. The separate PDF must not exceed one A4 page in length.

Claims for sensitive career disruptions will be reviewed and assessed by senior NHMRC staff. Their decision will be forwarded to the grant review panel without reference to details, advising if the career disruption is accepted and which years should be considered.

**CV-RO: 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 7 for information on what constitutes ‘relative to opportunity’.

**CV-Pub: Publications**
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 Research Grants Management System (RGMS) User Guide – Applying for Grants and on the Publication Uploads page in RGMS. 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.

**CV-RF: NHMRC Research Funding**
Provide sufficient details about the funding to make clear what the funding was intended for, what you achieved and your role within these grants.

**CV-ORF: Other Research Funding**
Provide sufficient details about the funding to make clear what the funding was intended for, what you achieved and your role within these grants.
It is important that Chief Investigators update their Profile and CV in RGMS prior to certification of the application by your RAO. Changes made to your CV after applicant certification will not appear in the submitted application.

7.3.7 The Grant Proposal

You will upload your Grant Proposal into RGMS as a PDF file. A pre-formatted Microsoft Word template for the Grant Proposal can be downloaded from this grant opportunity webpage on GrantConnect.

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

<table>
<thead>
<tr>
<th>Formatting Requirements for the Grant Proposal</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>File format</strong></td>
</tr>
<tr>
<td><strong>File size</strong></td>
</tr>
<tr>
<td><strong>File name</strong></td>
</tr>
<tr>
<td><strong>Page size</strong></td>
</tr>
<tr>
<td><strong>Page limits</strong></td>
</tr>
<tr>
<td><strong>Font</strong></td>
</tr>
<tr>
<td><strong>Header</strong></td>
</tr>
<tr>
<td><strong>Line spacing</strong></td>
</tr>
<tr>
<td><strong>Language</strong></td>
</tr>
<tr>
<td><strong>Web links</strong></td>
</tr>
</tbody>
</table>

Applications that fail to comply with the formatting requirements or the specified page limits will 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:

<table>
<thead>
<tr>
<th>Component</th>
<th>Page Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>A  Significance of the expected outcomes to the objectives of the grant</td>
<td>3 pages</td>
</tr>
<tr>
<td>opportunity</td>
<td></td>
</tr>
<tr>
<td>B  Scientific Quality of the Proposal</td>
<td>7 pages</td>
</tr>
<tr>
<td>C  Milestones and Performance Indicators</td>
<td>2 pages</td>
</tr>
<tr>
<td>D  Indigenous Research Excellence Criteria (if applicable)</td>
<td>2 pages</td>
</tr>
<tr>
<td>E  References</td>
<td>2 pages</td>
</tr>
<tr>
<td>F  Team Quality and Capability</td>
<td>1 page</td>
</tr>
<tr>
<td>G  Chief Investigator Capability and Achievement</td>
<td>2 pages per CI</td>
</tr>
</tbody>
</table>

A brief description of each component is provided below.

**A. Significance of the expected outcomes to the objectives of this grant opportunity** *(maximum three A4 pages)*

This section should be used to address criterion 1 - Significance 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 clinical trial addresses a serious health condition, or brain cancer, with limited effective treatment options. Where the condition is rare *(i.e. affects less than 1 in 2000 of the Australian population)* this must be clearly stated in the first paragraph and justified with reference to a publicly available dataset or equivalent.

**B. Scientific Quality of the Proposal** *(maximum seven A4 pages)*

This section should be used to address criterion 2 - Scientific Quality of the Proposal.

**C. Milestones and Performance Indicators** *(maximum two A4 pages)*

Please provide a table of milestones and performance indicators and corresponding dates. The approach should be specific to the proposed clinical trial and provide for effective monitoring of progress at twelve month intervals. Applicants are encouraged to include milestones such as 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. You are advised to justify your approach.

**D. Indigenous Research Excellence Criteria, if applicable** *(maximum two A4 pages)*

If at least 20% of your research effort relates to Aboriginal and/or Torres Strait Islander health and you answered ‘yes’ to the Aboriginal and Torres Strait Islander Research question at ‘A-PA: Application Properties’ in RGMS, you will need to describe and demonstrate what proportion of the research effort will be directed to Aboriginal and/or Torres Strait Islander health, and address the *Indigenous Research Excellence Criteria.*

**E. References** *(maximum two A4 pages)*

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

G. Chief Investigator Capability and Achievement *(maximum two A4 pages 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.

**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.
7.3.8 Declaration of Applicant Interests

Applicants are required to declare any conflicts of interest or perceived conflicts of interest that could affect the performance of the grant. Conflicts of interest may include whether a Chief Investigator or a member of their research team:

- 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
- a grant applicant has commercial or other interests that may be impacted by the outcomes of the proposed research
- the grant applicant has a relationship with an organisation that has commercial or other interests that may be impacted by the outcomes of the proposed research.

Chief Investigators are required to declare any perceived or existing conflicts of interests. Where a research team has no conflicts of interest to declare this must be confirmed within the Application Form in RGMS.

If at a later date you identify that there is an actual, apparent, or potential conflict of interest or that one might arise in relation to a grant application, you must inform NHMRC in writing immediately.

7.3.9 Submitting the application

Once all Profile and CV details, application form details and PDF documents have been entered/uploaded into RGMS, 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 NHMRC 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.

7.4 Applications from consortia

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 NHMRC that arrangements for the management of the grant have been agreed between all institutions associated with the application.
7.5 Questions during the application process

If you have any questions during the application period, please contact NHMRC’s Research Help Centre on 1800 500 983 (+61 2 6217 9451 for international callers) or by email to help@nhmrc.gov.au.

NHMRC will respond to emailed questions within two working days. Any alterations or addenda to these Guidelines will be published on GrantConnect.

7.6 Further grant opportunities

If there are not enough suitable applications to meet the program’s objectives, the Commonwealth may invite suitable applicant(s) to submit proposal(s) that meet the program’s objectives. Suitable proposal(s) may be selected for funding on a non-competitive basis.

8. Assessment of grant applications

8.1 Who will assess applications?

Applications will undergo rigorous peer review, whereby they are subject to scrutiny and evaluation by others who are expert in: the field(s) of the application; innovative trial design; and/or trials requiring multidisciplinary and novel methodology approaches. 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.

Applications will be allocated to a grant review panel taking into account the discipline(s) and field(s) of the research and other research keywords entered in RGMS. Each application will be assigned a Primary and Secondary Spokesperson from within the grant review panel who will assess it against the assessment criteria.

NHMRC will collate the scores provided by the Spokespersons to identify less meritorious applications. The grant review panel may remove these applications from further consideration in advance of, or during, the grant review panel meeting. If the grant opportunity is oversubscribed a proportion of applications may initially be excluded from further consideration based on an assessment against criterion 1. Significance of the grant outcomes.

The grant review panel will discuss and score all remaining applications. The grant review panel will review the requested budget of applications that may be recommended for funding. The grant review panel may recommend a budget less than that requested by the applicant to ensure 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 for approval. NHMRC may also provide copies of applications to the Department of Health.
The outcome of the assessment of applications to the Australian Brain Cancer Mission will be forwarded to Cancer Australia. NHMRC may also provide copies of applications to Cancer Australia.

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 2007* and result in the application being excluded from consideration.

### 8.2 Who will approve grants?

Grants will be approved by a delegate of the Minister for Health drawing on the outcomes of NHMRC’s assessment of the applications. The delegate will make the final decision to approve a grant. NHMRC may provide a copy of your application to the Department.

The Commonwealth’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 Commonwealth 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 13.1 *Complaints in Relation to Funding Outcomes*.

### 9. Notification of application outcomes

You will be advised of the outcome of your application following a decision by the Commonwealth. If you are successful, you will also be advised about any specific conditions attached to the grant.

#### 9.1 Feedback on your application

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.

### 10. Successful grant applications

#### 10.1 The grant agreement

If you are successful, your Administering Institution must enter into a legally binding grant agreement with the Commonwealth. For the purposes of this grant opportunity, standard terms and conditions for NHMRC grants will apply and cannot be changed. A schedule will be used to outline the specific grant requirements. Any additional conditions attached to the
grant will be identified in the grant offer or in the schedule. The standard terms and conditions for NHMRC grants are available on the NHMRC website.

Your Administering Institution will be required to indicate its acceptance of a schedule to the funding agreement that outlines the grant activity, payment schedule and conditions including milestones and reporting.

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 to NHMRC 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
- 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.

10.2 How the grant will be paid

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.

For grants in brain cancer receiving funding through the ABCM funding may be paid as a single payment at the commencement of the funding period, however, 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 and applicable indexation will be detailed in the schedule to the funding agreement. Your Administering Institution is responsible for paying any extra eligible expenses that are incurred.

10.3 Grant agreement variations

There are limited circumstances where it is appropriate to vary a grant under this program. However it is recognised that unexpected events do occur that may require a grant variation.
For the purposes of this grant opportunity, NHMRC and the Department of Health will consider variation requests in accordance with the NHMRC Grantee Variations Policy. The Policy does not allow for an increase to the approved grant amount.

11. Announcement of grants

If successful, your grant will be listed on the GrantConnect website 14 days after the date of effect 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).

12. Delivery of grant activities

12.1 Your responsibilities

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.

12.1.1 Registration of Clinical Trials

Funded clinical trials 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.

For cancer clinical trials, in registering the trial on ANZCTR 1) Condition category 'Cancer' is selected in step 2 of the online form; and 2) Recruitment country 'Australia' selected in step 7 of the form.

Selection of the condition category 'Cancer' and recruitment in Australia, will provided registrants with an additional small set of consumer specific items for competition. This will ensure your clinical trial will be made available through Cancer Australia's Australian Cancer

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4 See glossary
Trials site - a consumer friendly cancer clinical trials website about cancer trials being conducted in Australia and internationally.

12.1.2 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. Refer to the Department of Health website for details of format.

12.1.3 Non-Financial Reports

The grant agreement will require the CIA to prepare reports on the Research Activity. It is a condition of funding that outstanding obligations from previous NHMRC grants, including submission of a Final Report, have been met prior to the time of award. Scientific reporting requirements can be found on the NHMRC website under Administering Grants. NHMRC may provide reports to the Department of Health.

12.1.4 Additional reporting requirements

Additional reporting requirements apply to all MRFF grants. Grantees must report against the milestones and performance indicators in the grant offer and schedule to the funding agreement at twelve month intervals following commencement of funding (or other interval as advised by the Australian Government). The milestones and performance indicators will be based on those proposed in the application and the advice of the grant review panel.

The Research Achievements Summary in the Final Report has been identified as information that maybe publicly released. Use of this information may include publication on the NHMRC and MRFF websites, publicity (including release to the media), and the promotion of research achievements.

All information provided to NHMRC in reports may be used for internal reporting and reporting to the Department of Health and the Australian Government. This information may also be used when reviewing or evaluating funded research projects, programs and funding opportunities, or designing future programs and funding opportunities.

12.1.5 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:

- submit the clinical trial protocol to an open access repository within six months of HREC approval
- upon completion of the clinical trial, and within 12 months of completion, disseminate the research findings through:
ensuring that research findings are available in an open access repository
− content specific forums
− submission to peer-reviewed journals

• make lay summaries available to trial participants, concurrently with sharing and dissemination of research results.

Grantees are encouraged to publish de-identified research data following completion of the Research Activity in an open access repository and in accordance with best practice. The NHMRC Open Access Policy applies to publications arising from these grants.

12.2 The Commonwealth’s responsibilities

The Commonwealth will:
• meet the terms and conditions set out in the grant agreement
• provide timely administration of the grant
• evaluate the grantee’s performance
• reduce or terminate funding of poor performing grants.

We will monitor the progress of your clinical trial by assessing reports you submit. We may also seek additional information from you about the performance of the grant, or arrange for an expert review of the progress of your clinical trial.

12.3 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.

12.4 Evaluation

The Department of Health will evaluate the Grant Program to measure how well the outcomes and objectives have been achieved. Your grant agreement requires you to provide information to help with this evaluation.

12.5 Acknowledgement

The Administering Institution must ensure that the grant from the MRFF is properly acknowledged in any correspondence, public announcement, advertising material, research report or other material produced by, on behalf of or through the Administering Institution or a Participating Institution that relates to the funded research.

Any material published in respect of a Research Activity must:
a. include the Grant Identification Number for the Research Activity (where allocated), and

b. specify that the contents of the published material are solely the responsibility of the Administering Institution, a Participating Institution or individual authors and do not reflect the views of the Australian Government.

13. Probity

The Australian Government will make sure that the program 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.

13.1 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

13.2 Conflict of interest

NHMRC has established processes for handling conflicts of interest that arise during the assessment of grant applications in a manner consistent with Australian Government policies and procedures. Conflicts of interest for Australian Government staff will be handled as set out in the Australian Public Service Code of Conduct (Section 13(7)) of the Public Service Act 1999. NHMRC’s conflict of interest policy is available on the NHMRC website.

13.3 Privacy: confidentiality and protection of personal information

NHMRC complies with the Privacy Act 1988 (Privacy Act). The Australian Privacy Principles set out how Australian Government agencies should collect, use, store and disclose personal information and how individuals can access records containing their personal information. NHMRC’s Privacy Policy is available at www.nhmrc.gov.au/about/privacy
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. RGMS will prompt you with a notice that seeks your consent to overseas disclosures.

13.4 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 (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.

Requests must be 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