



## Clinical Trials and Cohort Studies Grants 2019 Guidelines

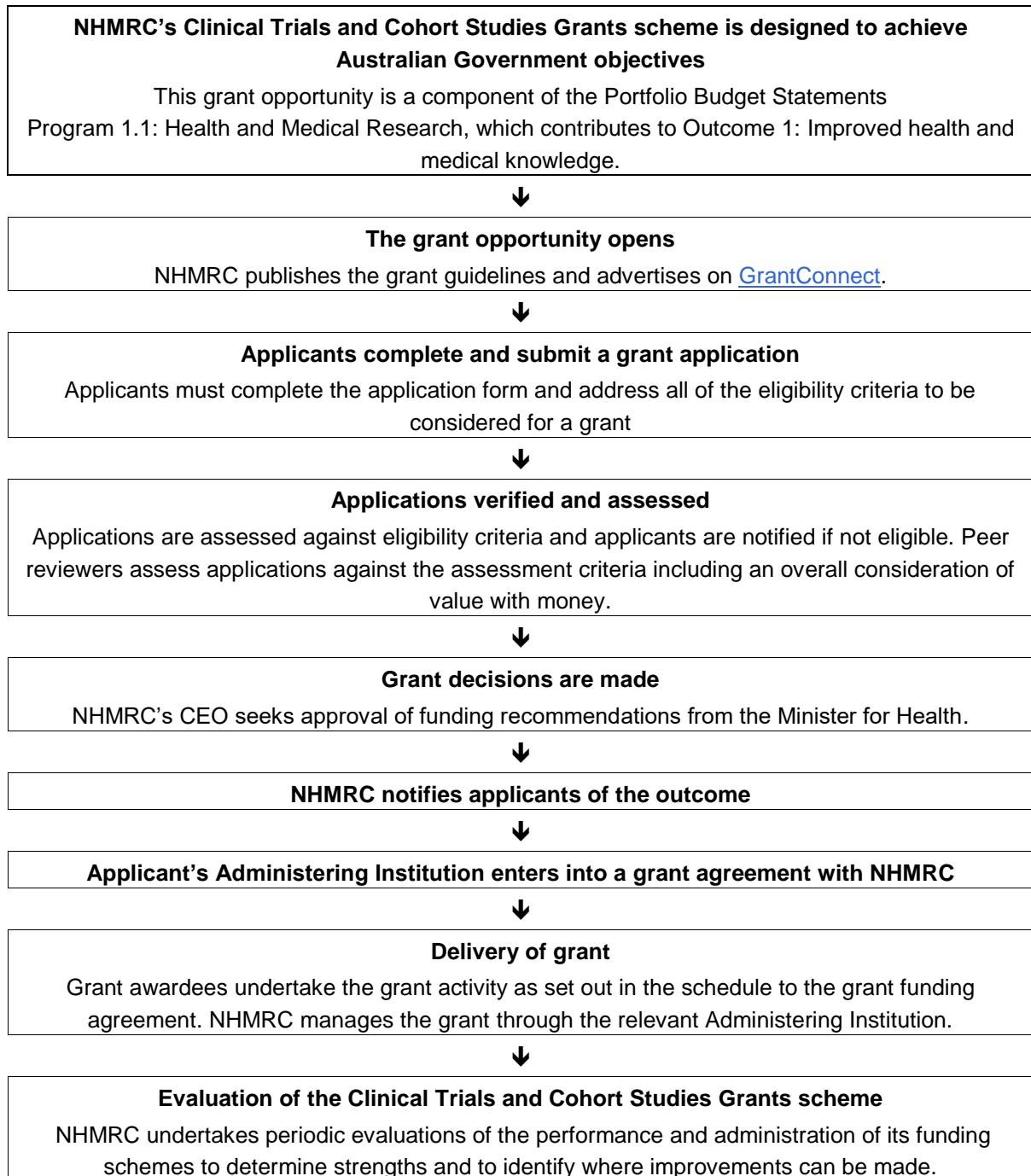
<b>Opening date:</b>	06 March 2019
<b>Closing date and time:</b>	17.00 AEST on 08 May 2019
<b>Commonwealth policy entity:</b>	National Health and Medical Research Council (NHMRC)
<b>Enquiries:</b>	<p>Applicants requiring further assistance should direct enquiries to their Administering Institution's Research Administration Officer. Research Administration Officers can contact NHMRC's Research Help Centre for further advice:</p> <p>Phone: 1800 500 983 (+61 2 6217 9451 for international callers)</p> <p>Email: <a href="mailto:help@nhmrc.gov.au">help@nhmrc.gov.au</a></p> <p>Frequently asked questions (FAQs) on scheme policy will be collated and then responded to via the scheme's FAQ document on GrantConnect. The final FAQ will be released on 1 May 2019.</p> <p>All policy enquiries should be submitted by COB 30 April 2019.</p> <p>NHMRC's Research Help Centre will continue to provide technical assistance to both applicants and RAOs.</p> <p>Note: The Research Help Centre aims to provide a reply to all requests for general assistance within two working days. This timeframe may be longer during peak periods or for more detailed requests for assistance.</p> <p>NHMRC will not respond to any enquiries submitted after 13.00 AEST on 08 May 2019.</p>
<b>Date guidelines released:</b>	06 March 2019
<b>Type of grant opportunity:</b>	Targeted competitive

# Contents

<b>1</b>	<b>Clinical Trials and Cohort Studies Grants 2019 Processes</b>	<b>4</b>
1.1	Introduction	5
<b>2</b>	<b>About the grant program</b>	<b>5</b>
2.1	NHMRC structural priorities, Clinical Trials and Cohort Studies Grants 2019 priorities and funding with other organisations	6
<b>3</b>	<b>Grant amount and grant period</b>	<b>6</b>
3.1	Grants available	6
3.2	Grant period	6
<b>4</b>	<b>Eligibility criteria</b>	<b>6</b>
4.1	Who is eligible to apply for a grant?	7
4.2	Exclusion of applications	7
<b>5</b>	<b>What the grant money can be used for</b>	<b>8</b>
5.1	Eligible grant activities and expenditures	8
5.2	Funding to support overseas grant activities and researchers	8
5.3	Duplicate funding	8
<b>6</b>	<b>The assessment criteria</b>	<b>9</b>
6.1	Health research involving Aboriginal and Torres Strait Islander People	11
6.2	Additional information	11
<b>7</b>	<b>How to apply</b>	<b>11</b>
7.1	Overview of application process and timing	11
7.2	Minimum data requirements	12
7.3	Application requirements	12
7.4	Consumer and community participation	12
7.5	Certification and submission	13
7.6	Retracted publications	14
7.7	Withdrawal of applications	14
7.8	Questions during the application process	15
<b>8</b>	<b>The grant selection process</b>	<b>15</b>
8.1	Assessment of grant applications	15
8.2	Who will assess applications?	15
8.3	Who will approve grants?	16
<b>9</b>	<b>Notification of application outcomes</b>	<b>16</b>
<b>10</b>	<b>Successful grant applications</b>	<b>16</b>
10.1	Information required from awardees	16
10.2	Approvals and licences	16
10.3	NHMRC Funding Agreement	16
10.3.1	Responsible conduct of research	16
10.4	NHMRC Policies	17

10.5	Payments .....	17
10.6	Suspension of grants .....	17
10.7	Tax implications .....	17
<b>11</b>	<b>Announcement of grants .....</b>	<b>17</b>
<b>12</b>	<b>How NHMRC monitors grant activity .....</b>	<b>17</b>
12.1	Variations .....	17
12.2	Reporting .....	17
12.3	Evaluation of the Clinical Trials and Cohort Studies Grant scheme .....	19
12.4	Open Access Policy .....	19
<b>13</b>	<b>Probity .....</b>	<b>19</b>
13.1	Complaints process .....	19
13.2	Privacy: confidentiality and protection of personal information .....	20
13.3	Freedom of Information.....	21
<b>14</b>	<b>NHMRC policies .....</b>	<b>21</b>
<b>15</b>	<b>Glossary.....</b>	<b>22</b>
<b>Appendix A. NHMRC structural priorities, Clinical Trials and Cohort Studies Grants 2019</b>		
	<b>Opportunity priorities and funding organisations .....</b>	<b>25</b>
<b>Appendix B. Relative to Opportunity policy .....</b>		<b>28</b>
<b>Appendix C. Clinical Trials and Cohort Studies Grants 2019 Category Descriptors .....</b>		<b>31</b>
<b>Appendix D. Guide to Applicants .....</b>		<b>36</b>

# 1 Clinical Trials and Cohort Studies Grants 2019 Processes



## 1.1 Introduction

These guidelines contain information for the Clinical Trials and Cohort Studies Grants 2019 opportunity.

Applicants must read these guidelines before filling out an application.

This document sets out:

- the purpose of the grant opportunity
- the eligibility and assessment criteria
- how grant applications are considered and selected
- how grantees are notified and receive grant payments
- how grantees will be monitored and evaluated
- responsibilities and expectations in relation to the opportunity.

GrantConnect ([www.grants.gov.au](http://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.

The Clinical Trials and Cohort Studies Grants 2019 opportunity will be undertaken according to the *Commonwealth Grants Rules and Guidelines 2017* (CGRGs), available from the [Department of Finance website](#).

### 1.1.1 About NHMRC

NHMRC is the Australian Government's key entity for managing investment in, and integrity of, health and medical research. The Clinical Trials and Cohort Studies Grants scheme is a component of the Portfolio Budget Statement Program 1.1: Health and Medical Research, which contributes to Outcome 1: Improved health and medical knowledge. NHMRC works with stakeholders to plan and design the grant program according to the *National Health and Medical Research Council Act 1992* (NHMRC Act) and the CGRGs.

NHMRC awards grants through several research funding schemes to advance health and medical knowledge and to improve the health status of all Australians. NHMRC invests in the highest quality research and researchers, as determined through peer review, across the four pillars of health and medical research: biomedical, clinical, public health and health services research.

## 2 About the grant program

The objective of the Clinical Trials and Cohort Studies Grants 2019 opportunity is to support high-quality clinical trials and cohort studies that address important gaps in knowledge, leading to relevant and implementable findings for the benefit of human health.

This grant opportunity is open to research proposals for clinical trials and/or cohort studies of any size – that is, they may be large or small clinical trials or cohort studies.

Please note that the Clinical Trials and Cohort Studies Grants scheme is not intended to provide ongoing support from NHMRC (see section 3 below for grant duration) and grant funding does not support infrastructure costs (see section 5 below). Grantees will be required to report against milestones at twelve-month intervals.

The desired outcomes of the Clinical Trials and Cohort Studies Grant opportunity are improvements in health and well-being, health care practice or policy, as a result of:

- high-quality clinical trials that provide reliable evidence of the effects of health-related interventions on health outcomes (or appropriate surrogates), and/or

- high-quality cohort studies that provide reliable evidence on the relation of important risk factors and other exposures to health-related outcomes.

Only applications that will deliver against the intended objective and outcomes will be competitive for funding.

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

- laboratory-based research, including research based on animal models or other pre-clinical studies, and
- mechanistic studies that are not clinical trials or cohort studies.

Applicants seeking funding for these types of research should consider other grant opportunities, such as NHMRC's Ideas Grant Scheme.

## 2.1 NHMRC structural priorities, Clinical Trials and Cohort Studies Grants 2019 priorities and funding with other organisations

NHMRC's Corporate Plan (the Plan) outlines strategic priorities and major health issues for the period covered by the Plan, including how NHMRC will address these issues, and a national strategy for medical research and public health research. Each year, NHMRC identifies structural priorities for funding to deliver against its strategic priorities.

Information on NHMRC's structural priorities and any Clinical Trials and Cohort Studies Grants priorities and funding with other organisations is outlined in [Appendix A](#).

# 3 Grant amount and grant period

## 3.1 Grants available

The provisional funding allocation for the Clinical Trials and Cohort Studies Grants 2019 opportunity is estimated to be up to \$70 million. NHMRC's Research Committee annually reviews and recommends indicative budget amounts to be awarded across individual funding schemes.

The amount of funding for a Clinical Trials and Cohort Studies Grant will be based on assessment of the requested budget. Applications must clearly justify the requested duration and budget, and how they will support the proposed outcomes of the research. Peer reviewers will consider this information and may reduce the duration and/or budget to ensure the research aims and objectives can be achieved while ensuring value with money.

## 3.2 Grant period

A Clinical Trials and Cohort Studies Grant can be requested for between one and five years depending on the proposal.

# 4 Eligibility criteria

Applications will only be accepted from NHMRC-approved Administering Institutions. A list of NHMRC-approved Administering Institutions and NHMRC's Administering Institution Policy are available on [NHMRC's website](#).

The Chief Investigator A (CIA) and Administering Institution must ensure applications meet all eligibility requirements, as set out in these guidelines, at the time of submission and for the duration

of peer review. Applications that do not meet these eligibility requirements may be ruled ineligible and may be excluded from further consideration.

An eligibility ruling may be made by NHMRC at any stage following the close of applications, including during peer review. Where an eligibility ruling is being considered, NHMRC may request further information in order to assess whether the eligibility requirement has been met.

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

Grant offers may be withdrawn and action taken over the life of a grant, if eligibility criteria to accept and/or continue holding a grant are not met.

NHMRC staff will not make eligibility rulings prior to an application being submitted.

## 4.1 Who is eligible to apply for a grant?

### 4.1.1 Chief Investigators and Associate Investigators

The maximum number of Chief Investigators (CIs) allowed on a Clinical Trials and Cohort Studies grant application is 10 (CIA – CIJ).

#### **Chief Investigator 'A' (CIA)**

At the time of acceptance and for the duration of a grant, the CIA must be an Australian or New Zealand citizen, or a permanent resident of Australia or have an appropriate work visa in place. The CIA must also be based in Australia for at least 80% of the Funding Period.

#### **Chief Investigators**

The role and contribution of each CI must be described in the grant application. PhD students may be named as CIs in exceptional circumstances where the PhD student is critical for the successful completion of the proposed research. CIs are expected to remain active on the Research Activity as outlined in the application for the duration of the grant.

#### **Associate Investigators**

An Associate Investigator (AI) is defined as an investigator who provides some intellectual and/or practical input into the research and whose participation may warrant inclusion of their name on any outputs (e.g. publications).

There is no restriction on who and the number of times a researcher can be named as an AI. However, a maximum number of 10 AIs may be listed on an application.

## 4.2 Exclusion of applications

An application may be excluded from further consideration if:

- it contravenes an eligibility rule or other requirement as set out in the Grant Guidelines
- it, or any CI named on the application, contravenes an applicable law or code
- it is inconsistent with the objectives of the NHMRC Act and/or the purposes of the Medical Research Endowment Account (MREA), and
- any CI named on the application is the subject of a decision by NHMRC's CEO or Delegate that any application they make to NHMRC, for specified funding schemes, will be excluded from consideration for a period of time, whether or not they otherwise meet the eligibility requirements. Such decisions will generally reflect consequential action taken by NHMRC in response to a finding of research misconduct or a breach of the

*Australian Code for the Responsible Conduct of Research* (the Code), or a Probrity Event. See the Code for a definition of 'research misconduct' and the *NHMRC Policy on Misconduct related to NHMRC Funding* available from [NHMRC's website](#).

Such exclusion may take place at any time following CIA and Administering Institution certification.

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 Research Administration Officer (RAO) in writing. The Administering Institution's RAO is responsible for advising applicants of the decision in writing. Decisions to exclude an application may be reviewable by NHMRC's Commissioner of Complaints.

## **5 What the grant money can be used for**

### **5.1 Eligible grant activities and expenditures**

Funding provided by NHMRC for a Research Activity must be spent on a cost directly incurred in relation to that Research Activity. Further guidance on the expenditure of funding for a Research Activity is provided in the Direct Research Cost Guidelines on the [NHMRC website](#).

Clinical Trials and Cohort Studies Grant funds can only be spent on direct costs of research as described in the NHMRC *Direct Research Cost Guidelines* on the [NHMRC website](#).

#### **5.1.1 Salary support**

Requested salaries (if any) must be based on Personnel Support Packages (PSPs). Individuals are not able to draw a salary from any Clinical Trials and Cohort Studies Grants on which they are named as an Associate Investigator.

### **5.2 Funding to support overseas grant activities and researchers**

The CIA may request funding to support specific grant activities to be undertaken overseas. In doing so, they must clearly demonstrate that the overseas grant activity is critical to the successful completion of the project, and the equipment/resources required for the grant activity are not available in Australia.

In some instances, the CIA may seek to conduct the majority of the work overseas. However, it is important that the CIA ensures such research is well-justified and conforms with the scheme eligibility requirements, including that the CIA is required to be based in Australia for at least 80% of the requested grant duration.

Salary support for specific research activities to be undertaken overseas may be requested, but the personnel who will receive such support are not allowed to be a CI on the grant.

Funding for research support staff based overseas can be considered where this is important to achieving the aims of the research.

### **5.3 Duplicate funding**

NHMRC may compare the research proposed in grant applications with grants previously funded, currently funded, and funded by other agencies (e.g. Australian Research Council or Department of Health) and published research. NHMRC will not fund research that it considers duplicates research previously or currently being funded.

Where NHMRC believes that a CI has submitted similar research proposals to NHMRC and has been successful with more than one application, the CI may be required to provide NHMRC with a



written report clearly identifying the difference between the research aims of the research activities. If NHMRC subsequently does not consider the research activities to be sufficiently different, the applicant will be required to decline or relinquish one of the grants.

NHMRC may disclose applicants' personal information to overseas entities, Australian, State/Territory or local government agencies, organisations or individuals where necessary to assess an application or to administer a grant. See [NHMRC's Privacy Policy](#) and the *Privacy: confidentiality and protection of personal information* section of these guidelines for further information (section 13.2).

## 6 The assessment criteria

Applications for Clinical Trials and Cohort Studies Grants are assessed by peers on the extent to which the application meets the scheme objectives. Applications will be assessed against the assessment criteria listed below and the category descriptors at [Appendix C](#). In addressing the assessment criteria, applicants should consider how the proposal addresses the associated points.

### 1. Significance (40%)

Significance for this grant opportunity is the extent to which the research findings will substantially advance knowledge to improve the prevention, diagnosis or treatment of medical conditions, or to improve health and wellbeing. Significance will be assessed in terms of, but not limited to, the following considerations:

- Is the research proposal directly relevant to the objectives and desired outcomes of the Clinical Trials and Cohort Studies Grant Opportunity? Specifically:
  - high-quality clinical trials and/or cohort studies that address important gaps in knowledge, leading to relevant and implementable findings for the benefit of human health
  - improvements in health and wellbeing, health care practice or policy, as a result of:
    - high-quality clinical trials that provide reliable evidence of the effects of health-related interventions on health outcomes (or appropriate surrogates), and/or
    - high-quality cohort studies that provide reliable evidence on the relation of important risk factors and other exposures to health-related outcomes.
- Is there evidence that there is a strong rationale for the proposed research?
  - What previous research has occurred? Has the applicant described a systematic review or literature review? Do the points of difference between these studies and the proposed research provide a strong justification for the proposed research?
  - Does the research question(s) meet the needs of research end-users, such as consumers, community members, policy makers and clinical practitioners?
  - If the research objectives are achieved, would the research have a significant impact on the health issue in question? This may include contributing to knowledge, health, economic and social impacts.

### 2. Research quality (40%)

Research quality for this grant opportunity encompasses the quality and feasibility of the proposed research, incorporating theoretical concepts, hypothesis, research design and robustness. Research quality will be assessed in terms of, but is not limited to, the following considerations:

- Is there a clear research question(s)?

- Are the clinical trial and/or cohort study design and methodologies appropriate for the research question(s)? For example:
  - Have any major pitfalls been overlooked?
  - Are the proposed inclusion and exclusion criteria appropriate and justified? This includes appropriate consideration of sex and gender, and other factors such as ethnicity, culture and language.
  - Are the proposed methodological approaches appropriate? Are the participants, intervention/exposure and comparators/controls clearly specified? Are data collection, management and statistical analysis described?
  - Were relevant research end-users, such as consumers, community members, policy makers and clinical practitioners, engaged during the development of the research plan? Will they be involved in the conduct of the clinical trial and/or cohort study? Will they be informed of the outcomes?
- Is the clinical trial and/or cohort study feasible? For example:
  - Are the required techniques established? Are the required expertise and resources available, including infrastructure, equipment and facilities?
  - Are targets for the recruitment of participants realistic? Is the sample size achievable and sufficient to detect meaningful effect differences?
  - Does the proposal include appropriate and realistic milestones and performance indicators and timeframes? Can the end-points be measured?

### **3. Team quality and capability (20%)**

This criterion is used to assess whether the CI team named in your application has the appropriate mix of research skills and experience to undertake the clinical trial and/or cohort study and achieve the stated objectives of the proposed research. Team quality will be assessed in terms of, but not limited to, the following considerations:

- Do the CIs collectively provide an appropriate mix of research skills and experience to successfully undertake this clinical trial and/or cohort study?
  - Is the CI expertise sufficient to anticipate and solve potential obstacles (e.g. higher than anticipated non-compliance rates or new competing therapies) to the success of the proposal? Do they have expertise in all aspects of the research proposal? Does the expertise include the methodological and scientific underpinnings (e.g. statistics, bioinformatics and health economics) of the research proposal?
- Do the CIs have high quality track records over the last five years? Have the CIs previously delivered high quality research outputs in this area of research? Does this demonstrate the team's capability to undertake the clinical trial and/or cohort study?
- Does the CI team reflect the contribution of early- and mid- career researcher/s to the clinical trial and/or cohort study?

Applications are assessed relative to opportunity, taking into consideration any career disruptions and recognising applicants' industry-relevant expertise, where applicable (see [Appendix B](#)).

It is recognised that Aboriginal and Torres Strait Islander applicants often make additional valuable contributions to policy development, clinical/public health leadership and/or service delivery, community activities and linkages, and are often representatives on key committees. If applicable, these contributions will be considered when assessing research output and track record.

## 6.1 Health research involving Aboriginal and Torres Strait Islander People

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

Qualifying applications must address NHMRC's *Indigenous Research Excellence Criteria* as follows:

- Community engagement - the proposal demonstrates how the research and potential outcomes are a priority for Aboriginal and Torres Strait Islander communities with relevant community engagement by individuals, communities and/or organisations in conceptualisation, development and approval, data collection and management, analysis, report writing and dissemination of results.
- Benefit - the potential health benefit of the project is demonstrated by addressing an important health issue for Aboriginal and Torres Strait Islander people. 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 people, 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 people, communities and researchers will develop relevant capabilities through partnerships and participation in the project.

These applications will be assigned to peer reviewers with specific expertise in Indigenous health research. The peer reviewer(s) will consider how well the application addresses the *Indigenous Research Excellence Criteria*.

## 6.2 Additional information

In preparing your research proposal, you may find the following resources useful:

- Chan A-W, Tetzlaff JM, Gøtzsche PC, Altman DG, Man H et al. SPIRIT 2013 explanation and elaboration: guidance for protocols of clinical trials. *BMJ* 2013; 346:e7586. Available at <http://www.bmj.com/content/346/bmj.e7586>. Accessed 25 Jul 2018.
- 2007 Strengthening the reporting of observational studies in epidemiology (STROBE) checklist for cohort, case-control, and cross-sectional studies (combined), Version 4, published in Oct/Nov 2007. Available at: <http://www.strobe-statement.org/index.php?id=available-checklists>. Accessed 25 Jul 2018.
- 2011 WHO International Standards for Clinical Trial Registries. Available at [http://www.who.int/topics/clinical\\_trials/en/](http://www.who.int/topics/clinical_trials/en/). Accessed 25 Jul 2018.

# 7 How to apply

## 7.1 Overview of application process and timing

<b>6 March 2019</b>	Applications open in NHMRC's granting system
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<b>17.00 AEST</b> <b>10 April 2019</b>	Minimum data due in NHMRC's granting system
<b>17.00 AEST</b> <b>8 May 2019</b>	Applications close in NHMRC's granting system
<b>August-September</b> <b>2019</b>	Anticipated peer review period
<b>November-December</b> <b>2019*</b>	Anticipated notification of outcomes

\* Date is indicative and subject to change.

Applications must be submitted electronically using NHMRC's granting system unless otherwise advised by NHMRC.

Electronic submission requires Administering Institutions and all CIs on an application to register for an account in NHMRC's granting system. Applicants who are not registered can submit a new user request via the login page of NHMRC's granting system.

Applicants should refer to NHMRC's granting system Training Program on [NHMRC's website](#) for detailed user instructions, or contact your RAO or NHMRC's Research Help Centre for further assistance.

**Late applications will not be accepted.**

## 7.2 Minimum data requirements

Minimum data must be entered in NHMRC's granting system by the specified due date to allow NHMRC to start identifying suitable peer reviewers. Applications that fail to satisfy this requirement will not be accepted. Applicants must complete the recommended fields with correct information. Using placeholder text such as "text", "synopsis" or "xx" etc. is not acceptable as minimum data.

Minimum data fields for Clinical Trials and Cohort Studies Grants 2019 are outlined within [Appendix D](#).

**Failure to meet this deadline will result in the application not proceeding.**

RAOs are not required to certify applications for the purpose of minimum data. Applications should only be certified once complete and ready for submission.

## 7.3 Application requirements

The application should contain all information necessary for assessment without the need for further written or oral explanation or reference to additional documentation. All details included must be current at the time of submission, as this information is relied on during assessment.

Applications must comply with all content and formatting requirements. Incomplete or non-compliant applications may be assessed as ineligible.

## 7.4 Consumer and community participation

The *Statement on Consumer and Community Involvement in Health and Medical Research* (the Statement) has been developed because of the important contribution consumers make to health and medical research. The Consumers Health Forum of Australia Ltd and NHMRC worked in partnership with consumers and researchers to develop the Statement.

Researchers are encouraged to consider the benefits of actively engaging consumers in their proposed research. Further information on the Consumer Health Forum and the Statement on Participation is available on [NHMRC's website](#).

## 7.5 Certification and submission

Once complete, applications must be electronically certified and then submitted to NHMRC through the RAO of an NHMRC approved Administering Institution using NHMRC's granting system.

Certification is required firstly by the CIA and then by the Administering Institution RAO by the specified due date or the application will be ruled ineligible and excluded from further consideration.

**Once submitted to NHMRC, the application is considered final and no changes can be made.**

### 7.5.1 CIA certification

The CIA must provide the RAO with evidence that the application is complete and that all CIs have agreed to it, i.e. through written evidence, such as email. Such written evidence should be retained by the Administering Institution and must be provided to NHMRC if requested.

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, and 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 on Ethical Conduct in 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 CIs and AIs have provided written agreement to be named on 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](#).
- All CIs have provided written agreement for the final application to be certified.

The application may be excluded from consideration if found to be in breach of any requirements.

And if funded,

- The research will be carried out in strict accordance with the conditions governing NHMRC grants at the time of award. Conditions may change during the course of the grant, for example, reporting obligations may change. CIs will need to meet new/changed conditions.
- The reported outcomes of the research may be used for internal NHMRC quality evaluations/reviews.
- Grant offers may be withdrawn and action taken over the life of the grant, if eligibility criteria to accept and/or continue holding the grant are not met.

### 7.5.2 Administering Institution certification

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.
- Where the CIA is not an Australian or New Zealand 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 at least 80% 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 for 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.

## 7.6 Retracted publications

If a publication relevant to an application is retracted after the application has been submitted, the applicant must promptly notify their RAO. The RAO must advise NHMRC at the earliest opportunity of the retraction by email ([help@nhmrc.gov.au](mailto:help@nhmrc.gov.au)) with an explanation of the reasons for the retraction.

In addition, where the publication forms part of the applicant's track record, the applicant must immediately record that information in their Profile & CV in NHMRC's granting system.

If an application is largely dependent on the results of a retracted publication, the applicant should also consider withdrawing the application. If, under these circumstances, an applicant chooses not to withdraw the application, the RAO must advise NHMRC in writing (to [help@nhmrc.gov.au](mailto:help@nhmrc.gov.au)), clearly outlining the reasons for not withdrawing the application.

## 7.7 Withdrawal of applications

Applications may be withdrawn at any time by written notice from the Administering Institution's RAO to NHMRC.

An application may be 'marked for deletion' by the applicant in NHMRC's granting system before the close of the round. This authorises NHMRC to delete the application once the round has closed. The application will not be deleted while the funding round remains open for application submission.

## 7.8 Questions during the application process

Applicants requiring further assistance should direct enquiries to their Administering Institution's RAO. RAOs can contact NHMRC's Research Help Centre for further advice.

All policy enquiries must be submitted in writing to NHMRC's Research Help Centre which will process enquiries as follows:

1. Enquiries from individual applicants will be redirected to the Administering Institution's RAO.
2. Frequently asked policy questions will be collated and responded to via the scheme Frequently Asked Question (FAQ) document on GrantConnect. NHMRC will advise if an enquiry will be responded to via the FAQ document which will be updated as needed.
3. Redirection to the FAQ document will occur when a specific enquiry has already been addressed in the FAQ document.

The final addenda will be released on 1 May 2019. All policy enquiries should be submitted by 30 April 2019.

NHMRC's Research Help Centre

P: 1800 500 983 (+61 2 6217 9451 for international callers)

E: [help@nhmrc.gov.au](mailto:help@nhmrc.gov.au)

Refer to the [Research Help Centre webpage](#) for opening hours.

## 8 The grant selection process

### 8.1 Assessment of grant applications

NHMRC considers applications through a targeted competitive grant process. Applications are required to meet eligibility requirements (see section 4) and are assessed against the assessment criteria (see section 6).

### 8.2 Who will assess applications?

NHMRC's peer review process is designed to provide a rigorous, fair, transparent and consistent assessment of the merits of each application according to the Code to ensure that only the highest quality, value with money research is recommended for funding.

NHMRC will conduct peer review for this funding round in accordance with the *NHMRC's Principles of Peer Review*, available from [NHMRC's website](#).

Applicants must not make contact about their application with anyone who is directly engaged with its peer review. Doing so may constitute a breach of the Code and result in the application being excluded from consideration.

#### 8.2.1 Clinical Trials and Cohort Studies Grants assessment process

Peer reviewers will independently undertake an initial assessment of applications using the assessment criteria (see section 6).

The outcome of this review will be used to create a shortlist of applications that are then assessed against the assessment criteria by a panel of peer reviewers. The overall scores from the panel assessment will be used to produce a rank ordered list of applications, on which funding recommendations will be based.

Further information on the assessment process is on the [NHMRC website](#).

### 8.3 Who will approve grants?

In accordance with paragraph 7(1)(c) of the NHMRC Act, NHMRC's CEO makes recommendations on expenditure from the MREA to the Minister with portfolio responsibility for NHMRC.

## 9 Notification of application outcomes

NHMRC may advise applicants of their outcome under embargo. An embargo is the prohibition of publicising information or news provided by NHMRC until a certain date or until certain conditions have been met. [NHMRC's website](#) provides further information on what can and cannot happen where information on a grant is released under embargo.

## 10 Successful grant applications

CIAs whose applications are approved will have access to a letter of offer through NHMRC's granting system. Administering Institutions responsible for administering approved applications will also have access to the letter of offer. In addition, the Administering Institution will have access, through NHMRC's granting system, to the Schedule to the Funding Agreement. The Administering Institution is responsible for accepting the Schedule through the online signing/acceptance process within NHMRC's granting system.

NHMRC's CEO or delegate may withdraw or vary an offer of a grant if they consider that it is reasonably necessary to protect Commonwealth revenue.

### 10.1 Information required from awardees

Awardees may be required to supply additional information about their Research Activity before payments commence. This will be stated in the letter of offer.

### 10.2 Approvals and licences

Where relevant, particularly for ethics and biosafety, NHMRC-funded Research Activities must have received approval from the relevant institutional committees and approval bodies before funding can commence. For further information see [NHMRC's website](#).

### 10.3 NHMRC Funding Agreement

All grants are offered in accordance with the Funding Agreement (with any conditions specified in Schedules and these Grant Guidelines), which is a legal agreement between NHMRC and the Administering Institution. In accepting the Schedules, the Administering Institution is agreeing to the conditions contained in the Funding Agreement and the Schedule.

Details of the Funding Agreement can be found on [NHMRC's website](#) under Funding Agreement and Deeds of Agreement. A grant will not commence, nor grant funds be paid, until:

- the Funding Agreement between NHMRC and the Administering Institution is in place
- the appropriate Schedule to the Funding Agreement is accepted by the Responsible Officer or their delegate and is accepted and executed by NHMRC.

#### 10.3.1 Responsible conduct of research

NHMRC expects the highest levels of research conduct and integrity to be observed in the research that it funds. Administering Institutions and CIAs are bound by the conditions of the Funding Agreement. NHMRC funded research must be conducted in accordance with the Code.



## 10.4 NHMRC Policies

Administering Institutions and CIAs are bound by the conditions of the Funding Agreement. It is the responsibility of Administering Institutions and CIs to be aware of, and be compliant with, all relevant legislation and policies relating to the conduct of the Research Activity.

For further information on the expectations of Administering Institutions and CIs, see [NHMRC's website](#).

## 10.5 Payments

Payments will commence once all outstanding obligations (e.g. conditions, eligibility rules or data requirements specified in the Schedule to the Funding Agreement, relevant grant guidelines or letter of offer) have been met by the CIA and the Administering Institution.

## 10.6 Suspension of grants

NHMRC funding may be suspended for a variety of reasons including, but not limited to, requests made by the CIA. Variations will generally only be granted if allowed in the grant guidelines and the NHMRC *Grantee Variation Policy* available on the [NHMRC website](#).

Funding may also be suspended by NHMRC when it is reasonable to consider there has been a failure to comply with a Policy or Guideline, or on the basis of a Probity Event or an investigation of alleged research misconduct, as set out in the Funding Agreement.

## 10.7 Tax implications

All amounts referred to in these Grant Guidelines are exclusive of GST, unless stated otherwise.

Administering Institutions are responsible for all financial and taxation matters associated with the grant.

# 11 Announcement of grants

Grant outcomes are publicly listed on the [GrantConnect website](#) 21 calendar days after the date of effect as required by the CGRGs.

# 12 How NHMRC monitors grant activity

## 12.1 Variations

A variation is a change (including a delay) to a grant. There are limited circumstances where it is appropriate to vary an NHMRC grant (including the Research Activity) relative to the peer reviewed application. Requests must comply with the grant guidelines and the NHMRC *Grantee Variation Policy*. Requests to vary the terms of a grant should be made to NHMRC via the Grantee Variation portal in NHMRC's granting system. For information on grant variations see NHMRC's *Grantee Variation Policy* on the [NHMRC website](#).

Grant variations cannot be used as a means to meet NHMRC eligibility requirements.

## 12.2 Reporting

Administering Institutions are 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, NHMRC may take action under the provisions of the Funding Agreement. Failure to report within timeframes may affect eligibility to receive future funding.

### 12.2.1 Financial reports

Annual financial reports are required in a form prescribed by NHMRC. At the completion of the grant or upon transfer to a new Administering Institution, a financial acquittal is also required. Refer to [NHMRC's website](#) for details of format and timing.

### 12.2.2 Non-financial reports

The Funding Agreement requires the CIA to prepare reports for each Research Activity. Scientific reporting requirements can be found on [NHMRC's website](#). It is a condition of funding that outstanding obligations from previous NHMRC grants, including submission of a Final Report, have been met prior to acceptance of a new grant.

Information in the Final Report may be publicly released. Use of this information may include publication on [NHMRC's website](#), 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 government. This information may also be used by NHMRC when reviewing or evaluating funded research projects, funding schemes, or designing future schemes.

### 12.2.3 NHMRC National Institute for Dementia Research

Grantees undertaking research related to dementia must contribute their expertise to the NHMRC National Institute for Dementia Research, which is responsible for strategically expanding, coordinating and translating the national dementia research effort. The NHMRC National Institute for Dementia Research is drawing on the expertise of researchers and other dementia stakeholders via a membership model to drive Australia's dementia research and translation effort, and work together to maximise the impact of research.

Additional reporting on NHMRC funded dementia research will also be sought from Administering Institutions as required to inform the Institute's work plan and subsequent research activities.

### 12.2.4 Additional reporting requirements

Additional reporting requirements apply to Clinical Trials and Cohort Studies 2019 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 NHMRC). The milestones and performance indicators will be based on those proposed in the application and the advice of the grant review panel.

Grant payments will depend on satisfactory progress being made against milestones and performance indicators set out in the Funding Agreement. Where milestones and performance indicators have not been achieved, grant payments may be suspended. See sections 10.4-10.5 above.

### 12.2.5 Registration of Clinical Trials

Funded clinical trials must be registered in the Australian New Zealand Clinical Trials Registry (ANZCTR) or equivalent before recruitment of the first participant. Information on how to register your clinical trial is available at [www.anzctr.org.au](http://www.anzctr.org.au).

Cohort studies can be registered in the ANZCTR and successful grantees are encouraged to register their study with the registry, if applicable.

### 12.3 Evaluation of the Clinical Trials and Cohort Studies Grant scheme

NHMRC undertakes periodic evaluations of the performance and administration of its funding scheme to determine their effectiveness and to identify where improvements can be made.

### 12.4 Open Access Policy

NHMRC supports the sharing of outputs from NHMRC funded research including publications and data. The aims of NHMRC's *Open Access Policy* are to mandate the open access sharing of publications and encourage innovative open access to research data. This policy also requires that patents resulting from NHMRC funding be made findable through listing in SourceIP. NHMRC's *Open Access Policy* is available on [NHMRC's website](#).

Combined, these approaches will help to increase reuse of data, improve research integrity and contribute to a stronger knowledge economy. Open access will also assist with reporting, demonstration of research achievement, improve track record assessment processes for the long term and contribute to better collaborations.

All recipients of NHMRC grants must comply with all elements of NHMRC's *Open Access Policy*.

## 13 Probity

### 13.1 Complaints process

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

Each complaint should be directed to the Complaints Team at: [complaints@nhmrc.gov.au](mailto:complaints@nhmrc.gov.au).

NHMRC will provide a written response to all complaints.

Refer to NHMRC's Complaints Policy and the Commissioner of Complaints webpage for further information.

Applicants or grantees may complain to the Commonwealth Ombudsman if they do not agree with the way NHMRC has handled their complaint. 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](mailto:ombudsman@ombudsman.gov.au)

Website: [www.ombudsman.gov.au](http://www.ombudsman.gov.au)

## 13.2 Privacy: confidentiality and protection of personal information

NHMRC treats applicants' personal information according to the 13 Australian Privacy Principles set out in the *Privacy Act 1988*. This includes identifying:

- what personal information NHMRC collects
- why NHMRC collects applicants' personal information, and
- who NHMRC gives applicants' personal information to.

Applicants are required as part of their application to declare their ability 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.

Personal information can only be disclosed to someone else if applicants are given reasonable notice of the disclosure; if the disclosure is related to the purpose for which it was collected; where disclosure is authorised or required by law or is reasonably necessary for the enforcement of the criminal law; if it will prevent or lessen a serious and imminent threat to a person's life or health; or if the applicant has consented to the disclosure.

The Australian Government may also use and disclose information about grant applicants and grant recipients under this scheme in any other Australian Government business or function. This includes giving information to the Australian Taxation Office for compliance purposes.

NHMRC may reveal confidential information to:

- the peer review committee and other Commonwealth employees and contractors to help NHMRC manage the scheme effectively
- employees and contractors of NHMRC to research, assess, monitor and analyse schemes and activities
- employees and contractors of other Commonwealth agencies for any purposes, including government administration, research or service delivery
- other Commonwealth, State, Territory or local government agencies in reports and consultations
- NHMRC approved Administering Institutions' Research Administration Offices
- the Auditor-General, Ombudsman or Privacy Commissioner
- the responsible Minister or Parliamentary Secretary, and
- a House or a Committee of the Australian Parliament.

Applicants or grantees must ask for the Australian Government's consent in writing before disclosing confidential information.

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
- *Criminal Code Act 1995*.

### 13.3 Freedom of Information

NHMRC is subject to the *Freedom of Information Act 1982* and is committed to meeting the Australian Government's transparency and accountability requirements.

## 14 NHMRC policies

Administering Institutions and CIAs are bound by the conditions of the Funding Agreement. It is the responsibility of Administering Institutions and CIs to be aware of, and be compliant with, all relevant legislation and policies relating to the conduct of the Research Activity.

NHMRC funded research must be conducted in accordance with the Code.

For further information on the expectations of Administering Institutions and CIs, see [NHMRC's website](#).

## 15 Glossary

Term	Definition
assessment criteria	The specified principles or standards against which applications will be judged. These criteria are used to assess the merits of proposals and, in the case of a competitive granting activity, to determine applicant rankings.
<i>Commonwealth Grants Rules and Guidelines 2017 (CGRGs)</i>	The CGRGs establish the overarching Commonwealth grants policy framework and the expectations for all non-corporate Commonwealth entities in relation to grants administration.
date of effect	This will depend on the particular grant. It can be the date the schedule to a grant agreement is executed or the announcement of the grant, whichever is later.
eligibility criteria	The principles, standards or rules that a grant applicant must meet to qualify for consideration of a grant.
final year	Is the final 12 calendar months of a grant.
Funding Agreement	For NHMRC MREA grants, the grant agreement is the NHMRC Funding Agreement and the Schedule to the Funding Agreement.
grant	<p>A grant is an arrangement for the provision of financial assistance by the Commonwealth or on behalf of the Commonwealth:</p> <ul style="list-style-type: none"> <li>a) under which relevant money, or other consolidated revenue funds, is to be paid to a recipient other than the Commonwealth</li> <li>b) which is intended to assist the recipient achieve its goals</li> <li>c) which is intended to help address one or more of the Australian Government's policy objectives.</li> </ul> <p>under which the recipient may be required to act in accordance with specified terms or conditions.</p>
grant activity	Is the project/tasks/services that the grantee is required to undertake with the grant money. It is described in the schedule to the NHMRC Funding Agreement.
GrantConnect	<p>GrantConnect is the Australian Government's whole-of-government grants information system, which centralises the publication and reporting of Commonwealth grants in accordance with the CGRGs. It is available at <a href="http://www.grants.gov.au">www.grants.gov.au</a>.</p> <p>Non-corporate Commonwealth entities must publish on GrantConnect to meet the grant publishing requirements under the CGRGs.</p> <p>Where information is published in more than one location, and there are inconsistencies, GrantConnect is the authoritative, auditable information source.</p>

Term	Definition
grant opportunity	A notice published on GrantConnect advertising the availability of Commonwealth grants.
grant program	Is a group of one or more grant opportunities under a single entity Portfolio Budget Statement Program. This is referred to as a scheme in this document.
grantee	An individual/organisation that has been awarded a grant.
Medical Research Endowment Account (MREA)	The purpose of the MREA is to provide assistance to Federal and State Government Departments, institutions, universities and/or persons engaged in medical research.
NHMRC's granting system	NHMRC's electronic grants management solution for grant application, assessment and administration. For the 2019 application round of Clinical Trials and Cohort Studies Grants, this is NHMRC's Research Grants Management System (RGMS).
peer reviewers	Individuals (peers) with knowledge and expertise appropriate for the applications they are reviewing.
Portfolio Budget Statement (PBS) Program	Described within the entity's PBS, PBS programs each link to a single outcome and provide transparency for funding decisions. These high level PBS programs often comprise a number of lower level, more publicly recognised programs, some of which will be Grant Programs (schemes). A PBS Program may have more than one Grant Program (scheme) associated with it, and each of these may have one or more grant opportunities.
Probity Event	<p>Probity Event means any event or occurrence which:</p> <ul style="list-style-type: none"> <li>a) has a material adverse effect on the integrity, character or honesty of the Administering Institution, a Participating Institution or Personnel involved in a Research Activity; or</li> <li>b) relates to the Administering Institution, a Participating Institution or Personnel involved in a Research Activity and has a material adverse effect on the public interest or public confidence in the Administering Institution, Participating Institution or Research Activity.</li> </ul>
schedule	Means the contract template used by NHMRC to form part of the Funding Agreement. The schedule sets out the research activity and is signed by NHMRC and the CIA's Administering Institution.

Term	Definition
value with money	<p>Value with money in this document refers to 'value with relevant money' which is a term used in the CGRGs and 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.</p> <p>When administering a grant opportunity, an official should consider the relevant financial and non-financial costs and benefits of each proposal including, but not limited to:</p> <ul style="list-style-type: none"> <li>• the quality of the project proposal and activities</li> <li>• fitness for purpose of the proposal in contributing to government objectives</li> <li>• that the absence of a grant is likely to prevent the grantee and government's outcomes being achieved</li> <li>• the potential grantee's relevant experience and performance history.</li> </ul>



# Appendix A. NHMRC structural priorities, Clinical Trials and Cohort Studies Grants 2019 Opportunity priorities and funding organisations

## A1 NHMRC key structural priorities

Each year, NHMRC identifies key structural priorities for funding to deliver against strategic priorities. NHMRC's current research key structural priorities are:

- Aboriginal and Torres Strait Islander health research and researchers
- health services research, and
- gender equality.

### **Aboriginal and Torres Strait Islander Health research and researchers**

NHMRC is committed to improving the health outcomes of Aboriginal and Torres Strait Islander people and encourages applications that address Aboriginal and Torres Strait Islander health. Support for health and medical research and research translation is central to achieving improvements in this area. It is also important to increase the number of Aboriginal and Torres Strait Islander researchers and recognise the diversity of Aboriginal and Torres Strait Islander people and communities, and how this diversity relates to health issues in these communities.

As part of NHMRC's stated commitment to advancing Aboriginal and Torres Strait Islander health research, NHMRC has established certain requirements and processes designed to ensure that research into Aboriginal and Torres Strait Islander health is of the highest scientific merit and is beneficial and acceptable to Aboriginal and Torres Strait Islander people and communities.

Applicants proposing to undertake research that specifically relates to the health of Aboriginal and Torres Strait Islander people, or which includes distinct Aboriginal and Torres Strait Islander populations, biological samples or data should be aware of, and must refer to, the following documents in formulating their proposal:

- *NHMRC Road Map 3: A Strategic Framework for Improving Aboriginal and Torres Strait Islander Health through Research*
- *Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research*, and
- *Keeping research on track: A guide for Aboriginal and Torres Strait Islander peoples about health research ethics.*

### **Health Services Research**

Increasing the number of health services research grants is a strategic priority. Of the total 1035 competitive grants awarded in 2017, only 6.9% of these grants were for Health Services Research, which is significantly lower than Basic Science at 47.3%, Clinical Medicine and Science at 31.2% and Public Health at 14.6%.

### **Gender Equality**

Funding outcomes have highlighted the underrepresentation of female chief investigators across many of NHMRC's funding schemes. This supports the need for a robust and sustainable approach to improving success rates for female researchers and to encourage more female researchers to apply to NHMRC funding schemes.

## A2 Clinical Trials and Cohort Studies Grants 2019 priority areas

In addition to these key priorities, NHMRC may award Clinical Trials and Cohort Studies Grants that:

- address other defined structural priorities
- acknowledge prominent Australians' contributions to health and medical research (Special Awards), and
- are funded with partner organisations.

Note: Special Awards have not been identified for this grant opportunity.

### **Electromagnetic Energy Research**

The Australian Government recognises public concern about the health effects of radio frequency (RF) electromagnetic energy (EME), and the need to ensure that standards and public health policies continue to be based on the best available scientific information. NHMRC administers the RF EME research program to provide funding for health and medical research on the health effects of RF EME. The program is funded by a levy paid annually by radiocommunication licence holders and collected by the Australian Communications and Media Authority.

To be considered for this funding, applicants must:

- show that their project investigates the effects of RF EME on human health
- provide a description of both the RF exposure (such as frequency range and source of the exposure) and the health effect that is being investigated, and
- provide a detailed justification on how their application aligns with the research agenda into RF EME and health outlined in the 2017 Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) Technical Report, *Radiofrequency Electromagnetic Energy and Health: Research Needs*.

NHMRC in conjunction with ARPANSA will determine if an application meets the criteria for RF EME research and is eligible to be funded through the RF EME program. Applications not in scope will be considered for standard NHMRC funding.

### **Clinical Trials and Cohort Studies Grants funded by other organisations**

Clinical Trials and Cohort Studies Grants may be funded by or in conjunction with other organisations. These grants offer opportunities to researchers whose work is particularly relevant to the priorities and research interests of the partner organisations.

Some funding partners may require a separate application to be provided to them, or may have specific criteria and requirements, in addition to NHMRC. Applicants may contact the funding partner to identify any additional requirements.

For the purposes of the *Privacy Act 1988*, applicants and other persons whose details appear in grant applications (e.g. other investigators) should be aware that NHMRC may provide their personal information, including all pertinent application documentation and peer review outcomes to the funding organisation(s) nominated by the applicant. The purpose of providing this information is to enable potential funding partners to assess the application's eligibility for funding under the funding organisation's policies.

In the event that a funding partner is unable to fulfil their obligation to a co-funded grant, NHMRC will continue to support the Clinical Trials and Cohort Studies Grant recipient under the conditions that would have been awarded by NHMRC.

Any additional benefits that may have been provided by the funding partner, including Clinical Trials and Cohort Studies Grants that may have been fully funded by the funding partner, will not be supported by NHMRC.

The following organisations are expected to partner with NHMRC in funding grants under this grant opportunity:

- Cancer Australia & Funding Partners.

## Appendix B. Relative to Opportunity policy

### Purpose

The purpose of this document is to outline NHMRC's Relative to Opportunity Policy with respect to:

- NHMRC peer review, and
- eligibility to apply for Emerging Leadership Investigator Grants.

NHMRC's objective is to support the best Australian health and medical research and the best researchers, at all career stages. NHMRC seeks to ensure that researchers with a variety of career experiences and those who have experienced pregnancy or a major illness/injury or have caring responsibilities, are not disadvantaged in applying for NHMRC grants.

### Policy approach

NHMRC considers Relative to Opportunity to mean that assessment processes should accurately assess an applicant's track record and associated productivity relative to stage of career, including considering whether productivity and contribution are commensurate with the opportunities available to the applicant. It also means that applicants with career disruptions should not be disadvantaged (in terms of years since they received their PhD) when determining their eligibility for Emerging Leadership Investigator Grants and that their Career Disruptions should be considered when their applications are being peer reviewed.

In alignment with *NHMRC's Principles of Peer Review*, particularly the principles of fairness and transparency, the following additional principles further support this objective:

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

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

### Relative to Opportunity considerations during peer review of applications for funding

During peer review of applications, circumstances considered under the Relative to Opportunity Policy are:

- 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 that can impact on track record and productivity
- clinical, administrative or teaching workload
- relocation of an applicant and his/her research laboratory or clinical practice setting or other similar circumstances that impact on research productivity
- for Aboriginal and Torres Strait Islander applicants, community obligations including 'sorry business'
- the typical performance of researchers in the research field in question
- research outputs and productivity noting time employed in other sectors. For example there might be a reduction in publications when employed in sectors such as industry
- carer responsibilities (that do not come under the Career Disruption policy below).

### Career Disruption considerations during peer review and eligibility to apply for Emerging Leadership Investigator Grants

A Career Disruption is defined as a prolonged interruption to an applicant's capacity to work, due to:

- pregnancy
- major illness/injury
- carer responsibilities.

The period of career disruption may be used:

- to determine an applicant's eligibility for an Emerging Leadership Investigator Grant
- to allow for the inclusion of additional track record information for assessment of an application
- for consideration by peer reviewers.

To be considered for the purposes of eligibility and peer review, a period of Career Disruption is defined as:

- a continuous absence from work for 90 calendar days or more, and/or
- continuous, long-term, part-time employment (with defined %FTE) due to circumstances classified as Career Disruption, with the absence amounting to a total of 90 calendar days or more<sup>1</sup>.

### Career Disruption and eligibility to apply for Investigator Grants

A Career Disruption can affect an applicant's eligibility to apply for an Emerging Leadership Investigator Grant. For such grants, the 10-year time limit on the number of years post-PhD may be extended commensurate with the period of the Career Disruption.

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<sup>1</sup> For example, an applicant who is employed at 0.8 FTE due to childcare responsibilities would need to continue this for at least 450 calendar days to achieve a Career Disruption of 90 calendar days.

## Implementation

Information on how applicants can demonstrate their track record, Relative to Opportunity, for the purposes of peer review is available in NHMRC's granting system and in NHMRC's [Guide to Peer Review](#).

## Appendix C. Clinical Trials and Cohort Studies Grants 2019 Category Descriptors

The following category descriptors are used as a guide to scoring an application against each of the assessment criteria.

While the category descriptors provide peer reviewers with some benchmarks for appropriately scoring each application, it is not essential that all descriptors relating to a given score are met.

The category descriptors are a “best fit” outcome. Peer reviewers will consistently refer to these category descriptors to ensure thorough, equitable and transparent assessment of applications.

### Assessing Aboriginal and Torres Strait Islander Contributions

To assist in assessing Aboriginal and Torres Strait Islander health research applications, the criteria for Indigenous health research have been integrated in the table below. This is to be used as a guide only.

### Significance (40%)

SCORE						
7	6	5	4	3	2	1
<p>The proposed clinical trial and/or cohort study:</p> <ul style="list-style-type: none"> <li>• will comprehensively and convincingly address the objective of this grant opportunity and will deliver against the desired outcomes</li> <li>• is informed by an exemplary analysis or review of existing and ongoing studies in the field</li> <li>• was developed with broad and meaningful involvement of research end-users to ensure it meets their needs</li> <li>• if successful, will have very significant research impacts.</li> </ul>	<p>The proposed clinical trial and/or cohort study:</p> <ul style="list-style-type: none"> <li>• will strongly address the objective of this grant opportunity and will deliver against desired outcomes</li> <li>• is informed by a thorough analysis or review of existing and ongoing studies in the field</li> <li>• was developed with meaningful involvement of research end-users to ensure it meets their needs</li> <li>• if successful, will have significant research impacts.</li> </ul>	<p>The proposed clinical trial and/or cohort study:</p> <ul style="list-style-type: none"> <li>• will address the objective of this grant opportunity with only minor concerns and deliver relevant desired outcomes</li> <li>• is informed by a good analysis or review of relevant existing and ongoing studies in the field, with only minor concerns with respect to the analysis</li> <li>• had research end-user involvement in a number of key aspects of the design</li> <li>• if successful, will have appreciable research impacts.</li> </ul>	<p>The proposed clinical trial and/or cohort study:</p> <ul style="list-style-type: none"> <li>• will partially address the objective of the grant opportunity and deliver desired outcomes of some relevance</li> <li>• there are several minor concerns about the analysis or review of existing and ongoing studies which informs the research</li> <li>• had research end-user involvement in a number of aspects of the design</li> <li>• if successful, may have moderate research impacts.</li> </ul>	<p>The proposed clinical trial and/or cohort study:</p> <ul style="list-style-type: none"> <li>• will not convincingly address the objective of this grant opportunity or is unclear in its approach to doing so</li> <li>• there are significant or major concerns about the analysis or review of existing and ongoing studies which informs the research</li> <li>• had limited research end-user involvement in the design</li> <li>• if successful, it is unlikely to have anything other than minor research impact.</li> </ul>	<p>The proposed clinical trial and/or cohort study:</p> <ul style="list-style-type: none"> <li>• will not address the objective of this grant opportunity or is unclear in its approach to doing so</li> <li>• is informed by a very limited analysis or review of existing and ongoing studies in the field</li> <li>• had minimal research end-user involvement in limited aspects of the design.</li> </ul>	<p>The proposed clinical trial and/or cohort study:</p> <ul style="list-style-type: none"> <li>• will not address any of the objectives of this grant opportunity</li> <li>• is informed by a poor analysis or review of existing and ongoing studies in the field and therefore will not translate into outcomes that improve treatment of a medical condition or improve health outcomes.</li> </ul>

SCORE						
7	6	5	4	3	2	1
Significance of the grant outcomes: Indigenous criteria						
<p><b>Sustainability and transferability</b></p> <ul style="list-style-type: none"> <li>• The outcomes of the study will definitely lead to major and effective health gains for Aboriginal and Torres Strait Islander peoples, beyond the life of the project</li> <li>• The outcomes of the study will have a very high impact on health services delivery or other community priorities.</li> </ul> <p><b>Benefit</b></p> <ul style="list-style-type: none"> <li>• The outcomes of the study will have a very significant health benefit for Aboriginal and Torres Strait Islander peoples.</li> </ul>	<p><b>Sustainability and transferability</b></p> <ul style="list-style-type: none"> <li>• The outcomes of the study will lead to considerable and effective health gains for Aboriginal and Torres Strait Islander peoples, beyond the life of the project</li> <li>• The outcomes of the study will have a high impact on health services delivery or other community priorities.</li> </ul> <p><b>Benefit</b></p> <ul style="list-style-type: none"> <li>• The outcomes of the study will have a significant health benefit for Aboriginal and Torres Strait Islander peoples.</li> </ul>	<p><b>Sustainability and transferability</b></p> <ul style="list-style-type: none"> <li>• The outcomes of the study will lead to effective health gains for Aboriginal and Torres Strait Islander peoples, beyond the life of the project</li> <li>• The outcomes of the study will have an impact on health services delivery or other community priorities.</li> </ul> <p><b>Benefit</b></p> <ul style="list-style-type: none"> <li>• The outcomes of the study will have some health benefit for Aboriginal and Torres Strait Islander peoples.</li> </ul>	<p><b>Sustainability and transferability</b></p> <ul style="list-style-type: none"> <li>• The outcomes of the study may lead to effective health gains for Aboriginal and Torres Strait Islander peoples, beyond the life of the project</li> <li>• The outcomes of the study may have an impact on health services delivery or other community priorities.</li> </ul> <p><b>Benefit</b></p> <ul style="list-style-type: none"> <li>• The outcomes of the study may have some health benefit for Aboriginal and Torres Strait Islander peoples.</li> </ul>	<p><b>Sustainability and transferability</b></p> <ul style="list-style-type: none"> <li>• The outcomes of the study may lead to limited or short- term health gains for Aboriginal and Torres Strait Islander peoples</li> <li>• The outcomes of the study may have a moderate impact on health services delivery or other community priorities.</li> </ul> <p><b>Benefit</b></p> <ul style="list-style-type: none"> <li>• The outcomes of the study are likely to have a minimal health benefit for Aboriginal and Torres Strait Islander peoples.</li> </ul>	<p><b>Sustainability and transferability</b></p> <ul style="list-style-type: none"> <li>• The outcomes of the study are unlikely to lead to any health gains for Aboriginal and Torres Strait Islander peoples</li> <li>• The outcomes of the study are unlikely to have any impact on health services delivery or other community priorities.</li> </ul> <p><b>Benefit</b></p> <ul style="list-style-type: none"> <li>• The outcomes of the study are likely to have little or no health benefit for Aboriginal and Torres Strait Islander peoples.</li> </ul>	<p><b>Sustainability and transferability</b></p> <ul style="list-style-type: none"> <li>• The outcomes of the study will not lead to any health gains for Aboriginal and Torres Strait Islander peoples</li> <li>• The outcomes of the study will not have any impact on health services delivery or other community priorities.</li> </ul> <p><b>Benefit</b></p> <ul style="list-style-type: none"> <li>• The outcomes of the study will have no health benefit for Aboriginal and Torres Strait Islander peoples.</li> </ul>



## Research Quality (40%)

SCORE						
7	6	5	4	3	2	1
<p>The proposed clinical trial and/or cohort study:</p> <ul style="list-style-type: none"> <li>• has a near flawless design and research methodologies appropriate to the research question</li> <li>• is comparable with the best international research in the field</li> <li>• is highly feasible with all of the required techniques and resources established</li> <li>• includes highly appropriate research end-user involvement</li> <li>• includes highly effective milestones and performance indicators.</li> </ul>	<p>The proposed clinical trial and/or cohort study:</p> <ul style="list-style-type: none"> <li>• has a strong, well defined and coherent design and research methodologies appropriate to the research question</li> <li>• is comparable with strong proposals in the field internationally</li> <li>• is feasible with required techniques and resources established</li> <li>• includes appropriate research end-user involvement</li> <li>• includes effective milestones and performance indicators.</li> </ul>	<p>The proposed clinical trial and/or cohort study:</p> <ul style="list-style-type: none"> <li>• is generally clear in its research methodology, logical and appropriate to the research question</li> <li>• raises only very few minor concerns with respect to the study design</li> <li>• is feasible in almost all areas: required techniques and resources established or nearly established</li> <li>• may not be highly competitive with similar research proposals internationally</li> <li>• includes some appropriate research end-user involvement</li> <li>• raises a few very minor concerns about the appropriateness of milestones and performance indicators.</li> </ul>	<p>The proposed clinical trial and/or cohort study:</p> <ul style="list-style-type: none"> <li>• is generally solid in design and is appropriate to the research question, but may not always be clear in its intent and focus</li> <li>• raises several minor concerns regarding the study design and research methodologies</li> <li>• raises doubts about feasibility in a number of areas</li> <li>• is not likely to be competitive with similar research proposals internationally</li> <li>• includes constructive research end-user involvement but with limited scope</li> <li>• raises minor concerns about the appropriateness of milestones and performance indicators.</li> </ul>	<p>The proposed clinical trial and/or cohort study:</p> <ul style="list-style-type: none"> <li>• is somewhat unclear in its design</li> <li>• is not appropriate to the research question or contains some major design or methodological flaws</li> <li>• raises major concerns about the feasibility and thus the likelihood of successful completion</li> <li>• includes minimal, tokenistic research end-user involvement</li> <li>• raises significant concerns about the appropriateness of milestones and performance indicators.</li> </ul>	<p>The proposed clinical trial and/or cohort study:</p> <ul style="list-style-type: none"> <li>• is unclear in its design</li> <li>• contains several major flaws in study design and research methodologies</li> <li>• raises several major concerns about the feasibility and thus the likelihood of successful completion.</li> </ul>	<p>The proposed clinical trial and/or cohort study:</p> <ul style="list-style-type: none"> <li>• has a poorly developed research proposal which does not seem to be feasible and is unlikely to be successfully completed.</li> </ul>
Research quality: Indigenous criteria						
<p><b>Community Engagement</b> The proposal has a research plan that:</p> <ul style="list-style-type: none"> <li>• has outstanding levels of community engagement, ensuring that the proposal is highly feasible</li> <li>• demonstrates how the research and potential outcomes are a priority for the community to an outstanding degree.</li> </ul>	<p><b>Community Engagement</b> The proposal has a research plan that:</p> <ul style="list-style-type: none"> <li>• has excellent levels of community engagement, ensuring that the proposal is feasible</li> <li>• demonstrates how the research and potential outcomes are a priority for the community to an excellent degree.</li> </ul>	<p><b>Community Engagement</b> The proposal has a research plan that:</p> <ul style="list-style-type: none"> <li>• has very good levels of community engagement, ensuring that the proposal is likely to be feasible</li> <li>• clearly demonstrates how the research and potential outcomes are a priority for the community.</li> </ul>	<p><b>Community Engagement</b> The proposal has a research plan that:</p> <ul style="list-style-type: none"> <li>• has good levels of community engagement</li> <li>• raises some concerns that the proposal is feasible</li> <li>• demonstrates how the research and potential outcomes are a priority for the community.</li> </ul>	<p><b>Community Engagement</b> The proposal:</p> <ul style="list-style-type: none"> <li>• has limited community engagement</li> <li>• raises several concerns whether the proposal is feasible and achievable.</li> </ul>	<p><b>Community Engagement</b> The proposal:</p> <ul style="list-style-type: none"> <li>• has little or no community engagement</li> <li>• is unlikely to be feasible and achievable.</li> </ul>	<p><b>Community Engagement</b> The proposal:</p> <ul style="list-style-type: none"> <li>• has no community engagement</li> <li>• will not be feasible.</li> </ul>

## Team Quality and Capability (20%)

SCORE						
7	6	5	4	3	2	1
<p>Relative to opportunity, the Chief Investigators (CIs):</p> <ul style="list-style-type: none"> <li>• have a high level of expertise and experience in all aspects of the proposed research</li> <li>• have over the last 5 years, a combined record of research achievement that is outstanding by international standards commensurate with their field of research (research achievement, quality and productivity)</li> <li>• have outstanding national and international reputations in clinical trial or cohort study methodology and relevant research fields</li> <li>• may include junior members who are strong contributors to overall team capability.</li> </ul>	<p>Relative to opportunity, the CIs:</p> <ul style="list-style-type: none"> <li>• have expertise and experience that is highly relevant to the proposed research</li> <li>• have over the last 5 years, a combined record of research achievement that is excellent by international standards commensurate with their field of research (research achievement, quality and productivity)</li> <li>• have excellent national and/or international reputations in clinical trial or cohort study methodology and relevant research fields</li> <li>• may include junior members who contribute to overall team capability.</li> </ul>	<p>Relative to opportunity:</p> <ul style="list-style-type: none"> <li>• there are only minor concerns about the CIs' level of expertise and experience required to undertake the proposed research</li> <li>• the CIs have over the last 5 years, a combined record of research achievement that is well above average by international standards commensurate with their field of research (research achievement, quality and productivity)</li> <li>• the CIs have very good national and/or international reputations in clinical trial or cohort study methodology and relevant research fields</li> <li>• the CIs may include junior members who have the potential to add to the team capability.</li> </ul>	<p>Relative to opportunity:</p> <ul style="list-style-type: none"> <li>• there are significant concerns about the CIs' level of expertise and experience required to undertake the proposed research</li> <li>• the CIs have over the last 5 years, a combined record of research achievement that is average by international standards commensurate with their field of research (research achievement, quality and productivity)</li> <li>• the CIs have good national and/or international reputations in clinical trial or cohort study methodology and the relevant research fields</li> <li>• the CIs may include junior members who have the potential to add to the team capability, but there is little evidence of a mentoring framework.</li> </ul>	<p>Relative to opportunity, the CIs:</p> <ul style="list-style-type: none"> <li>• have made contributions to the field of research but there are significant concerns regarding the depth and breadth of relevant expertise of the team</li> <li>• have over the last 5 years, a combined record of research achievement (research achievement, quality and productivity), that places them at an average level for their peers/cohort</li> <li>• have made limited progress towards research achievements warranting national or international recognition.</li> </ul>	<p>Relative to opportunity, the CIs:</p> <ul style="list-style-type: none"> <li>• are deficient in some areas of expertise required to successfully complete the proposed research</li> <li>• have published only a few works in relevant fields of research</li> <li>• are not well recognised nationally or internationally for their achievements in the relevant research fields.</li> </ul>	<p>Relative to opportunity, the CIs:</p> <ul style="list-style-type: none"> <li>• are deficient in the relevant expertise required to successfully complete the proposed research</li> <li>• are not productive to any significant extent in relevant fields of research</li> <li>• are not well recognised nationally or internationally for their achievements in the relevant research fields.</li> </ul>

SCORE						
7	6	5	4	3	2	1
<b>Team quality and capability: Indigenous criteria</b>						
<b>Building capability</b> <ul style="list-style-type: none"> <li>• The team has an outstanding track record in working with communities and building capability among Aboriginal and Torres Strait Islander peoples</li> <li>• The proposal will build outstanding capability among Aboriginal and Torres Strait Islander peoples.</li> </ul>	<b>Building capability</b> <ul style="list-style-type: none"> <li>• The team has an excellent track record in working with communities and building capability among Aboriginal and Torres Strait Islander peoples</li> <li>• The proposal will build excellent capability among Aboriginal and Torres Strait Islander peoples.</li> </ul>	<b>Building capability</b> <ul style="list-style-type: none"> <li>• The team has a very good track record in working with communities and building capability among Aboriginal and Torres Strait Islander peoples</li> <li>• The proposal will build very good capability among Aboriginal and Torres Strait Islander peoples.</li> </ul>	<b>Building capability</b> <ul style="list-style-type: none"> <li>• The team has a good track record in working with communities and building capability among Aboriginal and Torres Strait Islander peoples</li> <li>• The proposal may build good capability among Aboriginal and Torres Strait Islander peoples.</li> </ul>	<b>Building capability</b> <ul style="list-style-type: none"> <li>• The team has a marginal track record in working with communities and building capability among Aboriginal and Torres Strait Islander peoples</li> <li>• The proposal may build minimal capability among Aboriginal and Torres Strait Islander peoples.</li> </ul>	<b>Building capability</b> <ul style="list-style-type: none"> <li>• The team has an unsatisfactory track record in working with communities and building capability among Aboriginal and Torres Strait Islander peoples</li> <li>• The proposal is unlikely to build capability among Aboriginal and Torres Strait Islander peoples.</li> </ul>	<b>Building capability</b> <ul style="list-style-type: none"> <li>• The team has a poor track record in working with communities and building capability among Aboriginal and Torres Strait Islander peoples</li> <li>• The proposal will not build capability among Aboriginal and Torres Strait Islander peoples.</li> </ul>

## Appendix D. Guide to Applicants

This Appendix provides guidance for submitting an application for the CTCS 2019 Grant Opportunity through NHMRC's Research Grants Management System (RGMS). Parts of this Appendix were published previously as the *Clinical Trials and Cohort Study Grants 2019 Guide to Applicants on Preparing an Application*, which included the category descriptors. The category descriptors are now located at [Appendix C](#).

Clinical Trials and Cohort Studies Grants scheme-specific policy and instructions for applying in RGMS are provided in this Appendix. Applicants should refer to the [RGMS User Guide – Applying for Grants](#) for general instructions on how to apply in RGMS.

For further assistance during the application process, see section 7 of the *Clinical Trials and Cohort Studies Grants 2019 Guidelines* (the Grant Guidelines).

### 1. PREPARING AN APPLICATION

#### 1.1 Application Requirements

A complete application is comprised of:

- mandatory sections of My Profile and CV (section 2 below)
- a completed application form (section 3 below)
- a Grant Proposal as an attachment (section 4 below).

Applications, including the Grant Proposal attachment, must comply with all rules and requirements as set out in the Grant Guidelines and elsewhere in this Appendix. Failure to adhere to any of these requirements will result in non-acceptance or exclusion of your application (see section 4.2 of the Grant Guidelines).

#### 1.2 Minimum Data Requirements

Minimum data must be entered in NHMRC's granting system to allow NHMRC to start identifying suitable peer reviewers. Applications who fail to satisfy this requirement will not be accepted. Applicants must complete the required fields with correct information. Using placeholder text such as "text", "synopsis" or "xx" etc. is not acceptable as minimum data.

Minimum data is comprised of:

- Chief Investigator A
- Administering Institution
- Application Title
- Aboriginal/Torres Strait Islander Research (yes/no)
- Synopsis
- Plain English Summary
- Participating Institutions/s
- Research Classification (all fields)
- Privacy Consent – Int'l

Minimum data must be entered into RGMS by **17:00 AEST on 10 April 2019**. Applicants should refer to section 7.2 of the Grant Guidelines for further information.

Failure to meet this deadline will result in the application not proceeding.

Research Administration Officers (RAOs) are not required to certify applications for the purpose of minimum data. Applications should only be certified once complete and ready for submission to NHMRC.

### 1.3 Peer Review Areas

Applicants must nominate three peer review areas that are the most relevant to their application. This information will be used to determine the Grant Review Panel (GRP) most suitable to review the application. If an application covers multiple peer review areas, the primary area nominated should be the main focus of the application.

## 2. MY PROFILE AND CV REQUIREMENTS IN RGMS

Within an applicant's profile in RGMS, there is mandatory information that must be completed and/or updated prior to submitting an application. This information includes, but not exclusively, personal details, academic/research interests and peer review information.

The requirement to complete the mandatory sections of the Profile and CV applies to all Chief Investigators (CIs) named on the application. It is accordingly advisable to check that each of the CIs has completed and/or updated their profiles before an application is certified. In addition to this information, applicants are also required to complete the sections outlined below. Should more information be entered than is required, only the required information will be imported into the application.

It is important that relevant profile information is up to date at the time of application submission as it is imported into the application and used by peer reviewers. Any changes made to the profile after Chief Investigator A (CIA) certification will not appear in the submitted application.

### 2.1 CV-RO: Relative to Opportunity (within the last 5 years)

If applicable, the applicant should use this section to provide details of any Relative to Opportunity considerations and the effect they have had on their research and research achievements.

Guidance on what constitutes 'Relative to Opportunity' is provided in [Appendix B \(NHMRC Relative to Opportunity Policy\)](#).

#### **Circumstance**

Provide a brief explanation of the type of Relative to Opportunity circumstance (maximum of 200 characters including spaces and line breaks).

#### **Impact**

Provide a brief explanation of the impact this has had on the applicant's research, research achievements and associated productivity relative to their career stage (maximum of 1500 characters including spaces and line breaks).

#### **Date**

Applicants are required to nominate the periods when they have had a Relative to Opportunity circumstances (approximate dates).

## 2.2 CV-Pub: Publications

Publication information can be uploaded by exporting an EndNote® Library as an .xml file. NHMRC accepts nine types of publication: Journal Articles (Original Research), Journal Articles (Review), Books/Chapters, Research Report – commissioned by Government, industry or other, Technical Report, Text Book, Accepted for Publication, Editorials and Letters to the Editor.

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 to refer to specific publications in other sections of the application.

Provide details of your publications. The last five (5) years of publications will be included in your application and provided to peer reviewers for assessment. Applicants should verify that publication information has been correctly uploaded by requesting a CV Snapshot.

## 2.3 CV-CD: Career Disruption (within the last 5 years)

If applicable, applicants should use this opportunity to declare any career disruptions that may be relevant to their career history.

Guidance on what constitutes a career disruption and how it is considered is provided in [Appendix B \(NHMRC Relative to Opportunity Policy\)](#).

NHMRC is committed to ensuring that every applicant is treated fairly, and this means that it recognises some applicants will have had career disruptions that should be considered when evaluating their track record. A career disruption is defined as a prolonged interruption to an applicant's capacity to work due to pregnancy, major illness/injury and/or carer responsibilities.

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. Relative to Opportunity circumstances are not considered career disruptions.

### **Career Disruption**

To enter a Career Disruption, select the 'New' button. Select the nature of the career disruption from the drop down menu. Enter the 'Start date' and 'End date' and RGMS will automatically calculate the number of days.

### **Impact**

Clearly outline the impact the career disruption/s has/have had on your research and research achievements and associated productivity relative to stage of career. Only include details of the impact upon career, not the nature of the disruption, noting this information is provided to assessors. (Maximum of 2000 characters including spaces and line breaks).

### **Additional research outputs**

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

of 2000 characters including spaces and line breaks.)

#### **Dates**

Applicants are required to nominate the periods (approximate dates) when they have had a disruption.

## **2.4 CV-RF: NHMRC Research Funding**

Click 'New' to start a new entry of any previous and/or current NHMRC funding, including offers received for future funding. Entries will be listed in reverse chronological order.

Provide sufficient details about the funding to make clear what the funding was intended for, what you achieved and your role within these grants. You should ensure that your role is clearly defined on each grant, so that assessors can readily identify your contribution to the grant.

## **2.5 CV-ORF: Other Research Funding**

Click 'New' to start a new entry for any previous and/or current funding from sources other than NHMRC, including offers received for future funding. Entries will be listed in reverse chronological order. Complete all fields and provide as many details as you can in the spaces provided. You should ensure that your role is clearly defined on each grant, so that assessors can readily identify your contribution to the grant.

# **3. COMPLETING AN APPLICATION FORM IN RGMS**

All parts of the application form must be completed (see section 7.3 of the Grant Guidelines).

## **3.1 Creating an Application Form**

### **Initiative**

Select Clinical Trials and Cohort Studies from the drop down box.

### **Round**

Select 2019\_Clinical Trials and Cohort Studies Grants\_funding\_comencing\_2020.

### **Administering Institution**

There can only be one Administering Institution for each application. You must ensure that the institution you choose as your Administering Institution is the correct institution for your application. If in doubt, contact the RAO of the Administering Institution.

### **Application Title**

NHMRC will use the application title to identify the application at all times during the assessment process and it should accurately describe the nature of the research proposal (maximum of 250 characters including spaces and line breaks).

NHMRC will use the title for reporting purposes. It is important that spelling is correct and that any acronyms are spelled out in full.

### **Grant Duration**

A Clinical Trials and Cohort Studies Grant can be requested for between one and five years.

### **RAO Edit Access**

Select 'Yes' if you wish to allow your RAO to have edit rights to your application. NHMRC provides this functionality to support researchers and RAOs in managing the application process. NHMRC does not accept any responsibility for errors or omissions arising from the use of the RAO edit function and strongly recommends that RAOs, CIAs and Administering Institution(s) discuss the management of RAO edit access before selecting this function.

## **3.2 Completing Parts of the Application Form**

### **3.2.1 General**

#### **Aboriginal and Torres Strait Islander Research**

Select 'Yes' if you can demonstrate that at least 20% of your research effort and/or capacity building relates to Aboriginal and/or Torres Strait Islander health.

If you have answered 'Yes' to this question, you will be required to provide details of how your application addresses the *Indigenous Research Excellence Criteria* in your Grant Proposal (see section 6.1 of the Grant Guidelines).

#### **Synopsis**

The synopsis should accurately, and briefly, summarise the research proposal (maximum of 2000 characters including spaces and line breaks).

#### **Plain English Summary**

Describe the overall aims of the research and expected outcomes in simple terms that could be understood by the general public (maximum of 500 characters including spaces and line breaks).

#### **Privacy Notice**

Please ensure that you have carefully read and understood the [NHMRC Privacy Policy](#), prior to completing the application.

Tick the box to indicate that you have read and understood the NHMRC Privacy Policy.

#### **Consent to provide information to International Assessors**

Under amendments to the Privacy Act 1988 that took effect in March 2014, NHMRC requires your consent to send your personal information overseas, for the purposes of peer review of applications. Please indicate in the drop down box if you do or do not give permission for your application to be sent to international assessors.

#### **Consent to provide information to other organisations**

If you wish to be considered for funding by other organisations, please select 'Yes' for Funding Partner Consent. Applicants should be aware that if they indicate they wish to be considered for funding by a partner organisation, NHMRC will provide their application and assessment results to the funding partner. Refer to the [NHMRC website](#), [GrantConnect](#) and [Appendix A](#) for more information, including any specific application requirements.



### 3.2.2 A-PIInst: Institutions – Participating

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 that will be conducted in an affiliated teaching hospital.

This information is required by NHMRC to enable peer reviewers to identify potential institutional conflicts with your application.

#### **Research Effort (%)**

If the research will be conducted at more than one institution, enter the Research Effort percentage (%) allocated to each participating institution and department. The Research Effort entered cannot exceed 100%.

#### **Institution**

List the participating institution and department where the proposed research will be conducted. Complete this page for each institution if there is more than one.

### 3.2.3 A-RC: Research Classification

Research classification selections will be used in the peer review process to assist with the allocation of your application to the most suitable peer reviewers and grant review panel.

All fields on this page are mandatory and must be completed to meet minimum data requirements.

#### **Guide to Peer-Review Areas**

Three nominations are required and should be listed in order of relevance to the research proposal. Note: the same Peer-Review Area can be nominated three times, if appropriate.

### 3.2.4 A-BoD: Burden of Disease

You can select up to three types of Burden of Disease and allocate a percentage (%) of time against each. The percentage (%) total must not exceed 100%.

### 3.2.5 A-RT: Research Team

You may include a maximum of ten Chief Investigators (CIs) and ten Associate Investigators (AIs) in your research team. For further information on the eligibility requirements for CIs and AIs, please refer to section 4 of the Grant Guidelines.

List all members of your research team including CIs, AIs, Professional Research Personnel and Technical Support Staff. Complete a separate entry for each member of the team by selecting 'new'.

#### **Position Title**

This field is optional; you can use titles to identify specific PRP or TSS roles.

#### **Person (Chief Investigator and Associate Investigator only)**

All CIs must have an active RGMS account in order to be listed as part of the CI team. Use the browse function to search active RGMS account holders for your team member.

CIIs that cannot be located using the browse function will need to obtain an RGMS account.

If the candidate is an AI and cannot be located using the browse function, then you may enter their details manually in the fields provided.

**Role (Chief Investigators only)**

Select CIB-CIJ from the drop down box.

**Australian Based (Chief Investigators only)**

Indicate if the Chief Investigator will be based in Australia for the duration of the grant.

**Qualifications and Skills (Chief Investigators only)**

Outline the qualifications and skills relevant to the grant proposal for each Chief Investigator.

**3.2.5.1 A-RT: Research Team – Proposed Salary**

Salary contributions for research staff (CIIs, Professional Research Personnel 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.

Applicants can only draw one salary from one NHMRC grant/award. Further information about PSPs, including the levels, is available on the [NHMRC website](#).

This section only needs to be completed if you are seeking salary for a particular position.

Once you have created an entry for a team member, hover over the properties tab at the top of the screen and select 'A-RT: Proposed Salary' from the dropdown menu.

**Salary**

Level - Indicate the PSP level for the candidate.

Year % - Indicate the % of a full PSP package the candidate is to be paid for each year of the grant (in whole numbers only).

**Reason**

Provide detailed justification for the salary that is being requested for the candidate. The PSP level and the percentage of salary should both be well justified.

**3.2.6 A-EG: Ethics General**

If you answer 'Yes' to any of the questions, you will need to obtain ethics approvals and supply evidence of these to your research office in the event your application is funded. For further information, see *Ethics and Integrity* on the [NHMRC website](#).

**3.2.7 B-AI: Associate Investigators**

Als need to provide prior approval for their name(s) to be included in this application.

When completing this section, select the appropriate option from the drop down box. Written evidence will need to be provided to your RAO indicating that all Als have agreed to be named on the application.

### 3.2.8 B-SP: Research Type and Strategic Priorities.

The Clinical Trials and Cohort Studies scheme is open to research proposals for clinical trials and/or cohort studies that address important gaps in knowledge, leading to relevant and implementable findings for the benefit of human health. Applicants must identify in their application whether it is for a clinical trial and/or cohort study. This nomination, along with information provided as part of A-RC: Research Classification and Minimum Data will be used to determine a suitable Grant Review Panel (GRP) to review the application.

#### Electromagnetic Energy

If you are applying for Electromagnetic Energy (EME) funding, you must provide a justification that your application aligns with the research agenda into Radio Frequency (RF) EME and health outlined in the 2017 ARPANSA Technical Report '*Radiofrequency Electromagnetic Energy and Health: Research Needs*' (see [Appendix A](#)).

Select this field if your application is to be considered for EME funding.

#### **Justification**

Provide a justification of how your research proposal meets the criteria as RF research (maximum of 2000 characters including spaces and line breaks).

#### Funding Organisation

Applicants seeking funding from Cancer Australia and funding partners as part of Cancer Australia's Priority-driven Collaborative Cancer Research Scheme (PdCCRS) (either exclusively or in addition to NHMRC funding) must complete this part of the application. Those seeking funding from other funding organisation(s) must read their respective terms and conditions as they may have additional criteria which need to be addressed.

Select the organisation from which funding is sought. Multiple funding partners can be selected. If a box is not selected, the application will be assessed by NHMRC only.

Applicants for all categories of PdCCRS must meet NHMRC submission deadlines in addition to any Cancer Australia deadlines. Any questions about PdCCRS eligibility should be addressed to Cancer Australia.

### 3.2.9 B-GP: Grant Proposal

Information on what to include in your Grant Proposal and how to address the selection criteria can be found in Section 4 (below).

#### Grant Proposal (Upload)

To upload your Grant Proposal PDF, select the document from the location that it has been saved to by double clicking on it. The name will be displayed in the 'Choose File' field. Click 'Save' or 'Save and return' to upload the document.

To ensure that the document is displaying properly, applicants should open a copy of the uploaded document by selecting the open icon to the right of the document name after the document has been saved to in RGMS.

### 3.2.10 B-PBRF: Proposed Budget – Research Facilities

Applicants often need to receive services from research facilities to enable their research to be successfully undertaken.

Such facilities include but are not limited to: biospecimens and associated data from biobanks or pathology services, non-human primate colonies, the Australian Twin Registry, Cell Bank Australia, and the Trans-Tasman Radio Oncology Group.

Applicants will need to consult with research facilities to ensure that the services they require can be provided and that the charges included in the research budget are accurately reflected (Part B-PB Proposed Budget – DRC and Equipment). Letters from research facilities confirming their collaboration must be uploaded as a PDF on this page.

Indicate in the drop down list whether you will be using services provided by a research facility to complete your research.

If you select 'yes', then upload your letter(s) from the research facility confirming their collaboration.

To upload the documents, select the document from the location that it has been saved to by double clicking on it. The name will be displayed in the 'Choose File' field. Click 'Save' or 'Save and return' to upload the document.

To ensure that the document is displaying properly, applicants should open a copy of the uploaded document by selecting the open icon to the right of the document name after the document has been saved to in RGMS.

### 3.2.11 B-PB: Proposed Budget – DRC and Equipment

Enter details of the proposed research budget. Details on permitted uses of NHMRC funds and setting of budgets can be found in the *Direct Research Cost Guidelines* on the [NHMRC website](#), and Section 5 of the Grant Guidelines.

Provide details on:

- the item type (Direct Research Costs or Equipment Costs)
- the name/description of the item
- the total value of the item requested for each year
- a justification for the particular item requested.

This information must be aligned with the proposed aims of the study, be detailed on a yearly basis and be fully justified (including, in the case of equipment, why the equipment cannot be provided by the Institution).

Note:

- NHMRC funds the direct costs of research based on advice from peer review. Applicants should provide detailed justification of budgets requested. Poorly justified budgets run the risk of having their budget adjusted.
- Funding cannot be used for infrastructure.
- There is no provision to increase funds for any reason.

#### ***Equipment***

Applicants can request funding to pay for equipment costing over \$10,000 that is essential to the research. The total equipment requested cannot exceed \$80,000. Individual items of equipment costing less than \$10,000 must be requested within DRCs.

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, and be made available to NHMRC on request. The Administering Institution must be prepared to meet all service and repair costs in relation to equipment funded

### **Entering DRC and Equipment Costs**

You will need to create a separate entry for each cost.

Click 'New' to enter a cost.

#### **General**

For 'Item Type', select 'Direct Research Cost' or 'Equipment' from the drop down box.

Once you press 'Save' additional fields will become available.

Item – include a brief name/description of the item (50 character limit including spaces and line breaks).

#### **Budget Data**

Outline the cost of the item required for each year of the grant proposal. Only the relevant years should be completed.

#### **Justification**

Provide a comprehensive justification for the cost here (500 character limit including spaces and line breaks).

## **4. ADDRESSING THE SELECTION CRITERIA**

Applications for Clinical Trials and Cohort Studies Grants will be assessed by peer reviewers against the assessment criteria set out in section 6 of the Grant Guidelines.

Assessment by peer reviewers will be based on information provided in the application form and the grant proposal.

### **Grant Proposal**

The Grant Proposal must be written in English and submitted in a Portable Document Format (PDF) file, using the grant proposal template, which is available within the Grant Opportunity on [GrantConnect](#). Applicants must use this template. The Grant Proposal must then be uploaded into RGMS (see section 3.2.9 B-GP Grant Proposal below).

Naming and formatting requirements for the Grant Proposal are listed in **Table 1**. Applications that fail to comply with these requirements may be excluded from consideration.

Details to be addressed in the grant proposal and associated page limits are set out in **Table 2**. Applications that exceed the page limits may be removed from peer review.

**Table 1: Formatting Requirements**

<b>Component</b>	<b>Component Requirements</b>
File format	The grant proposal must be saved and uploaded as a Portable Document Format (PDF) file

File name	The PDF file must be named using the following: APPID_Applicant's Surname_Document Type/Name.pdf E.g.: APPID1234567_Smith_Grant Proposal.pdf
File size	The PDF file MUST NOT exceed 2 MB in size
Page size	A4
Header	Application ID and Applicant surname must be included in the header
Footer	Page number must be included in the footer
Font	NHMRC recommends a minimum of 12 point Times New Roman font. Applicants must ensure the font is readable
Line spacing	Single
Language	English

**Table 2: Grant Proposal Details**

Section	Page Limit
A. Research proposal	9 pages
B. References	2 pages
C. Milestones and Performance Indicators	2 pages
D. Team Quality and Capability	1 page
E. Chief Investigator Capability and Achievement	2 pages per CI
F. Indigenous Research Excellence Criteria (if applicable)	2 pages
G. Cancer Australia PdCCRS (if applicable)	1 page

You should consider the assessment criteria used to evaluate applications (provided in Section 6 of the Grant Guidelines) and the category descriptors in relation to each of the assessment criteria (provided at [Appendix C](#)).

**A. Research Proposal (9 pages)**

This section (A) and section C (Milestones and Performance Indicators) should address the following assessment criteria:

- Significance (40% of overall score)
- Research Quality (40% of overall score).

The research proposal should include the following components:

- Aims: describe the specific aims of the project, including a clear statement of hypotheses to be tested
- Background: provide a rationale for the project
- Research plan: outline the research plan in detail
- Timeline: provide a detailed timeline for the expected outcomes of the research proposal along with justification for the duration requested

- Outcome and significance: describe the importance of the problem to be researched, the planned outcome of the research plan, and the potential significance of the research.

Your research proposal should be written in English and provide enough information so that the research approach can be assessed by the reviewers. All scientific information relating to your application must be contained in this section. This is assessed by experts in the field and you should include any pilot or feasibility study data supporting the planned research.

References cited in this document are to be listed in the separate references section (see below).

## **B. References (2 pages)**

Provide a list of references cited in the application. References must:

- be listed in an appropriate standard journal format. NHMRC prefers the Author-date (also known as the Harvard) system, Documentary-note and the Vancouver Systems list authors in the order in which they appear in PubMed
- only include references to cited work
- be written in English.

## **C. Milestones and Performance Indicators (2 pages)**

Provide a table of milestones and performance indicators with corresponding dates. The approach should be specific to the proposed research and provide for effective monitoring of progress at twelve month intervals. You are encouraged to include recruitment targets and receipt of ethics approval. Please justify your approach.

## **D. Team Quality and Capability (1 page)**

This section (D) and the following section (E) should address the assessment criterion: Team Quality and Capability (20% of overall score). Provide a summary of the research team's quality and capability. Applicants should detail the following:

- the expertise and productivity of team members relevant to the proposed project
- their influence in this specific field of research
- how the team will work together to achieve the project aims
- how junior members are contributing to the proposed research and the overall team quality and capability.

## **E. Chief Investigator Capability and Achievement (2 pages per CI)**

Chief Investigators should use this section to highlight their research achievements. This section has two components:

### Overall track record in the last 5 years

Applicants should use this section to identify aspects of their track record that are in addition to their publication record listed in the CV section. This includes relative to opportunity considerations. The following areas may be relevant:

- career summary including qualifications, employment and appointment history
- collaborations
- community engagement and involvement
- contribution to the field of research, including the translation of research into health commercial outcomes, such as patents, including whether licensed (when, to whom and whether current) (see NHMRC's Guide to Evaluating Industry-Relevant Experience at <https://nhmrc.gov.au/about-us/publications/guide-evaluating-industry-relevant-experience>)
- international standing including invitations to speak and committee memberships

- peer review (e.g. for granting bodies, journals/editorial roles)
- research support including grants and fellowships
- professional activities (e.g. committees, conference organisation/participation)
- supervision and mentoring.

#### 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. Please provide reasons why these publications have been selected.

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.

#### **F. Indigenous Research Excellence Criteria (where applicable) (2 pages)**

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

- Community engagement
- Benefit
- Sustainability and transferability
- Building capability.

These criteria are set out in section 6.1 of the Grant Guidelines and further details are provided in the category descriptors at [Appendix C](#). Applicants should ensure that they address each Indigenous Research Excellence Criterion and demonstrate what proportion of the research effort will be directed to Aboriginal and Torres Strait Islander Health.

#### **G. PdCCRS Cancer Australia (where applicable) (1 page)**

Grants awarded through the PdCCRS are designed principally to support applied cancer research projects that relate to the research priority area/s of Cancer Australia and/or its funding partners and which have the potential to directly improve cancer outcomes by influencing clinical practice and/or policy.

Applicants who are applying for NHMRC funding and also seeking PdCCRS funding for the same project (where the NHMRC application is beyond the timeframe and budget that can be provided through PdCCRS) must provide a one page modified research proposal with reduced aims and timeframes.

The following should be included in the modified proposal.

This proposal is to be considered for funding from NHMRC and PdCCRS.

Funding from NHMRC is sought for a project addressing the following aims:

- Aim 1
- Aim 2
- Aim 3 etc.

Funding from the PdCCRS is alternatively sought for the same project modified to one/two year/s. In the one/two year/s timeframe the project will only address the following aim/s:

- Aim 1
- Aim 2 etc.

Applications that do not comply with the above guidelines may be deemed ineligible and excluded from further consideration.