Clinical Trials and Cohort Studies Grants 2019 Guidelines

Opening date:	06 March 2019
Closing date and time:	17.00 AEST on 08 May 2019
Commonwealth policy entity:	National Health and Medical Research Council (NHMRC)
Enquiries:	Applicants requiring further assistance should direct enquiries to their Administering Institution's Research Administration Officer. Research Administration Officers can contact NHMRC's Research Help Centre for further advice: Phone: 1800 500 983 (+61 2 6217 9451 for international callers) Email: help@nhmrc.gov.au NHMRC will not respond to any enquiries later than 16.30 AEST on 08 May 2019. Note: The Research Help Centre aims to provide a reply to all requests for general assistance within two working days. This timeframe may be delayed during peak periods or for more detailed requests for assistance.
Date guidelines released:	26 July 2018
Type of grant opportunity:	Targeted competitive

Contents

1. Clinical Trials and Cohort Studies Grants 2019 Processes

NHMRC's Clinical Trials and Cohort Studies Grants scheme is designed to achieve Australian Government objectives

This grant opportunity is a component of the Portfolio Budget Statements Program 1.1: Health and Medical Research, which contributes to Outcome 1: Improved health and medical knowledge.

The grant opportunity opens

NHMRC publishes the grant guidelines and advertises on GrantConnect.

Applicants complete and submit a grant application

Applications verified and assessed

Applications are assessed against eligibility criteria and applicants are notified if not eligible. Peer reviewers assess applications against the assessment criteria including an overall consideration of value with money.

Grant decisions are made

NHMRC's CEO seeks approval of funding recommendations from the Minister for Health.

NHMRC notifies applicants of the outcome

Applicant's Administering Institution enters into a grant agreement with NHMRC

Delivery of grant

Grant awardees undertake the grant activity as set out in the schedule to the grant funding agreement. NHMRC manages the grant through the relevant Administering Institution.

Evaluation of the Clinical Trials and Cohort Studies Grants scheme

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

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) 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 for grant duration) and grant funding does not support infrastructure costs (see section 5). 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 strategic 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.

Information on NHMRC strategic 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 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.

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 Probity 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

Funding provided by NHMRC for a Research Activity must be spent on a cost directly incurred in relation to that Research Activity.

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* (see Appendix C).

5.1 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.

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.

5.2 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. 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/. Accessed 25 Jul 2018.

7. How to apply

7.1 Overview of application process and timing

6 March 2019	Applications open in NHMRC's granting system
17.00 AEST **10 April 2019**	Minimum data due in NHMRC's granting system
17.00 AEST **8 May 2019**	Applications close in NHMRC's granting system
August-September 2019	Anticipated peer review period

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 are outlined within NHMRC's granting system.

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) 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), 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.

NHMRC's Research Help Centre

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

E: help@nhmrc.gov.au

Refer to the Research Help Centre webpage for opening hours.

8. Assessment of grant applications

8.1 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.

8.1.1 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 based.

Further information on the assessment process is on the NHMRC website.

8.2 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 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.

10.5 Suspension of awards

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.

10.6 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 Section 5.3 of 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.

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.

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
Website: 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.
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.
Commonwealth Grants Rules and Guidelines 2017 (CGRGs)	The CGRGs establish the overarching Commonwealth grants policy framework and the expectations for all non-corporate Commonwealth entities in relation to grants administration.
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	A grant is an arrangement for the provision of financial assistance by the Commonwealth or on behalf of the Commonwealth: a) under which relevant money, or other consolidated revenue funds, is to be paid to a recipient other than the Commonwealth b) which is intended to assist the recipient achieve its goals c) which is intended to help address one or more of the Australian Government's policy objectives. under which the recipient may be required to act in accordance with specified terms or conditions.
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	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 www.grants.gov.au. Non-corporate Commonwealth entities must publish on GrantConnect to meet the grant publishing requirements under the CGRGs. Where information is published in more than one location, and there are inconsistencies, GrantConnect is the authoritative, auditable information source.

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.
Medical Research Future Fund (MRFF)	The MRFF was established on 26 August 2015 by the *Medical Research Future Fund Act 2015* (MRFF Act). Refer to the Department of Health website: https://beta.health.gov.au/initiatives-and-programs/medical-research-future-fund.
NHMRC's granting system	NHMRC's electronic grants management solution for grant application, assessment and administration.
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	Probity Event means any event or occurrence which: 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 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.
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	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. 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: • the quality of the project proposal and activities • fitness for purpose of the proposal in contributing to government objectives • that the absence of a grant is likely to prevent the grantee and government's outcomes being achieved • the potential grantee's relevant experience and performance history.

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

A1 NHMRC strategic priorities

Each year, NHMRC identifies strategic priorities for funding. NHMRC's current research strategic 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 strategic priority areas

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

- address other defined strategic 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 may partner with NHMRC in funding grants under this grant opportunity:

- Cancer Councils
- Cancer Australia & Funding Partners, and
- Department of Health (MRFF).

Further information on Clinical Trials and Cohort Studies Grants funded by other organisations is available on the NHMRC website.

Appendix B. NHMRC 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.

The audience is applicants and peer reviewers.

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[1].

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.

[1] 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*.

Information on how applicants can demonstrate that a Career Disruption(s) affects their eligibility to apply for an Emerging Leadership Investigator Grant is also available in NHMRC's granting system and in the Investigator Grant Guidelines.

Appendix C. NHMRC Direct Research Cost Guidelines

A definitive list of Direct Research Costs (DRCs) is in many instances not appropriate, therefore core principles have been developed to be used to determine whether particular expenses are DRCs for the NHMRC funded research activity in question (Research Activity). The principles recognise that the aims and objectives of the Research Activity are a key factor in the decision to classify an expenditure item as a DRC.

These Guidelines also set out a small number of expenses that are not DRCs and on which Funds must not be spent. When deciding if expenditure is a DRC or not, reference should be made to these Guidelines. If clarification is required please contact your Administering Institution's Research Administration Officer (RAO) in the first instance. If required, they may then contact postaward.management@nhmrc.gov.au.

The NHMRC Funding Agreement specifies that NHMRC grant Funds can only be spent on the DRCs as described in these Guidelines.

DRC Principles

Funding provided by NHMRC for a Research Activity may be spent on a cost incurred in relation to that Research Activity that satisfies all of the following requirements:

- The cost must be integral to achieving the objectives and outcomes of the Research Activity as set out in the Application for Funding for that Research Activity, as approved by NHMRC.
- The cost must be directly related to the grant proposal as set out in the Application for Funding for that Research Activity, as approved by NHMRC.
- The cost must not be for a facility or an administrative cost that would be provided by an institution in the normal course of undertaking and supporting health and medical research.

DRCs include costs that the Research Activity's Funding Policy expressly states may be paid for with NHMRC funding. Conversely, a cost that the Research Activity's Funding Policy expressly states may not be paid for with NHMRC funding, will not be a DRC.

These Guidelines replace all previous guidance material on DRCs. These Guidelines do not apply to the Independent Research Institutes Infrastructure Support Scheme (IRIISS) Grants or Equipment Grants.

Guidance for the use of DRCs

Salaries and Salary on costs

Salary costs are to be requested in the application budget under Salaries/Personnel Support Packages (PSPs). In limited circumstances, such as engagement of staff on short-term contracts, salary costs can be requested under DRCs. Whilst Funds awarded for Research Support schemes[1] can be used to cover the gap in salaries (except for Investigator Grant holders), applicants cannot request additional Funds in their application to cover this cost.

[1] Investigator Grants Research Support Package component cannot be used to supplement the salary of the Investigator Grant holder, but may be used for salary costs to employ research staff.

NHMRC contributes to the cost of employing research personnel. The NHMRC salary contribution is usually calculated using a Salary Support Package (SSP), which is not designed to cover the full cost of employing the grant's research personnel.

NHMRC Funds provided for a Research Activity can be used for annual leave and long service leave entitlements that accrue in respect of research personnel during their employment on that Research Activity. Severance and termination payments and extended leave payments (leave entitlements accrued on non NHMRC Research Activities) are not DRCs and must not be paid for with NHMRC funding.

Fringe Benefits Tax (FBT) is specifically excluded as a DRC and NHMRC Funds are not to be used to pay for this expense.

It is recognised that because NHMRC does not fund the full cost of employing research personnel there is, in most cases, a gap between SSP rates and the institutions enterprise bargaining rate (or equivalent). Where this occurs, there is flexibility to use NHMRC Funds provided for Research Support schemes (except for Investigator Grant holders) to cover the gap between the SSP and the researcher's part or total salary including on-costs[2]. Such use of Funds is to be the outcome of agreement between institutions and Chief Investigator A (CIA).

Travel

Travel costs are only DRCs for a Research Activity, such as field work, research collaborations or for use of facilities in other countries, if the travel costs are directly related to the approved research objectives of that Research Activity. Airline membership, health insurance and travel insurance are generally not considered to be DRCs.

All travel, accommodation, meals and incidentals must be in accordance with the relevant travel policies and procedures of the Administering Institution.

Overseas travel must be formally approved and documented by the relevant Faculty Research Committee (or equivalent) prior to the travel being undertaken.

Conferences

Conference costs are not to be included in the application budget. When investigators apply for research funding, it is not possible to predict where and how knowledge translation and knowledge transfer of their work will occur (because the research is yet to be undertaken). Thus, the costs of conference attendance are not to be included as DRCs in grant application budgets.

However, if the application is successful grant Funds can be used to support conference attendance for the purpose of presenting the research outcomes, provided that the expenditure is in accordance with the DRC Principles.

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[2] **Funding Agreement Clause 7 Use and Accountability for Funds and Other Contributions**

The flexibility to choose the particular DRC on which the Funds may be spent does not apply to People Support schemes (see exceptions below). Funds awarded through People Support schemes are to be spent exclusively for the purposes provided for in the relevant schemes Funding Policy.

The only People Support schemes that allow Funds to be used flexibly are the NHMRC-ARC Dementia Research Development Fellowship scheme and the Boosting Dementia Research Leadership Fellowship scheme. These schemes have a funding condition which allows Funds to be used flexibly in accordance with the provisions of a Research Support scheme, e.g. to cover gap in salaries.

Clinical Trials

Refreshments for clinical trial participants are a DRC, as the refreshment relates directly to the achievement of the research aims for a Research Activity.

Entertainment, Meals, Hospitality

Restaurant meals, alcohol and other hospitality are generally not DRCs.

Computers

Only specialised computing requirements that are essential to meeting the specific research needs of a Research Activity would be considered DRCs. DRCs do not include personal computers, related peripherals or software needed for communicating, writing and undertaking simple analyses.

The only exceptions to this are that Scholarship and Early Career Fellowship grant holders may purchase personal computers with NHMRC funding.

Supplies, Postage, Telephones

For supplies, postage and telephone expenses to be considered DRCs, their usage for a Research Activity must be significantly greater than the routine level for such items provided by Administering Institutions and must be used specifically for the research purposes of the Research Activity rather than to support administrative or clerical efforts. Examples include a Research Activity that requires significant data collection through an extensive mail survey or a Research Activity that requires the provision of paper notebooks to a large number of workshop participants.

Publications and Open Access Costs

Publication and open access costs are not to be included in the application budget. When investigators apply for research funding, it is not possible to predict where and how knowledge translation and knowledge transfer of their work will occur (because the research is yet to be undertaken). Thus, the costs of publications and open access are not to be included as DRCs in grant application budgets.

However, if the application is successful, grant Funds can be used to support reasonable costs associated with publications and open access which are the result of the Research Activity and which are in accordance with the DRC Principles.

Land, Buildings and Fixtures

These items are not DRCs and must not be paid for with NHMRC Funds.

Inquiries and Clarifications

All inquiries are to be directed to the Administering Institution's RAO in the first instance, who may then contact NHMRC's Research Administration Section via postaward.management@nhmrc.gov.au.