NHMRC FUNDING RULES

incorporating the Project Grants scheme
for funding commencing in 2014

Applications for the Project Grants scheme open on 5 December 2012 and close at 17:00hrs (AEDT) on 19 March 2013.

Late applications will not be accepted.

Scheme-specific changes for 2013 are outlined on page 21.

This document must be read in conjunction with the NHMRC Project Grants Advice and Instructions to Applicants for funding commencing in 2014.
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PART 1 - NHMRC FUNDING RULES

1 Introduction

The National Health and Medical Research Council (NHMRC) is Australia’s leading funding agency promoting the development and maintenance of public and individual health standards. It is established under the National Health and Medical Research Council Act 1992, (the NHMRC Act) which is available on the NHMRC website at: http://www.nhmrc.gov.au/about/organisation-overview/nhmrcs-role.

The object of the NHMRC Act is to make provision for a national body to pursue activities designed to:

- raise the standard of individual and public health throughout Australia;
- foster the development of consistent health standards between the States and Territories;
- foster medical research and training and public health research and training throughout Australia; and
- foster consideration of ethical issues relating to health.

The NHMRC Strategic Plan (Strategic Plan) describes the agency’s strategic objectives and provides the context within which its funding schemes operate. NHMRC’s strategy for health and medical research is to invest in the highest quality research, as determined through peer review, across the four pillars of health and medical research: biomedical, clinical, public health and health services research.


NHMRC will only support excellence in research because the best outcomes flow from the best research. NHMRC is committed to all research relevant to health (including biomedical, clinical, public health and health services research) and recognises that multidisciplinary approaches are needed to solve the complex problems of health.

These rules apply to all NHMRC funding schemes. They were designed to provide researchers and the Research Administration Officers (RAOs) ease of access and consistency across funding schemes. They must be read in conjunction with Part 2 - Scheme-Specific Information and the relevant Advice and Instructions to Applicants documents.

These rules must be read in conjunction with Part 2 - Scheme-Specific Information and the relevant Advice and Instructions to Applicants documents.
2 Enquiries

Enquiries about the content of NHMRC Funding Rules should be addressed to your Administering Institution’s RAO in the first instance. If further assistance is required, please contact the Research Help Centre on 1800 500 983, or at help@nhmrc.gov.au or refer to the relevant funding scheme web page on the NHMRC website:

Applicants must not contact grant review panel members or external assessors in relation to their application, or the peer review process. Doing so may constitute a breach of The Australian Code for the Responsible Conduct of Research 2007 (the Code) (refer to subsection 2d) and the application may be excluded from further consideration. Applicants are to direct any queries concerning the peer review process to their Institution’s Research Office.

3 Submitting an Application

All applications must be submitted electronically using NHMRC’s Research Grant Management System (RGMS) at:

Applicants who are not registered RGMS users should submit a new user request via the RGMS login page at https://www.rgms.nhmrc.gov.au/, or contact help@nhmrc.gov.au for more information.


For help in learning to use RGMS, applicants are advised to use RGMS Tutor, a training tool, available at the RGMS Library within RGMS at:

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 application, as this will be used as the prime source of information available to the peer review panel.

Applications must be certified and submitted by an NHMRC registered Administering Institution. Further information on becoming an Administering Institution can be found in the NHMRC Administering Institutions Policy at:

It is important to check the closing dates for the funding schemes you wish to apply to. The closing dates for NHMRC funding schemes can be found at:

Applicants should note that Administering Institutions may have a submission date well in advance of NHMRC’s closing date, and should consider relevant institutional timeframes when preparing the application.
Applications submitted after the closing date will not be considered by NHMRC. Once submitted to NHMRC, the application will be considered final and no changes will be permitted.

Further information in relation to the completion of the application is located in the Library section of RGMS.

Retracted Publications
If a publication relevant to an application is retracted after the application has been submitted, applicants must advise NHMRC of the retraction at the earliest opportunity by email (help@nhmrc.gov.au) with an appropriate explanation regarding the retraction. Applicants are required to send this information to NHMRC through their RAO.

In addition, where the publication forms part of the applicant's Track Record, that information must be immediately recorded in their Profile & CV in RGMS.

If an application is largely dependent on the results of a retracted publication, applicants should also consider withdrawing the application. If, under these circumstances, applicants choose not to withdraw the application, they should make their reasons clear in their communications with NHMRC.

3.1 Profile and CV
RGMS provides an online Profile and CV function. This function must be used when applying for all types of grants in RGMS. Relevant information from the Profile and CV will be uploaded automatically into the application form. It is therefore important that the Profile and CV are up to date.

NHMRC has made a significant investment to ensure that RGMS has sufficient capacity for all applicants to have adequate access to the system to prepare their applications in a timely manner. However, congestion management may be necessary during times of extreme load on the system. To avoid any inconvenience applicants are encouraged to complete their Profile and CV as early as possible following the opening of applications for the funding round.

3.2 Withdrawal of Applications
Applicants may withdraw their application at any time in writing, through their Administering Institution’s Research Office to NHMRC.

3.3 Incomplete, False or Misleading Applications
All details in the application, particularly concerning any current grants and other applications, must be current and accurate at the time of application.

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. Such action can be punishable by up to 12 months imprisonment. If an application contains information that is false or misleading, it will be excluded from any further consideration for funding.

Examples of false or misleading information in an application include, but are not restricted to:
a) providing a dishonest statement regarding time commitments to the research for which support is being sought;
b) providing incomplete or inaccurate facts regarding other sources of funding;
c) providing fictitious track records; and
d) falsifying claims in publication records (such as describing a paper as accepted for publication when it has only been submitted).

If NHMRC believes that omissions or inclusion of misleading information are intentional, it may refer the matter for appropriate legal action.

3.4 Responsible Conduct of Research and Research Misconduct

NHMRC expects the highest levels of research conduct and integrity to be observed in the research that it funds. Institutions that administer grants, as well as Chief Investigators (CIs), are bound by the conditions of the *NHMRC Funding Agreement* (Funding Agreement), and through this agreement by the requirements of the Code available at: http://www.nhmrc.gov.au/guidelines/publications/r39.

The purpose of the Code, which was issued by NHMRC in partnership with the Australian Research Council and Universities Australia, is to guide institutions and researchers in responsible research practices. The Code promotes integrity in research and provides a mechanism by which a breach of the Code or an incident of research misconduct can be resolved.

All institutions must have a mechanism in place to handle and investigate research misconduct. All staff should be aware of this process. Researchers who become aware of research misconduct should follow the process outlined in the Code and can report on scientific misconduct by completing an e-form available from the NHMRC website at: https://www.nhmrc.gov.au/about/contact-us/complaint-form.

Administering Institutions are required to inform NHMRC of cases of research misconduct and NHMRC may exclude these applications from further assessment if the applicant is found to have committed serious research misconduct.

3.5 Removal of Applications

NHMRC reserves the right, at its absolute discretion, to remove applications from further consideration.

Exclusion of applications may take place at any time during the assessment process if they contravene these *Funding Rules*.

The application must:
 a) be submitted using RGMS by the advertised closing date;
b) declare the source, duration and level of funding already held for research in the particular area of the application;
c) be certified and submitted through the appropriate Research Office of an NHMRC approved Administering Institution;
d) be within the specified page limits; and
e) be formatted (including font sizes and margins) as specified in the *Advice and Instructions to Applicants* document.
Applications may be excluded under the following circumstances:

a) the application is clearly of a standard that will not gain support via the competitive funding scheme (note: NHMRC would only determine an application to be non-competitive on advice from a review panel);

b) the application does not comply with the eligibility criteria specified in either this document or *Scheme-Specific Information*;

c) the application includes any incomplete, false or misleading information;

d) the application is inconsistent with the objectives of the NHMRC Act and the purposes of the Medical Research Endowment Account (MREA) (refer to sections 3 and 51 of the NHMRC Act);

e) the application does not comply with the requirements of these rules, *Scheme-Specific Information*, or the *Advice and Instructions to Applicants* document; and

f) the application involves researcher/s against whom a finding of research misconduct has been made.

### 3.6 Relative to Opportunity

Peer reviewers’ consideration of relative to opportunity may take into account the amount of time spent as an active researcher; career disruption (see subsection 3.7); available resources; clinical, administrative or teaching workload; relocation of an applicant and his/her research laboratory or clinical practice setting; restrictions on publication associated with time spent working in other sectors (e.g., industry, policy and government) and the typical performance of researchers in the research field in question.

A number of the assessment criteria for NHMRC funding schemes are assessed relative to opportunity. This reflects NHMRC’s aim that assessment processes accurately measure an applicant’s track record relative to stage of career, including consideration as to whether productivity and contribution is commensurate with the opportunities available to the applicant.

### 3.7 Career Disruption

Career disruption represents a special category within the assessment of relative to opportunity, and includes pregnancy; major illness; and carer responsibilities including parental leave. Employment outside the research sector including time spent working in industry; clinical, administrative or teaching workload; relocation of laboratory or clinical practice setting or other similar circumstances that impact upon research productivity are not considered to be career disruption and are considered under relative to opportunity (see subsection 3.6).

### 4 Confidentiality and Privacy

Section 80 of the NHMRC Act prevents NHMRC Officers (including staff and members of NHMRC Council and committees) from disclosing commercial-in-confidence information acquired in the course of their duties and relating to matters under consideration by NHMRC, unless the disclosure is made in the performance of duties under the NHMRC Act. Information which may properly be regarded as confidential commercial information should be designated as such.

Information comprising the names of successful grant applicants and their Administering Institutions, together with the title of the research project and the funding awarded, may be published in the NHMRC Annual Report and are available through NHMRC’s website. NHMRC may also release information about the areas of research of the grant, funding partners and a brief
description of the grant. This information is provided by the applicant in response to the question on the application form designated as Media Summary.

4.1 Privacy
Documents containing personal information are handled and protected by NHMRC in accordance with the provisions of the Privacy Act 1988 (the Privacy Act), which sets standards for the collection, storage, use and disclosure of, and access to, personal information. Personal information is disclosed only with permission of the individual to whom it relates or where the Privacy Act allows.

4.2 Freedom of Information Act 1982 (Cth)
NHMRC is subject to the Freedom of Information Act 1982 (the FOI Act) and is committed to meeting the Australian Government’s transparency and accountability requirements. Changes to the FOI legislation as of late 2010 have implications for the way in which NHMRC responds to and reports on, requests for information under the FOI Act. The FOI Act provides a legal right of access to any person to obtain documents of Commonwealth agencies. Access to documents may only be refused where the FOI Act provides a legal basis for the refusal, such as where the documents are exempt.

However, subject to its FOI obligations, NHMRC remains committed to maintaining the confidentiality of grant applications, the peer review process and the privacy of people participating in peer review. If an FOI application is received in relation to peer review documents that contain your personal or business information, NHMRC will take into account the nature of those documents and where appropriate, consult with anyone whose personal information or business information may be affected by the release of those documents (this is known as “third party consultation”).

Sections 27 and 27A of the FOI Act prescribe when third parties must be consulted in relation to the information contained in documents that are subject to an FOI request. In addition, where appropriate and practicable, NHMRC will consult above and beyond those requirements. In the event that you are consulted as a third party, NHMRC will send you a detailed letter seeking your views and giving you a reasonable time to respond.

However, please note that whilst FOI decision-makers are required to take into account third parties’ views on the release or non-release of their information, decision-makers are not bound by those views. Should a decision-maker decide to release a document containing your personal or business information after you have submitted that it should not be released, the FOI Act states that that document must not be released to the FOI applicant until you, as a third party, have exercised and exhausted all your review rights, or chosen not to exercise them. Your review rights consist of:

a) a right to request the NHMRC to review its decision to release the document (called an internal review and conducted by a different decision-maker) or to request the Australian Information Commissioner to review the decision;
b) a right to appeal to the Australian Information Commissioner against an internal review decision if it is adverse; and
c) a right to appeal to the Administrative Appeals Tribunal against an adverse decision of the Australian Information Commissioner.

Until such time as all those appeal rights are exhausted, the contested document cannot be released.
More information about FOI, including third party rights, is available from the Australian Information Commissioner’s website at http://www.oaic.gov.au/.

5 Eligibility

Applications for all NHMRC funding schemes are subject to eligibility rules. Applications which do not meet these eligibility guidelines may be removed from the assessment process. For further information, refer to subsection 3.5 NHMRC Funding Rules (Removal of Applications).

NHMRC may compare the research proposed with Research Support grants it currently funds, and grants provided by other agencies. NHMRC may remove from consideration any application it considers to duplicate research previously, or currently being undertaken.

Additional eligibility criteria may apply and applicants should read this section and its subsections in conjunction with the Scheme-Specific Information.

5.1 Multiple Research Grant Eligibility

Project Grants

Individuals are limited to holding a maximum of six NHMRC Project Grants as a Chief Investigator (CI). A different requirement applies to CIs on Program Grants (please refer to subsection 5.1 Multiple Research Grant Eligibility – Program Grants).

The maximum number of Project Grant applications a CI (CIA-CIJ) may submit in any year will be six, less the number of NHMRC Project Grants that are scheduled to continue in the year that any new grants will commence. For example, if an investigator, at the time of submission of an application holds four NHMRC Project Grants, one of which will finish at the end of the year in which applications close, the investigator may submit up to three applications.

Where a CI (CIA-CIJ) has submitted applications in excess of the maximum number of grants and applications for which he/she is eligible, all applications that include that investigator as a CI will be automatically ineligible and removed from the assessment process; refer to subsection 3.5 NHMRC Funding Rules (Removal of Applications). It is the responsibility of all CIs to ensure that this condition is adhered to prior to submission of an application.

Program Grants

Full-time Program Grant CIs are not permitted to hold, or apply for more than one Project Grant.

Applicants should note that there can only be one Program Grant holder named as a CI on any Project Grant application. Program Grant CIs cannot be the only (sole) CI named on a Project Grant or a Project Grant application: there must be at least one other CI who is not also a CI on a Program Grant receiving funding in any year in which the Project Grant is funded.

A researcher can be a part-time CI on one or two Program Grants. Part-Time Program Grant CIs who hold one Program Grant are permitted to hold up to two Project Grants. Part-Time Program Grant CIs who hold two Program Grants are not permitted hold or apply for any Project Grants.

New Program Grant awardees who are named as a CI on more than one Project Grant must submit grant variation requests for all Project Grants they are no longer eligible to hold prior to
the commencement of funding for the Program Grant. The Grant Variation Request(s) will need to make the case that the viability of the Project Grant(s) will be maintained.

Targeted and Urgent Calls for Research
Awards of this funding type will not count towards the maximum of six NHMRC Project Grants held as a CI or towards the one Project grant held by CIs that also hold a Program Grant. Applications for other NHMRC funding schemes are subject to conditions outlined in their respective Funding Rules. Time commitments of CIs will be carefully considered in the review of applications.

5.2 Chief Investigators and Research Teams
Note: subsections 5.2 and 5.3 apply to Research Support schemes but do not apply to People Support awards (e.g. Fellowships and Scholarships).

Chief Investigators
The role and contribution of each CI must be described in the grant application. PhD students may be included as CIs in exceptional circumstances if appropriate for the proposed research project.

The maximum number of CIs allowed on an application is 10.

Unless support for personnel is being sought on the grant, funding for a grant depends on the continuing employment of each of the CIs over the period of the grant.

Chief Investigator A
CIA is the project leader who takes the lead role in the conduct of the research project, and is the investigator who takes responsibility for completion and lodgement of the application.

The Funding Agreement requires the Specified Person (CIA for Research Support schemes) prepare Progress and Final Reports for each Research Activity by the date specified in the Scheme-Specific Information.

Where a CIA requests a transfer of the administrative responsibility for a grant to a new institution, it is the responsibility of the CIA to drive the transfer process and to ensure that the completed transfer request is submitted to NHMRC in a timely manner.

It is generally required that, at the time of application submission, the CIA is an Australian citizen or is a permanent resident of Australia. It is also required that the CIA is based in Australia for the duration of the grant.

NHMRC may waive the requirement to be an Australian citizen or permanent resident where it can be demonstrated that the research is based in Australia and will benefit health and medical research in Australia. Requests to waive this requirement need to be made through the Research Administration Office of the Administering Institution and should be emailed to help@nhmrc.gov.au and marked for the Project Officer for the relevant scheme.

Note: Applicants who have applied for and received waivers for existing NHMRC grants, must again seek a waiver for each application round.
Exception: A CIA who is a New Zealand citizen is not required to seek a waiver if they are based in Australia for the duration of the grant.

Chief Investigators B to J

Researchers who are not Australian citizens or permanent residents in Australia are eligible to apply for a grant as a CI B to J. If they are based in Australia for the duration of the grant, they may be eligible to request a personnel support package.

CIs based overseas are not eligible to draw a salary from a grant unless additional provisions in Scheme-Specific Information state otherwise.

Associate Investigators

An Associate Investigator (AI) is defined as an investigator who provides intellectual input into the research and whose participation warrants inclusion of their name on publications.

Associate Investigators are not able to draw a salary from any grant.

There are no restrictions on individuals who may be named as an AI on an application. However, the maximum number of AIs who can be named is 10 per application.

5.3 Consent to be a Chief Investigator

The CIA must confirm with other CIs (B-J) that they agree to be named on the application. The CIA will provide written evidence (e.g. an email) to the RAO of all CIs’ endorsement of the application. The RAO will certify and submit the application in RGMS (Research Grants Management System).

The RAO should not submit the application to NHMRC until all CIs have completed this step and all relevant consents have been obtained as per this requirement.

5.4 Consent to be an Associate Investigator

The CIA must confirm with all AIs that they agree to be named on the application. Written evidence (e.g. an email), must be obtained from all AIs and provided to the RAO, stating their agreement to be on the application. AIs are not required to endorse an application prior to submission to NHMRC.

The RAO should not submit the application to NHMRC until the CIA has completed this step and all relevant AI consents have been obtained as per this requirement.

6 Use of NHMRC Funds

Note: Section 6 and its subsections apply to Research Support schemes but do not apply to People Support awards (e.g. Fellowships and Scholarships).

6.1 Access to NHMRC Funding

NHMRC seeks to promote collaboration between researchers and to remove artificial barriers that prevent multidisciplinary and multi-organisational proposals. However, NHMRC contributes funds only to the direct costs of a research project.

To access NHMRC funding, applicants are required to:
• Make a case for NHMRC grant funding in accordance with the *Scheme-Specific Information*. For further information, refer to section 3 *NHMRC Funding Rules* (Submitting and Application); and
• Declare the sources, duration and level of funding already held for research as part of the application.

NHMRC funds may be used for (see Appendix A):
• Supporting personnel, where the level of personnel support package requested matches the roles and responsibilities of the position, rather than the expertise of a specific occupant of the position;
• Equipment that is unique to the project and is essential for the project to proceed;
• Direct research costs (DRCs) for the purchase of research materials (not personnel) required to conduct the proposed research;
• Costs of animal agistment that are a direct requirement of the research project; and
• Travel costs directly related to achieving the objectives of the grant.

NHMRC does not fund:
• Research infrastructure that an institution with research as part of its mission would be expected to supply;
• Institutional overheads and administrative charges; or
• The other indirect costs of research.

For more information regarding direct and indirect research costs, refer to the links below:
1. Direct Research Costs – a guide for research and administrative staff: http://www.nhmrc.gov.au/_files_nhmrc/file/grants/admin/nhmrc_direct_research_costs_1209.pdf; and

Further information on the use of NHMRC Funding is available at Appendix A.

### 6.2 Salary Support for Chief Investigators

NHMRC Research Support awards are not normally intended to provide salary support for CIs and in some schemes, salary support for CIs is not offered. However, if applications are seeking salaries for CIs, this should be justified in the proposed budget as being directly associated with achieving the outcomes of the research.

Salaries for research staff must be based on Personnel Support Packages (PSPs). Further details on PSPs can be found at: http://www.nhmrc.gov.au/grants/apply-funding/project-grants/budget-mechanism-project-grant-funding-commencing-2012.

NHMRC does not support senior research salaries through Research Support schemes. Researchers seeking salaries outside of the range of PSP 1 to 5 must do so via NHMRC’s People Support schemes (ie, Research or Practitioner Fellowships). Information about NHMRC People Support schemes can be found at: http://www.nhmrc.gov.au/grants/apply-funding/fellowship-awards/people-support.
6.3 Registration of Clinical Trials

All NHMRC funded clinical trials must be registered in the Australian New Zealand Clinical Trials Registry (ANZCTR), or equivalent, prior to commencement of the clinical phase.

Applicants proposing to undertake a randomised controlled trial may request the administrative charge payable for the registration of the trial. Requests for funding of trial registration must be justified in the DRC component of the application.

Information pertaining to the ANZCTR or equivalent, and how to register can be found at: http://www.anzctr.org.au.

6.4 Paid Parental Leave Scheme

Information concerning the Australian Government’s Paid Parental Leave Scheme is available at the following website:

All NHMRC awards provide for investigators to undertake research on a part-time basis for all or part of the duration of the grant.

7 Outcome of Application

NHMRC will advise applicants and their nominated Administering Institution’s Research Office of the outcome of the application as early as possible following announcement of funding.

NHMRC will publish the following information on its website for all successful grants:
   a) Application Identity;
   b) All CI names;
   c) Administering Institution;
   d) Scientific title and/or simple title;
   e) Broad Research Area;
   f) Funding partners (if relevant); and
   g) Total funding awarded and duration.

NHMRC may publish this information in a manner that allows it to be searched and viewed in a variety of ways, including by CI name, State, Institution and/or Application ID.

The media summary may also be published.

8 Complaints in Relation to the Outcome of Funding Applications

Applicants may contact NHMRC seeking clarification on the outcome of their application for funding, or to state an objection to any part of the process. The complaint must be lodged in writing through the Administering Institution’s Research Office and be received within four weeks of the date of notification.

The complaint should be directed to the Complaints Officer at:
Complaints Officer
National Health and Medical Research Council
GPO Box 1421
CANBERRA ACT 2601

Or via email to: complaints@nhmrc.gov.au.

The NHMRC will provide a written response to all complaints.

The NHMRC policy on complaints can be found at: https://www.nhmrc.gov.au/about/contact-us/complaint-form.

8.1 Formal Complaints to the Commissioner of Complaints

The NHMRC Act provides for the Commissioner not to investigate a complaint where the complainant has not initially applied to the complaints officer as outlined above (see Section 8).

If an applicant is not satisfied with the outcome, they may lodge a formal complaint with the NHMRC Commissioner of Complaints, as detailed in Part 8 of the NHMRC Act.

A person whose interests are affected may at any time lodge a complaint under section 59 of the NHMRC Act. Section 61 of the NHMRC Act provides the Commissioner of Complaints with discretion, including where a complainant has not approached the CEO with the complaint, to choose not to investigate and refer the complaint to the CEO.

Complaints to the Commissioner should be addressed to:

NHMRC Commissioner of Complaints
National Health and Medical Research Council
GPO Box 1421
CANBERRA ACT 2601

Formal complaints can be mailed to the above address, or sent by email as a PDF letter to complaints@nhmrc.gov.au.

Complaints must be in writing, be signed by the complainant, describe the action complained about and specify the nature of and grounds for the complaint.

Complaints can only be considered against administrative process and not the merits of a particular decision. The grounds of complaint are detailed at section 58 of the NHMRC Act and are that:

a) the action involved a breach of the rules of natural justice;
b) the action was induced or affected by fraud;
c) there was no evidence or other material to justify the action;
d) an irrelevant consideration was taken into account in relation to the action;
e) a relevant consideration was not taken into account in relation to the action;
f) in the course of the action a discretionary power was exercised for a purpose other than the purpose for which the power is conferred;
g) the action involved the exercise of a discretionary power in bad faith;
h) in the course of the action, a personal discretionary power was exercised at the direction of another person;
i) the action involved the exercise of a discretionary power in accordance with a rule or policy without regard to the merits of the particular case; or
j) the action involved any other exercise of a power in a way that constitutes abuse of the power.

Complainants are advised to contact their RAOs prior to making a complaint to the Commissioner.

The Commonwealth Ombudsman can also investigate complaints about the actions and decisions of Australian Government agencies. For further information please refer to the Commonwealth Ombudsman website at: http://www.ombudsman.gov.au/

9 Approvals to be Obtained Prior to Funding Commencing

Funding for an NHMRC Grant (other than Research and Practitioner Fellowships and TRIPs) will not commence until all relevant approvals, particularly in relation to ethics and biosafety, have been received from the appropriate institutional committees and lodged with the Administering Institution's Research Office prior to the commencement of the research. Provisional approvals are not acceptable and no funding will be provided on the basis of a provisional approval.

The grant offer may be withdrawn if ethics approvals are not obtained within six months of the original grant commencement date.

Where an ethics clearance or regulatory approval is not required until the latter years of a Grant and the relevant committee cannot review the proposal without the results of the preliminary findings of the research then, NHMRC approval can be sought for the funds to be released. These requests will be considered by NHMRC on a case by case basis.

Applicants must ensure that where appropriate, a copy of the application is referred to the relevant institutional committees or approval bodies.

The Research Administration Officer, who is responsible for the application, must advise NHMRC when clearances have been granted by the relevant committees.

NHMRC reserves the right to request further information in relation to decisions made in response to an application for ethics committee or biosafety committee approval.

10 Approvals and Licenses

10.1 Research Involving Humans

Research funded by NHMRC that involves human participants must be reviewed by a Human Research Ethics Committee (HREC) or an institutional low risk review process in accordance with the National Statement on Ethical Conduct in Human Research 2007 (the National Statement). Consideration must also be given to the Privacy Act. The National Statement is available on the NHMRC website at: http://www.nhmrc.gov.au/guidelines/publications/e72.
Human research, in this context, includes research involving any human tissue, no matter what the source, and also includes research in which there is any intervention (physical or psychological) in the normal lives of humans.

All research involving the administration of drugs, chemical agents or vaccines to humans must be considered by a HREC to assess the appropriateness of their use. If such research is part of a clinical trial, then it falls under the responsibility of the Therapeutic Goods Administration (TGA) which administers the Clinical Trials Notification/Exemption schemes. Further information on these schemes can be obtained from the TGA:

In the case of multi-centred clinical trials, the relevant institutions and their HRECs may agree that the primary ethical and scientific assessment be made at one institution/organisation, with copies of the approvals being sent to the other institutions/organisations involved. Further information on multi-centre research approval is provided in the National Statement.

10.2 Human Embryo Research

For further information about the legislation refer to the NHMRC website at:
http://www.nhmrc.gov.au/guidelines/publications-0; and

10.3 Use of Personal Information in Research
Section 95 of the Privacy Act provides that the CEO of NHMRC may, with the approval of the Commissioner, issue guidelines for the protection of privacy in the conduct of medical research.

Any research involving humans that uses personal information held by Commonwealth agencies where identified information needs to be used without consent from the individual(s) involved should abide by NHMRC guidelines approved under section 95 of the Privacy Act (section 95 guidelines). In these situations, the proposed medical research must be approved by a properly constituted HREC in accordance with the section 95 guidelines.

NHMRC guidelines approved under section 95A of the Privacy Act (section 95A guidelines) are broader than the section 95 guidelines and apply to the collection, use and disclosure of health information held by organisations in the private sector for the purposes of research or the compilation or analysis of statistics, relevant to public health or public safety, without the consent of the individual(s) involved. Under the section 95A guidelines, a HREC must give approval for the use of this information.

10.4 Research Involving Animals
Research funded by NHMRC that involves the use of animals must be reviewed and approved by a properly constituted Animal Ethics Committee as being in accordance with the Australian Code for the Care and Use of Animals for Scientific Purposes 2004 (the Animal Code). The Animal Code is available on the NHMRC website at:
10.5 Generation or Use of Genetically Modified Organisms

Applicants proposing to undertake research involving genetically modified organisms (GMO) must ensure that all the requirements of the *Gene Technology Act 2000* and *Gene Technology Regulations 2001* have been met.

In the first instance, applicants should seek advice from their Institutional Biosafety Committee on the level of authorisation needed for any proposed GMO research. Information on the gene technology regulatory scheme, including the Act and Regulations, is also available from the Office of the Gene Technology Regulator website at: [http://www.ogtr.gov.au](http://www.ogtr.gov.au).

11 Considerations Relevant to NHMRC Funded Research

11.1 Health Research Involving Aboriginal and Torres Strait Islander Peoples

Ethics applications for research that involves the participation of Aboriginal and Torres Strait Islander Peoples should be developed with reference to the *Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research* (2003). Further information is available from the NHMRC website at: [http://www.nhmrc.gov.au/guidelines/publications/e52](http://www.nhmrc.gov.au/guidelines/publications/e52).

11.2 Use of Carcinogenic or Highly Toxic Chemicals


11.3 Use of Cultured Cell Lines for Research

Concern exists within the scientific community regarding the impact of contamination with mycoplasma and other cells in eukaryotic cell lines and the use of incorrectly characterised cell lines, on the validity of research outcomes. NHMRC recommends that researchers employ quality assurance procedures to ensure their eukaryotic cell lines are free from mycoplasma.

11.4 Use of datasets for research purposes


11.5 Nagoya Protocol

Applicants should be mindful of the Nagoya protocol and the likelihood of Australia becoming a signatory. The protocol seeks to establish a legally-binding framework for biotechnology researchers and other scientists to gain access to genetic resources. It also establishes a framework for researchers and developers to share any benefits from the use of genetic resources, or traditional knowledge associated with those resources, with the provider country. More information can be obtained at: [http://www.environment.gov.au/biodiversity/science/access/biological-diversity.html](http://www.environment.gov.au/biodiversity/science/access/biological-diversity.html).
11.6 Defence Trade Controls Act 2012

12 Consumer and Community Participation in Health and Medical Research
The Statement on Consumer and Community Participation in Health and Medical Research (the Statement) has been developed because many consumers and researchers recognise the contribution that consumers can make to health and medical research. The Consumers Health Forum of Australia Inc (CHF) 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. Applicants should refer to the CHF and NHMRC Statement available at: http://www.nhmrc.gov.au/guidelines/publications/r22-r23-r33-r34.

NHMRC and CHF are currently revising the Statement. Public consultation on a draft revised Statement is scheduled for the first half of 2013.

13 Administration of NHMRC Grants
Any enquiries regarding the administration of NHMRC grants should be directed firstly to the applicant’s RAO, then by email to postaward.management@nhmrc.gov.au.

13.1 NHMRC Funding Agreement
All grants are offered in accordance with the conditions specified in the Funding Agreement which is an agreement between NHMRC and the Administering Institution. In signing the Signature Block for 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 at: http://www.nhmrc.gov.au/grants/administering-grants/nhmrc-funding-agreement.

A grant may not commence, nor grant funds be expended, prior to:
- the Funding Agreement between NHMRC and the Administering Institution being in place; and
- the appropriate Signature Block for Schedules being signed by the signatories to the Funding Agreement, or an appropriate delegate, and signed and executed by NHMRC.

13.2 Payments
Subject to appropriations provided by the Commonwealth Department of Finance and Deregulation, payment of funds will be made to Administering Institutions in regular instalments, in accordance with approved payment arrangements made for assistance provided from the MREA. Funds must be used only for the purposes approved and detailed in the Funding Agreement and its Schedule.

Payments will commence once any outstanding reporting obligations have been met by the CIs and the Administering Institution.
13.3 Research Misconduct
Research funded by NHMRC must comply with the Code, which can be found at:

The Funding Agreement contains provisions for the handling of allegations of research misconduct. Applicants and grant holders are referred to the NHMRC Policy on Actions to be taken in the event of research misconduct involving NHMRC funding. This is available at:

13.4 Intellectual Property
Unless otherwise approved by NHMRC, applicants must agree to comply with the National Principles of Intellectual Property Management for Publicly Funded Research (2001) available at:

14 Reporting on NHMRC Grants

14.1 Progress Reports and Financial Reports
Annual progress and financial reports will be required by 30 April of each year in a form prescribed by NHMRC. At the completion of the grant, a final report and financial acquittal will be required within six months after the period of funding ends.

Failure to report within timeframes may also affect eligibility to apply for and receive funding.

Additional reporting requirements and reporting exemptions may apply: please check the Scheme-Specific Information for the scheme (e.g. People Support Schemes).

NHMRC has designated Section A of the End of Grant – Final Report as information that NHMRC may publicly release. Use of this information may include publication on the NHMRC website, publicity (including release to the media), and the promotion of research achievements.

All information provided to NHMRC in progress and final reports may be used for internal reporting and reporting to government. This information may also be used by NHMRC when reviewing or evaluating funding schemes, or designing future schemes.

The reporting requirements are included in the Schedule to the Funding Agreement and can also be found at:

NHMRC may suspend payment of further instalments of:
- the relevant grant, and/or
- all grants held by the CIA, and/or
- all grants administered by that Administering Institution until the appropriate reports have been received and assessed as satisfactory.

In addition, where an institution fails to submit satisfactory reports as required, NHMRC may also terminate funding and determine that all or part of the funding must be repaid. Alternatively, NHMRC may withhold the remainder of the Institution’s payments under the scheme for the current year or initiate recovery of funding.
15 Open Access Statement

15.1 Dissemination of Scientific Results

The Australian Government makes a major investment in research to support its essential role in improving the wellbeing of our society. To maximise the benefits from research, findings need to be disseminated as broadly as possible to allow access by other researchers and the wider community.

NHMRC acknowledges that researchers take into account a wide range of factors in deciding on the best outlets for publications arising from their research. Such considerations include the status and reputation of a journal or publisher, the peer review process of evaluating their research outputs, access by other stakeholders to their work, the likely impact of their work on users of research and the further dissemination and production of knowledge. Taking heed of these considerations, both organisations want to ensure the widest possible dissemination of the research supported by their grants, in the most effective manner and at the earliest opportunity.

NHMRC encourages researchers to consider the benefits of depositing their data and any publications arising from a research project in an appropriate subject and/or institutional repository wherever such a repository is available to the researcher(s). If a researcher is not intending to deposit the data from a project in a repository within a twelve-month period, they should include the reasons in the project’s Final Report. Any research outputs that have been or will be deposited in appropriate repositories should be identified in the Final Report.

Section 4 of the Code, outlines these and other responsibilities of Institutions and researchers, which apply to all forms of dissemination.

Grant recipients must ensure that they comply with NHMRC policy on the dissemination of research findings, which is available at: http://www.nhmrc.gov.au/grants/policy/dissemination-research-findings.

16 Resources

16.1 NHMRC Resources


NHMRC Administering Institutions policy at:

NHMRC complaints handling policy:

_NHMRC Funding Agreement_ at:

NHMRC policy on the dissemination of research findings:

_NHMRC Strategic Plan 2010-2012_ at:

*Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research* at:

### 16.2 Legislation

_Criminal Code Act 1995_ at:

_Freedom of Information Act 1982_ at:

_National Health and Medical Research Council Act 1992_ (NHMRC Act) at:

_Privacy Act 1988_ at:

_Prohibition of Human Cloning for Reproduction Act 2002_ (PHCR Act) at:

_Research Involving Human Embryos Act 2002_ (RIHE Act) at:
PART 2 – SCHEME-SPECIFIC INFORMATION

PROJECT GRANTS

1 Introduction to this Scheme

The Project Grants scheme is NHMRC’s main avenue of support for individuals and small teams of investigators undertaking health services, public health, clinical and biomedical research in Australian universities, medical schools, hospitals and other research institutions.

There are no exclusions for applications to the Project Grants scheme, which supports all research approaches relevant to human health. Applicants can apply for grants from one to five years in duration.


2 Description and Objectives

The Project Grants scheme aims to fund research leading to improved health of all Australians. To achieve this aim, the scheme provides support for investigator-initiated research relevant to health across all fields of research, from basic research through to research in clinical and community settings. Single investigators or small teams of investigators (up to ten investigators) are supported as well as early career investigators (new investigators).

The scheme also identifies and supports research in NHMRC’s Priority Research Area of Indigenous Health, and NHMRC Special Initiative Areas where additional funding has been received for specific research, and where Research Committee has advised of its relevance to the goals of NHMRC.

A Project Grant is an agreement with an eligible Australian Administering Institution specifying financial support for specific investigators to undertake a defined research project. Administering Institutions are responsible for supporting the indirect costs of the research project and for administering the grant, which includes accepting financial responsibility for the grant.

Advice on Whether to Apply to the NHMRC or the Australian Research Council

In some instances, applicants may not be clear about whether their application is more appropriately considered by NHMRC or the Australian Research Council (ARC).

The ARC’s definition of medical and dental research is available from the ARC website at http://www.arc.gov.au/. At the time of certifying an ARC Discovery Project submission, Administering Institutions are to ensure that the submission is not medical and dental research according to ARC’s definition. NHMRC will assess all applications submitted for support of health and medical research.
3 Changes to the 2013 Application Round
Applicants should note the following changes to the Project Grants Funding Rules this year.

- Clarification of New Investigator eligibility – refer to Part 2, Section 7.1
- Alignment of multiple grant eligibility (Program/Project Grants) - refer to Part 1, Section 5.1
- Requirement to seek consent from Associate Investigator(s) to include their name on an application – refer to Part 2, Section 4
- Strategic Plan Initiative Areas that align with the 2010-2012 NHMRC Strategic Plan have now been removed
- Requirement that applications indicating a focus on Aboriginal and Torres Strait Islander health research are required to demonstrate that at least 20% of their research effort and/or capacity building relates to Aboriginal and/or Torres Strait Islander health
- Budgets can now include a request for the costs of biospecimens and associated data provided they are a direct requirement of the research project - refer to Appendix A, Research Facilities

4 Research Teams

Chief Investigators and Research Teams
Apart from the specific exclusions and other conditions noted below, in Part 1, Section 5.2 and in Part 2, Section 5, NHMRC Project Grants are available to all investigators working in any field of research relevant to health.

The Chief Investigator A (CIA) takes the lead role in the conduct of the research project, and is the investigator who takes responsibility for completion and lodgement of the application. The contribution of a CIA will be reviewed by the GRP to determine whether it is adequate for the research proposed. The CIA must seek agreement from Associate Investigators (AIs) for their name to be included in the application. Written evidence, such as an email, must be attained from the AI to state their agreement to be on the application. However the AI is not required to endorse the final application.

5 Funding

5.1 Level of Funding
There is no specific limit to funding for each application under the NHMRC Project Grants scheme. Applicants are advised to justify clearly the requested budget, paying particular attention to any research cost(s) which may be atypical for the particular field of research (Refer to the following web-link: http://www.nhmrc.gov.au/_files_nhmrc/file/grants/admin/nhmrc_direct_research_costs_1209.pdf).

NHMRC funding is provided by the Australian Government under the NHMRC Funding Agreement (refer to http://www.nhmrc.gov.au/grants/administering-grants/nhmrc-funding-agreement).
5.2 Duration of Funding
Applicants may apply for Project Grants funding for between one and five years duration. NHMRC does not prescribe the duration of Project Grants and funding requests ranging from one to five years duration will be assessed on their merits. The Grant Review Panel (GRP) will recommend the duration of the grant, taking into consideration the detailed research plan and budget to cover the proposed research plan, and any milestones and/or funding conditions.

NOTE: Investigators applying for grants awarded by other funding bodies, for example Cancer Australia, must refer to the relevant guidelines provided by these organisations as specific conditions on the level and duration of funding and the items supported may differ. These guidelines can be found at the relevant link provided in Part 2, Section 5.5.

5.3 Funding to Support Overseas Research Activities
Applicants may request funding to support specific research activities to be undertaken overseas. In doing so the applicants must clearly demonstrate that the research activity is critical to the successful completion of the project, and the equipment/resources required for the research activity are not available in Australia.

Funding for research support staff based overseas may only be considered where this is essential to achieving the aims of the research.

5.4 Co-funding of Clinical Trials
NHMRC will only be able to fund a limited number of clinical trials and may require applicants to find co-funding as a prerequisite for NHMRC support.

NHMRC Clinical Trial Grant Review Panels (CT-GRPs) can consider applications in advance of a commitment for co-funding support. In such situations, NHMRC will provide the applicant with a response indicating whether the application would be funded if co-funding became available within the following 12 months.

Evidence of the financial commitment of co-funder(s) will be required before the Minister with portfolio responsibility for NHMRC approves NHMRC support of a co-funded clinical trial.

For a more detailed explanation on the use of NHMRC funds and to prepare the budget in the application, refer to Appendix A (NHMRC Budget Guidelines for Research Support Grants) and the NHMRC website: http://www.nhmrc.gov.au/grants/apply-funding/project-grants.

5.5 Funding by Other Organisations
The NHMRC Project Grants scheme has established a number of different arrangements with Government agencies, Administering Institutions and not-for-profit organisations to support research in specific areas.

An example of this is when NHMRC conducts the peer review of applications on behalf of a third party. At the completion of the peer review process, NHMRC provides the third party with application details (which includes personal information about the applicant) including the peer review outcomes for their consideration. The decision to fund the application remains with the third party.

Another example is when a third party provides NHMRC with funding to support applications that address a specific health issue, but do not take any part in the decision making process.
In accordance with the *Privacy Act 1988 (Cth)*, NHMRC is required to seek consent from applicants before providing personal information, that is, the application, snapshot reports and information about the results of NHMRC’s assessment outcome to a third party.

Applicants who wish to be considered for funding will be asked to consent to their personal information being provided to a third party (including their Administering/ Actual Institution or state/territory government) for the purposes of consideration for funding.

Consent will be obtained via the CIA (through RGMS), however applicants should be aware that it is the CIA’s responsibility to ensure all persons named in an application including Chief Investigators (CIB to CIJ) and Associate Investigators consent to their personal information being provided to a third party.

Organisations that have confirmed arrangements for 2013 Project Grants funding round are listed on the NHMRC website. Please refer to [http://www.nhmrc.gov.au/grants/apply-funding/project-grants](http://www.nhmrc.gov.au/grants/apply-funding/project-grants) for more information on the arrangements in place.

**Applying for funding from another organisation through NHMRC**

Applicants are able to choose whether to apply for funding from only one organisation or from several organisations that offer funding through the NHMRC Project Grants scheme. In 2013, applicants can choose to apply from:


If an applicant chooses to apply for funding from NHMRC and one of the organisations listed above, and the application is ranked as fundable following NHMRC peer review, NHMRC has the first option to fund the application.

Applications for NHMRC funding must comply with all NHMRC funding criteria. Applicants must comply with any additional, specified criteria from the relevant funding organisation. Please refer to the above webpages for information on additional criteria that may apply.

Applications for funding from only the Cancer Council, or Cancer Australia, and not NHMRC, are exempt from:

- the specific eligibility criteria found in Part 1 Section 5, and Part 2 Section 7 of this document; and
- from making a case for NHMRC funding as stated in Part 1, Section 6.

**6 Critical Dates**

Applications for this scheme will open in the NHMRC Research Grants Management System (RGMS) on 5 December 2012. Applications must be submitted by 17:00 hrs (AEDT) 19 March 2013.

Late applications or changes to applications after the closing date are not accepted.

Applicants applying for funding under this scheme should note the following critical dates:
7 Additional Eligibility

The following eligibility criteria are in addition to those in Part 1, Section 5 NHMRC Funding Rules and should be read conjunctionally.

Applicants should note that Project Grant applications must be eligible when submitted. CIs cannot seek to become eligible after the application is submitted to NHMRC.

In relation to the eligibility criteria described in Part 1 Section 5.2 the NHMRC Funding Rules requests to waive citizenship/permanent residency requirements must be received by NHMRC by 23 January 2013.

Applicants that currently hold an NHMRC Program Grant should refer specifically to Part 1, Section 5 – Program Grants.

All CIs must have fulfilled all obligations from previous NHMRC grants, including submission of required progress and final reports.

7.1 Eligibility criteria for Chief Investigators on an application for New Investigator funding

The New Investigator initiative aims to support investigators who have not previously received significant research funding through a competitive grants scheme.

To be eligible to apply in this category, all CIs (CIA-CIJ) on an application for New Investigator (NI) funding must not be named as a CI1 (or equivalent) on a previously funded NHMRC grant (e.g. Project Grant, Program Grant, Development Grant etc.), Australian Research Council (ARC) grant (e.g. Discovery Grant etc.), or equivalent2, which included funding for research support.

Applicants may have held a salary-only award (Scholarship or Fellowship) from any funding source including NHMRC (e.g. NHMRC Career Development Award, Early Career Fellowship Award or Training Award).

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1 A CI does not include an investigator identified as a Co-Investigator on NHMRC Program Grants awarded before 2009.
2 Domestic equivalents include, but are not restricted to: Cancer Australia Priority-driven Standard/Young Investigator Project Grants, or Cancer Council Victoria Grant-in-Aid. International equivalents include, but are not restricted to: Medical Research Council (UK) Research Grants, National Institutes of Health (US) Project Grants, Canadian Institutes of Health Research Operating Grants, or the Human Frontier Science Program (France) Research Grants.
Applicants will be required to provide justification within the application stating why the application should be considered for New Investigator status.

Applicants unsure of their eligibility can seek a formal ruling by emailing NHMRC. Applicants should clearly outline details of any previously received funding and their role on the funded project(s). Emails should be marked for attention of Director, Project Grants Section and must be submitted to Project Grants projects@nhmrc.gov.au by 23 January 2013.

8 Call for Applications in NHMRC’s Priority Area and Special Initiatives for 2013

In addition to the general aims of the Project Grants scheme, each year the scheme is used to identify and support specific research. Further details are provided at: http://www.nhmrc.gov.au/grants/apply-funding/project-grants. In 2013, the following areas will be supported:

<table>
<thead>
<tr>
<th>NHMRC Priority Research Area</th>
<th>• Indigenous Health</th>
</tr>
</thead>
</table>
| Special Initiatives for 2013 (additional funding available from other funding partners) | • Electromagnetic Fields  
• Hearing Loss Prevention |

Special Initiatives are health areas in which NHMRC has received additional research funding from other parties to support research.

Applicants will have the opportunity to indicate whether their application addresses NHMRC’s Priority Research Area or a Special Initiative. All applications will be assessed to determine whether they address these areas and this will be taken into consideration when NHMRC determines funding recommendations.

All applications for Project Grant support, regardless of whether an application is confirmed by NHMRC as addressing a Special Initiative, are peer reviewed in the same manner.

8.1 NHMRC Priority Research Area – Indigenous Health

In 2013, NHMRC is again seeking applications that relate to the improvement of Aboriginal and Torres Strait Islander health as a Priority Research Area. All Indigenous health research applications will be assessed against the Project Grant assessment criteria (refer to Part 2, Section 9.1). Applications are also required to address NHMRC’s Criteria for Health and Medical Research of Indigenous Australians (refer to Part 2, Section 9.3).

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

9 Assessment

All Project Grant applications are regarded by NHMRC as new applications for funding. Applications undergo rigorous peer review whereby they are subject to scrutiny and evaluation by others who are expert in the field(s) of the application. Assessors and GRPs will bring their expertise and experience to the evaluation of the merit of applications for funding. This process also ensures value for money for all grants recommended for funding. Therefore, applicants can expect that any matter relevant to the scientific quality, significance and/or innovation, applicant track record(s) and budget may be brought to the consideration of their application by assessors and the GRP.

In developing their applications, applicants should take into account the nature of peer review. Assessors and GRPs may draw as appropriate from the research literature and from their breadth of knowledge in the relevant discipline(s) and field(s). Issues not relevant to the scientific quality, significance or innovation, and track record are not to be considered.

9.1 Assessment Criteria

Applications for Project Grants are assessed by peers according to the three internationally benchmarked assessment criteria of:

1. scientific quality;
2. significance or innovation; and
3. track record - relative to opportunity.

The following paragraphs describe the criteria.

1. Scientific Quality (50%)

This includes the clarity of the hypotheses or research objectives, the strengths and weaknesses of the study design and feasibility.

The research proposal may be assessed in terms of, but not limited to the following.

a) Clarity of the hypothesis or research objectives.
   i. Has the method/framework/approach been partially tested?
   ii. What outcome is sought in the proposed study? What exactly is the outcome measure?
   iii. Is it well integrated and adequately developed?

b) Is there a clear and appropriate research plan?
   i. What are the strengths and weaknesses of the study and its design?
   ii. Have any major pitfalls or problems been overlooked? Have alternative approaches been considered?
   iii. Is the plan well informed by knowledge of the literature?
iv Is the design appropriate for the aims of the research?

c) Feasibility.
   i Will the research plan successfully address the stated hypothesis or research objectives?
   ii Are the goals concrete and achievable?
   iii Is the investigating team appropriate – is it capable of achieving the goals? Does it have the right skills and expertise?

2. **Significance and/or Innovation (25%)**

   This includes the potential to increase knowledge about human health, disease diagnoses, or biology of agents that affect human health, or the application of new ideas, procedures, technologies, programs or health policy settings to important topics that will impact on human health.

   Applications do not need to be rated on both significance and innovation. Truly innovative ideas and research may not reveal their significance until sometime in the future (this is the case for many Nobel Prize winning discoveries). Similarly research of the highest significance such as important randomised clinical trials or public health intervention studies may use 'tried and true' methods only, yet be of immense significance to health. GRPs will use peer review judgement.

   Applications may be assessed in terms of, but not limited to the following questions.
   a) Is the problem important?
   b) Will the work or research have an impact?
   c) Is the proposed research new/novel or creative (has imagination been used)?
   d) How will scientific knowledge be advanced?
   e) What will be the effect of the study on the concepts or methods that drive this field?
   f) Does the research challenge existing models or develop new technologies or new study methods?
   g) How well does the proposal describe the new ideas, procedures, technologies, programs or health policy settings?

3. **Track Record – relative to opportunity (25%)**

   The NHMRC Funding Rules provide more detailed descriptions of “relative to opportunity” and “career disruption”. Please refer to Part 1, Sections 3.6 and 3.7.

   Track record is considered in terms of whether an applicant’s previous research demonstrates that the investigator(s) is capable of achieving the proposed project and/or ability to deliver the proposed project in terms of having the appropriate mix of research skills and experience.

   Where an application involves a CI team, the track record of all CIs is considered and will be assessed relative to opportunity (including career stage), based on relevance to the research being proposed and taking into account time commitment.

   Track record may encompass the national and international standing of the applicant(s) based upon their research achievements, including but not limited to:
• research outputs (most recent significant publications, publications that illustrate innovation and significance to past accomplishments, impact or outcome of previous research achievements, including effects on health care practices or policy, awards or honours in recognition of achievements);

• contribution to discipline or area (invitations to speak at international meetings, editorial appointments, specialist and high level health policy committee appointments); and

• other research-related achievements (influence on clinical/health policy or practice or provision of influential advice to health authorities and government, impacts on health via the broad dissemination of research outcomes; e.g. via mainstream media, the community or industry involvement).

Track record is considered in relation to opportunity – with regard to factors such as career disruption, administrative and clinical/teaching load, and typical performance (including publications) for the field in question. For Project Grants, Track Record will be judged on the most recent five years, except as described for career disruption (Refer Part 1, Section 3.7).

The track record of CI(s) and other key personnel listed on the application, relative to opportunity, may be assessed in terms of:

a) record of achievement, relative to opportunity;

b) contribution to their field of research; and

c) their national and/or international reputation in their fields.

The Project Grants Category Descriptors are currently being amended and when available will be posted on the NHMRC website.

9.2 Assessment Process

Applicants will have the opportunity to indicate their preferred Peer Review Area (PRA) in RGMS (refer to the Project Grants Advice and Instructions to Applicants document – Guide to Peer Review Process), for NHMRC’s consideration. NHMRC will use this information to assist in directing applications to a peer review panel. These are preliminary allocations only. NHMRC will use research expertise to review these allocations prior to assigning them to GRPs.

Applicants also have the opportunity to identify which of the Broad Research Areas (BRA) listed below are most relevant to their application.

- Basic Science
- Clinical Medicine and Science
- Health Services Research
- Public Health

Details on applications to be assessed by the Indigenous Grant Review Panel (IGRP) and the Clinical Trials panels can be found at Part 2, Sections 9.3 and 9.4 respectively.
Applications will be allocated to a Grant Review Panel (GRP), which will assess each application against the assessment criteria. NHMRC will seek reviews from external assessors for all Project Grant applications.

Prior to the GRP meeting, applicants will have an opportunity to respond to the reviews provided by external assessors and Primary Spokespersons.

NHMRC will collate the scores provided by the Primary and Secondary Spokespersons for each application and identify applications that fall in the bottom third of applications after preliminary assessment by the GRP. These applications will be considered by the GRP for removal in advance of the detailed GRP discussion (the Not for Further Consideration [NFFC] Process). The GRP will score all remaining applications to one of the scoring categories. The final score will determine which category the application is allocated.

NHMRC may seek additional advice on any grant application.

Once GRPs have categorised and ranked applications, NHMRC seeks advice from its Research Committee and Council on the total allocation of expenditure for the Project Grants scheme and on the extent of support for applications within the Priority and Special Initiative areas. NHMRC and its committees do not challenge the category or the ranking of individual grants, subsequent to the GRP views.

In accordance with Subsection 7(1)(c) of the NHMRC Act, the CEO accepts Council’s recommendation (as advised by Research Committee) and then formally seeks the Minister with portfolio responsibility for NHMRC’s approval to expend public money from the MREA.

9.3 Additional Criteria for Indigenous Health applications

Part B of the application includes the question ‘Does this research proposal include Aboriginal and/or Torres Strait Islander health research and/or capacity building?’ Applicants should only select ‘YES’ if they can demonstrate that at least 20% of their research effort and/or capacity building relates to Aboriginal and/or Torres Strait Islander health. Applicants who select ‘YES’ need to address the Criteria for Health and Medical Research for Indigenous Australians (Indigenous Criteria) in their application (refer: http://www.nhmrc.gov.au/_files_nhmrc/file/grants/indighth.pdf). Such applications will be initially reviewed by Indigenous health research experts to determine whether the application should be assessed as an Indigenous health research application and, therefore, whether it will be assessed by the Indigenous Grant Review Panel (IGRP).

In scoring applications against the assessment criteria, the IGRP will use its discretion, experience and expertise to reflect the relative strength of the application in terms of how well it addresses and meets the Indigenous Criteria.

NHMRC will take advice provided by the IGRP into account when determining funding recommendations.

9.4 Clinical Trials

The Clinical Trial Grant Review Panels (CT-GRP) will assess applications where an applicant identifies in their application that the research proposal involves a clinical trial and where the scale and scope of the application is substantial.
The CT-GRPs may also review other applications where NHMRC determines that it has the appropriate expertise. Applications for larger cohort studies and population studies may also be referred to these panels.

NHMRC will only be able to fund a limited number of very large clinical trials and may require applicants to find co-funding as a prerequisite for NHMRC support.

For further information regarding clinical trial applications, refer to Part 2, Section 5.4.

A clinical trial should be considered as the evaluation of any health care intervention (including prevention, early detection, treatment, health service, behavioural change and pharmaceutical) in a human population with disease or at risk of disease.

The clinical trial will usually involve the comparison of a new treatment or intervention against a standard care/management assessing the impact of each on health outcomes or intermediate endpoints, using a controlled design. A trial could also involve early phase 1 or phase 2 trials without a control group.

Investigators whose applications are being assessed by the CT-GRPs will be able to specify modifications to their proposal in their Applicant Response in response to assessor reports. Applicants are not permitted to add named investigators to the research team as part of the Applicant Response, however applicants may indicate their intention to involve additional expertise.
APPENDIX A: NHMRC BUDGET GUIDELINES FOR RESEARCH SUPPORT GRANTS

Introduction

NHMRC funds the direct costs of the research proposal based on advice from peer review. This document is designed to assist NHMRC grant applicants in identifying resources which can or cannot be funded using NHMRC funds, and to assist applicants in the preparation of the budget component of their grant application.

Level of funding

Applicants are advised to clearly justify the requested budget paying particular attention to any research cost(s) which may be specific to this field of research and specially needed for their application.

The PRP advises NHMRC of a budget for each application. The PRPs recommendation is based on the budget requested by the applicant, the requirements of the proposal as assessed by the PRP and its knowledge of the costs associated with the research.

Grant applicants are required to:

- make a case for NHMRC grant funding in accordance with the Scheme-Specific Information.
- declare the sources, duration and level of funding already held for research.

Where co-funding has already been secured, applicants should indicate the components of the budget for which NHMRC support is being sought.

Budget considerations

There are three areas to consider when preparing a budget proposal:

1. support for personnel engaged in the conduct of the research;
2. direct research costs; and
3. equipment costs necessary to conduct the research.

These and other budget considerations are discussed below.

Support for Personnel

Researchers who are not Australian citizens or permanent residents in Australia are eligible to apply for an NHMRC grant as CI B to J.

Associate Investigators are not permitted to draw salary from a NHMRC grant.
Casual computing and similar casual staff requirements, which will be contracted at hourly rates, should be included under DRCs.

Funds to support personnel are provided as Personnel Support Packages (PSPs). The level of PSP requested in an application should match the roles and responsibilities of the position, rather than the expertise of a specific person whom the CIs may intend to appoint to the position. Information on PSP amounts can be found at: http://www.nhmrc.gov.au/grants/apply/projects/budget.htm.

Personnel Support Packages (PSPs) are designed to contribute to salary and salary on-costs (e.g. payroll tax, workers compensation, leave loading, compulsory and contributory superannuation and long service leave). Administering Institutions should seek their own advice on any potential taxation implications.

All applicant CIs must indicate the proportion (%) of their research time that they will commit to NHMRC funded research for the currently submitted grant application. Further information on how to indicate the amount of time proposed to be devoted to the grant, should it be awarded, is provided in the Advice and Instructions to Applicants document.

Applicants may apply for a full PSP provided that 80% or more of the occupant’s time will be devoted to the Project.

An annual indexation will be applied to PSPs, based on the Australian Government Wage Cost Index (WCI).

**Direct Research Costs**

DRCs are awarded for the purchase of research materials (not personnel) required to conduct the proposed research. For example: items such as consumables, printed materials, microfilms, survey or field expenses, purchase costs for animals and computing charges.

DRCs are available in multiples of $5,000. Individual items of equipment costing less than $10,000 must be requested as DRC.

All requests for funds must be fully justified, especially requests for:

- programming, preparation and data storage or the hire of external computer time. Funds will not be provided for the hire of computer time on a computer within the applicant’s institution,
- covering the liability insurance for human clinical trials; and
- administrative charges associated with registration of clinical trials.

Using Research Facilities

Biospecimen and Associated Data

Requests for biospecimens and associated data must be fully justified in the DRC component of the application form.

The NHMRC will support the costs of biospecimens and associated data that are a direct requirement of the research project. Biospecimen and associated data costs must be based upon published cost recovery schedules of biobanks or similar accredited bodies (e.g. Pathology services). An indicative list of these is available below. Such costs will typically represent cost recovery for the costs of collection, processing, storage and distribution. Consideration for additional project development and management costs for utilising biospecimens and associated data may be requested.

Given the significant expansion in biobank activities in Australia in the last decade, any future proposal for prospective funding of a biobank must specify why the samples cannot already be sourced from an existing biobank. Any proposal to establish a new biospecimen collection should seek to use infrastructure or services provided by biobanks or similar accredited bodies. Comprehensive justification for not using one of these must be provided.

Following is an indicative list of Biobanks and services that provide services based upon international standards of best practice (ISBER):

- Australian Ovarian Cancer Study http://www.aocstudy.org/
- Australian Schizophrenia Research Bank www.schizophreniaresearch.org.au
- Cancer Institute NSW Biobanking Network. Including
  - GynBioBank
  - Kolling Institute of Medical Research Neuroendocrine, Gynaecological, Breast and Upper GI Banks
- Genetic Repositories Australia (GRA) http://www.neura.edu.au/GRA
- Lowy Biorepository http://powcs.med.unsw.edu.au/research/adult-cancer-program/services-resources/biorepository
- NATA Accredited Pathology Practices
- NSW Children’s Hospital Network
- The Leukaemia and Lymphoma Tissue Bank A joint research initiative of ALLG and the Leukaemia Foundation email: allg_tissue_bank@health.qld.gov.au
- Victorian Cancer Biobank www.viccancerbiobank.org.au
- WA Research Tissue Network (Operated by St John of God HealthCare)
- Wesley Institute
Appendix A

Other Research Facilities
The costs of utilising the services of other research facilities can also be sought through DRCs. Examples of organisations that are included in this category include Non-Human Primate colonies, the Australian Twin Registry, Cell Bank Australia, the Trans-Tasman Radiation Oncology Group (TROG) and suppliers of clinical trials services. This list is illustrative and is by no means exhaustive.

Researchers should consult with research facilities to ensure that the services they are seeking DRC funding for can be provided and that the research budgets reflect these charges. Letters from research facilities confirming their collaboration should be included with the application to assist the Grant Review Panel in assessing the application.

Animal Agistment Costs
Requests for animal agistment costs must be fully justified in the DRC component of the application form.

The NHMRC will support the costs of animal agistment that are a direct requirement of the research project. Animal agistment costs may include the costs of food and caging, and of experimental breeding, during the course of the project. For information on animal agistment costs, consult your Administering Institution. The purchase of animals should be included in DRC.

Funds will be provided for the full purchase price of non-human primates. Applicants should contact the relevant non-human primate breeding colony to obtain information about the terms and conditions associated with the purchase of animals and agistment fees.

The NHMRC will not support infrastructure costs that should normally be provided by the Animal House of the host institution (such as administration or support of Animal House staff) regardless of whether or not the institution has its own Animal House.

Equipment
Where an applicant is requesting funding for an item of equipment, the equipment must be unique to the project and essential for the project to proceed. Equipment requests must not include the type of apparatus normally provided from institutional funds such as freezers, etc.

Applicants must provide details as to why the equipment is not being provided by their institution. For each item of equipment requested, a written quotation must be received and held with the Research Office of the Administering Institution and must be made available to the NHMRC on request.

The applicant must ensure the Administering Institution is prepared to meet all service and repair costs in relation to equipment awarded.
Funds will not be provided for the purchase of computers except where these are an integral component of a piece of laboratory equipment or are of a nature essential for work in the research field. For example: a computer which is dedicated to data collection from a mass spectrometer, or used for the manipulation of extensively large datasets (i.e. requiring special hardware) may be supported.

Individual items of equipment costing less than $10,000 must be requested as DRCs. Applicants may not seek funding for equipment totalling more than $80,000 for the entire period of the grant.

An annual indexation will be applied to equipment, based on the WCI.

**Medicare Claims**

The following information relates to health services NHMRC grant applications having clinical relevance in order to attract Medicare benefits.

Medicare is governed by the *Health Insurance Act 1973* which sets out the services attracting benefits. Sub-section 19(5) of the *Health Insurance Act 1973* provides that benefits are for where services are clinically relevant for the treatment of the patient. Clinical relevance is a matter of judgement for the patient's medical practitioner.

Where a range of services or tests are carried out by the patient’s medical practitioner as part of the deliberate management of the patient's health, Medicare rebates are payable.

However, a range of tests offered to a patient by a clinic for which there is no apparent clinical necessity, as determined by a medical practitioner, do not attract benefits.

In light of this information, Medicare rebates would not be available for patient visits to General Practitioners as part of a research project, where such visits would not be deemed clinically relevant for the treatment of the patient.

**Infrastructure, Indirect Costs and Institutional Overheads**

NHMRC does not fund:

- the indirect costs of research; or
- research infrastructure; or
- institutional overheads and administrative charges (levied to pay for institutional research; and
- general infrastructure.

This policy applies regardless of whether the institution, department, unit or individual researcher is in receipt of any form of Commonwealth or State support for research infrastructure.
Appendix A

Research infrastructure includes facilities necessary to the research endeavour that a responsible institution with research as a part of its mission would be expected to supply as a prerequisite to its engagement in research, and includes:

- physical space and all the services associated with it;
- furniture for research staff;
- administrative services;
- office services and consumables that are not specific to the research project;
- laboratory services and consumables that are not specific to the research project;
- animal house facilities;
- computer networks and basic network utilities; and
- personal computers, related network peripherals and software needed for communicating, writing, and undertaking simple analyses.

Research infrastructure does not include:

- office services and consumables that are specific to the project;
- individual human research subjects or research animal services specific to the project;
- laboratory services and consumables that are specific to the project;
- computer network facilities required to meet project specific needs;
- personal computers, related network peripherals and software required to meet project specific needs; and
- other items of equipment that are required to meet project specific needs.
APPENDIX B: NHMRC PROJECT GRANTS CATEGORY DESCRIPTORS

The following category descriptors are used to score an application against each of the assessment criteria: 1) Scientific Quality; 2) Significance of the Expected Outcomes and/or Innovation of the Concept; and 3) Team Quality & Capability, relative to opportunity. The Category Descriptors provide GRP members with indicators that should be sampled to guide appropriate scores for each application. The process of consistently referring GRP members to these descriptors is vital to ensuring equity, thoroughness and process consistency both within and across all GRPs.

<table>
<thead>
<tr>
<th>CATEGORY</th>
<th>Scientific Quality 50%</th>
<th>Significance and/or Innovation</th>
<th>Track Record – relative to opportunity</th>
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</table>
| 7 Outstanding by International Standards | The proposal:  
- has objectives that are well-defined, highly coherent and strongly developed.  
- has a flawless design.  
- is without question, highly feasible given that all of the required expertise and research tools and techniques are present in the relevant research environment(s). | The planned research:  
- will result in a major advance in knowledge in this field which addresses an issue of great importance to human health.  
- will translate into fundamental outcomes in the science and/or practice of clinical medicine or public health or fundamental changes in health policy.  
- is highly innovative and introduces advances in concept(s).  
- will likely be the subject of invited plenary presentations at international meetings.  
- will result in highly influential publications. | Relative to opportunity, the applicant team:  
- has a combined record of research achievement (quality and productivity) and/or translation into practice that is outstanding by international standards commensurate with their field of research.  
- expertise specifically targets the proposed research both in terms of its depth and breadth.  
- members have outstanding national and international reputations. |
| 6 Excellent | The proposal:  
- has objectives that are well-defined, highly coherent and strongly developed.  
- has a near flawless design.  
- is highly feasible given the experience, skills and readiness of the team in the relevant research environment(s). | The planned research:  
- will result in a significant advance in knowledge in this field which addresses an issue of significant importance to human health.  
- is likely to translate into fundamental outcomes in the science and/or practice of clinical medicine, public health or provide fundamental changes in health policy.  
- is highly innovative in approach  
- will likely be the subject of invited plenary presentations at international meetings.  
- will likely result in influential publications. | Relative to opportunity, the applicant team:  
- has a combined record of research achievement (quality and productivity) and/or translation into practice that is excellent by international standards commensurate with their field of research.  
- expertise is highly relevant to the proposed research both in terms of its depth and breadth.  
- members have excellent national and/or international reputations. |
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| **5 Very Good** | The proposal:  
- is clear in its intent and logical.  
- raises only minor concerns with respect to the study design.  
- is feasible with most techniques and tools either established or nearly established in the relevant research environment(s). | The planned research:  
- will result in a major advance in knowledge in this field which addresses an issue of importance to human health.  
- may translate into fundamental outcomes in the science and/or practice of clinical medicine, public health.  
- is innovative in approach.  
- could be the subject of invited plenary presentations at international and national meetings.  
- is likely to result in some very strong publications. | Relative to opportunity, the applicant team:  
- has a combined record of research achievement (quality and productivity) and/or translation into practice which places it well above average for their peers or cohort.  
- raises only minor concerns regarding the depth and breadth of expertise relevant to the proposed research.  
- members have very good and growing national and/or international reputations. |
| **4 Good** | The proposal:  
- has clear objectives.  
- raises several potentially significant concerns regarding study design.  
- will likely be successfully achieved, although some concerns exist about the ongoing need to develop or obtain some research tools or techniques. | The planned research:  
- addresses an issue of importance to human health.  
- is unlikely to be the subject of invited plenary presentations at international meetings.  
- is solid in concept.  
- may result in some good but not excellent publications. | Relative to opportunity, the applicant team:  
- has a combined record of research achievement (quality and productivity) and/or translation into practice, that places them above average for their peers/cohort.  
- members have track records in fields relevant to the proposed research but with several potentially significant concerns regarding depth and breadth of relevant expertise.  
- members have good and growing national and/or international reputations. |
| **3 Marginal** | The proposal:  
- is unsound in terms of some of its objectives.  
- raises several significant concerns regarding the experimental design.  
- raises some major concerns about the likelihood of successful completion. | The planned research:  
- addresses an issue of some importance to human health.  
- may have some novel aspects, while others underpin or extend existing knowledge.  
- may result in some strong or influential publications. | Relative to opportunity, the applicant team:  
- has a combined record of research achievement (quality and productivity) and/or translation into practice, that places them at an average level for their peers/cohort.  
- members have made contributions to the field of research but there are significant concerns regarding the depth and breadth of relevant expertise. |
### Appendix B

<table>
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<tr>
<th>CATEGORY</th>
<th>Scientific Quality 50%</th>
<th>Significance and/or Innovation</th>
<th>Track Record – relative to opportunity</th>
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| 2 Unsatisfactory | The proposal:  
- contains a number of areas of significant concern regarding the feasibility of the proposal.  
- contains several major study design flaws.  
- is unlikely to be successfully completed. | The planned research:  
- addresses an issue of some concern to human health.  
- provides a program of research which will not significantly advance current knowledge in the field.  
- has relatively little novelty. | Relative to opportunity, the applicant team:  
- has published only a few works in relevant but other fields of research.  
- is deficient in some areas of expertise that will be required to successfully complete the proposed research.  
- members have limited track records in the field of the proposed research. |
| 1 Poor | The proposal:  
- contains a research plan which does not seem to be feasible.  
- is poorly designed.  
- is unlikely to be successfully completed. | The planned research:  
- does not address an issue of more than marginal concern to human health.  
- will not advance current knowledge in the field.  
- only follows behind previously well documented and studied concepts or previously well used approaches. | Relative to opportunity, the applicant team:  
- is not productive to any significant extent in relevant fields.  
- is heavily underpowered in terms of relevant expertise required to successfully complete the research program.  
- members have track records which do not relate well to the proposed research. |

1 Assessment of Team Quality & Capability should take into account the productivity of the team, including the number of senior authorships and the team’s influence in the field (relevant to the project application) without reference to H Index or journal impact factors. Assessment of research achievement should take into account impact of the team’s research in terms of seminal contributions to new knowledge and/or translation into policy, practice and improved health outcomes. The assessment of Team Quality & Capability should recognise that CIA is the project leader who is responsible for the successful completion of the research proposal. The assessment should also recognise that these descriptors apply to the team, rather than each member of the team individually since more junior members of the team may be integral to achieving the research objectives. Track Record is always assessed relative to opportunity.