

# NHMRC Program Grants

## Funding Policy

for funding commencing in 2010

(Applications close 5.00 PM AEST Friday 8 August 2008)

**IMPORTANT:** The closing date had initially been advertised as 11 July, but has now been changed to 8 August.

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## 1. INTRODUCTION

The National Health and Medical Research Council (NHMRC) is Australia's leading expert body promoting the development and maintenance of public and individual health standards. It is established under the *National Health and Medical Research Council Act 1992*, which is available on the NHMRC website at:

<http://www.nhmrc.gov.au/about/index.htm>

The Act establishes four statutory obligations for the NHMRC:

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

In aiming to achieve the best possible health for all Australians the NHMRC adheres to and promotes the following values:

**Excellence:** In all we do.

**Relevance:** Meeting the needs of all Australians.

**Responsiveness:** Addressing Australia's immediate and longer term health challenges.

**Leadership:** Leading Australia's national health and medical research efforts, setting authoritative advice, supported by high ethical standards.

**Balance:** Supporting all forms of research including molecular, cellular, and clinical research targeted at individual health.

**Working with others:** Supporting research across in a wide range of research organisations.

**Impact:** Promoting policy, practice and commercial impacts.

**Engagement:** Collaborating nationally and internationally.

**Accountability:** Operating at the highest professional, and transparent standards.

**Diversity:** Embracing a richly diverse workforce, operating in a collaborative, open and sharing environment.

## 2. PURPOSE

This document is intended to assist all researchers who are considering applying for NHMRC Program Grant support for funding commencing in January 2010. It provides advice on access and eligibility criteria, application processes, ethics requirements, provision of funding, appeal mechanisms and administration of grants. Where applicable, applicants will be directed to documents relating to other NHMRC funding schemes to ensure eligibility requirements for Program Grants and other funding mechanisms are met.

## 3. POLICY CHANGES

The following details the major policy changes that have been made to NHMRC Program Grants for funding commencing in January 2010:

- Applicants' records of achievement will no longer be assessed against a 'RORA' grid.
- The category of Co-Investigator (CoI) will not exist in future Program Grants.
- Existing Program Grant holders will only be eligible to apply for a new Program Grant in years 4 and 5 of their current grant.
- Applicants will have the opportunity to submit a 'biosketch' with their application, allowing them to expand on, and go beyond their CVs and provide narrative on their main achievements and any interruptions that may have occurred to their research career as a result of family circumstances, illness, industry experience etc.
- Applications will be required to provide more detailed descriptions of how the teams will operate, including strategies, and meeting and decision making arrangements.

**IMPORTANT:** The closing date for this round had initially been advertised as 11 July 2008, but this date has now been changed to 8 August 2008. In addition, the Application Form, Guide to Applicants and Funding Policy have been revised, and applicants are advised to ensure they use versions of these documents which specify the closing date of 8 August 2008 on the document coversheets and page headers.

#### 4. AIM

The NHMRC Program Grants Scheme aims to provide support for **teams of researchers**, to pursue **broadly based collaborative research activity**. The support provided for successful applicants is for the **research team**, to support the team's broad research theme. The team will be expected to:

- contribute new knowledge at a leading international level in important areas of health and medical research
- develop novel ideas and approaches
- tackle problems for which longer term stable funding is essential
- develop training and career development opportunities within the team
- facilitate collaborative use of specialised facilities or expertise.

The Program Grants scheme is available for all research approaches that are relevant to better health (eg biomedical, clinical, public health and health services research).

#### 5. CRITICAL DATES

Applicants applying for funding commencing in January 2010 should note the following dates:

Applications Open	31 May 2008
Application Close	8 August 2008
Interviews	anticipated for 17 – 21 November 2008

**NOTE:** Whilst holders of Program Grants which will be in their 4<sup>th</sup> or 5<sup>th</sup> years in 2008 are eligible to apply, it should be noted that those in their 5<sup>th</sup> year who apply and are successful would experience one year with no Program Grant funding ie. between when their existing funding ceases (December 2008), and when their new funding commences (January 2010).

## 6. APPLICATION PROCESS

Program Grant Funding applications are to be received by the NHMRC by **5.00 PM AEST Friday 8 August 2008**. Applications submitted after the closing date will not be considered by the NHMRC. The application form and associated information can be found on the NHMRC website at:

<http://www.nhmrc.gov.au/funding/apply/granttype/programs/index.htm>

Program Grant applications must be certified and submitted through the Research Office of an NHMRC Administering Institution. The NHMRC's Administering Institutions Policy can be found at:

<http://www.nhmrc.gov.au/funding/policy/admininst.htm>

NHMRC considers all Program Grant applications (including those from current Program Grant holders) to be new applications.

## 7. CONFIDENTIALITY

Information contained in applications is regarded as in-confidence unless otherwise stated and will be received and treated as in-confidence by the NHMRC. It is the responsibility of all NHMRC committee members, and persons assisting these committees, not to disclose to any person confidential information to which they become privy as a result of the exercise of their responsibilities to the NHMRC.

Section 80 of the *National Health and Medical Research Council Act, 1992* requires Council and committee members, assessors, and staff assisting committees or the Council not to disclose confidential commercial information, 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, are published in the NHMRC Annual Report and are available through the NHMRC's website. The NHMRC may also release information about the areas of research of the grant and a brief description of the grant provided by the applicant in response to the question on the application form designated as *Significance – Lay description (suitable for media)*.

## 8. CONFLICT OF INTEREST

The NHMRC is committed to fair review of all grant applications ensuring any conflicts of interest are dealt with consistently, transparently and with rigour. The essence of a quality peer review process demands all participants act in good faith, in an open and sensible manner. The NHMRC has policies in place for conflict of interest situations that may arise in the course of its various activities and these guidelines will assist in the interpretation and implementation of that policy.

All persons involved in the review of Program grant applications must disclose any potential, actual or perceived conflicts of interest to the NHMRC which will, in association with the Chair of the Program Grants Review Panel/s (PGRP), take steps to ensure that all conflicts of interest are dealt with appropriately.

## **9. PRIVACY**

Documents containing personal information are handled and protected in accordance with the provisions of the *Privacy Act 1988*, 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 Act allows.

## **10. INCOMPLETE, FALSE OR MISLEADING INFORMATION**

Once submitted to the NHMRC, the full application will be considered final and no changes will be permitted. The application is the prime source of information available for assessment. As such it must contain all the information necessary for assessment of the project without the need for further written or oral explanation, or reference to additional documentation, including the World Wide Web. All details in the application, particularly concerning any successful grants, must be current at the time of application.

Under s 136.1 of the Commonwealth Criminal Code, it is an offence to provide false or misleading information to a Commonwealth body in an application for a benefit, punishable by up to 12 months imprisonment. In addition, if an application contains information that is false or misleading, it may be excluded from any further consideration for funding. The Commonwealth Government is committed to protecting its revenue, expenditure and property from any attempt, either by members of the public, contractors, sub-contractors, agents, intermediaries or its own employees to gain financial or other benefits by deceit.

If the NHMRC believes that omissions or inclusion of misleading information are intentional, it will refer the matter for appropriate legal action. Examples of false or misleading information in an application include, but are not restricted to:

- Providing fictitious track records
- Omitting advice of publications which have been retracted or are to be considered for retraction
- Falsifying claims in publications records (such as describing a paper as accepted for publication when it has only been submitted).

## **11. ACCESS TO NHMRC FUNDING**

The NHMRC is seeking to promote collaboration between researchers and is working to remove any artificial barriers to this occurring. However, the NHMRC does not fund the total cost of research. Applicants employed by publicly funded research agencies are required to:

- Declare the source, duration and level of funding already held for research in the particular area of the application
- Make a case for NHMRC funding under the policy for the particular funding scheme.

## 12. RESEARCH INVOLVING ABORIGINAL OR TORRES STRAIT ISLANDER PEOPLES

As part of its commitment to advancing Aboriginal and Torres Strait Islander health research, the NHMRC has established certain requirements and processes which are designed to ensure that research into Aboriginal and Torres Strait Islander health is not only of the highest scientific merit but that it is beneficial and acceptable to Aboriginal and Torres Strait Islander peoples.

The NHMRC has also made a commitment to a target of at least 5% of its total research funding being allocated to Aboriginal and Torres Strait Islander health research. Your responses to the following questions enable the NHMRC to accurately monitor its performance relative to that target.

Researchers proposing to do research which 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, should be aware of, and refer to, the following documents in formulating their proposal:

*The NHMRC Road Map: A Strategic Framework for Improving Aboriginal and Torres Strait Islander Health through Research* – describes broad research themes which were identified through a national consultative process and reflect the health and medical research priorities of Aboriginal and Torres Strait Islander peoples.

*Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research* – provide guidance to researchers for conceiving and designing research proposals which meet the highest ethical standards and ensure respect for the principles and values of the Aboriginal and Torres Strait Islander culture/s in which the research will be conducted.

## 13. TEAM STRUCTURE

The team will need to demonstrate that significant gains can be achieved from their collaboration.

Research teams will include, but are not restricted to:

- **Established teams** of researchers working collaboratively across a broad theme and/or taking a multidisciplinary approach to an area of research. The team will consist mainly of investigators who have worked together successfully. In addition, the applicant team may include new collaborators to expand the team.
- **New teams.** As 20% of the Program Grant assessment is based on collaborative gain, new collaborative teams must demonstrate the new collaborative gain that will result from the investigators combining as a team and the new opportunities that will arise from their collaboration.

If the applicants have had the opportunity to collaborate before and have not done so an explanation will be required as to why this has not occurred and how the direction of their research has now changed to necessitate the new collaboration. They will also need to explain how they will ensure the cohesive running of the

grant. This may involve the use of specific contractual arrangements.

All applicants will need to explain how they will ensure that teams are well integrated and have effective working collaborations, including descriptions of:

- How the teams will operate, including meeting and decision making arrangements.
- How junior staff will be integrated into the teams, including approaches to mentoring.

#### **14. TEAM MEMBERS**

Chief Investigators (CI) will normally:

- Hold a PhD or relevant professional qualification (for example, MBBS, MPH)
- Be at Level C, NHMRC Senior Research Fellow, or equivalent level, and above
- Be Australian citizens, or have permanent resident status
- Have a strong record of achievement in competitive peer-reviewed research or industry-supported research.

##### **Full Time Chief Investigators Commitment**

Each full time CI is required to devote 80-100% of their NHMRC research time to the Program, classifying them as full-time Program researchers. Therefore the available time for additional research activity funded by the NHMRC is restricted to a maximum of 20% unless otherwise stated in specific schemes. The amount of NHMRC available time committed to the Program at the time of peer review is taken into account during the assessment process. As a consequence, each Program Grant CI is permitted to hold only one Project Grant.

##### **Part-Time Chief Investigators Commitment**

In general, NHMRC expects that CIs on Programs will devote their NHMRC research time to the Program on a full-time basis. However, there may be exceptional cases such as:

- Personal circumstances; or
- A CI applying to be a member of two Program teams of researchers. NHMRC expects this to be an unusual circumstance, but may apply when a researcher has particular and essential skills that he/she brings to the research efforts of both teams. In this case the applicant may potentially be part of two Program Grant applications. If one of the Program Grant applications is unsuccessful and one is successful, then the part-time CI on one Program may apply for and hold up to two Project Grants provided all other eligibility criteria is met.

A part-time CI on a Program Grant cannot devote less than 50% of their NHMRC research time to any Program.

##### **Other Team Members**

Teams may include members who will contribute to the Program without being listed as CIs. These team members can be named in a Program Grant's list of 'additional personnel', and a

description of how they will participate in the Program can be included under the Research Plan and/or Collaborative Gain sections of the application. Team members who are not CIs will not contribute to the Program's budget. Overseas investigators (i.e. researchers who are primarily based overseas) may be included in teams but not as CIs.

Applicants are advised to critically review the composition of their team prior to submission of a Program Grant application. Several instances have occurred where an otherwise competitive application was disadvantaged by the inclusion of clearly non-competitive CIs i.e. CIs with poor/mediocre track records.

## **15. NEW COLLABORATIONS**

NHMRC's Research Committee (RC) is conscious of the need to allow holders of Program Grant funding the opportunity to pursue additional areas of research and realise potential new collaborations during the course of their Program Grant. To achieve this, the budget provided will be generous and allow flexibility to redirect funds to new initiatives.

CIs will also be eligible to hold one project grant which will allow new collaborations during the Program's period of support. They are also eligible to apply for and hold an Australia Fellowship providing all other eligibility criteria are met.

## **16. NHMRC PROGRAM AND PROJECT GRANT ELIGIBILITY**

Program Grant holders will only be eligible to apply for a new Program Grant in years 4 and 5 of their existing Program Grant. Unsuccessful applicants will not obtain bridging support beyond year 5 of their existing Program Grant.

**Each Program Grant holder** is permitted to **hold** only **one** Project Grant, and may be named as the Chief Investigator A (CIA) on that Project Grant, but cannot be the sole CI.

Program Grant holders may apply for a Project Grant with or without members of the same Program, providing that at least one CI on the Project Grant application is not a current member of any Program Grant team, and this CI must contribute substantial expertise to the Project Grant as determined by the Project Grant Review Panels.

The NHMRC's Project Grants Funding Policy contains restrictions on the numbers and types of grants that can be applied for and held at any time. Program Grant applicants who hold, or intend to apply for NHMRC Project Grants, should ensure that they are applying in accordance with the requirements of the NHMRC Project Grants Funding Policy.

As relevant, all members of teams applying for Program Grant funding must nominate, in their application, the NHMRC Project Grant/s each would retain if their Program Grant application is successful. All other NHMRC Project Grants will cease from 31 December 2009, other than the single Project Grant identified for retention.

Program Grant applicants must inform the affected Project Grant CIs of the possible consequences of their Program Grant application **before** their Program Grant application is submitted, and the affected Project Grant CIs must have indicated their acceptance of the possible consequences in the Program Grant application.

If a CI intends departing from an existing Program Grant with the intention of applying as a CI on a new Program Grant application, that CI must advise the NHMRC before submitting the new Program Grant application. If the departing CI has not submitted this advice, the new application will be deemed ineligible and will not proceed to peer review. Regardless of the outcome of the new Program Grant application, the departing CI will not be permitted to return to the original Program.

## **17. REMOVAL OF APPLICATIONS**

The NHMRC reserves the right to remove ineligible from further consideration in the peer review process. Exclusion of ineligible applications may take place at any time during the selection process under the following circumstances:

- The application is inconsistent with the objectives of the *National Health and Medical Research Council Act 1992* (the Act) and the purposes of the Medical Research Endowment Account (MREA) (refer to Sections 3 and 51 of the Act)
- The application contravenes, or is inconsistent with this policy and the relevant guides for the completion of application forms
- The application was not submitted through the appropriate Research Administration Officer (RAO) of an NHMRC Administering Institution
- The application does not address the selection criteria
- The application includes any incomplete or misleading information.

Applications may also be removed from consideration during the peer review process if they are considered to be non-competitive (see Section 19. *Peer Review Process*).

## **18. WITHDRAWAL OF APPLICATIONS**

CIAs may withdraw applications at any time by letter or email submitted to the NHMRC via the RAO of their Administering Institution.

## **19. PEER REVIEW PROCESS**

NHMRC will appoint one or more Program Grant Review Panel/s (PGRP) based on the number and breadth of applications received. The PGRPs will be comprised of experts who will consider applications against the assessment criteria. Applications that are not competitive in the current round will be removed from further consideration and applicants advised accordingly. The PGRPs will recommend that the remaining applications are sent to external assessors, and that those applicants be interviewed by a PGRP during the week commencing 20 October 2008. Under exceptional circumstances, NHMRC can deem that additional applications receive peer review and an interview. Prior to the interview, reports from external assessors will be forwarded to the applicants who will be given the opportunity to respond to those at interview.

The interviews will be one to two hours in duration, and will be conducted by a PGRP which may include international reviewers and/or additional experts. All CIs on competitive applications will be invited to attend the interview.

Each PGRP will rank its applications against the written descriptors outlined below. The PGRP recommendations, which include individual reports, rankings and budgets, will be combined to determine a final ranking. The final ranking and budget will be presented to

RC which will provide its recommendations (through Council) to the CEO. The CEO's recommendations will then be forwarded to the Minister for Health and Ageing.

PGRPs will provide applicants with a detailed written report on completion of the peer review process, highlighting strengths and weaknesses and stating any concerns identified with the application.

## 20. ASSESSMENT PROCESS

Awards of Program Grants will be highly competitive. They will be awarded primarily on the quality and impact of CIs' research achievements, and the proposal's Research Plan and Collaborative Gain. It should be noted that this is a competitive application process, and therefore the standard of applications that result in recommendations for funding will vary from year to year.

In evaluating competing proposals, the PGRP will consider the CIs' time that is available for research on the proposal, recognising that applicants have other responsibilities, including commitments to teaching, health care, and external grant and industry collaborations. The budget formulation will also take into account each CI's time available for research.

It is recognised that some applicants will have high levels of achievement, but whose records have unusual features, or who may have had interruptions (family, illness, industry experience). It is up to the applicants to make the case that a particular level of achievement applies and there is provision in the application form to include a 'Biosketch' in which applicants may address any such circumstances.

PGRPs will score applications against weighted assessment criteria, so as to permit the scoring of applications in rank order across diverse disciplines.

## 21. ASSESSMENT CRITERIA

The assessment criteria and weightings have been designed to reflect the nature and intent of the scheme. PRGP members draw on their field and discipline expertise when scoring the applications. In addition, Panel members will refer to score descriptors when scoring.

The assessment criteria and their weightings are specified below:

	<b>Assessment Criteria</b>	<b>Score</b>
1	Record of Research Achievement	60
2	Research Plan	20
3	Collaborative Gain	20
	<b>Maximum score</b>	<b>100</b>

### 1. Record of Research Achievement (RORA)

**60%** of the application score will be based the combined RORA of **each CI** on the application. Research achievements will be interpreted broadly and appropriate judgements about research achievement will be made by peer reviewers, paying particular attention to factors most relevant to the applicants' fields of research.

Applicants can attain a maximum of **60** points for their RORA score. This will be distributed across two parts; **Academic Recognition (45 points)** and **Research Application (15 points)**, allowing scientific outputs, and applications, to be considered. The **60** points for RORA will be distributed within these two parts as follows:

**Academic Recognition** **45 points**

Comprising (*with the following distribution of its 45 points*):

<b>Publications*</b>	<i>35 points</i>
<b>Grants</b>	<i>5 points</i>
<b>Invitations / Prizes / Awards over Career</b>	<i>5 points</i>

\* The Publications section of the application should focus on the significant, enduring impact of published works, not the impact factor of the journals in which the research is published (though there is often a relationship between the two). It is therefore left to the applicants to make a case in the appropriate section of their application as to how particular research outputs rate against the criteria. Inclusion of information such as impact factors, journal specialty ranking and citations may assist the Panel in the scoring process. Similarly, applicants may indicate other areas in which their research has been applied, and Panels will be asked to take this into account.

**Professional Achievement and Research Application** **15 points**

Factors that will be taken into account by the PGRPs under this part include:

- Employment history and career development, including any clinical practice and/or industry consultation
- Postgraduate training
- Postgraduate and undergraduate teaching involvement
- International reputation and standing, and peer recognition
- Organising local, national and international meetings
- Professional memberships and executive positions held
- Review activities e.g. grant applications, manuscripts, editorial boards etc.
- Involvement with the wider community and the media
- Participation in clinical trial design and/or implementation
- Participation in clinical or health development committees or fora
- Influence on clinical/health policy or practice, or provision of advice to health care authorities
- IP developments and commercialisation activities
- Any other relevant achievements.

**2. Research Plan**

**20%** of the application score will be based on the quality of the application's Research Plan. This will involve consideration of the following aspects of the proposed research:

- Relevance/significance
- National/international competitiveness

- Innovativeness
- Potential for future contribution to knowledge
- Approach/feasibility

The **20** points for RESEARCH PLAN will be distributed across the following four elements:

<b>Significance and Relevance</b>	<b>5 points</b>
<b>Innovation and Potential</b>	<b>5 points</b>
<b>Competitiveness</b>	<b>5 points</b>
<b>Feasibility</b>	<b>5 points</b>

### **3. Collaborative Gain**

**20%** of the application score will be based on:

- Evidence of existing collaborations amongst CIs, and a description of working strategies employed previously, or appropriateness of proposed new collaborative arrangements
- Integration and cohesiveness of the team, and the likely effectiveness of their working collaborations and intellectual exchange
- Collective achievements of previously existing teams, and likely impact of new team members
- How the teams will operate and coordinate, including meeting, planning, decision making and financial arrangements
- Team skills, and how the team components will combine into a broad theme
- Productivity gains resulting from a synergistic pursuit of the Program's components (as opposed to pursuing the components as separate projects).
- Performance measures/milestones
- How junior staff will be integrated into the teams, including mentoring strategies
- Contribution of each CI.

With new teams, the following will also be taken into account:

- Proposed meetings and workplans
- Establishment of advisory panels
- Research seminars
- Explanation of why the new team had not collaborated previously
- Plans for geographical collaboration
- Benefits, and relevant indicators of potential collaborations and synergy
- Measures to ensure accountability.

The **20** points for COLLABORATIVE GAIN will be distributed across the following four elements as follows:

<b>Integration of the Research Teams and Program</b>	<b>5 points</b>
<b>Team Skills</b>	<b>5 points</b>
<b>Resource Management</b>	<b>5 points</b>
<b>Intellectual Exchange</b>	<b>5 points</b>

## **22. BUDGET**

Budget construction will be based on the team, rather than the research.

The budget allocation will be based on the PGRP's assessment of the record of research achievement (RORA) of each individual CI. The size (quantum) of the budget allocation for each CI will be relative to the assessment of his/her RORA. That is, those CIs with an established RORA at the highest level, especially in recent years, will attract more NHMRC funding (higher quantum) than CIs whose RORA is not as enduring or strong in recent years.

Successful CIs who devote 80-100% of their NHMRC research time to the Program may receive a full quantum. CIs that devote less of their research activity to the work incorporated in the Program will also attract a proportionally smaller allocation. For instance, CIs who devote only 50% of their NHMRC research time to the Program may be allocated half a quantum.

Notwithstanding that, applicants are asked to provide a one-page summary on the time commitment of each CI and their participation in the broad research plan proposed in the application. They may also provide advice on the level of quantum they consider appropriate for each CI on the Program.

The quanta are intended to allow the team to support a range of senior and junior postdoctoral researchers, research and technical assistants and higher degree candidates, as well as providing for direct research costs and minor items of equipment. The budget for the Program will not provide support for salaries of CIs unless special circumstances exist. It would need to be clearly demonstrated that a CI had no alternative source of salary support and that salary costs were not being inappropriately shifted from another budget. A clear outline of the circumstances and salary being sought must be submitted to the PGRP who may recommend an appropriate increase in the Program's budget.

Individuals whose salary is supported through the NHMRC's People Support schemes (eg. Australia Fellow, Research Fellow, Practitioner Fellow and Career Development Awards) may be included as CIs.

## **23. INDEXATION**

The first year's budget will be awarded, and subsequent years' budgets may be indexed each year by the annual NHMRC out-turn factor. No additional funds will be provided, although the budget may be altered depending on the outcome of any Administrative Review (see Section 26. *Administrative Review*). The budget will be provided as a one-line budget with CIs free to determine the use of the funds, provided that expenditure is consistent with the Program proposal, and that funds are not used for purposes excluded in the Deed of Agreement covering the funding. See:

<http://www.nhmrc.gov.au/funding/funded/manage/policy/deeds.htm#a1>

All staff funded by the grant must be employed through an NHMRC Administering Institution.

## 24. DURATION

Program Grants will be of five years duration, commencing in January 2010.

## 25. REPORTING

Annual progress and financial reports will be required on 31 March from 2011 onwards, detailing scientific achievements, administration and expenditure of the grant. The template for the annual Progress Reports and annual Financial Statements can be found at:

<http://www.nhmrc.gov.au/funding/funded/manage/policy/progreport.htm>

At the completion of the grant, a Final Report and Final Financial Acquittance will be required within 6 months after the period of funding ends, or the termination of funding. The reporting requirements can be found at:

<http://www.nhmrc.gov.au/funding/funded/manage/projects/index.htm#1>

The NHMRC will review all Financial, Progress and Final Reports. NHMRC may conduct an Administrative Review at any time, and take any appropriate follow up action.

The NHMRC may suspend payment of further instalments of any current grant until the appropriate reports have been received and assessed as satisfactory. Where an institution fails to submit satisfactory reports as required, the Minister may terminate funding and determine that all or part of the funding must be repaid. In this case, the NHMRC may withhold the remainder of the institution's payments under the scheme for the current year and/or initiate recovery of funding.

## 26. ADMINISTRATIVE REVIEWS

NHMRC may conduct an Administrative Review of a Program grant for a variety of reasons.

For instance, if a CI intends leaving the Program, or changing their institution or employment from that specified in the Program Grant application, an Administrative Review will be triggered. Changes to CIs on Program Grants may result in changes to the Program's budget.

NHMRC is to be notified in advance of any change by submitting a *Program Grants Variation Request Form* to the NHMRC through the RAO of the Program's Administering Institution. Further information on Administrative Reviews, including how to notify NHMRC of changes to the Program, is available at:

<http://nhmrc.gov.au/funding/funded/manage/programs.htm>

## 27. ETHICS AND OTHER REQUIRED APPROVALS

Program Grant research activity and funding will not commence until all relevant ethical and other approvals and licences (such as a licence for the use of excess ART embryos) have been received from the appropriate bodies and lodged with the RAO. **Provisional approvals are not acceptable.**

The offer of funding will be withdrawn if ethics approvals are not obtained by **30 June** in the year that funding is to commence.

The NHMRC reserves the right to request all information relating to decisions regarding ethical issues arising from an application and the institutional response to the application.

It is the responsibility of the applicant to ensure that a copy of the Program Grant application is referred to the relevant Institutional Ethics Committee or other approval body. It is also the responsibility of the applicant to ensure that the completed approval is forwarded to the RAO who is responsible for providing the appropriate clearance advice to the NHMRC.

The RAO must advise the NHMRC when ethics clearances have been granted by the relevant Ethics Committee.

**a. Responsible Conduct of Research**

Research funded by the NHMRC must comply with the *Australian Code for the Responsible Conduct of Research (2007)* which can be found at:

<http://www.nhmrc.gov.au/publications/synopses/r39syn.htm>

**b. Use of Personal Information**

Under the Privacy Act 1988, any form of research involving humans (including epidemiological research) that uses personal information obtained from a Commonwealth department or agency must be considered by a Human Research Ethics Committee (HREC). This applies only to projects that require information obtained by Australian Government Departments or Agencies after 1 January 1989.

An Australian Government Agency includes Australian Government Ministers and Australian Government Departments (other than the Commonwealth Parliamentary Departments), bodies or persons established and performing functions under Commonwealth laws. Specifically included are the Federal Courts, the Australian Federal Police and the Australian Capital Territory Courts. Examples of some other agencies include the Australian Bureau of Statistics, the Electoral Commission, Telstra, the Department of Veterans' Affairs, the Department of Family and Community Services (formerly Social Security), the Department of Health and Ageing, the Health Insurance Commission and the Australian Institute of Health and Welfare.

Under *Section 95 of the Act*, the NHMRC is able, with the approval of the Privacy Commissioner, to issue guidelines for the protection of privacy in the conduct of health and medical research. Under *Section 95 of the Privacy Act 1988*, acts of agencies undertaken in the course of health and medical research will not be an infringement of the Information Privacy Principles contained in the Privacy Act.

**c. Administration of Drugs to Humans**

All Program Grants involving the administration to humans of drugs, chemical agents or vaccines must be considered by the relevant Human Research Ethics Committee to assess the appropriateness of their use. They may also be subject to the Clinical Trials

Notification/Exemption schemes administered by the Therapeutic Goods Administration (TGA). Further information on the Clinical Trials Notification/ Exemption schemes can be obtained from the TGA:

Phone: 1800 020 653

Internet Address: [www.tga.gov.au](http://www.tga.gov.au)

Further information on multi-centre research approval is provided in the Chapter 3 of the *National Statement on Ethical Conduct in Research Involving Humans* ('the National Statement') which is available at:

<http://www.nhmrc.gov.au/publications/synopses/e35syn.htm>

In the case of multi-centred clinical trials the principal researchers may agree that the primary ethical and scientific assessment be made at one agreed to 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*.

#### **d. Ethical Implications of Human Research**

The NHMRC requires assurance that research involving humans has been reviewed and is approved by the relevant HREC as complying with *the National Statement*, which is available at:

<http://www.nhmrc.gov.au/publications/synopses/e35syn.htm>

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. Projects supported by the NHMRC must conform to the general principles outlined in the *National Statement*.

#### **e. Health Research Involving Aboriginal and Torres Strait Islanders**

Research proposals involving Indigenous Australians should be developed with reference to the *Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research*), which is available at:

<http://www.nhmrc.gov.au/publications/synopses/e52syn.htm>

An explanation of how the proposal meets those guidelines must be included in the ethics section of the application form.

#### **f. Animal Research**

Research supported by the NHMRC must conform to the provisions of the *Australian Code of Practice for the Care and Use of Animals for Scientific Purposes* and the general principles encapsulated in Section 1 of the Code. The Code is available on the NHMRC website at:

<http://www.nhmrc.gov.au/publications/synopses/ea16syn.htm>

**g. Genetic Manipulation**

Applicants proposing research involving genetically manipulated organisms (GMOs) must ensure that all aspects of the Gene Technology Regulations have been met. In the first instance, applicants must obtain approval for the use of GMOs from their Institutional Biosafety Committee (or equivalent). A copy of the Gene Technology Regulations is available at:

<http://www.ogtr.gov.au/>

**h. Human Embryo Research**

The *Research Involving Human Embryos Act 2002* and *Prohibition of Human Cloning Act 2002* were passed by Parliament in December 2002. These Acts establish a strong regulatory framework to prohibit certain unacceptable practices including human cloning, and to regulate uses of excess human embryos created through assisted reproductive technology (ART).

Applications for a research grant which involves the use of excess ART embryos may require a licence under the *Research Involving Human Embryos Act 2002*.

Further information regarding research using excess human ART embryos can be found from the NHMRC website at:

<http://www.nhmrc.gov.au/embryos/index.htm>

**i. Use of Carcinogenic or Highly Toxic Chemicals**

Applicants proposing research involving the use and disposal of potent carcinogenic or other highly toxic chemicals are referred to the National Occupational Health and Safety Commission (NOHSC) guidelines and the National Code of Practice for the Preparation of Material Safety Data Sheets which are available from the NOHSC web site at:

<http://www.ascc.gov.au>

**j. Use of Datasets for Research Purposes**

Applications for funding to support datasets for use in research must comply with the *Minimum Guidelines for Health Registers for Statistical and Research Purposes*, which is available on the internet at:

<http://www.aihw.gov.au/publications/index.cfm/title/9792>

**28. OUTCOME OF APPLICATION**

The NHMRC will advise the leading CIs, via their RAO, of the outcome of the application as early as possible following approval by the Minister.

The NHMRC will publish the following information on its website for all successful research grants:

- Application ID.
- All CIs' names.
- Administering Institution.
- Research Grant Type.
- Simplified title.
- Total funding awarded.
- Other information such as the lay description or project summary may also be published.

## **29. DISSEMINATION OF GRANT OUTCOMES**

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.

The 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, the NHMRC wants to ensure the widest possible dissemination of the research supported by NHMRC funding, in the most effective manner and at the earliest opportunity.

The NHMRC therefore 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 six month period, s/he 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.

## **30. OBJECTIONS AND COMPLAINTS PROCESS**

### **a. Objections**

Applicants may contact the NHMRC seeking clarification on the outcome of their application for Program Grant funding, or to state an objection to that outcome. The objection must be lodged in writing through the RAO and be received by the NHMRC within 28 days of the date on the letter notifying the outcome of the application.

The objection should be directed to the NHMRC's Chief Executive Officer in the first instance. If an applicant is not satisfied with the outcome, they may refer their objection to the NHMRC Commissioner of Complaints, as detailed in Section 31 b.

All objections must be addressed to the Chief Executive Officer through the Complaints Officer at:

Complaints Officer  
National Health and Medical Research Council  
GPO Box 1421  
CANBERRA ACT 2601

Or via email to: [grantnet.help@nhmrc.gov.au](mailto:grantnet.help@nhmrc.gov.au)

The NHMRC will provide a written response to all objections.

**b. Formal Complaints to the Commissioner of Complaints**

A person whose interests are affected may at any time lodge a complaint under Section 59 of the Act.

Section 61 of the Act provides the Commissioner of Complaints with discretion including, where a complainant has not approached the Chief Executive Officer with the complaint, to not investigate the complaint or refer it to the Chief Executive Officer of the NHMRC. The Act may be found at:

<http://www.nhmrc.gov.au/about/role/index.htm>

Complaints to the Commissioner should be addressed to:

Dr Kerry Breen  
NHMRC Commissioner of Complaints  
GPO Box 1421  
CANBERRA ACT 2601

The complaint 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 Act and are listed below:

- (a) that the action involved a breach of the rules of natural justice;
- (b) that the action was induced or affected by fraud;
- (c) that there was no evidence or other material to justify the action;
- (d) that an irrelevant consideration was taken into account in relation to the action;
- (e) that a relevant consideration was not taken into account in relation to the action;
- (f) that 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) that the action involved the exercise of a discretionary power in bad faith;
- (h) that, in the course of the action, a personal discretionary power was exercised at the direction of another person;
- (i) that 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) that the action involved any other exercise of a power in a way that constitutes abuse of the power.

## **31. ADMINISTRATION OF GRANTS**

### **a. Deed of Agreement**

All research grants are offered in accordance with a Deed of Agreement between the NHMRC and the Administering Institution. This Deed of Agreement includes Schedules that detail specific conditions for each grant (eg budget). By initialling the Schedule, the applicant is agreeing to the conditions contained in the Deed of Agreement and the Schedule. Details of the Deed of Agreement can be found at:

<http://www.nhmrc.gov.au/funding/funded/manage/policy/deeds.htm>

A research grant may not commence, nor grant funds be expended, prior to:

- the Deed of Agreement between the NHMRC and the Administering Institution being in place;
- the appropriate Schedule being signed and executed by the NHMRC; and
- all required ethics clearances/licences and approvals having been obtained.

Requests to vary the terms contained in the Deed of Agreement or its Schedule must be submitted to the NHMRC in writing by the Administering Institution.

### **b. Payments**

Subject to appropriations provided by the Commonwealth Department of Finance, 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 Deed of Agreement and its Schedule.

### **c. Guidelines on Research Practice**

Research funded by the NHMRC must comply with established guidelines, including the *Joint NHMRC/AVCC Statement and Guidelines on Research Practice* which can be found at:

<http://www.nhmrc.gov.au/publications/synopses/r39syn.htm>

### **d. Intellectual Property**

Applicants in receipt of NHMRC Program Grant support must agree to comply with the *Interim Guidelines Intellectual Property Management for Health and Medical Research* available at:

<http://www.nhmrc.gov.au/funding/policy/ipmanage.htm>

## **32. FURTHER INFORMATION**

Further information can be obtained from the NHMRC's website at:

<http://www.nhmrc.gov.au/funding/apply/index.htm>

For further information, the RAO should be contacted in the first instance.

Enquiries about Program Grants can be emailed to the NHMRC at:

[program.grant@nhmrc.gov.au](mailto:program.grant@nhmrc.gov.au)

The NHMRC's GrantNet Help Desk can be telephoned on Ph. 1800 500 983.