



**Australian Government**

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**National Health and Medical Research Council**

# **Centres for Clinical Research Excellence**

## **Funding Policy**

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# CENTRES FOR CLINICAL RESEARCH EXCELLENCE

## 1. Introduction

This document is intended to assist researchers who are considering applying for support under the Centres of Clinical Research Excellence (CCRE) Scheme, commencing in 2009. It should be read in conjunction with the Advice and Instructions to Applicants document and the CCRE Application Form, which can be found on the NHMRC website at:

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

In 2009 the NHMRC anticipates funding six Centres of Clinical Research Excellence at up to \$2.5 million per grant. Based on previous rounds, 30% of applications were successful.

## 2. Background

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 NHMRC is responsible for:

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

The NHMRC Strategic Plan 2007 – 2009 describes the agency's strategic objectives and provides the context within which its funding schemes operate. To meet the health challenges facing Australia, NHMRC is committed to funding the best and most relevant research to improve the health of Australians. Further information can be found at:

[http://www.nhmrc.gov.au/publications/synopses/\\_files/strat\\_plan0709.pdf](http://www.nhmrc.gov.au/publications/synopses/_files/strat_plan0709.pdf)

## 3. Description, Aims and Selection Criteria

### 3.1 Description

The CCRE Scheme provides funding for innovative, high quality clinical research to be conducted either by established investigators with a strong track record in clinical research and clinical training, or new clinical research collaborators.

Centres of Clinical Research Excellence may be actual (i.e. comprising a single physical entity or institute) or virtual (i.e. geographically disparate, linking a collaborative research effort from several different organisations).

Researchers are encouraged to collaborate with, and participate in, international research studies. Proposed international collaborations should be indicated in the application and all funding must be administered through an Australian Administering Institutions.

Applications relating to indigenous health research are welcome.

### 3.2 Aims

The aims of the CCRE Scheme are:

- Aim 1: Support clinical research with potential to lead to improved health outcomes for the community.
- Aim 2: Foster training of clinical researchers, particularly those with a capacity for independent research and future leadership roles.
- Aim 3: Ensure effective translation of research outcomes into clinical practice.

### 3.3 Selection Criteria

Applications will undergo peer review, which will focus on how well the application meets NHMRC's aims for the CCRE program. When considering each of the three aims of the CCRE Scheme, applicants must illustrate how the proposal will address the following selection criteria corresponding to each aim.

1. Scientific and clinical merit of the proposed research activities (*Aim 1*);
2. How the CCRE funding will make a unique contribution to existing, and give rise to new, research activities (*Aim 1*);
3. How the Centre intends to recruit clinical researchers, foster their training and their career development (*Aim 2*); and
4. How the Centre will improve the translation of research into clinical practice and health outcomes (*Aim 3*).

In responding to the selection criteria, the applicant is to address the following:

- The record of research achievement of the Chief Investigators (relative to opportunity) and their record of fostering training and career development of clinical and other researchers;
- Information on infrastructure that can support the proposed CCRE's proposed activities;
- The proposed management and governance arrangements; and
- The proposed budget (value gained from NHMRC support).

Further, in addressing the aims of the CCRE Scheme through responding to the selection criteria, applicants may wish to incorporate information on:

- synergistic approaches between basic biomedical sciences and clinical research and/or between clinical research and population health research or health services research;
- collaborative interactions between different clinical disciplines;
- community consultation with relevant groups; and
- a process for consultation and management of health issues relating to Indigenous Australians.

## **4. Eligibility**

### **4.1 Who should apply**

The CCRE program is open to all clinical researchers in Australia who are seeking to promote collaboration between health and medical researchers. Groups funded under previous CCRE Programs are eligible to apply.

### **4.2 Eligible Administering Institutions**

Applications must be certified and submitted by a NHMRC approved Administering Institution. Intending applicants and institutions should refer to the NHMRC Administering Institutions Policy which can be found at:

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

### **4.3 Access to NHMRC Funding**

The NHMRC acknowledges that it does not fully fund the total cost of research activities. Applicants are required to declare the source, duration and levels of research funding held by each applicant.

The NHMRC may liaise with other funding agencies to discuss any overlap between applications in order to avoid duplication of funding.

### **4.4 Multiple Grant Eligibility**

CCRE applicants may apply for and hold other NHMRC grants. The time commitments of the Chief Investigator to the proposed CCRE and to other grants will be considered in the review of the CCRE application. The Chief Investigators should ensure that the time commitment is sufficient to ensure the viability of the CCRE.

### **4.5 Investigators**

#### **Chief Investigator A**

The Chief Investigator A must be an Australian citizen or hold permanent residency in Australia. It is also required that the research proposal involves Chief Investigator A being based in Australia for the duration of the grant.

#### **Non Australian/Permanent Resident - Chief Investigator A**

In exceptional circumstances, the CEO of the NHMRC may waive this eligibility requirement. In this instance the CIA must submit a one page statement to support their position as CIA to the CEO NHMRC through the Research Administration Officer (RAO) of the Administering Institution **by 25 June 2008**.

The statement should contain a clear reference/subject line such as “CCRE – Request to allow a Non Australian/Permanent Resident to be CIA”.

The address for correspondence is: CEO NHMRC, GPO Box 1421, Canberra ACT 2601.

## **Co-Chief Investigators**

Non-Australian researchers and researchers based overseas are eligible to apply for a CCRE grant as a Chief Investigator, but not as the Chief Investigator A.

## **Associate Investigators**

Associate Investigators (AI) provide intellectual input into the research and participate in a way that warrants inclusion of their name on publications.

There are no restrictions on individuals who may be named as an AI on an NHMRC CCRE grant application.

## **5. Funding**

### **5.1 Administration responsibility**

The Administering Institution is responsible for administration of the award and accepts financial responsibility for the grant.

### **5.2 Level and duration of Funding**

CCRE funding will not exceed a maximum total of \$2.5 million over five years.

### **5.3 Budget**

Applicants are required to provide a detailed budget to justify their funding request. An annual indexation will be applied to all budget items and is based on the Commonwealth Government Wage Cost Index (WCI).

It is expected that NHMRC supported CCRES will attract funding from other sources and that all or part of salaries for staff may come from one or more employing organisations. However the CCRE activities funded by NHMRC must be identifiable with the capacity for discrete reporting.

Further details on budget items are contained in the Advice and Instructions to Applicants documentation located on the website at:

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

## **6. Application Process**

### **6.1 Applications**

The application is to contain all the information necessary for assessment without the need for further written or oral explanation, or reference to additional documentation. All details in the application must be current at the time of application as this will be used as the prime source of information available to the CCRE Grant Review Panel.

All NHMRC Grant applications must be submitted through the Research Office of an NHMRC Administering Institution.

Once submitted to the NHMRC, an application may be revised and then resubmitted **before** the closing date for applications. Applications submitted after the closing date will not be considered by the NHMRC. Applicants may withdraw their application at any time.

Applications relating to Aboriginal and Torres Strait Islander Health will be subject to additional review by the Indigenous Health Research Review Panel (IHRRP) against the *Criteria for Health and Medical Research of Indigenous Australians*.

## **6.2 Advice and Instructions Form and Application Form**

Applications for CCRE funding are to be submitted electronically on a *Centres for Clinical Research Excellence Application Form*, as advised in the *Centres for Clinical Research Excellence Advice and Instructions to Applicants*, which can be found at:

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

Other important information associated with the submission can be downloaded from this site.

## **6.3 Closing date for applications**

Applications for CCRE Grants for funding commencing in 2009 will close on **Friday, 8 August 2008 at midnight (AEST)**.

**Late applications will not be accepted.**

# **7. Peer Review Process**

## **7.1 CCRE Grant Review Panels (CCREGRP)**

NHMRC will establish CCRE Grant Review Panels (CCRE Panels) to assess applications against the aims and selection criteria for the CCRE program. CCRE Panels will conduct an initial review of applications to develop a short-list of competitive applications. CCRE Panels will identify any ineligible applications and reserves the right to remove from further consideration applications that are clearly non-competitive judged against other applications. Applicants will be advised if CCRE Panels determine that their application is ineligible or is non competitive.

NHMRC will seek reviews from assessors on the short-listed applications and applicants will have an opportunity to respond to comments from assessors and any comments from the Peer Review Panels. The CCRE Panels will consider the responses when ranking applications.

The CCRE Panels will meet to rank applications against the selection criteria, taking into consideration the application, the assessor comments, and the response from applicants to the assessor and Panel comments.

## **7.2 Removal of Applications**

Exclusion of ineligible applications may take place at any time during the selection process, and includes those that are deemed non-competitive. Grounds for exclusion include, but are not limited to:

- failing to submit the application in accordance with the Funding Policy and the Advice and Instructions to Applicants;
- not meeting the eligibility criteria;
- providing incomplete or misleading information; and/or
- deemed clearly uncompetitive against other applicants in the funding round.

### 7.3 Advice of Outcome of Applications

As soon as practicable after the outcomes are known, the NHMRC will advise the Chief Investigator A, via the Administering Institution's Research Office, on the outcome of their application.

## 8. Objections and Complaints Process

The NHMRC policy on complaints can be found at:

<http://www.nhmrc.gov.au/contact/compliant.htm>

### 8.1 Objections

Applicants may contact the NHMRC seeking clarification on the outcome of their application for CCRE funding, or to state an objection to any part of the process. The objection must be lodged in writing through the Administering Institution's Research Office and be received within 4 weeks of the date on the letter notifying the outcome of the application.

The objection 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](mailto:complaints@nhmrc.gov.au)

The NHMRC will provide a written response to all objections.

The *National Health and Medical Research Council Act 1992* (NHMRC Act) provides for the Commissioner not to investigate a complaint where the complainant has not initially approached the CEO for resolution.

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.

The NHMRC Act may be found at:

[http://www.comlaw.gov.au/ComLaw/Legislation/ActCompilation1.nsf/0/23029FDD3FCC3FD7CA25719C008331D3/\\$file/NatHeaMedResCou1992WD02.pdf](http://www.comlaw.gov.au/ComLaw/Legislation/ActCompilation1.nsf/0/23029FDD3FCC3FD7CA25719C008331D3/$file/NatHeaMedResCou1992WD02.pdf)

## **8.2 Formal Complaints to the Commissioner**

Part 8 of the NHMRC Act outlines the establishment and functions of the Commissioner for Complaints.

The NHMRC Act may be found at:

[http://www.comlaw.gov.au/ComLaw/Legislation/ActCompilation1.nsf/0/23029FDD3FCC3FD7CA25719C008331D3/\\$file/NatHeaMedResCou1992WD02.pdf](http://www.comlaw.gov.au/ComLaw/Legislation/ActCompilation1.nsf/0/23029FDD3FCC3FD7CA25719C008331D3/$file/NatHeaMedResCou1992WD02.pdf)

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 NHMRC Act.

## **9. Administration**

### **9.1 Deed of Agreement**

All grants are offered in accordance with the Deed of Agreement between the NHMRC and the Administering Institution through schedules relating to the grant. 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 project 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
- all required ethics/biosafety clearances and approvals having been obtained (see Section 9.4).

### **9.2 Financial Management - Payments**

Subject to appropriations, payment of funds will be made to institutions in regular instalments, in accordance with approved payment arrangements made for assistance provided from the Medical Research Endowment Account. Funds must be used only for purposes approved under the CCRE Scheme and in accordance with the Deed of Agreement.

### **9.3 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>

### **9.4 Ethics Clearances and Approvals**

Funding for a CCRE will not commence until all relevant approvals, ethical and/or biosafety, have been received from the appropriate institutional committees and lodged with the Administering Institution's Research Office.

It is the responsibility of the applicant to ensure that applications are made to the relevant institutional committees or approval bodies. It is also the responsibility of the applicant to ensure that the completed approval form is forwarded to the Institution's Research Office who will hold a copy of the form.

The Research Administration Officer, who is responsible for the application, must advise the NHMRC when clearances have been granted by the relevant institutional committee or approval body.

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. Provisional approvals are not acceptable.

Grants may be forfeited if ethics approvals are not obtained within six months of the original grant commencement date.

### **Health Research Involving Aboriginal and Torres Strait Islander Australians**

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 (2003)*, which available on the NHMRC website 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.

### **9.5 Privacy of individuals**

Documents containing personal information are handled and protected by the NHMRC 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 Privacy Act allows.

### **9.6 Use of Personal Information**

Section 95 of the *Privacy Act 1988* (the Privacy Act) provides that the CEO of the NHMRC may, with the approval of the Privacy 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 the NHMRC *Guidelines approved under Section 95 of the Privacy Act 1988, 2001* (Section 95 Guidelines). In these situations, the proposed medical research must be approved by a properly constituted Human Research Ethics Committee (HREC) in accordance with the Section 95 Guidelines.

NHMRC *Guidelines approved under Section 95A of the Privacy Act 1988* (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, an HREC must give approval for the use of this information.

## 9.7 Confidentiality

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 the 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, 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)*.

## 9.8 Intellectual property

Applicants must agree to comply with the *National Principles of Intellectual Property Management for Publicly Funded Research (2001)* available at:

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

## 9.9 False or Misleading Information

If an application is incomplete or contains information that is considered misleading, it will be excluded from any further consideration for funding.

Under s136.1 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.

If the NHMRC believes that omissions or inclusion of misleading information are intentional, it may 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; or
- falsifying claims in publications records (such as describing a paper as accepted for publication when it has only been submitted).

## 9.10 Contacting the NHMRC

For further information, the institution's Research Office should be contacted in the first instance. Enquiries about CCREs may be addressed to the GrantNet Help Desk on:

Phone: 1800 500 983  
Fax: (02) 6217 9165  
E-mail: [grantnet.help@nhmrc.gov.au](mailto:grantnet.help@nhmrc.gov.au)

## 10. Reporting

### 10.1 Reporting requirements

Annual progress and financial reports will be required each year on the form prescribed by the NHMRC. Applicants are required to submit sufficient information in mandatory fields. At the completion of the grant, a final report and financial acquittal 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 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.

## 11. Open Access Statement

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 acknowledge 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.

The NHMRC therefore encourage 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.