



# Medical Research Policy

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# The Australian Research Council

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The ARC is a non-corporate Commonwealth entity established under the Australian Research Council Act 2001 (ARC Act), located within the Australian Government's Education portfolio, and reporting to the Minister for Education. The ARC is a vital component of Australia's innovation and research system. It plays an integral role in supporting the research sector to produce excellent and impactful research for Australia's economic, social, environmental and cultural benefit through the delivery of the National Competitive Grants Program. The NCGP funds excellent pure basic, strategic basic and applied research in all disciplines except medical research.

The ARC's broader remit includes the provision of high-quality research policy advice to the Australian Government, supporting research integrity and promoting ethical research, evaluating the excellence, impact and depth of Australian research and expanding Indigenous Australian knowledge systems. It also facilitates partnerships between researchers and industry, government, community organisations and the international community

## Purpose and scope

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This policy is applicable to all grant schemes within the NCGP. It may also be relevant to other ARC-administered grants programs, as specified in the relevant Grant Guidelines.

Applications that involve medical research as defined in this policy are not eligible to be funded. The intended aim of this policy is to reduce the likelihood of applicants preparing and submitting applications to the ARC which are ineligible for funding.

# 1 Definitions

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<b>Medical research</b>	Medical research has the same meaning as it has in the National Health and Medical Research Council Act 1992. i.e. medical research includes the laboratory-based or clinical study, or group or community-based study of the causes, treatment, and prevention of human diseases, and also includes dental research. For the purposes of this policy, 'causes, treatment, and prevention' also include the diagnosis, monitoring, and management of human diseases.
<b>Diseases</b>	Diseases means any deviation or interruption of the normal i.e., non-disease-associated, structure or function of any cell, tissue, organ or system (or combination thereof) of the body that is manifested by a characteristic set of symptoms and signs, and whose causes, prevention, diagnosis, monitoring, management or treatment may be known or unknown. For the purposes of this policy, diseases also includes human health conditions pertaining to any disorder, syndrome, condition, injury, impairment, sign, symptom, or other problem that generally leads to contact with, or utilisation of, health services.
<b>Therapeutic Goods</b>	Therapeutic goods has the same meaning as it has in Section 3 of the Therapeutic Goods Administration Act 1989, or any successor legislation, and includes chemical, biological and pharmaceutical compounds, and/or electronic, mechanical and bioengineering devices.
<b>Interventional</b>	Interventional includes (i) the collection and/or use of human organs, tissues, tumour, hair, bones, biopsy specimens, body fluids e.g. skin, blood, urine, saliva, or exhaled breath, (ii) behavioural or dietary interventions, and (iii) pre-clinical or clinical trials of devices, diagnostic procedures or therapeutic goods.

## 2 Eligible Research

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Research eligible for ARC support:

- (a) research whose aims or purpose is the understanding of normal i.e., non-disease-associated, human biological processes; or
- (b) research whose aims or purpose is the understanding of human biological processes that may have future medical research applications, but are clearly justified as being outside the scope of the application; or
- (c) research, including observational research using human participants or populations, whose aims or purpose is to understand the normal human life cycle (e.g. infancy, childhood, adolescence and ageing) and/or traits and behaviour ; or
- (d) research, including observational research, whose aims or purpose is to understand the human life cycle (e.g. infancy, childhood, adolescence and ageing) and/or traits and behaviour using human participants or populations that may have future medical research applications, but are clearly justified as being outside the scope of the application; or
- (e) research whose aims or purpose is the development or use of equipment, facilities, technology platforms, management systems, tools, games, devices, software, smart phone applications or other items to support eligible non-medical research as listed above.

## 3 Ineligible research

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Research ineligible for ARC support:

- (a) research whose direct aims or purpose is medical research, as defined in this policy; or
- (b) research involving the use of i) animals or ii) human tissue, or iii) the development or use of *in vivo* animal models or *in vitro* cellular models, or a combination thereof, whose aims or purpose is medical research as defined in this policy; or
- (c) research involving the development, testing or use of devices, diagnostic procedures or therapeutic goods, whose aims or purpose is medical research as defined in this policy; or
- (d) interventional research, whose aims or purpose is medical research as defined in this policy; or
- (e) research involving the development or use of equipment, facilities, technology platforms, management systems, tools, games, devices, software, smart phone applications or other items, whose aims or purpose is medical research as defined in this policy.

## Process

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If applicable, applications must include justification detailing why the application is compliant with this policy. The ARC may rely solely on the Medical Research Statement in the application to determine whether an application is eligible – the ARC will not seek further information from the applicant.

The ARC may, in its absolute discretion, seek further advice from its Medical Research Advisory Group, an expert committee convened by the ARC.

Recognising that an integrated research project or program may sometimes include a small element of incidental medical research not supported under this policy, the ARC may, but is not obliged to, deem such an application eligible for funding provided the application predominantly comprises eligible research as set out in this policy.

Applications are still subject to all other eligibility requirements set out in the relevant Grant Guidelines.

Applications deemed ineligible cannot be recommended or approved for funding under the *Australian Research Council Act 2001*.

## Contact details

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### Stakeholder Relations

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## Document control

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0.1	..	SMCC	SMCC draft