

2021

HEALTH+MEDICAL RESEARCH

—
Early-Mid Career
Researcher Grants
Gene and Cell Therapies

Guidelines



NSW Health

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www.health.nsw.gov.au

www.medicalresearch.nsw.gov.au

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SHPN: (OHMR) 210099

Call for applications

NSW Health invites eligible individuals to apply for the NSW Gene and Cell Therapies Program Early-Mid Career Researcher Grants. Funding for these Grants will be provided for three years from 2020-21 to 2023-24. Clinician researchers, researchers from culturally and linguistically diverse backgrounds, Aboriginal and Torres Strait Islander researchers and primary carers who have experienced career disruptions are encouraged to apply.

For the purpose of this Grant, an early-mid career researcher is defined as a researcher who is within 15 years between the conferral of their PhD (or equivalent) and the submission deadline and has not reached professorial level. PhD students who expect to have their PhD awarded by June 2021 are eligible to apply.

Host organisations are invited to submit a maximum of ten (10) applications. Applications close on 9 April 2021.

Objectives

Early-Mid Career Researcher Grants aim to:

- fund talented researchers in the early-mid stages of their career, to undertake research that improves wellbeing and health outcomes for patients
- embed high-quality, innovative research in the NSW health system
- encourage the development of research skills in a supportive environment
- support early-mid career researchers to gain research grants and fellowships from bodies such as the National Health and Medical Research Council (NHMRC), Australian Research Council (ARC) and Medical Research Future Fund (MRFF)
- bridge the gap between research, policy and practice to increase research impact and translation.

Pre-application workshop

The NSW Cardiovascular Research Network (CVRN) will host an interactive workshop in March 2021 to help applicants understand NSW Health requirements (including Program Logic) and prepare their application.

To participate, you must register your interest by **26 February 2021** by emailing your name, contact details,

host organisation, field of research and your preferred attendance mode for the workshop— face to face or online to: cvrn@heartfoundation.org.au.

Further information about the workshop will be provided to interested applicants.

Commercialisation Training Program

NSW Health is developing a Commercialisation Training Program, which grant recipients are required to complete during their candidature. The training will provide students with a high-level understanding of the pharmaceutical industry, its structure, corporate roles and the process of taking a product from a concept through to market. Specifically, students will understand the essential steps required to create successful therapeutics from a formulation, manufacturing, regulatory and reimbursement strategy point of view. At the completion of the course students will understand how to construct a target product profile and associated business case for a new therapeutic product.

Eligible areas of research

This funding will support the recruitment of early-mid career researchers to undertake research projects within the gene and gene-modified somatic cell therapy development and manufacture sectors. Research projects describing stem cells as the therapeutic product will be deemed ineligible and will be excluded from further consideration.

Clinician researchers

Clinicians, both medical and non-medical, are encouraged to apply. Clinical experience will be taken into consideration during the review process.

Clinicians may use up to 50% of the grant to backfill their clinical role, with appropriate justification. If the grant is to be used for this purpose the application must be signed by the appropriate department head in the local health district. The salary limits are as follows:

- **Clinician – medical:** Salary limit – up to 0.6 FTE Staff Specialist. A similar arrangement is also available for Visiting Medical Officers.
- **Clinician – non-medical:** Salary limit – up to 0.6 FTE as per Allied Health (including Pharmacist and radiographers) and Nursing awards.

PhD candidates

Applicants who are currently enrolled in a PhD may apply, if the date of award is expected to be before June

2021. Evidence of award of the PhD must be provided to NSW Health prior to the announcement of funding. Announcement dates will be advertised on the OHMR website. Note that evidence of submission of a PhD is not sufficient.

Funding amounts

Early-mid career grants of **up to \$130,000 per year for the 3-year duration of the grant (maximum total grant amount \$400,000)** will be awarded.

Grants are for research projects or programs and can cover a combination of salaries of the research team (clinical and/or non-clinical), backfill for clinicians to quarantine research time, consumables, equipment and other research infrastructure

Funding conditions and exclusions

1. Research funded through an Early-Mid Career Researcher Grant must be conducted in the NSW health system or affiliated organisation (university, medical research institute, industry partners).
2. Early-Mid Career Researcher Grants must not be spent on capital works, general maintenance costs, organisational infrastructure or overheads, telephone/communication systems, basic office equipment, such as desks and chairs, rent and the cost of utilities.
3. Applicants are required to declare the source, duration and level of funding already held for research in the subject area of the application.
4. Funding is conditional on the early-mid career researcher and the Chief Executive of the host organisation signing the declaration on the application form, which outlines the host organisation's obligations to the early-mid career researcher.
5. Grants may be applied for regardless of other funding currently held or applied for, including NHMRC fellowships. Applications must clearly describe the purpose of the additional funding and justify that the additional research will be complementary but not duplicative.
6. Grants provided under this funding round are one-line grants, not fellowships.
7. Successful applicants who do not meet the requirements outlined in the funding agreement without written approval may have their funding withdrawn.

8. Successful applicants must apply for federal funding (NHMRC, MRFF, ARC) at least once during the funded period and provide evidence of the application, scores, feedback and outcome to NSW Health.

Submission of applications

Applicants must use the Early-Mid Career Researcher Grants 2021 Application Form and attach any supporting evidence. The form is available at:
<https://www.medicalresearch.nsw.gov.au>.

The admin contact at the host organisation or administering organisation (listed in the Application Form) must submit the complete application form by email to MOH-OHMRGrants@health.nsw.gov.au by 9 April 2021.

The submission is not complete until a confirmation email is received by the person submitting the application. If the person submitting the application does not receive a confirmation email, it is their responsibility to follow up within 24 hours, by emailing MOH-OHMRGrants@health.nsw.gov.au. Attachments should not be included within the follow up email.

The confirmation email should be retained as this may be required by NSW Health as evidence of submission. If an email confirming receipt of the application is not available, no further correspondence regarding the application will be entered into.

Please note NSW Health will ONLY accept:

1. Submission of the application by email to MOH-OHMRGrants@health.nsw.gov.au
2. Application forms that have been endorsed by the Chief Investigator and Research Director and Chief Executive of the Host Organisation. Applications without a signed declaration by the Chief Investigator and Host Organisation will not be reviewed. Late submission of signature pages is not permitted.

Files less than 20MB in size. Please note emails larger than 20MB will be blocked and **NSW Health does not receive notification of blocked emails.**

Answers to frequently asked questions and updates on the Early-Mid Career Researcher Grants Program are available on the following webpage:

<https://www.medicalresearch.nsw.gov.au/cell-gene-therapy/>.

Any queries regarding this Program may be directed by email to MOH-OHMRGrants@health.nsw.gov.au.

Before you apply

Research collaborations and partnerships

Applicants are encouraged to identify and engage relevant partners who will provide a meaningful contribution to delivery of the research project and implementation of outcomes.

Partners may include:

- NSW Health System partners including NSW Ministry of Health, Pillars, and statewide health services
- local health districts and specialty health networks
- Advanced Health Research Translation Centres and Centres for Innovation in Regional Health
- universities and medical research institutes
- Aboriginal Community Controlled Health Services
- Primary Healthcare Networks
- clinical networks
- non-government organisations
- consumers and patients.

The research must be conducted in NSW but may be part of a wider collaboration.

Industry Partnerships

The program encourages outcome-focused collaborative research partnerships between industry entities and research organisations.

The following principles apply:

- Industry collaborations must involve a lead applicant who is based at an eligible host organisation and who is the main driver of the project. Industry organisations are not eligible to be host organisations.
- Only an eligible lead applicant can apply for grant funding and submit an application on behalf of project partners.
- Applications may include and maintain among project partners one or more industry entities.
- All partners must contribute resources to the project. Industry matched funding is encouraged, but not required.

Priority populations

It is important that all research projects consider and respond to the distribution of the burden of disease within the population and the needs of under-represented, higher risk and priority populations where appropriate. These may include women, Aboriginal and Torres Strait Islander people, people from a non-English speaking background, socioeconomically disadvantaged groups, and people living in regional and remote areas.

Relevant partners should be engaged early to ensure that the research design and conduct will be effective and appropriate for these population groups.

Program logic and research impact

Applicants are required to submit a Program Logic diagram, which includes the project need, aims, activities, outputs, end users, pathway to adoption and anticipated impacts (short and long-term outcomes).

Applicants should consider the interactions between each component of the Program Logic i.e. each output should be supported by at least one activity; each impact should be realised through the adoption and use of output(s) by the end user(s). The impact section should consider how the findings are expected to improve the outcomes of the end users (beneficiaries).

Research Translation

All research projects should have potential to lead to changes in clinical practice or policy in the short and/or long term. Applications must clearly describe:

- The clinical significance of the research
- The expected pathway for this to occur
- Links to research partners and other stakeholders who will take the research to the next step on the translation pathway.

Research Impact Assessment

The program logic will be used to assess likelihood of research impact at application stage. If the research is funded, the program logic will guide the measurement of impact throughout the project and at its conclusion.

Research impact will be considered across five domains:

Domain 1: Knowledge Generation

- New treatments, diagnostics or drug targets
- New clinical or medical prototypes

- Peer-reviewed publications and presentations at conferences
- Media coverage and other non-peer-reviewed publications
- Patent applications.

Domain 2: Capability Building

- New partnerships leveraged
- Training and professional development
- Research students supported.

Domain 3: Policy and Practice

- Instances where research findings are considered in policy development
- Instances of change in clinical practice
- Instances of new health technology or new treatments used in clinical care

Domain 4: Patient health and population outcomes

- Improved health outcomes, including:
 - Reducing the time to an outcome or change in the
 - Change in the likelihood of an outcome occurring

Domain 5: Economic outcomes

- Research jobs created and sustained
- Patents and commercialisation
- Value of leveraged research funding (external grants awarded due to NSW Health funding)
- Reduction in cost of delivering care
- Potential for return on investment.

Intellectual Property

Intellectual property (IP) arrangements should be agreed between all research partners and organisations, according to local policy. IP arrangements must cover both background IP and IP that is developed during the project. IP arrangements should consider the contributions of all parties. The arrangements should be detailed in the application.

Eligibility criteria

Applications must meet all eligibility criteria.

Early-mid career researcher

Based in NSW

The early-mid career researcher must reside in or plan to move to NSW and must be employed by a NSW based medical research institute, university, or non-government organisation.

Gene and Genetically-modified Cell Therapies Research

The early-mid career researcher must satisfy the requirement that their research is in the field of gene and genetically-modified cell therapies research.

Submit a complete application

The early-mid career researcher must fully complete the Application Form, attach all relevant and required documentation; sign the declaration on the form and include certification from the host organisation.

Australian citizen, permanent residency status or appropriate visa

The researcher must be an Australian citizen, a permanent resident of Australia or have an appropriate working visa for the full term of the Grant. Researchers who are neither Australian citizens nor permanent residents must provide evidence of residency status and the right to remain in Australia for the duration of the funding period, certified by a Justice of the Peace (JP) or equivalent. Note that for electronic documents, an official VEVO statement is sufficient, JP certification is not required. Australian Citizens and Permanent Residents are not required to provide evidence.

Classified as an EMC researcher

The early-mid career researcher must be less than 15 years postdoctoral and not have reached professorial level.

Host organisation

- The host organisation is where most of the research is conducted.
- The host organisation must be based in NSW and employ the early-mid career researcher for the duration of the grant.

The host organisation must conduct health and medical research and be a:

- university
- independent medical research institute
- not-for-profit organisation
- NSW Health local health district or specialty health network.

The early-mid career researcher's host organisation must provide appropriate infrastructure support for the research project, such as wet/dry lab space, computer equipment, and desk space.

An authorised representative of the host organisation is required to sign the application form indicating support from the Research Director and Chief Executive for the application and to certify that the organisation complies with the requirements of the grant.

Administering Organisation

An administering organisation is only required where the funds are held by a separate organisation to the host organisation.

In such cases, the administering organisation will enter into the funding agreement with NSW Health, manage the funds, submit financial reports and coordinate other reporting requirements as outlined in the funding agreement.

If the host organisation is a NSW Health Organisation, grant funds must be paid to an administering organisation that can manage funds across financial years.

The administering organisation must be:

- a university
- a medical research institute, or
- a non-government organisation in NSW.

Selection criteria

All applications for funding that meet the eligibility criteria will be assessed against the following selection criteria. In addressing the selection criteria, applicants should specifically highlight the relevance to gene and genetically-modified cell therapies research.

Applications should be written in plain English, as applications may be reviewed by a panel member with expertise in a different area to that of the application.

Applicant

Applicants will be assessed on:

- academic and relevant clinical qualifications
- research, clinical and industry experience, including demonstrated capacity to work in multidisciplinary teams
- skills and experience directly related to the topic area(s) and methodology of the research project
- track record in research, relative to opportunity
- responsibilities that could reasonably be considered to have had a negative impact on research track record over the previous ten years.

Research project

A clear and detailed description and justification for the project is required, including aims, methodology, and expected outputs and outcomes. The research project will be assessed according to the following criteria:

- how the proposed project will advance existing knowledge and why this is important
- the extent to which the proposed research is innovative and novel
- strength, rigour and appropriateness of the research methodology
- potential outputs and outcomes of the research and how the research will improve clinical practice and/or patient outcomes in the short or long term
- host organisation track record in development and delivery of gene and genetically-modified cell therapies
- ability to deliver the research outputs, outcomes and/or objectives within the grant period
- scalability and generalisability of results

- the skills of the proposed research team that are relevant to the project, and each team member's ability to contribute meaningfully to the research
- relationship to existing research undertaken by the host organisation and the research team
- proposed translation pathway, including consideration of commercialisation and intellectual property where appropriate
- consideration of priority population groups if relevant.

Budget

Full details of the budget should be clear in the application. The budget will be assessed on:

- appropriateness of the funding amount and purpose
- existing funding for the research, and how this relates to the additional funding requested
- other contributions and support for the project.

Skill development

The application will be assessed on skill development activities undertaken to date, and proposed skill development during the period of the grant. Activities undertaken should align with the researcher's vision for their career in research.

Examples of skill development activities that may be undertaken include:

- applications for national grant funding
- leading or participation in clinical quality assurance activities
- receiving regular formal mentoring
- attending training, for example in research skills or research leadership
- taking on leadership roles
- mentoring or supervising junior researchers
- involvement in collaborations, for example with other research groups or policy agencies
- active roles in relevant networks, advisory committees or governance groups
- collaboration with clinicians and others involved in translation of research findings.

Selection process

Step 1: Eligibility check

Following the closing date for applications, the NSW Ministry of Health will make an appraisal as to whether or not each Application has satisfied ALL of the eligibility criteria.

Step 2: Review by independent expert panel

An independent selection panel of expert reviewers, chaired by the Executive Director of the Office for Health and Medical Research, will assess each application against the selection criteria.

Step 3: Funding recommendation

The independent selection panel will agree on the final ranking of all eligible applications and will make a recommendation for funding to the NSW Ministry of Health.

Step 4: Decision and notification

The NSW Ministry for Health will make a determination on grant recipients and amounts. All applicants will be informed as to whether they have been awarded funding. This decision is final and may not be appealed.

Step 5: Grant Agreements

The NSW Ministry of Health will contact administering organisations for successful early-mid career researchers to execute a funding agreement. A standard, non-negotiable funding agreement will be used.

Funding will be paid as per arrangements in the Funding Agreement.

Reporting requirements

A schedule for reporting will be outlined in the funding agreement and will include a requirement to provide:

- annual progress reports
- annual financial reports
- a final report following the conclusion of the term of the grant