

Cell and Gene Therapy Grants

APPLICATION GUIDELINES 2018/19
Applications close COB 19 April 2018



NSW Ministry of Health
73 Miller Street
NORTH SYDNEY NSW 2060
Tel. (02) 9391 9000
Fax. (02) 9391 9101
TTY. (02) 9391 9900
www.health.nsw.gov.au

Produced by: NSW Ministry of Health

This work is copyright. It may be reproduced in whole or in part for clinical use, study or training purposes subject to the inclusion of an acknowledgement of the source. It may not be reproduced for commercial usage or sale. Reproduction for purposes other than those indicated above requires written permission from the NSW Ministry of Health.

© NSW Ministry of Health 2018

SHPN (OHMR) 180157
ISBN 978-1-76000-839-0

Further copies of this document can be downloaded from
<http://www.health.nsw.gov.au/ohmr/Pages/cell-and-gene-therapy-grants.aspx>

2018



Overview

These guidelines provide information about the submission and selection process for the Cell and Gene Therapy Grants 2018/19 (CGTG 2018/19).

Further information on the CGTG2018/19 is available at <http://www.health.nsw.gov.au/ohmr/Pages/cell-and-gene-therapy-grants.aspx>

Please email any questions to ohmr@doh.health.nsw.gov.au

Application closing date

Applications must be received by **COB, Thursday 19 April 2018**. Late or incomplete application forms will not be considered.

Indicative Timeline

Activity	Date
1. Applications open	22 March 2018
2. Applications close	COB 19 April 2018
3. Internal review of eligibility	April 2018
4. Independent Panel meets to review applications	May 2018
5. Recommendations for funding considered	June 2018
6. Successful applicants announced	July 2018

Contents

- Overview..... 2
- 1 Purpose and Objectives 3
- 2 Eligibility Criteria..... 4
- 3 Application Process..... 5
- 4 Assessment Process 6
- 5 Selection Criteria..... 7
- 6 Reporting Requirements 10

1. Purpose and Objectives

The CGTG 2018/19 will support the development, delivery and commercialisation of innovative therapies using cell and gene therapies.

The CGTG 2018/19 aims to position NSW as a global leader in the development, delivery and commercialisation of innovative cell and gene therapies. The funding will be used to:

- reduce the time between gathering evidence of effective treatments to delivering those treatments at scale
- support the rapid, efficient and effective delivery of innovative therapies
- engage commercial and industry partners early to rapidly scale up therapies found to be effective.

The CGTG also aims to build workforce and infrastructure capacity and capability in NSW for research and development in cell and gene therapy.

Peer-reviewed and scientifically promising research will be supported including:

- NSW based pre-clinical trials feasibility studies
- NSW manufacturing for the purposes of translational research
- NSW based clinical trial development.

NSW statewide infrastructure should be used where possible, including biospecimens from the NSW Health Statewide Biobank. Any manufacturing of cell and gene therapy products must use NSW facilities (Westmead campus and Royal Prince Alfred Hospitals).

2. Eligibility Criteria

To be eligible for funding, applicants must demonstrate they meet all eligibility criteria.

The Project

A. Institutional Support

Applicants should show evidence of institutional support for the project in the form of a letter signed by the Chief Executive of the host institution or a duly authorised officer. The letter should demonstrate that the project is part of a reporting line to the host organisation's Chief Executive.

B. Foundations of the project based in NSW

Grants will only be provided to projects which demonstrate that significant development has occurred in NSW/Australia, including a significant component of the preclinical work and/or generation of Australian held intellectual property.

The research team

C. Team based in NSW

The research team must be led by a NSW-based researcher. The research team may be comprised of up to 50 per cent of investigators from outside NSW.

D. Conducts health and medical research

The research team must conduct health and medical research and be one of the following organisations: a department or research centre within a NSW University, a NSW Health entity, an independent NSW based medical research institute or a NSW based non- government organisation.

Funding is not available (directly or indirectly) to support international biotech companies seeking to conduct trials in Australia where the only local contribution is provision of access to patients or infrastructure.

3. Application process

All applications must be submitted on the Application Form which is available from <http://www.health.nsw.gov.au/ohmr/Pages/cell-and-gene-therapy-grants.aspx>.

Each application should include:

- Completed Application Form including budget and all supporting documents
- A letter from the host institution providing evidence of institutional support for the project
- If relevant, an endorsement of the application by the manufacturing facility.

The electronic copy of the Application Form and all associated documents should be emailed to: ohmr@doh.health.nsw.gov.au. The Application Form and all associated documents should be PDF'd together and named [CHIEF INVESTIGATOR NAME]_CGTG2018/19_ _[DATE document emailed].

4. Assessment Process

Step 1: Internal review of eligibility

Following the closing date, Office for Health and Medical Research (OHMR) will review all applications according to the eligibility criteria. Further information may be requested in order to clarify or confirm material in the application.

Step 2: Independent review of applications

An Independent Panel will review OHMR's appraisal of eligibility. The Panel will be chaired by the Executive Director, OHMR, Ministry of Health and at least three independent members with experience in cell and gene therapies. The independent members may be interstate or international. The chair may co-opt additional reviewers as required.

Step 3: Recommendations to the Deputy Secretary/Chief Health Officer

The Panel will make recommendations on which applicants should be funded and the level of funding.

Step 4: Successful applicants decided

Once approved, all applicants will be informed in writing of the results.

Step 5: Funding agreements initiated

OHMR will make contact with successful applicants to execute funding agreements.

5. Selection Criteria

Scientific Quality and Feasibility (35%)

A. Strong scientific basis for the work proposed

The application must include a research and development (R&D) plan that: has clear and well-defined objectives, a strongly developed scientific approach relevant to the scope of the plan and strong study design.

The R&D plan should include: the research question/s, where relevant the development of the intervention, the evidence gaps the research will explore, purpose and objectives, detailed study methodology and what will be achieved in the study period.

Applicants are strongly encouraged to collect biospecimens pre- and post-intervention, so that biomarkers can track any future illness, and to bank the biospecimens in the NSW Health Statewide Biobank. Projects should include appropriate consent processes for biospecimen collection and data linkage (ie. use the NSW Health Statewide Biobank Consent Toolkit).

The R&D plan should indicate when research translation and stakeholder engagement activities will occur (reflecting the research translation plan, see Selection Criteria F and G below).

B. Methods that have a high probability of achieving the objectives

The R&D plan should be highly feasible given the required expertise, research tools and techniques present in the relevant research environment. This includes management of perceived risks.

a. Safety and efficacy

The project must include safety and efficacy assessments and demonstrate that all relevant ethics and regulatory approvals will be obtained before clinical trials commence.

b. Manufacturing of cell and gene therapy products should use NSW facilities

Any manufacturing of cell and gene therapy products must use NSW facilities (Westmead campus and Royal Prince Alfred Hospitals).

c. Continued use of therapeutic drugs

If relevant, projects must have suitable arrangements in place for the continued use of therapeutic drugs by clinical trial participants (if their clinician requests it) after the clinical trial has ceased.

C. Ability to translate research into a clinical trial within 1-3 years

A list of key project milestones and related deliverables with an indication of when each will be completed is required. There is an expectation that at the completion of the project it will be possible to report on meaningful outcomes, such as the start of a clinical trial, and the dissemination of project findings.

The project milestones must align with the research translation plan (see F below).

Significance of the Expected Outcomes and/or Innovation (40%)

D. Demonstrate significance of concept

The application must demonstrate the extent to which the project will result in a significant or major advance in treatment and/or knowledge in this field and/or address an issue of significant importance to the health of people in NSW.

E. Translate to a health benefit for people of NSW

The project must show how significant patient cohorts in NSW (including the likely outcomes for a defined patient group/s) will benefit from the project. The health benefit could be at a patient, health service or population level.

The application should indicate **where** the project sits on the pathway between concept and implementation.

The application must demonstrate that the project is:

- *research that is translatable*: research that can be generalised and scaled across the state, and/or
- *translation research*: research that examines how to more effectively apply best practice models of care.

F. Show potential to impact clinical medicine

The application must include a research translation plan which demonstrates **how** the research will be translated into practice. This includes:

- what activities will help generalise, implement and scale the evidence, if found, and
- **how, where** and **when** the evidence will affect clinical medicine.

The research translation plan should be linked to key project milestones and to a communication and stakeholder engagement plan. It should include a list of planned activities to support the translation of knowledge to and from the research project into policy and/or practice where relevant. Each activity should include information on who will be engaged, when, and how, as well as the intended impact of each engagement and how it will support successful implementation of the research findings.

The application must also describe how the team intends to submit results for publication to a reputable peer reviewed and open source publication.

G. Demonstration of successful collaboration or the potential for successful collaboration

Applications must include stakeholder engagement activities demonstrating engagement with appropriate stakeholders for the project (e.g. researchers, clinicians, consumers, policy makers and the community) including:

- Consultation with partners and consumers in the development of the application
- Engagement with essential partners who will contribute to the conduct and management of the research project
- Ongoing engagement with relevant stakeholders for the dissemination of new knowledge as it emerges, including clear links to the groups that will likely implement positive outcomes from the research.

H. Build capacity in NSW

The project should include a component to build the capacity and capability of staff and the infrastructure supporting the project in NSW (such as manufacturing processes, not capital infrastructure). This will support scaling of the project. Capacity/capability building activities should be reflected in the research translation plan.

I. Partnership with industry and consideration of commercial viability

Partnership with industry/commercial is not necessary at the application stage. If the applicant has an industry/commercial partner at the time of application, a letter from a duly authorised officer outlining the partner's commitment to the project and any further development of the therapy should be included in the submission.

Commercialisation is not essential, however consideration of how commercialisation opportunities and intellectual property will be managed needs to be outlined if relevant.

Team Quality & Capability, Relative to Opportunity (25%)

J. Expertise and experience that is highly relevant to the proposed research

Applicants are required to list their academic qualifications and any relevant professional qualifications with the year awarded, the awarding body and country.

Applicants are required to list any research, clinical and industry appointments and positions held for the previous ten years and highlight the different disciplines they engaged with through each role.

Applicants are also asked to describe their existing skills and experience that:

- Directly relate to the topic area(s) and/or methodology of the project, or
- Relate to the nominated area(s) for development (and how participation in the project will help to strengthen these skills).

K. Demonstration of a globally/nationally competitive track record of relevant work commensurate with opportunity

Applicants are required to provide the details of their top career journal articles, books, reports or patents, and presentations at conferences. Details of any funding awarded to previous projects is also requested.

Applicants should highlight their track record in cell and gene therapy R&D, and provide evidence of any successful translation of an intervention into clinical practice, health policy or population health. The scale of the research translation should be included, that is, facility, local health districts, state, national or global.

To assess track record relative to opportunity, applicants should highlight any significant career disruptions or clinical responsibilities that could reasonably be considered to have had an impact on their track record over the previous ten years.

6. Duration, Size and Payment of Grants

Funding of up to \$5 million in 2018/19 is available. Projects should be a maximum of three years duration.

Grants will be provided to support the following activities:

- Project and business development activities
- Laboratory staff and consumables
- Fees for pre-clinical toxicology studies, assays and testing, animal models and validation testing
- Processing fees at the cell and gene therapy facilities in NSW (for non-commercial entities only).

Funding is conditional on appropriate ethical and governance approval processes.

Funding will not support:

- International travel.
- International biotech companies seeking to run trials in Australia where the only local contribution is provision of access to patients or infrastructure.

Allocating Funding

Grants will be capped at a maximum of \$2 million. Partial funding may be offered if there are insufficient funds to support all successful grants.

All current funding and future funding sought for this project must be disclosed including how funding is, or intends to be, allocated in the project.

An Administering Institution must be nominated to hold and be accountable for funds on behalf of the project.

7. Reporting Requirements

Successful applicants will be required to sign a Funding Agreement that outlines the State's obligations in relation to the flow of funds and the grant recipient's obligations in relation to reporting and accountability. This will include submission to OHMR of six-monthly financial statements and progress reports.

An authorised signatory from the grant recipient's organisation will be required to sign the Funding Agreement before funds are made available.





SHPN (OHMR) 180157