

2020

HEALTH+MEDICAL RESEARCH

—
Gene & Cell Therapy
PhD Program

Guidelines



NSW Health
100 Christie Street
St Leonards NSW 2065
(02) 9391 9228
www.health.nsw.gov.au
www.medicalresearch.nsw.gov.au

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Call for Applications

NSW Health invites eligible Host Universities (enrolling universities) to apply for the NSW Health Gene & Cell Therapy PhD Program (the Program). The Program has two components; the first is the selection of the PhD Project, and the second is the selection of the PhD candidate.

The Program awards funding for PhD candidates to undertake research within the gene and gene-modified somatic cell therapy development and manufacture sectors. These Guidelines apply to Stage One of the application process, the PhD Project, which is outlined on page 4.

Program outline

The Program supports opportunities for PhD candidates to conduct research in gene and gene-modified somatic cell therapy development and manufacture under academic supervision. Funding and in-kind support is drawn from two sources: NSW Health and the Host University.

- NSW Health provides \$20,000 per annum for four years as a contribution to a stipend for a PhD candidate;
- Host Universities provide a financial contribution of \$20,000 per annum to match NSW Health's contribution, bringing the PhD candidate's total stipend to \$40,000 per annum for four years. Host Universities may also provide in-kind support and fund the candidature beyond four years at their discretion and according to local arrangements.
- Host Universities may partner with a medical research institute, NSW Health local health district or specialty health networks, or other affiliated NSW research organisations. The application must include details of the partnering organisation(s) and the role and contribution that the partnering organisation(s) have in the project. Appropriate executive sign-off from the partnering organisations must be included in the application.

Program objectives

The objectives of the Program are to:

- attract high quality PhD students that strengthen successful gene and gene-modified somatic cell therapy research programs
- build workforce skills in the development and manufacture of gene and gene-modified somatic cell therapies in NSW

- create new opportunities for PhD students to study the development and manufacture of advanced therapeutics
- improve graduate understanding of the diversity of employment opportunities in the NSW advanced therapeutics sector
- improve graduate understanding of the commercialisation pathway for these therapies to support closer engagement with industry.

Commercialisation Training Program

NSW Health is developing a Commercialisation Training Program, which PhD students 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 that they can then apply to the gene and gene-modified somatic cell therapy sector. 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.

Application Process

PhD Project Application

Stage One: Host University submits PhD Project application to NSW Ministry of Health

To apply, the academic supervisor(s) and Host University must download and complete the NSW Health Gene & Cell Therapy PhD Program 2020 Application Form for the proposed PhD Project, which is available at www.medicalresearch.nsw.gov.au. PhD Project applications are not to be completed by a prospective PhD candidate.

Applications must be approved by a designated senior representative (Research Director, Dean of Research etc.) and submitted by a representative from the Grant Office of the Host University. All applications must use the NSW Health Gene & Cell Therapy PhD Program 2020 application form and attach supporting evidence as required.

Applications must be saved using the following format for naming in the email subject line: *'Host University_Short project title'*.

For each additional attachment, the following format for naming should be used: *Supervisor Surname_Supervisor First Name_Document name*.

All applications and attachments should be submitted by email to moh-ohmrgrants@health.nsw.gov.au by **5pm on 3 February 2020**. Applications submitted by any other means will not be considered. Please refer to www.medicalresearch.nsw.gov.au for relevant program dates and updates to the program.

Host Universities are invited to submit a maximum of ten (10) applications only.

Answers to frequently asked questions are available on www.medicalresearch.nsw.gov.au. For all other queries regarding the Program, please email moh-ohmrgrants@health.nsw.gov.au.

Stage Two: NSW Ministry of Health notifies Host Universities of successful applications

The NSW Ministry of Health will notify Host Universities of successful and unsuccessful applications following expert panel review.

PhD Candidate Application

Stage Three: Host University selects a suitable PhD candidate to undertake the research project

PhD candidates will be recruited to funded project opportunities according to Host University (enrolling university) procedures for **merit-based recruitment**. This process is to be administered by the Host University for each project. Aboriginal and Torres Strait Islander researchers, people from culturally and linguistically diverse backgrounds, and primary carers who have experienced career disruptions, should be encouraged to apply.

Following recruitment, a selection report and other required documentation for the proposed candidate must be submitted to the NSW Ministry of Health. Further guidance on the format for this report will be provided to successful Host Universities. Once the proposed candidate has been reviewed and approved by the NSW Ministry of Health, candidates will be notified of the outcome of their application.

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¹ Applicants who are not citizens or permanent residents must provide evidence, certified by a Justice of the Peace (JP) or equivalent, of residency status and right to remain and work in Australia for at least the projected duration of the PhD candidate's studies. For electronic

The NSW Ministry of Health will enter into a funding agreement with the Host University. Following this process, an announcement of successful candidates will be made.

Indicative application timeline

Gene & Cell Therapy PhD Program 2020	Date
Call for PhD Project applications	December 2019
PhD Project Applications close	3 February 2020
Announcement of successful PhD Project Applications	February 2020
Advertisement for PhD candidate recruitment commences	March 2020
Funding awarded by NSW Health	March – May 2020
Commencement of studies	April 2020 – February 2021

Eligibility Criteria

ALL criteria must be met for applications to be eligible.

Academic supervisor

Note that the number of academic supervisors per PhD student will vary depending on the Host Universities' policy. Details and track records of all academic supervisors should be included in the application.

- 1. Australian citizen, permanent resident or appropriate visa**
The nominated academic supervisor must be an Australian citizen or permanent resident, or hold an appropriate visa¹.
- 2. Contract with eligible host**
The academic supervisor must be employed by the Host University on an ongoing basis, or have an employment contract and/or affiliation agreement for at least the projected duration of the PhD candidate's studies.
- 3. Commits to releasing their candidate for the Commercialisation Training Program**
The academic supervisor must commit to releasing their PhD candidate for the Commercialisation Training Program.

documents, an official VEVO statement is sufficient; JP certification is not required. Australian citizens and permanent residents are not required to show evidence.

Host University

The Host University is the enrolling university and holds an employment contract and/or affiliation agreement with the academic supervisor AND at which the PhD candidate will undertake the research project. Host Universities may partner with a Medical Research Institute(s), NSW Health Local Health District(s), NSW Health Specialty Health Networks or other affiliated NSW research organisation(s). The application must include details of the partnering organisation(s) and the role and contribution that the partnering organisation(s) have in the project. Appropriate executive sign-off from the partnering organisations must be included in the application.

- 1. Located in NSW**
The Host University and partnering organisation(s) must be located in NSW.
- 2. Guarantee of financial support by providing matching funding to NSW Health**
The Host University must provide a financial contribution of \$20,000 per annum to match NSW Health's contribution, bringing the PhD candidate's total stipend to \$40,000 per annum for four years. Host Universities may fund additional candidature beyond four years at their discretion and according to local arrangements.
- 3. Legally compliant and committed to providing appropriate support**
The Host University must meet all standard employer responsibilities required by law, and accommodate and support the academic supervisor and PhD candidate for the duration of the PhD.
- 4. Compliant and committed to policies and practices that ensure recruitment is fair, responsive and inclusive**
The Host University must apply policies and practices concerning under-represented groups in the selection of prospective PhD candidates.

PhD Candidate

Should the PhD Project application be successful, the prospective PhD candidate who is selected by the Host University must also meet **ALL** applicable eligibility criteria. Candidate selection process reports will be reviewed by NSW Health as outlined in Application Process – Stage Three to ensure these criteria are met.

- 1. Australian citizen, permanent resident or appropriate visa**
The candidate must be an Australian citizen or permanent resident, or hold an appropriate visa¹.
- 2. Nomination by the Host University**
The candidate must be nominated by the Host University for support under the program.
- 3. Academic track record and research experience**
The candidate must hold an undergraduate degree with at least a credit average (or equivalent). Candidates must also have research experience through an Honours program (first class, or second class division one) or Master's degree by research in a relevant subject. Candidates with a Master's degree by coursework will not be deemed eligible.
- 4. Commits to completing Commercialisation Training Program**
The candidate must commit to completing the Commercialisation Training Program.

Intellectual Property

Intellectual property (IP) arrangements should be agreed according to local policy. IP arrangements must cover both background IP and IP that is developed during the project. IP arrangements should consider the contribution of the PhD candidate. The arrangements should be detailed in the application.

Eligible areas of research

This funding will support the recruitment of PhD candidates 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.

PhD Project Selection Criteria

All applications for funding that meet the eligibility criteria in Section B of the application form will be assessed against the following selection criteria. Reviewers may not all be content experts in each specific field, so all technical terms must be explicitly defined, methods clearly explained, and thorough background for the research proposal should be provided.

Summary of Selection Criteria and Weighting

Selection Criteria	Section of Application Form	Weighting
Research Proposal	C-D	30%
Skill Development Plan	E	40%
Host University and Academic Supervisor(s)	D-G	30%

Research Proposal (30%)

Applications should describe the proposed research project by including:

- a clearly defined research question or problem
- a detailed study methodology and outcomes, which are appropriate to research objectives
- a relevant evidence gap that the project aims to fill
- the patient need and potential impact of research on human health
- an approximate timeline and key milestones mapped across the PhD project, and the likelihood of being able to complete the project within the timeframe of a PhD
- an indicative budget that is realistic and appropriate
- roles of researchers who will work on the project
- a program logic model, including inputs, activities, outputs and outcomes for the proposed project.

Skill Development Plan (40%)

Applications should include a well-articulated skill development plan for the student including:

- the specific skills to be developed during the PhD, and why the development of these skills are a priority for building the cell and gene therapy workforce in NSW
- the strategies that will be used to support the student attain the skills in collaboration with the

Academic Supervisor and any other career development partners

- the evaluation measures that will be undertaken to demonstrate the successful attainment of the skills by the student.

Host University and Academic Supervisor(s) (30%)

Applications should include:

- track record of the academic supervisor(s) with respect to the PhD research area
- track record of the academic supervisor(s) in developing the gene and cell therapy sector in NSW
- track record of the academic supervisor(s) with respect to successful outcomes for students
- Curriculum Vitae of the academic supervisor(s)
- the extent to which the Host University will support the skill development plan
- financial and in-kind contributions from the Host University and any other sources, which will be provided for the duration of the PhD candidate's studies.

PhD Project Selection Process

STEP ONE: Initial eligibility appraisal

Following the closing date for applications, the NSW Ministry of Health will determine whether each application has satisfied ALL the eligibility criteria.

STEP TWO: Review by panel of experts

The NSW Ministry of Health will convene a selection panel, comprising experts in relevant fields. The panel will assess applications against the selection criteria and assign a total score to each. Based on these scores, recommendations for funding will be made to the NSW Ministry of Health.

STEP THREE: Notification of successful PhD Projects

The NSW Ministry of Health will notify applicants of the result of their application. This decision is final and may not be appealed. The Host Universities will then, through a merit-based competitive process, select eligible and suitable PhD candidates (see below).

PhD Candidate Selection Process

STEP FOUR: Identification of PhD candidate

The Host University is responsible for identifying a suitable PhD candidate to undertake the research project through Host University procedures for merit-based recruitment. The Office for Health and Medical Research can assist with advertising the available position if desired. The successful candidate should commence studies no later than the end of February 2021, otherwise the scholarship will be rescinded and all funds recovered.

Step FIVE: Funding Agreements

The NSW Ministry of Health will make contact with successful applicants' Host University to establish funding agreements. Note: Funds may not be drawn down until an eligible PhD candidate is selected, approved and commences study.

Prospective PhD Candidates

Details of funding

The table below outlines all funding details for the NSW Health Gene & Cell Therapy PhD Program:

Funding Source	Amount	Duration	Purpose of funding
NSW Health	\$80,000 (\$20,000 per annum)	4 years full time or part time equivalent	Salary costs of PhD candidate
Host University	\$80,000 (\$20,000 per annum)	4 years full time or part time equivalent	Salary costs of PhD candidate

Duration of candidature

The NSW Ministry of Health will support the PhD candidate for four years full time, or part time equivalent. PhDs longer than four years are permitted depending on the Host University's policy, however, the Host University must negotiate funding and other arrangements. These arrangements should be clearly outlined in the application.

Part time students

NSW Health recognises that full-time study may not be possible for all prospective candidates. The Host University will be required to assess applications for part-time study on equal terms with applications for full-time study.

Funding will be pro-rata for part time candidates based on the student load approved by the Host University (e.g. a 50 per cent student load will be awarded \$20,000 per annum over eight years). Confirmation that the Host University has accepted the part time enrolment and the terms of that enrolment will be required.

Conditions applying to the scholarship

The standard scholarship conditions and administrative requirements of the Host University will apply to these scholarships (e.g. recreation leave, sick leave, leave of absence).

Funding conditions and exclusions

The NSW Health scholarship is allocated to the PhD candidate's stipend and cannot be expended on capital works, general maintenance costs, organisational infrastructure or overheads, telephone/communication systems, basic office equipment, rent, or the cost of utilities.

Funding is conditional on the Host University, supervisor(s) and the PhD candidate remaining compliant with all eligibility criteria for the duration of the research program. Recipients must meet all reporting and program evaluation requirements set out in the Funding Agreement. The Agreement emphasises the Host University's role in supporting the candidate's career development.

Once successful PhD candidates and their Host Universities are notified and the Funding Agreement is finalised, a revised copy of the application submitted incorporating any amendments required by NSW Ministry of Health, will act as a record of the planned activities.

PhD Candidates are advised to obtain independent tax advice regarding the PhD Scholarships.

No funding may be drawn down until the PhD candidate has been selected and commenced studies. The PhD candidate may not receive any other scholarship in addition to the NSW Health Gene & Cell Therapy PhD Program scholarship.

NSW Health will not provide additional funding for PhDs greater than four years duration, or part time equivalent, whether this extended candidature is due to pre-arrangement with the Host University, delays with the project, or leave of any type taken by the candidate.

Reporting Requirements

The Host University will enter into a Funding Agreement with NSW Health that sets out its obligations. A schedule for reporting will be outlined in the agreement and will include a requirement to provide:

- Annual Progress Report, with input from the supervisor(s) and the PhD candidate
- Annual Financial Report
- A Final Report upon the conclusion of the project.

Program Evaluation

The NSW Health Gene & Cell Therapy PhD Program will be evaluated against its intended purpose and objectives. NSW Health will perform this evaluation in collaboration with the Host University, supervisor(s), and the PhD candidate. This may include face-to-face meetings for which all parties will be required to make themselves available. Feedback received will be used to inform the future directions of NSW Health PhD support programs.