2022

HEALTH+MEDICAL RESEARCH

COVID-19 Vaccine Acceleration Research Grants

Guidelines

NSW GOVERNMENT

NSW Health

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www.health.nsw.gov.au

www.medicalresearch.nsw.gov.au

Further copies of this document can be downloaded from the Office for Health and Medical Research webpage:
www.medicalresearch.nsw.gov.au

SHPN (OHMR) 220478

1. Call for Applications

NSW Health invites eligible individuals to apply for the NSW COVID-19 Vaccine Acceleration Research Grants Program.

Funding of up to $1 million per project, for a period of up to 24 months, is available.

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.

Application closing date and indicative timelines

Applications open	Applications close	Outcomes notified
Wednesday 22 June 2022	12pm Monday 22 August 2022*	October 2022**

*Late applications will not be accepted under any circumstances.

**Projects must have capacity to commence research within 3-4 weeks of the Outcomes notified date and provide a report on interim outcomes within 6 months from the research start date.

2. Program overview

2.1. Background

The NSW COVID-19 Vaccine Acceleration Research Grants Program has been designed to ensure that research and development of next-generation COVID-19 vaccines in NSW continues to support NSW's rapid response to the pandemic. This means that:

- This funding round will be conducted with compressed time frames, to enable accelerated notification and start date
- Only studies developing next-generation COVID-19 vaccine candidates that meet the definition of Technology Readiness Levels (TRL) 3B-6 will be eligible (see Appendix A).

The grant program has been designed with a robust governance and management framework to ensure that it is conducted in accordance with these principles:

- be **priority-driven**, with a focus on later-stage, next-generation COVID-19 vaccine research that can be commercialised within NSW
- be **agile and responsive** to relevant research findings emerging locally or internationally to ensure that the project remains cutting-edge
- be **expedited** to ensure research and development is planned, conducted and reported in an accelerated manner to rapidly inform clinical and policy decision-making
- **incorporate appropriate governance mechanisms** to ensure accountability

2.2. Objectives

The NSW COVID-19 Vaccine Acceleration Research Grants Program aims to:

- specifically support research projects at TRL 3B-6 (**Appendix A**) that can rapidly undertake preclinical or early phase clinical studies to develop next-generation COVID-19 vaccines
- support research projects that address a need that is not being fully met by currently available COVID-19 vaccines, including but not limited to:
    - improving vaccine safety profile;
    - improving resistance to new and/or multiple variants of SARS-CoV-2;
    - increasing vaccine efficacy;
    - improving responses in immunocompromised or other at-risk populations; and/or
    - improving the longevity of immunity.
- reduce the time from evidence generation to implementation, through rapid planning, conduct and reporting of research that will make good progress towards commercialisation and translation into clinical practice and policy
- fund collaboration, leadership and capacity-building in the NSW vaccine research environment
- bridge a funding gap which may halt the progress of next-generation COVID-19 vaccine research and development in NSW
- support research that will add value to existing or planned initiatives, within the current Australian and international research landscape

2.3. Research Translation

All research projects must have potential to lead to changes in public health practice or policy in the short and/or long term, which may be beyond the funded period. Applications must clearly describe:

- The long-term goal and clinical significance of the research
- The expected pathway for this to occur (note this may not be linear)
- How the researchers will engage with 'next users', i.e. research partners and other stakeholders who will take the research to the next step on the translation pathway.

2.4. Priority populations

Research projects should include consideration of the distribution of the burden of disease within the population and the needs of higher risk and priority populations. These may include older Australians, Aboriginal and Torres Strait Islander people, individuals from a non-English speaking background, socioeconomically disadvantaged groups, people living in regional and remote areas, people with compromised immune systems, people with diagnosed chronic medical conditions, people living in group residential settings such as residential aged care facilities, disability group homes, detention facilities, boarding schools and cruise ships.

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

3. Funding

3.1. Funding amounts

Funding of up to $1 million per project is available. Funding requests over $1 million may be considered with clear justification.

Grants are for research projects or programs and can include a combination of salaries of the research team (clinical and/or non-clinical), backfill for NSW Health clinicians to quarantine research time, and consumables.

Funding for equipment, including single large pieces of equipment, may be funded with justification. Other research infrastructure may also be included in the budget.

3.2. Infrastructure funding

Leverage of existing infrastructure is encouraged and should be detailed in the application.

Funding for additional project-specific enabling infrastructure may be included in the budget.

3.3. Existing funding and co-contributions

Leverage of existing funding to support the proposed research is encouraged, however the applicant must ensure their application does not duplicate or overlap significantly with existing funding (see 5.1). Projects that are currently funded should provide a detailed budget to justify the requirement for additional funding. The additional funding should be specific to the objectives of the COVID-19 Vaccine Acceleration Research Grant Program outlined in these Guidelines.

Funding co-contributions from host and partner organisations are encouraged. At a minimum, host organisations must provide in-kind support, which should be detailed in the budget.

4. Eligibility

Applications must meet all eligibility criteria. Any applications that do not meet one or more of the eligibility criteria will be deemed ineligible and declined without further assessment.

4.1. Alignment with Objectives

All applications will only be eligible for funding if the application demonstrates it aligns with the objectives of the Program (see 2.2).

Projects that do not demonstrate how they align with the objectives of the program will be deemed ineligible and declined without further assessment.

4.2. Chief Investigator

Applicants must nominate a Chief Investigator who will take the lead role in submitting the application, conducting the research, and reporting as required under the grant agreement.

4.2.1. Based in NSW

The Chief Investigator 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, for the entire period of the grant.

4.2.2. Right to work

The Chief Investigator must be an Australian citizen, a permanent resident of Australia or have an appropriate working visa for the full term of the Grant. Chief Investigators 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 also required to provide evidence of their status.

4.2.3. Host organisation

The host organisation is where most of the research is conducted.

The host organisation must conduct health and medical research and be one of the following:

- a university
- an independent medical research institute
- a not-for-profit organisation
- a local health district or other public health organisation.

The host organisation must be in NSW. Clinical Scientists may undertake clinical work separately from where research is undertaken. If the grant is to be used to quarantine research time and backfill a clinical position, the application must also be endorsed by the Chief Executive/Executive Director of the organisation where clinical duties are undertaken.

The host organisation will provide the appropriate infrastructure support for the research project, including wet/dry lab space, computer equipment, and desk space.

4.2.4. 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.

Grant funds must be paid to an administering organisation that can manage funds across financial years, as the full grant amount will be paid upfront.

The administering organisation must be a university, medical research institute, or non-government organisation in NSW.

4.2.5. Ethics and Regulation

The host organisation (and/or where appropriate the administering organisation) must certify that the project has received all appropriate research ethics and regulatory approvals and must ensure these are maintained as required for the duration of the grant. All organisations and personnel contributing to the project must:

- have familiarised themselves with the *Australian Code for the Responsible Conduct of Research*, the *National Statement of the Ethical Conduct of Human Research*, the *Australian Code for the Care and Use of Animals for Scientific Purposes* (including but not limited to the application of the 3Rs 'replacement', 'reduction' and 'refinement' at all stages of animal care and use) or their replacements and other relevant National Health and Medical Research Council policies concerning the conduct of research and agree to conduct themselves in accordance with those policies;
- comply with any requirements of relevant Commonwealth or State or Territory laws; and
- comply with any requirements of regulatory bodies that have jurisdiction over the project. This includes, but is not limited to, the Therapeutic Goods Administration and the Office of the Gene Technology Regulator.

5. Exclusion Criteria

5.1. Duplication of Research

Applicants are required to declare the source, duration and level of funding applied for or already held for the vaccine technology and associated research projects. Applications must clearly describe the purpose of the additional funding and clearly justify how the additional research will be complementary but not duplicative.

Proposals that are deemed to duplicate or overlap significantly with existing or planned research without clear justification of additional value will be deemed ineligible and declined without further assessment.

6. Application process

Applicants must use the appropriate COVID-19 Vaccine Acceleration Grants 2022 Application Form and attach any supporting evidence.

The form is available at: www.medicalresearch.nsw.gov.au

All applications should be submitted by email before 12pm 22 August 2022 to: MOH-OHMRGrants@health.nsw.gov.au.

All applications will be acknowledged within 24 hours by return email. If an acknowledgement is not received, you must contact MOH-OHMRGrants@health.nsw.gov.au immediately. Please

note that the maximum file size is 20MB. Larger files will be rejected by the NSW Health webmail server.

Any queries regarding the COVID-19 Vaccine Acceleration Research Grants 2022 may be directed by email to: MOH-OHMRGrants@health.nsw.gov.au.

7. Review process

7.1. Selection criteria

All applications that meet all eligibility criteria will be assessed against the following selection criteria. Applications should be written in plain English and technical terms explained.

7.1.1. Chief Investigator, Team and Environment (30%)

- Strength, experience and diversity of the multidisciplinary team:
    - skills and experience of team members directly related to the research topic area(s) and methodology of the research project
    - team members' ability to contribute to the research and research translation
    - each team members' relationship to existing research undertaken in the field and with the Chief Investigator
    - the experience, skills and contribution of team members from industry partners, if relevant.
- The key stakeholders and their roles in the research design and the translation of findings.
- Strong project governance structure including evidence of appropriate and sustainable partnerships.
- Evidence of co-development of the proposal and clear ongoing links to the stakeholders that will likely implement the outcomes from the research.
- Extent to which the proposal fosters and maintains a collaborative approach between the researchers and decision makers throughout the project.
- Additional sources of funding are encouraged. For example, co-contributions from host and partner organisations. At a minimum, host organisations must provide in-kind support, which should be detailed in the budget.

7.1.2. Significance and Feasibility (30%)

- Clarity of the research hypothesis and objectives.
- Relevance and alignment of the research hypothesis and objectives to the development of a next generation COVID-19 vaccine in NSW.
- Strength, rigour and appropriateness of the proposed research design and methodology in achieving the aims.
- Feasibility of successfully completing the research project within the proposed timeframe.
- Strength and appropriateness of the risk management plan.
- How the proposed research fits within the current Australian and International research landscape and will add value to existing initiatives and respond to relevant research findings emerging locally or internationally to ensure that the project remains cutting-edge.

7.1.3. Translation and Impact (40%)

- Likelihood and extent of impact the project will have on addressing an unmet need for COVID-19 vaccine technology.
- Likelihood of technology progressing:
    a. through Technology Readiness Level(s) by the end of the funding period; and
    b. beyond the funding period to patient impact, considering acceptability, safety, cost-effectiveness and compatibility with existing infrastructure.
- Scalability and generalisability of results.
- Consideration around equity of access in implementation to ensure the intervention will not contribute to an increased disparity in health outcomes.
- Program Logic with planned outputs and outcomes of the research and how the research will improve clinical practice and/or patient or population outcomes in the short and/or long term. See section 9 for further details.

7.2. Budget

The budget should be detailed and well justified. Budgets will be reviewed based on:

- appropriateness and purpose of each line item
- justification for equipment, facilities and other items of expenditure for the projects

- existing funding for the research, and how this relates to the additional funding requested
- other cash and/or in-kind contributions for the project.

8. Selection and funding process

Step 1: Eligibility check

Following the closing date for applications, NSW Health will determine if the application has satisfied all eligibility criteria.

Step 2: Assessment by independent expert panel

An independent selection panel of expert reviewers 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 NSW Health.

Step 4: Decision and notification

NSW Health will determine grant recipients and amounts. All applicants will receive a notification of the outcome of their application.

Step 5: Funding Agreements

NSW Health will contact organisations for successful projects to execute a funding agreement. A standard, non-negotiable funding agreement will be used.

9. Program Logic and research impact

9.1. Program Logic

Applicants are required to submit a Program Logic diagram with their application, including project aim, inputs, activities, outputs, and expected outcomes and impacts.

Note that outcomes and impacts may not be realised during the funded period, they may be projected to occur in the future. Particularly for basic science, the 'next users' who are responsible for taking the research findings to the next step for translation should be involved from the start of the project so they understand the research and can move the findings towards translation.

9.2. Research Impact Assessment

The Program Logic will be used to optimise the probability 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 Advancement

- New interventions, treatments, diagnostics, or targets.
- New clinical or medical prototypes.
- Peer-reviewed publications and presentations at conferences.
- Media coverage and other non-peer-reviewed publications.

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: Health and Community Impact

Improved health outcomes, including change in time to develop an outcome likelihood of an outcome occurring.

Domain 5: Economic Benefit

- 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.

10. Funding conditions and exclusions

1. Research must be conducted in the NSW health system or affiliated organisation (university, medical research institute, industry partner) based in NSW.
2. Research may link with projects outside NSW but funding must be expended in NSW and the research must directly improve health in NSW.

3. The grant 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.
4. Programs of research must incorporate appropriate governance mechanisms to ensure accountability across the NSW public health system.
5. Biobanking costs that do not utilise the NSW Health Statewide Biobank are not funded via this program.
6. Funding is conditional on the Chief Investigator and the Chief Executive(s) of the host organisation (and administering organisation where relevant) signing the declaration on the application form, which outlines the host organisation's (and administering organisation's) obligations to the Chief Investigator.
7. Successful applicants who fail to meet milestones without adequate justification will have their funding withdrawn.
8. Grants may be applied for regardless of other funding currently held or applied for, including NHMRC fellowships, provided there is no duplication as outlined in section 5.1.

10.1. Intellectual Property

Intellectual property (IP) arrangements must 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 must be detailed in the application.

10.2. Reporting requirements

The host organisation (or administering organisation where appropriate) will enter into a funding agreement with NSW Health that sets out reporting and other obligations.

The schedule for reporting will include requirements to provide:

- At one month, a complete study protocol and confirmation that the study has commenced with appropriate ethics and governance approvals
- Any updates to study protocols throughout the study
- Preliminary results at six months
- Annual progress reports including milestones and deliverables
- Annual financial reports
- A final report following the conclusion of the term of the grant

10.3. Program assessment and evaluation

The grants program will be assessed periodically to ensure it is meeting its objectives. This will be done in collaboration with the host organisations and grant recipients.

Grant recipients may be asked to meet with NSW Health from time to time during the funding and afterwards. Meetings with recipients will facilitate feedback and inform the future direction of the grants.

Appendix A

Technology Readiness Levels

Level	Description	Eligible for COVID-19 Vaccine Acceleration Research Grant Program?
TRL 1	**Review of Scientific Knowledge Base** Active monitoring of scientific knowledge base. Scientific findings are reviewed and assessed as a foundation for characterizing new technologies.	No
TRL 2	**Development of Hypotheses and Experimental Designs** Scientific "paper studies" to generate research ideas, hypotheses, and experimental designs for addressing the related scientific issues. Focus on practical applications based on basic principles observed. Use of computer simulation or other virtual platforms to test hypotheses.	No
TRL 3	**Target/Candidate Identification and Characterisation of Preliminary Candidate(s)** Begin research, data collection, and analysis in order to test hypothesis. Explore alternative concepts, identify and evaluate critical technologies and components, and begin characterisation of candidate(s). Preliminary efficacy demonstrated *in vivo*. **3A** Identify target and/or candidate.	No
	3B Demonstrate *in vitro* activity of candidate(s) to counteract the effects of the threat agent. **3C** Generate preliminary *in vivo* proof-of-concept efficacy data (non-GLP (Good Laboratory Practice)).	Yes
TRL 4	**Candidate Optimisation and Non-GLP In Vivo Demonstration of Activity and Efficacy** Integration of critical technologies for candidate development. Initiation of animal model development. Non-GLP *in vivo* toxicity and efficacy demonstration in accordance with the product's intended use. Initiation of experiments to identify markers, correlates of protection, assays, and endpoints for further non-clinical and clinical studies. **Animal Models:** Initiate development of appropriate and relevant animal model(s) for the desired indications. **Assays**: Initiate development of appropriate and relevant assays and associated reagents for the desired indications. **Manufacturing:** Manufacture laboratory-scale (i.e. non-GMP (Good Manufacturing Practice)) quantities of bulk product and proposed formulated product.	Yes

	4A Demonstrate non-GLP *in vivo* activity and potential for efficacy consistent with the product's intended use (i.e. dose, schedule, duration, route of administration, and route of threat agent challenge). **4B** Conduct initial non-GLP toxicity studies and determine pharmacodynamics and pharmacokinetics and/or immune response in appropriate animal models (as applicable). **4C** Initiate experiments to determine assays, parameters, surrogate markers, correlates of protection, and endpoints to be used during non-clinical and clinical studies to further evaluate and characterise candidate(s).	
TRL 5	**Advanced Characterisation of Candidate and Initiation of GMP Process Development** Continue non-GLP *in vivo* studies, and animal model and assay development. Establish draft Target Product Profiles. Develop a scalable and reproducible manufacturing process amenable to GMP. **Animal Models:** Continue development of animal models for efficacy and dose-ranging studies. **Assays:** Initiate development of in-process assays and analytical methods for product characterisation and release, including assessments of potency, purity, identity, strength, sterility, and quality as appropriate. **Manufacturing:** Initiate process development for small-scale manufacturing amenable to GMP. **Target Product Profile:** Draft preliminary Target Product Profile. Questions of shelf life, storage conditions, and packaging should be considered to ensure that anticipated use of the product is consistent with the intended use for which approval will be sought from the TGA. **5A** Demonstrate acceptable Absorption, Distribution, Metabolism and Elimination characteristics and/or immune responses in non-GLP animal studies as necessary for Clinical Trial Notification (CTN) or the Clinical Trial Application (CTA) filing. **5B** Continue establishing correlates of protection, endpoints, and/or surrogate markers for efficacy for use in future GLP studies in animal models. Identify minimally effective dose to facilitate determination of "humanised" dose once clinical data are obtained.	Yes
TRL 6	**GMP Pilot Lot Production, CTN/CTA Submission, and Phase 1 Clinical Trial(s)** Manufacture GMP-compliant pilot lots. Prepare and submit CTN/CTA package to TGA and conduct Phase 1 clinical trial(s) to determine the safety and pharmacokinetics of the clinical test article. **Animal Models:** Continue animal model development via toxicology, pharmacology, and immunogenicity studies. **Assays:** Qualify assays for manufacturing quality control and immunogenicity, if applicable. **Manufacturing:** Manufacture, release and conduct stability testing of GMP-compliant bulk and formulated product in support of the CTN/CTA and clinical trial(s). **Target Product Profile:** Update Target Product Profile as appropriate. **6A** Conduct GLP non-clinical studies for toxicology, pharmacology, and immunogenicity as appropriate. **6B** Prepare and submit ethics and governance applications to support initial clinical trial(s).	Yes

	6C Complete Phase 1 clinical trial(s) that establish an initial safety, pharmacokinetics and immunogenicity assessment as appropriate.	
TRL 7	**Scale-up, Initiation of GMP Process Validation, and Phase 2 Clinical Trial(s)** Scale-up and initiate validation of GMP manufacturing process. Conduct animal efficacy studies as appropriate. Conduct Phase 2 clinical trial(s). **Animal Models:** Refine animal model development in preparation for pivotal GLP animal efficacy studies. **Assays:** Validate assays for manufacturing quality control and immunogenicity if applicable. **Manufacturing:** Scale-up and validate GMP manufacturing process at a scale compatible with USG requirements. Begin stability studies of the GMP product in a formulation, dosage form, and container consistent with Target Product Profile. Initiate manufacturing process validation and consistency lot production. **Target Product Profile:** Update Target Product Profile as appropriate. **7A** Conduct GLP animal efficacy studies as appropriate for the product at this stage. **7B** Complete expanded clinical safety trials as appropriate for the product (e.g., Phase 2).	No
TRL 8	**Completion of GMP Validation and Consistency Lot Manufacturing, Pivotal Animal Efficacy Studies or Clinical Trials, and TGA Approval or Licensure** Finalise GMP manufacturing process. Complete pivotal animal efficacy studies or clinical trials (e.g., Phase 3), and/or expanded clinical safety trials as appropriate. Prepare and submit application to register with regulator(s). **Manufacturing:** Complete validation and manufacturing of consistency lots at a scale compatible with USG requirements. Complete stability studies in support of label expiry dating. **Target Product Profile:** Finalise Target Product Profile in preparation for TGA approval. **8A** Complete pivotal GLP animal efficacy studies or pivotal clinical trials (e.g., Phase 3), and any additional expanded clinical safety trials as appropriate for the product. **8B** Prepare and submit application to register with regulator(s). **8C** Obtain regulatory approval or licensure.	No
TRL 9	**Post-Licensure and Post-Approval Activities** **9A** Commence post-licensure/post-approval and Phase 4 studies (post-marketing commitments), such as safety surveillance, studies to support use in special populations, and clinical trials to confirm safety and efficacy as feasible and appropriate. **9B** Maintain manufacturing capability as appropriate.	No

Source: Amended from https://www.medicalcountermeasures.gov/trl/integrated-trls/