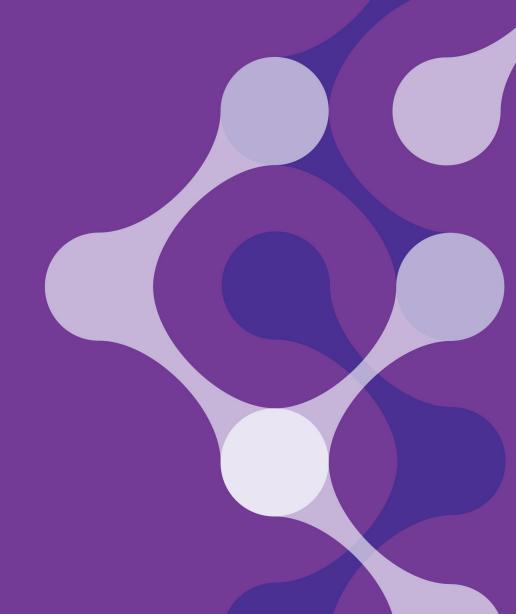
HEALTH+MEDICAL RESEARCH

COVID-19 Research Grants Round 1

Guidelines





NSW Health 100 Christie Street St Leonards NSW 2065 (02) 9391 9228

www.health.nsw.gov.au

https://www.medicalresearch.nsw.gov.au/covid-19-research/

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# **Call for Applications**

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

Funding of up to \$1 million per project, for a period of up to 24 months, is available. Funding requests over \$1 million may be considered with clear justification.

Grants open: 6 May 2020 Closing date: 20 May 2020

# **Program overview**

The COVID-19 research program has been designed to produce evidence that supports the NSW response to the COVID-19 pandemic. This means that:

- Round 1: Funding will be allocated to an initial rapid funding round with short application and review timeframes. This initial round will focus on research topics that address key COVID-19 response needs. This funding round has been developed for projects that are ready to commence shortly and require rapid funding.
- Round 2: Funding will be reserved for a second round of proposals requiring a longer development period. This round will encompass a broader range of topic areas that have been identified as important to support patients, health care workers, the community and the health system in responding to COVID-19.
- The peer review process will be targeted to projects that are high priorities for NSW Health to address the NSW pandemic.

# NB: There is sufficient funding to support both funding rounds.

The research 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 issues of greatest policy and practice impact on the COVID-19 response
- Be expedited to ensure research is planned, conducted and reported in a timely manner to inform clinical and policy decision making
- Incorporate appropriate governance mechanisms to ensure accountability across the NSW public health system and NSW community.

# **Objectives**

The objectives of this Program are to:

- Support research that provides evidence to inform priorities for the immediate COVID-19 response in NSW
- Support research into medium and longer term issues related to the pandemic in patients, the community and the health system.
- Reduce the time from evidence generation to implementation. The program supports the rapid planning, conduct and reporting of research, so that positive findings can be rapidly translated into clinical practice and policy.

# **Funding areas**

Round 1 funding will be targeted specifically to the research topic areas at Appendix A. In accordance with the objectives of the program, projects that do not directly address one or more of these topic areas will be deemed ineligible.

Funding will be available for two types of project.

# Additional funding for existing research

Applications requesting funding for the expansion of currently funded research that may be applicable to COVID-19. Funding may enhance or expand existing projects to incorporate elements addressing COVID-19, or expedite outcomes related to COVID-19. Projects will be assessed for alignment with criteria outlined in these COVID-19 Research Grant Guidelines. Evidence of existing peer-reviewed funding and ethics and governance approvals must be supplied.

### ii. New projects

Applications for new projects that align with topic areas and meet the eligibility criteria may be submitted.

# **Closing dates**

#### Round 1

The initial round will fund projects that will provide rapid evidence to inform the current COVID-19 response in NSW.

Funding round	Applications open	Applications close	Outcomes notified
Round 1	6 May 2020	20 May 2020	By 30 June 2020

Round 1 projects must have capacity to commence research within 3-4 weeks of receiving funding, and provide a report on interim outcomes within 6 months from the research start date.

#### Round 2

The second round is planned for release in June 2020 to accommodate projects that require a longer lead time for development. A broader list of research topics will be released for round 2, including:

- 1. Diagnostics
- 2. Prevention of infection
- 3. Treatment
- 4. Public and population health
- 5. The health system response
- 6. Mental health and wellbeing
- 7. Behavioural insights and communications
- 8. Whole of Government response and impacts

Further details on round 2 research topics will be released in June. Applications submitted for the first round but not funded may be reconsidered in the second round depending on alignment with priorities. Applicants in this category may be offered an opportunity to revise their proposal if required.

#### **Clinical Trials**

Applications are sought for clinical trials, both commercial and non-commercial, particularly vaccine and therapeutic trials. For therapeutic trials, applicants are strongly encouraged to use an adaptive platform trial study design.

Clinical trial applicants are encouraged to develop collaborations between academic and other research organisations and industry.

For clinical trials, a protocol or protocol synopsis must be attached to the application form, along with an Investigators Brochure if required. The following funding principals apply:

- If the lead Principal Investigator is within NSW, funding for both the project management (lead component) and NSW sites may be sought.
- If the lead Principal Investigator is outside NSW, funding may only be sought for NSW sites.
- Funding for clinical trials infrastructure may be included on the application.

Applicants seeking funding for commercial and non-commercial vaccine and therapeutic clinical trials are strongly encouraged to consult clinicaltrialsNSW for advice on integration with existing research and enabling infrastructure, before submitting the application. Please contact

<u>clinicaltrialsNSW@health.nsw.gov.au</u> early in the development of your application for advice.

#### **Context assessment**

Applicants must include a concise summary of how the proposed research fits within the current Australian and International research landscape, with justification of how the proposal will add value to existing initiatives. Proposals that duplicate existing research without clear justification of additional value will not be funded.

Applications should also include consideration of how the research may be modified if the suppression phase of COVID-19 is sustained in NSW and COVID-19 patient numbers are maintained at a low level over time. The application may include a table of power calculations based on different scenarios of case numbers and/or a possible modified research hypothesis that would be relevant within the projected COVID-19 context in 3-6 months.

# Research collaborations and partnerships

Host Organisations may identify and engage relevant partners to support effective 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.

For assistance with engaging with a NSW Ministry of Health Policy Branch, please contact MOH-COVID-19Grants@health.nsw.gov.au.

# **Industry Partners**

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.
- 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 Australian industry entity.
- All partners must contribute resources to the project. Industry matched funding is encouraged, but not required.

# **Existing funding and co-contributions**

Leverage of existing funding to support the proposed research is encouraged. 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 NSW Health priorities for COVID-19 published with each funding round.

Funding co-contributions from host and partner organisations are encouraged.

Host organisations must provide in-kind support, which should be detailed in the budget.

#### Clinician researchers

Clinicians, both medical and non-medical, are encouraged to apply.

Clinicians may use up to 50% of the grant to backfill their clinical role, with justification. The salary limits are as follows:

- Clinician medical: Salary limit up to 0.6 FTE Staff Specialist or Visiting Medical Officers.
- Clinician non-medical: Salary limit up to 0.6
  FTE as per Allied Health (including Pharmacist and radiographers) and Nursing awards.

#### **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.

# **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.

# **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 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.

# 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.

# **Funding conditions**

- Research must be conducted in the New South Wales health system or affiliated organisation (university, medical research institute, industry partners).
- 2. Research may link with projects outside NSW, but funding must be expended in NSW.
- 3. Research must be conducted in accordance with ethical requirements, noting that studies

conducted as part of a public health investigation under the NSW Public Health Act 2010 do not require review by a human research ethics committee.

- Programs of research must incorporate appropriate governance mechanisms to ensure accountability across the NSW public health system.
- Grants must not be spent on capital works, general maintenance costs, organisational infrastructure or overheads, telephone and communication systems, basic office equipment, such as desks and chairs, rent and the cost of utilities.
- 6. Biobanking costs are not funded via this program.
- 7. Funding is conditional on the Chief Investigator and the Chief Executive of the host organisation (and administering organisation where required), signing the declaration on the application form, which outlines the organisations' obligations to the Chief Investigator.
- 8. Grants provided are one-line grants, not fellowships.
- 9. Grants may be applied for regardless of other funding currently held or applied for, including NHMRC fellowships. Leverage of existing and other funding sources is encouraged. Applicants are required to declare the source, duration and level of funding already held for research in the subject area of the application.
- Successful applicants who fail to meet milestones without adequate justification will have their funding withdrawn.

# **Application process**

Applicants must use the appropriate COVID-19 Grants 2020 Application Form and attach any supporting evidence.

The form is available at:

https://www.medicalresearch.nsw.gov.au/covid-19-research/

All applications should be submitted by email to: MOH-COVID-19Grants@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-COVID-19Grants@health.nsw.gov.au immediately.

Any queries regarding NSW COVID-19 Research Program grants may be directed by email to: MOH-COVID-19Grants@health.nsw.gov.au.

# **Eligibility criteria**

Applications must meet all eligibility criteria.

# 1. Rapid start

Round 1 projects must have demonstrated capacity to commence research within 3-4 weeks and provide a report on interim outcomes within 6 months from the research start date.

#### 2. Address specific topic areas

Applications must directly address advertised research topic areas for each round.

#### 3. Based in NSW

The Chief Investigator must reside in NSW and must be employed by an eligible NSW-based host organisation for the entire period of the grant.

Note: for clinical trials the Chief Investigator for the grant must reside in NSW, but the lead Principal Investigator is not required to reside in NSW.

#### 4. Submit a complete application

The Chief Investigator must fully complete the application form, attach all relevant and required documentation, sign the declaration on the form and include certification from the host and other organisations as required.

# 5. Australian citizen, permanent residency status or appropriate visa

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. 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.

# 6. Host organiation requirements

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

#### 7. Administering organisation requirements

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

- a. 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.
- b. If the host organisation is a Local Health District or other public health organisation, grant funds must be paid to an administering organisation.
- The administering organisation must be a university, medical research institute, or nongovernment organisation in NSW.

# Selection criteria

Applications that meet all eligibility criteria and are selected at first review will be assessed against the following selection criteria. Applications should be written in plain English and technical terms explained.

# 1. Skills and experience of the research team and collaborators (30%)

The following criteria will be considered by reviewers:

- 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.
- Key stakeholders involved in the research design and the translation of findings, with roles clearly identified.
- 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.

# 2. Scientific quality of the research project (30%)

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:

- Clarity of the research hypothesis and objectives.
- Relevance and alignment of the research hypothesis and objectives to the COVID-19 response in NSW, with potential to adapt the research protocol to the changing COVID-19 situation as required.

- Demonstration of how the research will advance existing COVID-19 knowledge and why this is important.
- The extent to which the proposed research and intervention is innovative and novel and addresses known COVID-19 research gaps.
- Strength, rigour and appropriateness of the proposed research design and methodology.
- Feasibility of the research project within the proposed timeframe.
- Potential 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.

# 3. Evidence generated will be directly translatable into supporting the COVID-19 response in NSW (40% weighting)

The following criteria will be considered by reviewers:

- Likelihood and extent of impact the study results will have on the COVID-19 pandemic response.
- Potential to generate new and relevant evidence that is directly linked to a NSW Health COVID-19 research topic.
- Potential to yield new methods and techniques for responding to the COVID-19 pandemic.
- Quality, completeness and feasibility of the pathway to research translation, 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.
- How the proposed research fits within the current Australian and International research landscape and will add value to existing initiatives.

# **Budget**

The budget should be detailed and well justified. NSW will review budgets for recommended projects 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.

# Selection and funding process

# **Review process**

- Eligibility check Applications will undergo initial review by NSW Health to ensure eligibility criteria are met.
- First review an initial assessment of eligible applications will be undertaken by NSW Health and scientific experts to identify applications that directly answer questions of relevance to the NSW COVID-19 response and will add significant new knowledge to the area and not duplicate other research planned or underway.
- Second review applications selected to progress will undergo scientific review according to published selection criteria. Additional peer reviews may be requested from other technical experts as required. Applicants may be required to present their proposal to NSW Health and/or independent reviewers, and address issues raised in person.
- 4. The scientific review process will result in recommendations to NSW Health who will then make a final decision on grant recipients and amounts. Applicants will be notified.
- 5. NSW Health will enter into funding agreements with the host or administrative organisation for each successful applicant.
- NSW Health reserves the right to seek further scientific review of study protocols, including any updates throughout the study, to ensure ongoing alignment with program objectives and priorities.

# **Funding agreements**

A standard, non-negotiable funding agreement will be used. All projects will be required to report regularly against key milestones and deliverables, and provide funding acquittals as outlined in the agreement.

# Reporting requirements

The host or administrative organisation 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 1 month, a complete study protocol including program logic, output and outcome measures and confirmation that the study has commenced with appropriate ethics and governance approvals
- Any updates to study protocols throughout the study
- Preliminary results at 6 months
- Annual progress reports including milestones and deliverables
- Annual financial reports
- A final report following the conclusion of the term of the grant.

# **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 period. Meetings with recipients will facilitate feedback and inform the future direction of the grants.

#### Appendix A: COVID-19 Research Program Topic Areas

#### Research Topics - Round 1

#### Diagnostics research

- Enabling representative seroprevalence studies and improving ease and efficiency of serology testing
- Diagnostic approaches that reach vulnerable populations, including ease of access and supply chain issues
- Nucleic Acid Testing (NAT) testing and increasing access/scale/testing efficiency/turnaround time (TAT)

#### **Prevention of infection**

- COVID vaccine clinical trials (excluding vaccine research and development)
- Preventing infection in health and aged care workers, including transmission mechanisms and use of Personal Protective Equipment (PPE)
- Infection control practices in the community
- Preventing transmission in vulnerable community settings and workplaces
- · Preventing transmission in Aboriginal communities, including rural, remote and urban settings

#### Treatment, including antivirals and immunosuppressive agents

- Increasing uptake and ease of access to adaptive clinical trial platforms, to enable rapid assessment of existing drugs, including repurposed and experimental drugs
- Using adaptive clinical trials to prevent or minimise unmonitored off-label use of drugs
- Predicting and managing early disease and severe disease in acute care facilities and the community
- · Post-acute management, rehabilitation, and longer term sequelae

#### Public and population health

- Impacts of COVID-19 prevention measures such as social distancing, including on preventive health habits
- Safe self-isolation barriers and enablers and reducing onward transmission, including in Aboriginal communities
- Natural history, immunity and re-infection of COVID in different groups/subpopulations
- Assessing and maintaining the uptake and effectiveness of population level screening programs, e.g. breast cancer screening
- Assessing impacts of COVID-19 on uptake and effectiveness of existing population-level prevention programs and preventive health habits
- Assessing the effectiveness of newly emerging technologies and apps in the public health response

#### **Exclusions**

The following topics are either not currently required or already funded. These topics will not be funded via COVID-19 grants.

- Modelling the surge capacity of the health care system including ICU utilisation, and growth rates and case projections for SARS CoV-2 infections in NSW.
- Visual display of existing epidemiological information including maps of cases.
- Building new statewide information technologies and systems.
- Further assessment of previously validated commercial serology and diagnostic tests.
- · Vaccine research and development.
- Population-based COVID-19 serological surveys (note these are already underway).
- Assessment of COVID-19 exposure in high risk groups including close contacts of cases and health care workers; and attack rate, hospitalisation, and death rates in health and aged care setting.
- · Descriptive epidemiological studies.
- Investigation and analysis of COVID-19 in schools and early learning settings.
- Case control studies comparing health and aged care worker PPE use and practices with controls have already been funded. If your application is in this area, please justify how your proposal adds evidence and value.