# HEALTH+MEDICAL RESEARCH

# COVID-19 Research Grants: Round two

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**

The NSW Health COVID-19 Research Grants Program has been designed to produce evidence that supports the NSW response to the COVID-19 pandemic. Round one of the program has concluded. Round two is now open.

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.

### New for Round Two:

- Round two has an Expression of Interest (EOI) stage. Submission of a full application is by invitation only.
- 2. EOIs will be submitted online, not by email.
- Research Topics and Exclusions have been updated to reflect current NSW Health system priorities (Appendix 1).

### **Round Two Timelines**

Round two stage	Open	Close	Outcomes notified
Expression of Interest	27 July 2020	17 August 2020	16 September 2020
Invitation to Full Application	16 Sept 2020	October 2020	November 2020

Host organisations must endorse EOIs prior to submission. Late submission of signature pages or other supporting documentation will not be accepted for round two.

### Applications which were not successful in Round One may be re-submitted in Round Two

Applications submitted for Round One which were unsuccessful may submit an EOI in Round Two if the project fulfils eligibility requirements, including alignment with updated research topics at Appendix A.

Round One projects will not automatically rollover into Round Two. A new EOI must be submitted.

General feedback on Round One applications is available at <u>https://www.medicalresearch.nsw.gov.au/covid-19-</u> <u>research/.</u>

### **Program overview**

### Introduction

The research program has been designed with a robust governance and management framework to ensure that it is conducted in accordance with the following 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.

The peer review process will be targeted to projects that are high priority for NSW Health to address the NSW pandemic.

### **Program 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 significant findings can be rapidly translated into clinical practice and policy.

### **Research Topic Areas**

Round Two funding will be targeted specifically to the research topic areas at Appendix 1. 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.

### **Types of projects**

Funding will be available for two types of projects:

### i. Additional funding for existing research

Applications may be made to expand a research project which has already been awarded funding via a peer review grant process, by adding a COVID-19 research question. Grant funds 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 the research topic areas listed in Appendix A and must meet eligibility criteria outlined on page 7. Evidence of existing peer-reviewed funding, ethics and governance approvals must also be supplied at full application stage.

#### ii. New projects

Applications may be made for new projects that have not been awarded funding via a peer review grant process. New projects must align with the research topic areas listed in Appendix A and meet the eligibility criteria outlined on page 7.

### **Budget guidelines**

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 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.

### i. 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.

#### ii. Existing funding and co-contributions

Use 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 research topics at Appendix 1.

# Before you apply

### Value of proposed research

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 considered for funding.

Further information about what is required at the Expression of Interest and Full Application stages is outlined in the Selection Criteria on pages 8-10.

Applications may 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 are strongly encouraged to 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 <u>MOH-COVID-19Grants@health.nsw.gov.au</u>.

### **Industry Partnerships**

The program encourages outcome-focused collaborative research partnerships between industry entities and research organisations. The following principles apply:

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

### **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.

Applicants should consult the resources on engaging with Aboriginal and Torres Strait Islander communities available at

https://www.medicalresearch.nsw.gov.au/designingresearch-study/.

NSW Health encourages diversity in the composition of research teams, for example by including Aboriginal people. Projects that focus on different population groups should include representatives from those populations in the research team.

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

### **Diagnostics applications**

Projects proposing new technologies in the diagnostics space must nominate where the technology currently sits on the Technology Readiness Level Scale (Appendix 2), where funding from a COVID-19 research grant would place the technology on the scale at the conclusion of the project, and where future funding would be sought to continue progression along the scale. **Note: technologies are expected to be ready to use in a clinical setting within two years from commencement of research.** 

Please provide a brief outline at EOI stage. More detail will be required at full application stage.

### Evaluations of models of virtual care

NSW Health is currently developing a monitoring and evaluation approach to assess the impact of virtual care. This approach will measure impact across the four domains of value-based health care:

- the outcomes that matter to patients (e.g. clinical and patient reported outcomes)
- patient and carer experience of receiving care
- clinician experience of providing care
- effectiveness and efficiency.

The monitoring and evaluation approach will be:

 coordinated and utilise common measures to assess patient and clinician experience from the patient cohort, service, system and care modality perspectives

• Staggered and utilise a blended approach across the short, medium and longer terms.

This grant provides an opportunity to undertake research that will complement the NSW Health monitoring and evaluation approach to virtual care, as well as provide insight into other COVID-19 related areas of interest.

For assistance with engaging with a NSW Ministry of Health Policy Branch that can provide advice on the NSW Health monitoring and evaluation approach to virtual care, please contact <u>MOH-COVID-</u> <u>19Grants@health.nsw.gov.au</u>.

# Australian National Fabrication Facility support

The Australian National Fabrication Facility (ANFF) can provide qualifying projects with supported access to the ANFF portfolio of micro/nanofabrication equipment and expertise. Please contact the ANFF directly at FightingCOVID@anff.org.au for more information if relevant to your project.

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# **Clinical Trials**

### i. Types of trials eligible under Round Two

Applications are sought for the following types of clinical trials:

- Early-phase interventional trials of novel vaccines, therapeutic agents or devices that may have direct application for COVID-19. Locally developed interventions are also encouraged. Please contact <u>clinicaltrialsNSW@health.nsw.gov.au</u> for advice on your application.
- Trials in other eligible research topics, excluding therapeutic intervention trials (see adaptive platform trials section below).

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

### ii. Adaptive platform trials

Other clinical intervention trials, apart from those listed above, are not eligible to apply under this grants program. NSW Health is currently considering future funding models for clinical trials that take into account the low number of new COVID-19 cases, the international trend to use platform trials, the use of adaptive trial methodology and the rapidly evolving evidence for COVID-19 therapeutics. Information will be posted on <u>https://www.medicalresearch.nsw.gov.au</u> when available.

### **Application requirements**

For clinical trials, a protocol or protocol synopsis may be uploaded at the Expression of Interest stage, if required. An Investigators Brochure can be attached at the full application stage, 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 noncommercial vaccine and therapeutic clinical trials are strongly encouraged to consult <u>clinicaltrialsNSW</u> for advice on integration with existing research and enabling infrastructure, before submitting the application. Please contact clinicaltrialsNSW@health.nsw.gov.au early in the development of your application for advice.

### Infrastructure funding for clinical trials

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

### **Application Process Overview**

The application process for Round Two of the COVID-19 Research Grant Program has two stages.

Stage 1. Expression of Interest (EOI)

Stage 2. Full application (by invitation only)

### Steps in the application process

### 1. Eligibility check

Expressions of Interests will undergo initial review by NSW Health to ensure eligibility criteria are met.

### 2. EOI review

An assessment of eligible Expressions of Interest will be undertaken by NSW Health and scientific experts according to the selection criteria outlined on pages 8-9. Please note that that project summary will be used for this review.

### 3. Invitation to progress to full application

Applicants selected to progress to stage two will be invited to submit a full application on forms supplied by NSW Health. Applicants who are not selected to progress will be notified that they were not successful.

### 4. Full application review

Expressions of Interest selected to progress to Full Application Stage will undergo scientific peer review according to the selection criteria outlined on pages 9-10. Additional peer reviews may be requested from other technical experts as required. Applicants may be required to discuss their proposal to NSW Health or independent reviewers, and address any issues raised, before a final funding decision is made.

### 5. Recommendations to NSW Health

The scientific review process will result in recommendations to NSW Health who will make a final decision on grant recipients and amounts. Applicants will be notified.

# **Eligibility criteria**

Applications must meet all eligibility criteria.

### 1. Address specific topic areas

Applications must directly address Round Two Research Topic Areas listed in Appendix A of these Guidelines.

### 2. 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.

# 3. Submit a complete EOI (and full application if progressing to Stage 2)

The Host Organisation or Administering Organisation must submit a complete EOI through the online form, including the Project Summary signed by an authorised representative of the Host Organisation.

Applicants that progress to Stage 2 must submit a complete full 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.

# 4. 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.

### 5. Host organisation requirements

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

a. 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.

b. 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 full application must also be endorsed by the Chief Executive/Executive Director of the organisation where clinical duties are undertaken.

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

# 6. 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 that can manage funds across financial years, as the full grant amount will be paid upfront.
- c. The administering organisation must be a university, medical research institute, or non-government organisation in NSW.

# Stage One: Expression of interest

### **Overview of EOI Stage**

- i. The **Project Summary** is developed and endorsed by the Host Organisation using the template available <u>here.</u>
- ii. Once the Project Summary is ready, the online EOI form can be completed at: <u>https://ohmrredcap.health.nsw.gov.au/surveys/?</u> s=T9XEJ3XHTW
- Expressions of Interest (EOIs) must be submitted using the online form by 17:00hrs AEST Monday 17 August 2020.

The following information is required in the online EOI form:

- 1. Administrative information: Sections A-E
- The Project Summary: to be uploaded in Section
  F. The Project Summary must be signed by an authorised representative of the Host Organisation.

The table below provides an overview of the sections included in the EOI online form:

Section A	Registration	
Section B	Chief Investigator Details	
Section C	Host Organisation Details	
Section D	Administering Organisation Details	
Section E	Project Details	
Section F	Section F Upload Project Summary endorsed and signed by the Host Organisation	

# Project Summary to be endorsed prior to submitting the EOI

- 1. The Chief Investigator completes the Project Summary using the template available.
- The Chief Investigator submits the project summary to their Host Organisation for authorisation and sign off in advance of the submission deadline. Additional time has been built into the EOI preparation phase to allow this to occur.
- 3. An authorised representative of the Host Organisation signs the Project Summary.
- The Project Summary is saved in PDF format, ready to be uploaded in Section F when submitting the EOI.

### **EOI Submission Process**

#### 1. Who should submit?

The Host Organisation or Administering Organisation should submit the EOI on behalf of the Chief Investigator, through the <u>online form</u>.

Once the Project Summary is ready, the online submission process is expected to take 15-20 minutes. If the person submitting the EOI does not complete the online submission in one sitting, they will have the option to 'Save & Return' and be automatically emailed a return code.

The return code email should be retained. If the return code is lost, the EOI form can be started again.

### 2. Completing submission

The EOI is not complete until a confirmation email is received by the person submitting the EOI. Once 'Submit' is clicked, it is recommended that the person submitting the EOI downloads a copy of the completed EOI form for the Host Organisation's/Administering Organisation's records.

### NSW Health will immediately acknowledge receipt of the EOI by sending a confirmation email with a PDF copy of the completed EOI to the person submitting the EOI.

If the person submitting the EOI does not receive a confirmation email, it is their responsibility to follow up within 24 hours, by emailing <u>MOH-COVID-</u> <u>19Grants@health.nsw.gov.au</u> or calling 02 9461 7120. Please do not include attachments within the follow up email.

The acknowledgement email must be saved and provided to NSW Health if required as evidence of submission. If an email acknowledging receipt of the EOI is not available, no further correspondence regarding the EOI will be entered into.

### Please note NSW Health will ONLY accept:

- 1. Submission of the EOI through the online form.
- 2. Project summaries endorsed by an authorised representative of the Host Organisation, and uploaded though the <u>online form</u>. Project summaries without a signed declaration by the Host Organisation will not be reviewed. Late submission of signature pages is not permitted.
- 3. Files less than 10MB in size.

# Selection criteria at EOI stage

Across all research topics, NSW Health will prioritise projects for funding that fulfil the following criteria:

- Research using a system-wide approach so that findings can be scaled in NSW.
- Research that has potential to be translated directly into policy and practice.
- Studies measuring clinically important outcomes.
- Large, multidisciplinary and/or collaborative projects and trials.
- Research that includes consideration of health equity between different population groups.

### **Expression of Interest Selection Criteria**

The Project Summary will be forwarded to reviewers for shortlisting purposes. It should aim to clearly justify that the research topic under investigation is important for the COVID-19 response in NSW, and that the

research proposed can provide strong evidence and be translated into policy and practice.

The summary should be succinct and written in plain English, and the format should be easy to follow.

Reviewers will use the following selection criteria to assess the Project Summary:

- 1. Strength and utility of the research plan and project team (50%)
- 'Need' for the research is clearly explained and is relevant to the NSW COVID-19 response.
- Research question and aim are clearly aligned with priority research topics at Appendix 1.
- Methods are detailed and clear, with description of a strong and appropriate study design, the sample size required, and data analysis methods proposed.
- Intended outcomes of the study are clinically important and able to provide useful information for the COVID-19 response in NSW. Outcomes must be clearly described and achievable within the specified timeframe.
- Impacts of the research on patients, the community and/or health system in NSW should be significant, with a clearly articulated pathway to translation.
- Skills and experience of the research team.

#### Evidence generated will be directly translatable into supporting the COVID-19 response in NSW (50%)

- The research will usefully advance and/or complement existing COVID-19 knowledge and research activity.
- Feasible and appropriate plan for how the findings, if positive, will be implemented into policy and practice.
- A plan for ongoing engagement between the research team and appropriate partners to evaluate the research for implementation as the project progresses. There should be a plan to implement any positive findings if warranted by the evidence at any point in the project.
- For diagnostic technologies only: the proposed translation pathway will also be assessed according to where the technology currently sits on the Technology Readiness Level Scale; where funding from a COVID-19 research grant would place the technology on the scale at the conclusion of the project; and where future funding would be sought to continue progression along the scale.

# Stage 2: Full Application

### **Overview of full application stage**

Submission of a full application is by invitation only. The full application form will be provided directly to successful EOI applicants following notification of EOI outcome.

### Selection Criteria at full application stage

The following criteria will be considered by reviewers:

- 1. Skills and experience of the research team and collaborators (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.
- 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.
- Evidence generated will be directly translatable into supporting the COVID-19 response in NSW (40% weighting)
- 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. Budgets will be considered 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.

# Funding process for successful applicants

### **Funding conditions**

- 1. Research must be conducted in the New South Wales health system or an affiliated organisation (university, medical research institute, industry partners).
- 2. Research may link with projects outside NSW, but funding must be expended in NSW.
- Research must be conducted in accordance with ethical requirements. All COVID research requires appropriate ethics approvals and site specific governance approvals. The Public Health Act may bypass the need for ethics approval for government work under certain circumstances but it should be assumed that all research requires appropriate HREC approval for the purposes of this grant.
- Programs of research must incorporate appropriate site specific governance mechanisms to ensure accountability across the NSW public health system.
- 5. 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.
- 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.
- If specimens require biobanking, this must be done via the NSW Health Statewide Biobank. Funding for biobanking must be discussed with the NSW Health Statewide Biobank: Telephone 02 4920 4140 or email <u>NSWPATH-Biobanking@health.nsw.gov.au</u>.

Grants provided are one-line grants, not fellowships. 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

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area of the application. Successful applicants who fail to meet milestones without adequate justification will have their funding withdrawn.

### **Funding agreements**

NSW Health will enter into funding agreements with administering organisation for each successful applicant.

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 funding agreement will include a schedule for reporting detailing requirements to provide:

- at one 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

- six monthly progress reports including preliminary results, milestones and deliverables
- six monthly financial reports
- a final report following the conclusion of the term of the grant.

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.

### **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.

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# Appendix 1: COVID-19 Research Program Topic Areas – Round Two

### **General principles**

For all research topics, NSW Health will prioritise projects that fulfil the following criteria:

- Research using a system-wide approach so that findings can be scaled in NSW.
- Research that has high potential for translation into policy and practice.
- Studies measuring clinically important outcomes.
- Large, multidisciplinary and/or collaborative projects and trials.
- Research that includes consideration of health equity between different population groups.

Note: applicants proposing new technologies for diagnostics must address future translation potential using the Technology Readiness Level Scale at Appendix 2 (see EOI Selection Criteria on page 9 of the Guidelines).

### **Research topics**

### 1. Identifying effective models of care

- Evaluation of the effect of virtual care approaches on specific patient cohorts to health care delivery on clinical and patient-reported outcomes, compared to usual practice, including in GP practices, and particularly in population groups that may be at higher risk of poor outcomes.
- Conduct rapid cycle evaluations of major affected clinical services. For example, what are the immediate and longer-term impacts of COVID-19 on clinical services? Are there changes that should be sustained? What is the economic impact of reconfigured services? Are there remedial actions we need to take to protect patients who missed out on care?
- Research to understand the changed visiting patterns to emergency departments, outpatient services and General Practices during COVID-19. For example, what are the consequences of the reduced visits to emergency departments and GPs during the COVID-19 pandemic? What are the best strategies for patient management outside of hospital settings during and after the pandemic? What were the experiences of patients who did not access the ED and what impact did this have on their health and wellbeing?

### 2. Mental health impact of COVID-19

- Models of care to predict and respond to increases in morbidity and mortality in mental health during the recovery phase. For example, what are the best ways to support the mental health and wellbeing of the NSW community during the pandemic?
- Designing and testing ways to reduce mental health issues related to quarantine, isolation, and social distancing, particularly in groups that are already at risk of isolation in the community, for example CALD communities, and the disability sector. For example, what interventions are effective for protecting mental health in different populations during the COVID-19 response?
- Measuring and reducing the mental health impact of COVID-19 in Health Care Workers and other essential workers.
- Determinants of successful interventions to support the mental health needs of populations at risk of mental illness during the COVID response, and impact of location on interventions for mental health support for particular population groups, including regional and rural communities, and Aboriginal communities.

### 3. Public health messaging

- Designing and testing the effectiveness of communication strategies and platforms to communicate public health messages and increase compliance with these, for example hand hygiene and social distancing.
- Designing and/or testing the effectiveness of strategies/interventions to maintain high rates of testing and increase testing rates in groups with low rates, including how to reach marginalised groups.
- Populations of most interest are those who may be at high risker of ongoing transmission, higher risk of serious disease, or marginalised. This includes Aboriginal people, CALD communities, young people, people living in poor quality housing and on low incomes, and marginalised workers who may be highly socially mobile or employed in higher risk settings.

### 4. Prevention and therapeutics

• Early-phase interventional trials of novel vaccines, therapeutic agents or devices that may have direct application for COVID-19. Locally developed interventions are also encouraged.

### 5. Diagnostics

- Rapid testing platforms, how these are applied and used, and the development of novel approaches.
- Routine quantification of viral loads, rapid methods for assessing this, and viral loads in other samples e.g. blood, upper and lower respiratory tract, and the correlation of these with clinical indicators.
- Biomarkers simple clinical biomarkers (or packages of these) and novel biomarkers.
- Improving diagnosis through viral load assays and genomic sequencing including further assessment of clinically false positive assays, and causes of persistently positive assays in some patients.
- Utility of routine serology in outbreak investigation and development of novel approaches outside PC3 facilities to reference standard serological diagnosis.
- Virus viability in different transmission modalities, e.g. droplet, aerosol, and in different settings.

### Out of Scope

Topics not listed above are out of scope for this round.

Also out of scope:

- Pre-clinical drug discovery research and development.
- Descriptive studies
- Modelling
- Visual display of existing epidemiological information including maps of cases.
- Building new statewide information technologies and systems.

- Assessing the effectiveness of newly emerging technologies and digital apps in the public health response.
- All evaluations of the COVIDSAFE app.
- Studies of the uptake and effectiveness of population level screening programs, prevention programs and preventive health habits.

# Appendix 2 – Technology Readiness Level Scale

TRL	TRL Description	Evidence of Achievement
1	Basic principles observed and reported	Published research that identifies the principles that underlie this technology
2	Technical Device concept formulated	Practical applications (e.g. devices) of the basic principles are invented
3	Technical proof of concept demonstration	The basic performance of the invention is demonstrated in a laboratory setting
4	Alpha prototype validation in laboratory environment	A simple prototype is developed and its performance is demonstrated in a laboratory environment. The performance indicates its potential for solving a clinical need
5	Beta prototype validation in clinical environment	A more advanced prototype is developed and its performance is demonstrated in a clinical environment and further clinical feedback is gained for the final design phase
6	Final Device design validation with clinical pilot study	The design of the device is frozen and a small number of devices are manufactured and a clinical pilot study is conducted by a key opinion leader. A pilot study report is prepared showing the results of the study
7	Device from pilot manufacturing line is being clinically trialled in multiple geographical locations	A larger sample of devices are manufactured and sent to multiple clinical sites in different geographical locations for clinical trials. The reports from these trials will be used for submissions to regulatory authorities (e.g. TGA, CE, FDA)
8	Device is partially approved and in clinical use	The device has been approved in limited geographical regions and is in clinical use in those regions
9	Device is fully approved and in clinical use worldwide	The device is approved for use worldwide and is in clinical use worldwide