

# **NSW HEALTH COVID-19 RESEARCH PROGRAM**



#### **CENTRE FOR EPIDEMIOLOGY AND EVIDENCE**

NSW Ministry of Health 1 Reserve Road ST LEONARDS NSW 2065

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### **GLOSSARY**

ACCHS Aboriginal Community Controlled Health Service
ACCO Aboriginal Community Controlled Organisation

APT Adaptive Platform Trials

ASCOT Australasian COVID-19 Trial

CALD Culturally and Linguistically Diverse

ELISA Enzyme Linked Immunosorbent Assay

**EOI** Expression of Interest

**FAIT** Framework to Assess the Impact from Translational health research

HMRI Hunter Medical Research InstituteHREC Human Research Ethics Committee

ICPMR Institute of Clinical Pathology and Medical Research

ICU Intensive Care Unit
ILI Influenza-like Illness
KD Kawasaki Disease

mAbs Monoclonal Antibody/iesMBS Medicare Benefits Schedule

MDF Medical Devices Fund

NCIRS National Centre for Immunisation Research and Surveillance

**PHEOC** Public Health Emergency Operations Centre

PHRB Public Health Response Branch

PHU Public Health Unit

PIMS-TS Paediatric Inflammatory Multisystem Syndrome Temporally associated with SARS-CoV-2

**RDT** Rapid Diagnostic Testing

**REMAP-CAP** Randomised, Embedded, Multi-factorial, Adaptive Platform Trial for Community-Acquired Pneumonia

RIA Research Impact Assessment

**SCHN** Sydney Children's Hospitals Network

**SSA** Site Specific Assessment

**TRAG** Therapeutics and Research Advisory Group

**UNSW** University of New South Wales

### **EXECUTIVE SUMMARY**

In April 2020, the NSW Government dedicated an additional \$25 million into research to support the NSW COVID-19 response and recovery. As a result, the NSW Health COVID-19 Research Program ('the Program') was established to contribute knowledge to minimise the health and social impacts of the COVID-19 pandemic in NSW.

An Evaluation Framework and Program Logic Model were developed to guide the evaluation of the Program's impact. These were endorsed by the NSW Health COVID-19 Research Leadership Team on 11 August 2020. The Program Logic Model is available in Appendix A.

The Evaluation Framework outlines three **key evaluation questions**:

- 1. To what extent were the objectives of the Program achieved?
- 2. To what extent has the Program contributed to the COVID-19 response and recovery in NSW?
- 3. To what extent have benefits been generated by the Program for the NSW economy and community?

This report provides an update on progress and examines preliminary outcomes of the Program as of 31 January 2021 (approximately nine months after Program initiation). Many research projects within the Program are ongoing and, due to the limited timeframe since initiation, this report will focus on a modified version of the first evaluation question: **To what extent have the objectives of the Program been achieved to date?** As such, **this report is specifically focused on how the Program's activities have enabled progress or achievement of the intended objectives**.

A Final Impact Evaluation Report ('Final Report') will be developed at the end of the funding period for research grants within the Program. The Final Report will include additional analyses to address the three key evaluation questions.

Throughout the report, interim outcomes have been evaluated according to **domains of benefit**, which align with the Program Logic Model for the Program:



### **Contribution to Knowledge Generation**

The work has contributed to creation or advancement of knowledge related to the COVID-19 response or recovery.



### **Contribution to Policy and Programs**

The work has impacted on NSW policy or programs related to the COVID-19 response or recovery.



### **Contribution to Clinical Care**

The work has contributed to improved clinical care related to COVID-19.



### **Contribution to the Community and Health Outcomes**

The work has led to an impact on COVID-19 related health outcomes for patients or contributed to community outcomes related to the COVID-19 response or recovery.



#### **Contribution to Economic Benefits**

The work has indirectly contributed to economic benefits for NSW either during the COVID-19 pandemic or in supporting the recovery phase through improved health outcomes, increased productivity and industry activity in NSW, and potential earlier re-opening of the NSW economy.

Throughout the report, these domains of benefit icons have been used to signal the Program's contributions which are in progress or have been achieved.

### Extent to which the objectives of the Program are being achieved

The Program consists of interconnected workstreams across three themes:

### 1. Research Funding Schemes

Two key research funding mechanisms were used by the Program to generate evidence to support the NSW COVID-19 response and recovery.

The **COVID-19 Research Grants** established a pathway to create knowledge and innovations to support the COVID-19 pandemic response through two rounds of competitive funding.

An additional **Emergency Response Priority Research** workstream enabled rapid creation of local evidence to support urgent operational work for the public health management of COVID-19 in NSW.

#### **OBJECTIVE**

#### COVID-19 Research

**Grants**: to create knowledge and innovations for the pandemic response

#### **INTERIM OUTCOMES**

Round 1 of the COVID-19 Research Grants has contributed to the NSW Health COVID-19 response through creation of knowledge and innovation. Examples include:



A new methodology enabled improved sensitivity of genome sequencing from clinical samples with low viral loads, meaning more accurate viral sequences could be established.



Rapid information on the health and social impacts of COVID-19 and related restrictions from 61,000 NSW residents.



Clearer assessment of the difference between naturally acquired antibodies and antibodies acquired due to vaccination through the development of assays.

# **Emergency Response Priority Research**: to create evidence for urgent public health management

Evidence from the Emergency Response Priority Research projects has played a critical role in informing the NSW public health response. Examples include:



Identification of transmission in school and childcare settings, which informed NSW Government policy and were disseminated internationally in a high impact journal.



Validation of Sydney Water analysis protocol for SARS-CoV-2 detection in sewage to inform the methodology and use of sewage surveillance in the NSW Health COVID-19 response.



Estimate of SARS-CoV-2 specific antibody seroprevalence among three subpopulations in Sydney, contributing to the NSW Enhanced Surveillance Plan for COVID-19.

### 2. Enhancement of the research ecosystem and infrastructure

Three workstreams were established to enhance and strengthen the NSW research environment to enable critical research to be undertaken during the COVID-19 response and recovery phases.

The **Clinical Trials** workstream aims to develop infrastructure to build NSW capacity to conduct adaptive clinical trials for the treatment of COVID-19, while linking NSW researchers to a global network of experts. To support this, the Waratah Vaccine Trial Alliance was established to facilitate collaboration among NSW vaccine stakeholders and coordination for industry and investigators to conduct vaccine trials in NSW, and to increase NSW access to clinical vaccine trials.

The COVID-19 pandemic brought about a need for the **Expediting Statewide Administrative Processes** workstream, aimed at minimising unnecessary delays in gaining approval for human research ethics applications and Site Specific Assessments (SSAs) for COVID-19 related research.

COVID-19 also presented a threat to the local medical devices industry, including those funded through the NSW Medical Devices Fund (MDF). In response, the **Industry Schemes** workstream aimed to support the commercialisation of therapeutics and devices for COVID-19 and ensure the NSW medical devices industry remained intact during the pandemic to support the COVID-19 recovery phase.

### **OBJECTIVE**

**Clinical Trials**: to increase NSW-based participation in clinical trials in the COVID-19 environment





Establishment of networks and infrastructure associated with Adaptive Platform Trials and statistical support provides an agile and innovative clinical trials environment for COVID-19 research, as well as for post-pandemic recovery.



A COVID-19 Clinical Trial Guidance Document provides guidance to minimise the adverse impacts of the COVID-19 pandemic on clinical trials in NSW.



The NSW Health COVID-19 Vaccine Advisory Group (VAG) and COVID-19 Therapeutics and Research Advisory Group (TRAG) have provided strategic expert advice to NSW Health on a range of priority areas.

**Expediting Statewide Administrative Processes**: to expedite Human Research Ethics Committee (HREC) and SSA processes and hardwire innovations into the post-COVID-19 research environment



Monitoring of HREC and SSA processing has shown that COVID-19 research has been expedited and new pathways have been implemented to ensure both COVID-19 and non-COVID-19 related research could continue without unnecessary delay. Where monitoring showed delays in approvals, remediation activities enacted by the Office for Health and Medical Research resulted in improved performance.



Process changes adopted during the pandemic, such as virtual meetings and electronic signatures, have potential to be continued to maintain observed efficiencies into the COVID-19 recovery phase.

**Industry Schemes**: to support the medical devices industry during COVID-19 and into the recovery



Four MDF firms left vulnerable from the pandemic received assistance through the NSW Medical Devices Fund COVID-19 Relief Package and no MDF recipients permanently shut down due to COVID-19.



Three MDF recipients pivoted to producing COVID-19 related technology or products.



During the COVID-19 pandemic, the Industry Schemes workstream fulfilled a critical triage and referral role between key industry stakeholders and relevant policy teams within NSW Health.

### 3. Enabling research translation

To expedite the translation of funded research into the COVID-19 pandemic response, a framework has been established across two complementary workstreams for effective and efficient dissemination of research findings.

Across the workstreams, the Program is engaging with a wide range of stakeholders.

### **OBJECTIVE**

### Research Translation and Impact Assessment:

to expedite the use of research outputs by end users and measure the impact of the Program





A workflow and template have been established for rapid translation of research findings to ensure there is no unnecessary delay between delivery of research outcomes and application to policy and practice.



An Evaluation Framework and Program Logic Model for the Program have been established, and data collection metrics and tools have been co-designed with workstream leads.

**Communications**: to communicate and promote the Program's achievements



Throughout the COVID-19 pandemic, NSW Health has communicated key activities and research outcomes publicly, including through the NSW Health and Medical Research website and social media accounts.



The NSW Health and Medical Research website has had a total of 41,025 hits on pages related to COVID-19; overall, this has formed 22% of total activity on the site.



### **INTRODUCTION**

An established and agile research infrastructure is a powerful tool in enabling rapid research production and knowledge dissemination as a response to a public health emergency such as the COVID-19 pandemic.<sup>1</sup>

Starting in April 2020, the NSW Government dedicated an additional \$25 million into research to support the NSW COVID-19 response and recovery. As a result, the NSW Health COVID-19 Research Program ('the Program') was established to contribute knowledge to minimise the health and social impacts of the COVID-19 pandemic in NSW. Investment in some aspects of the Program was supplemented by other existing and newly established funding sources. The Program consists of seven interconnected workstreams across three themes.

The **Research Funding Schemes** fund research projects in priority areas to directly support the NSW Health COVID-19 response and recovery. Two separate workstreams fund this critical research.

- The **COVID-19 Research Grants** workstream established a pathway to create knowledge and innovations to support the COVID-19 pandemic response through two rounds of competitive funding. Seven targeted studies were funded in Round 1 and 10 studies were funded in Round 2.
  - Round 1 had short application and scientific review timeframes; designed for projects that were ready to start within four weeks of funding, with preliminary data available within six months to support the short-term needs of the pandemic response. Research priorities for Round 1 covered diagnostics research, prevention of infection, treatment, and public and population health.
  - Round 2 provided slightly longer timeframes and included an Expression of Interest (EOI) process to streamline the number of research organisations submitting full applications. Round 2 was designed to support the medium- and long-term needs of the response and recovery. Round 2 priorities covered identification of effective models of care, mental health impacts of COVID-19, public health messaging, prevention and therapeutics, and diagnostics.
- The **Emergency Response Priority Research** workstream enabled rapid creation of evidence to support urgent operational work for the public health management of the COVID-19 pandemic in NSW.
  - This workstream leverages existing research infrastructure and partnerships to rapidly generate local evidence to inform policy and practice throughout the COVID-19 pandemic. A key mechanism to achieve this has been embedding research personnel in the response to work directly with key policy decision makers and frontline workers within NSW Health, and leveraging NSW Health datasets to inform the pandemic response. As of 31 January 2021, the Emergency Response Priority Research workstream consisted of eight funded research projects across a range of priority areas.

The **Enhancement of the Research Ecosystem and Infrastructure** theme connects three workstreams aimed at strengthening the NSW research landscape and infrastructure in response to COVID-19.

• The **Clinical Trials** workstream aims to develop infrastructure to build capacity in NSW to conduct adaptive clinical trials for the treatment of COVID-19, while linking NSW researchers to a global network of experts. Several networks and advisory groups have been established to provide expert advice.

- The **Expediting Statewide Administrative Processes** workstream is aimed at minimising unnecessary delays in approvals for research ethics applications and Site Specific Assessments (SSAs) for COVID-19 related research, as well as monitoring the impact the pandemic had on approval numbers and times for non-COVID-19 related research.
- The **Industry Schemes** workstream was established to assist medical device businesses funded through the Medical Devices Fund (MDF) to remain viable during the pandemic to contribute to a sustained infrastructure and the NSW recovery. The workstream also enabled commercialisation of therapeutics and devices for COVID-19.

The **Enabling Research Translation** theme aims to expedite the translation from the funded research into the COVID-19 pandemic response and recovery through two workstreams:

- The **Rapid Translation and Impact Assessment** workstream enables rapid research synthesis of Program outputs and targeted dissemination to key decision makers as required and facilitates the evaluation of the Program.
- The **Communications** workstream consists of a range of external communication activities enabling key activities and research outcomes to be shared publicly, including through the NSW Health and Medical Research website and social media accounts such as the @NSWMedResearch Twitter account.

### **Purpose of this report**

This report assesses preliminary outcomes of the Program as of 31 January 2021, approximately nine months after the Program's initiation.

An Evaluation Framework and Program Logic Model have been developed to guide the evaluation of the Program's impact. The Program Logic Model is available in Appendix A.

### The Evaluation Framework outlines the approach to the evaluation and key evaluation questions:

- 1. Extent to which the objectives of the Program were achieved
  - a. To what extent did the Program achieve its objectives?
  - b. To what extent did the workstreams achieve their intended purposes?
- 2. Extent to which the Program has contributed to the COVID-19 response and recovery in NSW
  - a. To what extent did the Program contribute to the COVID-19 pandemic response?
  - b. To what extent did the Program contribute to the COVID-19 pandemic recovery?
- 3. Extent to which benefits were generated by the Program for the NSW economy and community
  - a. What were the successes from the Program for the NSW economy and community?
  - b. To what extent have successes been hardwired as business-as-usual practices to strengthen the NSW research ecosystem?

Due to the limited timeframe since initiation of the Program for outcomes to be realised and measured, this report will focus on a modification of the first evaluation question: Extent to which the objectives of the Program have been achieved to date. The report is specifically focused on how the Program's activities have enabled progress or achievement of the intended objectives.

This report includes a deep dive of the Sewage Surveillance Program through applying the Framework to Assess the Impact from Translational health research (FAIT) established by the Hunter Medical Research Institute (HMRI).

The Program Logic Model classifies outcomes of the Program according to the following domains of benefit:



### **Contribution to Knowledge Generation**

The work has contributed to creation or advancement of knowledge related to the COVID-19 response or recovery.



### **Contribution to Policy and Programs**

The work has impacted on NSW policy or programs related to the COVID-19 response or recovery.



#### **Contribution to Clinical Care**

The work has contributed to improved clinical care related to COVID-19.



### **Contribution to the Community and Health Outcomes**

The work has led to an impact on COVID-19 related health outcomes for patients or contributed to community outcomes related to the COVID-19 response or recovery.



#### **Contribution to Economic Benefits**

The work has indirectly contributed to economic benefits for NSW either during the COVID-19 pandemic or in supporting the recovery phase, through improved health outcomes, increased productivity and industry activity in NSW, and potential earlier re-opening of the NSW economy.

Throughout the report, these domains of benefit icons have been used to signal the Program's contributions which are in progress or have been achieved.

### **Final Impact Evaluation Report**

A Final Impact Evaluation Report ('Final Report') will be developed at the end of the funding period for research grants within the Program.

The Final Report will include analyses according to the three key evaluation questions and identify quantifiable metrics of impact and value for money through outcome metrics which have emerged since February 2021, and additional project deep dives.

The Next Steps section of this report provides further detail on specific focus areas for the Final Report.



### **COVID-19 RESEARCH GRANTS**

The COVID-19 Research Grants were designed to fund research projects in priority areas to directly support the NSW Health response to the COVID-19 pandemic. Two rounds of competitive funding have commenced. Additional information on the research projects is in Appendix B.

#### **ROUND 1 PROJECTS**



45 and Up COVID Insights - The Sax Institute:

Extends the existing 45 and Up Study dataset by surveying 86,000 study participants using purpose-built questions about the impact of COVID-19.

Across two surveys to date, data has been collected from around 61,000 NSW participants on the health and social impacts of COVID-19. These surveys have been co-produced by the Sax Institute and the Centre for Epidemiology and Evidence, NSW Ministry of Health. Consultations were held with a range of clinical and policy stakeholder groups in NSW Health to identify policy-relevant survey questions; those consulted include the Clinical Council, Clinical Intelligence Group, Research Intelligence Group, Public Health Response Branch (PHRB), and Mental Health and Alcohol and Other Drugs key stakeholders. Preliminary findings have been provided to these stakeholders and published in a NSW Health 'COVID-19 Insights' newsletter (February 2021). As of 31 January 2021, a survey is being fielded which responds to the NSW Ministry of Health's need to better understand attitudes and predictors of vaccination uptake.





Improved confirmatory diagnosis of SARS-CoV-2 infection using protein mass spectrometry – NSW Health Pathology:

Aims to develop a new test to detect viral proteins in patient samples.

Methods to detect the viral proteins on the COVID-19 virus are a promising complementary and confirmatory strategy for diagnosis. Patients who have tested positive for COVID-19 infection using nucleic acid amplification testing (NAAT) may continue to return positive results after the typical window of infection when symptoms have cleared. Continued re-testing of these patients places additional workload on laboratories and reduces testing capacity. An alternative method for detecting viral proteins may lead to efficiencies gained through reduced workload on laboratories and increased testing capacity.

To date, the research has found that existing liquid chromatographymass spectrometry (LC-MS) instrumentation can detect SARS-CoV-2 and other viruses, albeit with reduced sensitivity compared to NAAT. Benefits of this methodology include turnaround times comparable to NAAT, the potential for providing a differential diagnosis in a single test, and development of a template for rapid deployment of new LC-MS assays in the event of a future pandemic. Preliminary findings have been presented on five occasions including at a Royal College of Pathologists of Australasia board meeting and to the Immunisation Coalition.



A place-based pandemic response to the strengths and vulnerabilities of Aboriginal communities in south-eastern New South Wales - University of Wollongong: Addresses a gap in knowledge of how urban and regional Aboriginal Community Controlled Organisations (ACCOs) are responding to the complex health and social challenges confronting local Aboriginal communities in the context of the COVID-19 pandemic. The project aims to develop a culturally safe, place-based response to COVID-19 for NSW Aboriginal communities and to safeguard effective service provision by ACCOs by developing a collaborative protocol for Aboriginal communities in response to crises.

Phase 1 of the study (Contextualising Aboriginal Responses to COVID-19) has included a pandemic response rapid literature review, stakeholder engagement through discussions with key regional stakeholders from Government, non-government and Aboriginal Community Controlled Sectors, and social media analysis to explore culturally safe health messaging.







Development, evaluation and validation of Enzyme Linked Immunosorbent Assay (ELISA) assays for both the diagnosis of COVID-19 and utility in seroprevalence in communities – NSW Health Pathology, Institute of Clinical

**Pathology and Medical Research (ICPMR):** To enable reliable serological diagnosis of COVID-19, tests must be accurate, sensitive and specific, easily performed in high numbers, and achieve rapid turnaround times. This research was funded to support both diagnosis of COVID-19, and for utility in assessing seroprevalence in communities.

A full-time scientific officer has been employed and three assays have been developed. Once assays have passed evaluation and validation, they will be used to accurately detect antibodies of SARS-CoV-2. **The combination of the three assays will also allow NSW Health to determine the difference between naturally acquired antibodies and antibodies acquired due to vaccination**, which will be critical for contact tracing and pinpointing the timing of infection.





Impact of COVID-19 on Indigenous

Australians' preventive health

behaviours: A mixed methods study -

University of New England: Aims to investigate barriers and enablers of attendance of preventive health services by Indigenous Australians in NSW. This research will increase the health system's understanding of the unique barriers to engaging in preventive health behaviours due to COVID-19 and help develop and implement specific intervention strategies to increase engagement with preventive health services.

Collaboration with communities is underway to enable recruitment for interviews with participants across six sites. While approvals required to access the data outlined in the study protocol are being obtained, Medicare Benefits Schedule (MBS) data has been analysed to determine uptake of 715 health assessments. A paper describing these analyses is under review by the Medical Journal of Australia.



A rapid qualitative assessment of COVID-19 health needs in an urban Aboriginal community – University of New South Wales: Uses qualitative peer-led interviewing methods to describe COVID-19 related prevention knowledge, control strategies, vaccine acceptability, and health service needs in one regional and two metropolitan Aboriginal communities in NSW.

Data collection through 30 interviews at the first site (Campbelltown) has completed and preliminary findings have been distributed in the form of a report and three presentations. Findings were also discussed with the NSW Chief Health Officer, South Western Sydney LHD Aboriginal Health, Nepean Blue Mountains LHD Aboriginal Health and Population Health, Hunter New England Aboriginal Health, Koolyangarra Aboriginal Neighbourhood Service, and the Aboriginal Health and Medical Research Council of NSW. As of 31 January 2021, this study is ongoing; data collection is in progress at a second site (Cranebrook) and planned for a third site (Lithgow).

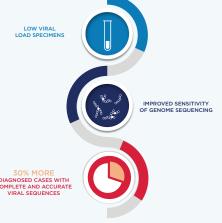




Enhanced genomic tracking of COVID-19 importations and transmissions in NSW - NSW Health Pathology: Aims to improve sensitivity of SARS-

CoV-2 genome sequencing from clinical samples with low viral loads by implementing novel, highly sensitive methods of target genome enrichment that have demonstrated success with other viruses.

A significant challenge facing genomic surveillance of SARS-CoV-2 is incomplete and inaccurate sequence generation in low viral load specimens often associated with minimal disease or asymptomatic infection. The project has evaluated three novel methodologies and achieved significant improvement in the sensitivity of NSW's current approach to genomic surveillance. With the new methodology examined and evaluated it was possible to produce complete and accurate viral sequences in an additional 30% of diagnosed cases, significantly reducing the proportion of cases with unconfirmed genomic links.



### **ROUND 2 PROJECTS**

Round 2 projects within the COVID-19 Research Grants scheme have been announced and cover a range of topic areas. The outcomes of these research projects will be examined in the Final Report (see Next Steps section).

### **DIAGNOSTICS**



Novel diagnostics for evaluating duration of immunity after COVID-19 and for Phase I/II vaccine trials – Westmead Institute for Medical Research: Examines the duration of immunity in patients recovering from COVID-19.

Ultra-sensitive PC2 serology and rapid viral outgrowth assays - Kids Research at Sydney Children's Hospitals Network (SCHN): Aims to improve SARS-CoV-2 antibody and virus diagnostic detection of low levels of COVID-19 antibodies.

### MENTAL HEALTH IMPACTS

The eCliPSE COVID-19 project: an electronic pathway to care for NSW residents to reduce depression, anxiety, and alcohol use problems in the face of COVID-19 - The University of Newcastle: Aims to develop and scale up a digital tool to help NSW bend the predicted curve in depression, anxiety, and alcohol use due to COVID-19.

A digital solution to address the mental health and financial impacts of the pandemic for children and their parents in the first 2000 days - South Western Sydney Local Health District: Aims to use the Watch Me Grow -Electronic Platform to engage parents to identify and address parental mental health, psychosocial wellbeing, and child developmental needs for families of children aged 0-5 years from culturally and linguistically diverse (CALD) and regional/ rural communities.

Rapid evaluation of a scalable program for reducing common mental disorders during COVID-19 - University of **New South Wales:** Evaluates a video-conferencing program led by clinicians and supported by an app program to reduce mental disorders during COVID-19.

Supporting the mental health of health workers at **Aboriginal Community Controlled Health Services (ACCHS)** in NSW during the COVID-19 pandemic and beyond - The Sax Institute: Examines the mental health of ACCHS health workers and how it is impacted by COVID-19 related changes over 18 months. It will also test the feasibility, acceptability and early indicators of impact of community-nominated interventions to support staff mental health.

### **EFFECTIVE MODELS OF CARE**

24/7 eICU model of care for Level 4 ICUs in rural NSW -South Western Sydney Local Health District: Aims to implement and study virtual care enhanced management of patients in Level 4 rural and regional ICUs using a NSW Health value-based care model.

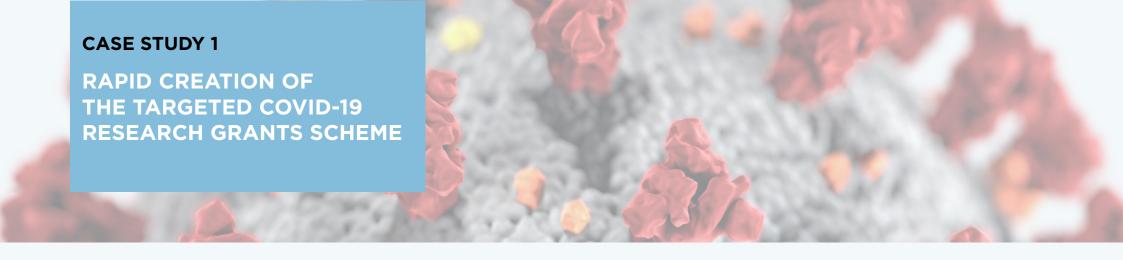
Evaluation of the Virtual Rural Generalist Service (VRGS) as an effective, "COVID-19 resilient" model of care - Western NSW Local Health **District and University of Sydney:** Aims to evaluate the VRGS as a workforce solution for communities during COVID-19.

### PUBLIC HEALTH MESSAGING

Designing and testing COVID-19 vaccine public health messages - National Centre for Immunisation Research and Surveillance (NCIRS) and SCHN: Aims to develop evidence-based public health messages for a COVID-19 vaccine program by understanding NSW community perspectives on COVID-19 vaccines.

**THERAPEUTICS** Manufacture of banked SARS-CoV-2 specific T lymphocytes derived from recovered COVID-19 patients to prevent

progression to severe COVID-19 in vulnerable individuals - University of Sydney: Will build capacity to commence a clinical trial of infusion of COVID-19 specific immune cells to high-risk COVID-infected patients if the need arises in the future.



### Scheme created to administer priority NSW Health COVID-19 research

NSW Health successfully developed a grants scheme to fund the generation of priority research evidence to inform NSW's COVID-19 pandemic response. Two rounds of the scheme were established in 2020.

### Targeted research grants within an evolving pandemic

Given the changing and uncertain landscape of COVID-19, it was important to communicate the current funding priorities to potential applicants. The scheme was designed to feed research results rapidly into the response, thus reducing the time from evidence generation to translation into policy and practice. Clear and transparent procedures were implemented to ensure competitiveness and accountability.

### Leveraging existing mechanisms to rapidly initiate the scheme

The Office for Health and Medical Research leveraged its existing management infrastructure and expertise to rapidly set up the new grants scheme. With increased workforce surge, the team completed work within weeks which would typically take months.

"My team has a lot of experience managing grants. This allowed us to quickly pivot to the COVID response."

(Principal Policy Officer, Office for Health and Medical Research)

### Broad consultation and engagement identified timely priorities for the response

To identify targeted research priorities for NSW's pandemic response, the Office for Health and Medical Research undertook its most extensive consultation process for a grant scheme to date.

Consultation on the priorities for each round included roundtables with senior experts dedicated to the response, and discussions with policy areas in the Ministry of Health and COVID-19 advisory groups including the Critical Intelligence Unit and Clinical Council, statewide agencies, and Communities of Practice. Short-listed applications were subject to internal and external peer review before final funding decisions.

"The review process was undertaken by external scientific reviewers as well as internal experts involved in the response, to make sure funding decisions were made according to scientific merit and evidence needed to support the response."

(Principal Policy Officer, Office for Health and Medical Research)

### Advice and direction from NSW Health Executive facilitated the scheme's success

Clear oversight from senior executives was crucial to the accelerated and targeted rollout of the scheme. Regular reporting was provided to the Secretary, NSW Health, and there was a clear mandate regarding urgency of timeframes. Support from the A/Deputy Secretary, Population and Public Health ensured that any signoffs required were fast-tracked, which was critical to the scheme's success.

### **EMERGENCY RESPONSE PRIORITY RESEARCH**

Priority research projects were established to provide evidence to directly inform operational decisions throughout the pandemic response. The structure of the projects allowed for researchers to be embedded in the public health response and to facilitate co-production and collaboration, resulting in research papers and reports. At the time of this report the Emergency Response Priority Research workstream consisted of eight funded research projects across a range of priority areas. A more detailed list of known reports and publications from this workstream is in Appendix B.





**COVID-19 NSW outcomes study - University of** New South Wales (UNSW): Cross-sectional analysis of confirmed COVID-19 cases linked to routinely collected hospitalisation data to determine disease severity and hospital utilisation and underlying causes of admission.

Research questions and methods were developed in partnership with senior NSW Health epidemiologists, and outputs were regularly reported to the PHRB. Findings of this project were published in the Communicable Diseases Intelligence journal<sup>2</sup> and by NSW Health.<sup>3</sup> Two further papers are currently in preparation (high-risk groups for severe COVID-19, and recovery time). Outcomes have also been shared with relevant bodies to calibrate forecasting and scenario models of ward/ICU occupancy. This project has been selected by the NSW Office of the Chief Scientist for the 2021 NSW Research Impact Showcase.



Burden of influenza-like illness (ILI) disease in adults ≥65 years in aged care facilities - University of Sydney, Western Sydney Local Health District: A study to estimate attack, hospitalisation

and death rates of viral respiratory infection outbreaks in aged care facilities.

Updates were provided to the PHRB and the study was completed with no COVID-19 outbreaks in aged care facilities in the study area. A 2020 end of year report is being finalised.





Serosurveillance for SARS-CoV-2 infection - National Centre for Immunisation Research and Surveillance (NCIRS) and **UNSW:** A cross-sectional serosurvey of residual blood specimens collected April-June 2020 to estimate SARS-CoV-2 specific antibody seroprevalence among three subpopulations in Sydney.

The project was identified in the Enhanced Surveillance Plan for COVID-19 in NSW4 and outcomes from the project were published in the Medical Journal of Australia.<sup>5</sup> Findings were also presented to the PHRB leadership (6 August 2020), the COVID-19 Research Leadership Team (11 August 2020), and at the Australasian COVID-19 Virtual Conference (10 December 2020).





NSW Health COVID-19 schools transmission investigation project - NCIRS: A study to document transmission in school and childcare settings, with enhanced investigations via home/school visits of close contacts.

This study was commissioned by the NSW Ministry of Health under the Public Health Act 2010 (NSW) and implemented with approval and support from the NSW Department of Education. This cross-agency collaboration informed policy on whether school and childcare centres should remain open during the pandemic, and provided evidence about high-risk activities in education settings to reduce transmission risk. A journal article published in The Lancet Child & Adolescent Health<sup>6</sup> has been cited 112 times through Google Scholar (as of 8 March 2021). Findings were also presented to the PHRB (24 June 2020), the NCIRS seminar series (22 September 2020), and at the Australasian COVID-19 Virtual Conference (10 December 2020).

"...we've engaged with NCIRS around (...) what the experience here in NSW has been in relation to student transmission rates whilst at school. It's really important we get as much information as we can because that then informs some of the policy decisions we are undertaking jointly with NSW Health under their expert advice and also at the national level.."

Executive Director Health & Safety, NSW Department of Education<sup>7</sup>

"The technical expertise that has come to us at a national and a state level has been outstanding (...) those relationships and that expert advice has been absolutely essential and vital to us being able to keep schools functioning and operating safely." Executive Director Health & Safety, NSW Department of Education<sup>7</sup>

"One of the key learnings through COVID is that the research has happened seamlessly. It adds no burden to do the research on either side. Some researchers have been able to be very nimble and can thrive in these environments. We see them as part of the team. The researchers are given access to our data, it's efficient, it's evidence based, it's a win-win and a new way of working with researchers."

### NSW Chief Health Officer<sup>8</sup>





Wastewater-based epidemiology for COVID-19 -**Sydney Water:** Validation of Sydney Water analysis protocol for SARS-CoV-2 detection in sewage.

This validation process involved testing 100 raw sewage samples to verify the sensitivity and specificity of the method and subsequent use for monitoring. A valid method was established, and sewage monitoring using this method continues to inform the pandemic response (which is now funded outside of the Emergency Response Priority Research workstream). Updates are currently published on the website daily.

"There were a lot of pre-existing relationships with academics across a whole range of areas of health protection. I think that's the fundamental success factor for the whole initiative: leveraging existing relationships. Then we created a structure, governance and reporting framework to ensure that is done in a fair, transparent and publicly accountable way."

Director, **Evidence and Evaluation Unit, Centre for Epidemiology and Evidence** 





Surveillance of paediatric COVID-19, Kawasaki disease and PIMS-TS via PAEDS - Sydney Children's Hospitals Network: Surveillance for

COVID-19. Kawasaki disease (KD) and Paediatric Inflammatory Multisystem Syndrome Temporally associated with SARS-CoV-2 (PIMS-TS).

Case count reports are being provided to the PHRB and Health Protection NSW fortnightly. One case of PIMS-TS was reported, along with 94 cases of COVID-19 and 57 cases of KD.





Retrospective infected health care worker study - UNSW: Case series study of health facility acquired COVID-19 in NSW health care workers.

Findings from this study were published by NSW Health<sup>9</sup> and presented at the Infectious Diseases Community of Practice and Clinical Council (19 August 2020), Kirby Institute Seminar Series (20 October 2020) and the Australasian COVID-19 Virtual Conference (10 December 2020). The NSWdeveloped questionnaire and accompanying survey database were shared with the Tasmanian outbreak response team and used in a cohort study as part of the investigation of the response to the health facility outbreak in Tasmania.



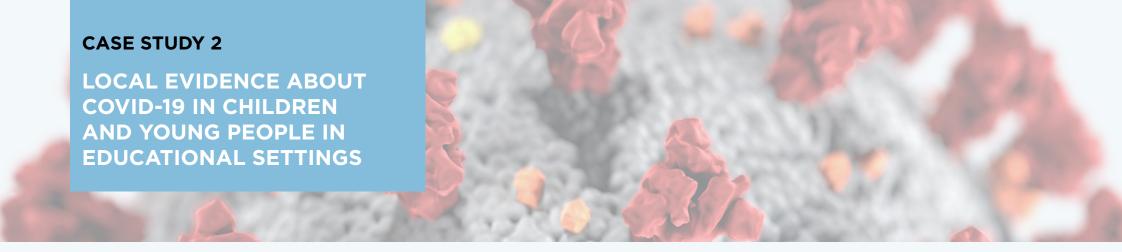


### The Australian First Few 'X' (FFX) Project for COVID-19 - NCIRS:

**FFX** National prospective case-ascertained transmission study involving collection of enhanced data and specimens from laboratory confirmed cases and household contacts to study household transmission.

Interim results for NSW were provided fortnightly to the PHRB and, as of November 2020, 66.7% of participating households were from NSW.

The study was presented at the Australasian COVID-19 Virtual Conference in December. Due to low case numbers, there were currently no households in data collection phases at the time of their last report.



### Need identified for local evidence to inform decisions about schools

Early in the COVID-19 response, the Chief Health Officer required local evidence to inform decisions about whether schools should operate face-to face, as closures and distance learning arrangements would have significant social and economic impacts. Outbreaks in schools in Term 1, 2020 highlighted the urgency of information required by NSW Health and the NSW Department of Education.

### Existing relationships leveraged to enable rapid generation of NSW evidence

A series of conversations between PHEOC (now PHRB), the Office of the Chief Health Officer and experienced researchers from the National Centre for Immunisation Research and Surveillance (NCIRS) enabled establishment of the study among staff and children in NSW schools and early childhood care settings. Use of existing facilities and infrastructure from NCIRS and NSW Health Pathology enabled high-quality data collection for rapid analysis.

"The research happened so quickly. Within weeks the research started without being stuck in negotiating contracts. It would be impossible in the context of an emergency to commission this research if we didn't have existing relationships with these academics who have been working with us for many years."

(Executive Director, COVID-19 Public Health Response Branch)

### Direct communications between researchers and pandemic response decision makers

Through an active partnership, NSW Health initiated and then facilitated the study within the Emergency Response Priority Research workstream, and NCIRS conducted the study with input from key stakeholders from the NSW Department of Education, NSW Health Pathology and several Local Health District Public Health Units (PHUs). These partnerships enabled seamless translation, integrating information about transmission in schools with the wider public health response.

"Research insights were rapidly communicated to education and emergency health response decision makers. We didn't have to formally disseminate it because it was a part of the project; communicating findings directly and providing regular updates."

(Director, Evidence and Evaluation, Centre for Epidemiology and Evidence)

### Policy decisions informed by timely local evidence

The NSW findings were consistent with international studies, demonstrating low SARS-CoV-2 transmission rates in children. The findings provided current, high-quality local evidence, giving decision makers and the community greater confidence about safely returning to face-to-face learning in NSW.

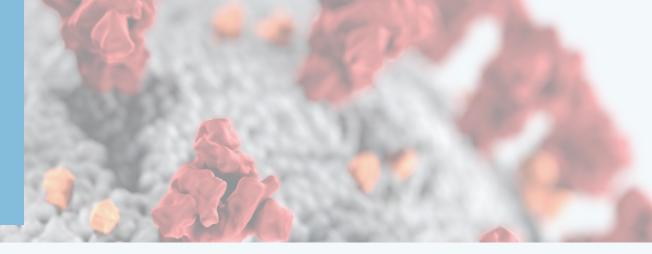
"Emergency response priority research projects were able to leverage long term and trusted relationships with the research sector, and pivoted established research infrastructure to enable a rapid response to research needs during the COVID-19 pandemic. There was respect for the shared and different drivers of researchers and the public sector, and the strengths of each were harnessed to deliver timely results for the NSW health system."

(Executive Director, Centre for Epidemiology and Evidence)

### **CASE STUDY 3**

THE AUSTRALIAN FIRST FEW 'X'

SHOWCASE OF THE UNIQUE ESTABLISHMENT OF EMERGENCY RESPONSE PRIORITY RESEARCH PROJECTS TO INFORM THE NSW HEALTH COVID-19 RESPONSE



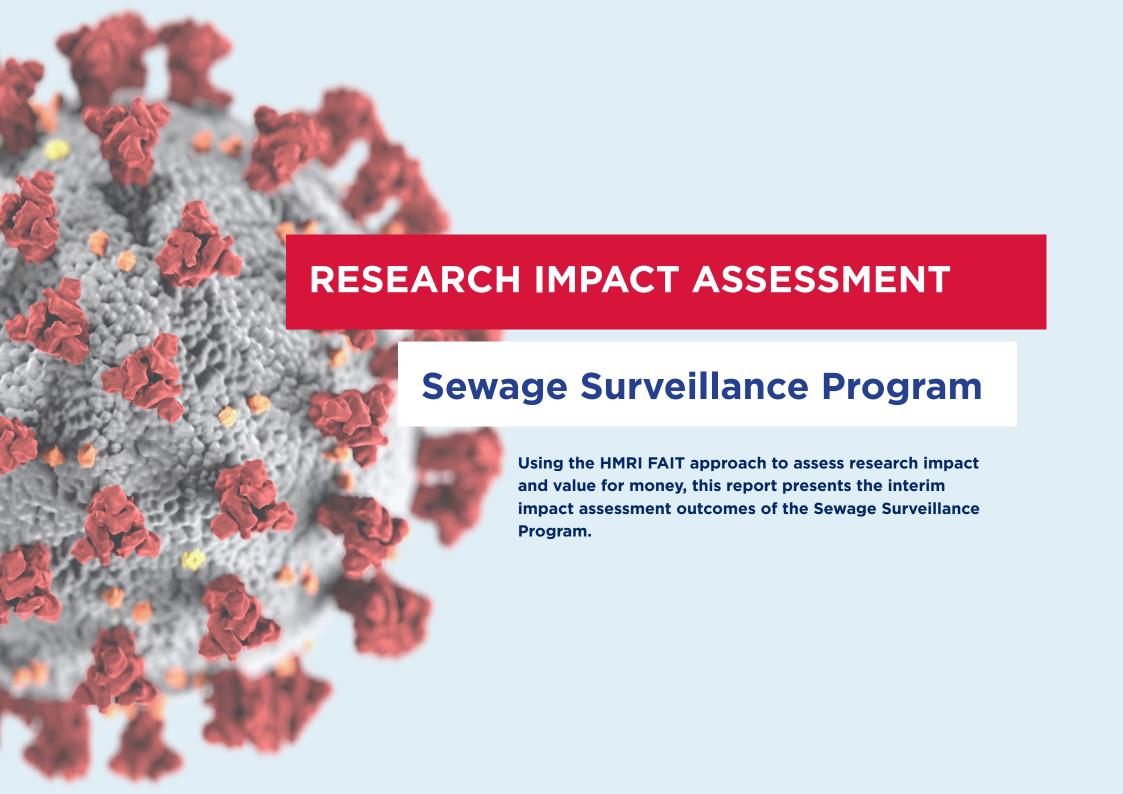
Mechanisms to expedite research projects included **embedding research personnel in NSW Health** to work directly with NSW Health datasets to inform the pandemic response, **adapting existing research projects** to collect local evidence, and establishing new **COVID-19 research projects with experienced and trusted NSW researchers**. These projects integrated high-quality research techniques, timely evidence generation and direct translation of findings into the NSW Health response, as outlined below.

PROJECT	METHOD FOR RAPID MOBILISATION OF EACH PROJECT			
COVID-19 NSW OUTCOMES STUDY	A senior epidemiologist with expertise in linked data research was seconded from UNSW to work within NSW Health. <b>This</b> efficiently enabled establishment of a new linked data resource for ongoing analysis.			
BURDEN OF INFLUENZA-LIKE ILLNESS DISEASE IN AGED CARE FACILITIES	A pre-existing study of influenza-like illness in adults ≥65 years in western Sydney residential aged care settings was adapted to include COVID-19 surveillance, a <b>cost-efficient method of repurposing existing research</b> to address emerging priorities.			
SEROSURVEILLANCE FOR SARS-CoV-2 INFECTION	NSW Health supported the accelerated conduct of serological surveys in NSW, undertaken as part of a national survey to understand the prevalence of asymptomatic community infection. <b>Research centres with serosurveillance expertise were rapidly engaged</b> to generate the required evidence.			
NSW HEALTH COVID-19 SCHOOLS TRANSMISSION INVESTIGATION PROJECT	<b>NSW Health rapidly commissioned research centres with known expertise</b> to undertake enhanced surveillance of COVID-19 transmission in NSW schools. This enabled data from the early stages of the pandemic to be reported (from 27 January 2020).			
WASTEWATER-BASED EPIDEMIOLOGY FOR COVID-19	NSW Health and Sydney Water <b>leveraged an existing research partnership, enabling rapid piloting of a new COVID-19 detection method</b> in sewage that was readily adopted by Health Protection NSW.			
SURVEILLANCE OF PAEDIATRIC COVID-19, KAWASAKI DISEASE AND PIMS-TS	<b>Existing surveillance research on Kawasaki disease at The Children's Hospital at Westmead was extended</b> to include Sydney Children's Hospital Randwick and to develop a surveillance protocol to include cases of Paediatric Inflammatory Multisystem Syndrome Temporally associated with SARS-CoV-2 (PIMS-TS).			
RETROSPECTIVE INFECTED HEALTH CARE WORKER STUDY	<b>Experienced and highly skilled research staff were seconded</b> from UNSW to study COVID-19 infections in health care workers.			

data collection (from 6 April 2020).

A national study into household transmission was underway, but urgent funds were provided by NSW Health for rapid

establishment and data collection in NSW while awaiting Commonwealth funds. NSW was the first jurisdiction to commence



Evidence on the progress and benefits realised to date from the Sewage Surveillance Program are presented, which include a narrative of research translation and impact, and metrics of the Program's impact for NSW.

This research impact assessment will be updated in the Final Report and will include a light-touch economic analysis of the benefits generated for NSW from the Sewage Surveillance Program (detailed in Appendix C).

### **NARRATIVE**

Early in the COVID-19 pandemic, it was established that genetic material from COVID-19 could be detected in sewage. This finding provided a unique opportunity for state, national and international collaborations to develop wastewater epidemiology, contributing to surveillance efforts and complementing existing community testing efforts.

NSW Health, Water Research Australia's Australia-wide Collaboration on Sewage Surveillance of SARS-CoV-2 (ColoSSoS), Sydney Water and UNSW collaborated to rapidly pivot existing technology to address the COVID-19 threat. The collaboration was initially funded under the NSW Health COVID-19 Emergency Response Priority Research workstream to validate Sydney Water's method with stored samples. An additional ~\$1.9 million COVID-19 Priority Research Grant was secured to operationalise the method and roll out the surveillance program. This work led to a commitment from NSW Health of approximately \$2.3 million to further expand the surveillance program. Appropriate tests for the virus and new knowledge to inform the application of the technology were produced. To improve coverage and data specificity, additional collection sites in regional NSW were introduced and catchment sizes reduced in Sydney. Research is continuing with a focus on capabilities to identify COVID-19 clusters and strains.

Rapid translation of the surveillance findings into decision-making was supported by daily reporting of findings directly to the NSW Health Executive, Leadership Team, PHUs, and counterparts in other jurisdictions and the Commonwealth. Results are also public and updated daily on the NSW Health website.

### **Contribution to knowledge generation**

The regular reporting of COVID-19 detection in sewage has provided an additional tool for managing the pandemic response in NSW, as it has contributed to the interpretation of clinical and other data being gathered. Technical knowledge including methods and protocols which have guided sewage surveillance have been shared internationally via publications such as *The Water Research Foundation report on COVID-19 Genetic Signal in Sewersheds* – *Recommendations from Global Experts* (2020). Journal papers documenting methodologies for COVID-19 detection through sewage surveillance, retrospective epidemiological analysis, and case notifications data are being drafted. A microbiological sampling procedure and checklist for COVID-19 sewage surveillance have been produced and contributed to the Water Research Australia's good practice guide and the National Wastewater Testing and Reporting Framework.

### Contribution to policy and practice

Sewage surveillance findings enabled NSW Health to target messaging and testing to high-risk areas, tracking possible COVID-19 clusters and outbreaks. This data has also been used to manage border restrictions following a known outbreak. For example:

- In Oran Park in Sydney's Southwest, the detection of COVID-19 in sewage preceded the first clinical detection. This allowed for potential community transmission to be avoided by notifying the public and increasing clinical testing efforts earlier.
- In the Northern Beaches of Sydney, detection of COVID-19 in sewage occurred on 16 December 2020, the same day as two confirmed clinical cases. Findings were published and testing increased from 1 per 1,000 residents to over 90 per 1,000 by 20 December 2020. The specificity of the data contributed to the Northern Beaches being segmented into the upper and lower regions with customised restrictions. Continued monitoring of COVID-19 detections in sewage also informed easing of restrictions in the lower region, which may not have been possible without the specificity of the sewage results.

### Contribution to capacity building

Staff have been trained to increase the capacity for analysis of sewage samples. Public Health Units have been working with regional utilities to organise sample collection and transport to the laboratory for analysis. The Commonwealth Department of Foreign Affairs and Trade (DFAT) recently provided a grant towards overseas capability building in this area through the Australian Government's Partnerships for Recovery — Australia's COVID-19 Development Response. This initiative is administered via the Australia-Mekong Water Facility program and will connect Australian universities, utilities, health agencies

"The NSW Sewage Surveillance
Program has provided critical
intelligence to understand COVID-19
in the community. A key aspect of this
program is that it's passive so people
do not need to change their routine.
The benefits of the program include
the potential to provide early warning
of an increase in infections in the
community or undiagnosed cases and
identifying areas to target increased
community testing."

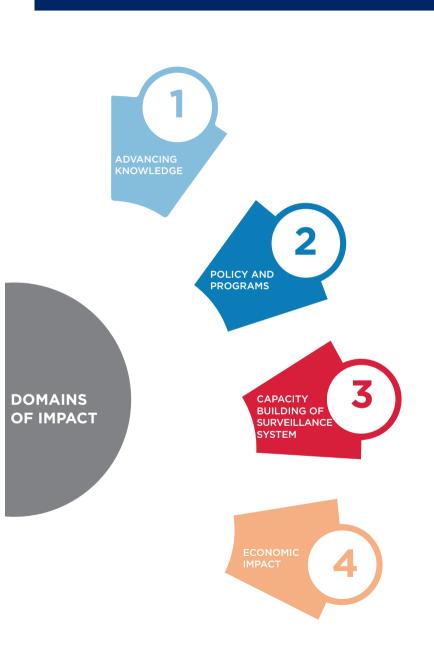
A/Executive Director,
Health Protection NSW

and laboratories with their counterparts in the Mekong region (which covers 250 million people) to enhance capacity in COVID-19 sewage surveillance.

### Contributions to health and the economy in NSW

The ability to detect and respond to the presence of COVID-19 in sewage has downstream impacts on the health of the NSW community and the economy. The ability to perform the tests, translate the results to policymakers, inform the public, ramp up testing in at-risk locations, and further inform policymakers within NSW Health as to appropriate restrictions is likely to have prevented additional community transmission. Similarly, where easing of restrictions and border closures have been informed by sewage surveillance results, this is likely to have enabled industries such as domestic tourism to contribute to the NSW economy.

### PAYBACK METRICS OF IMPACT



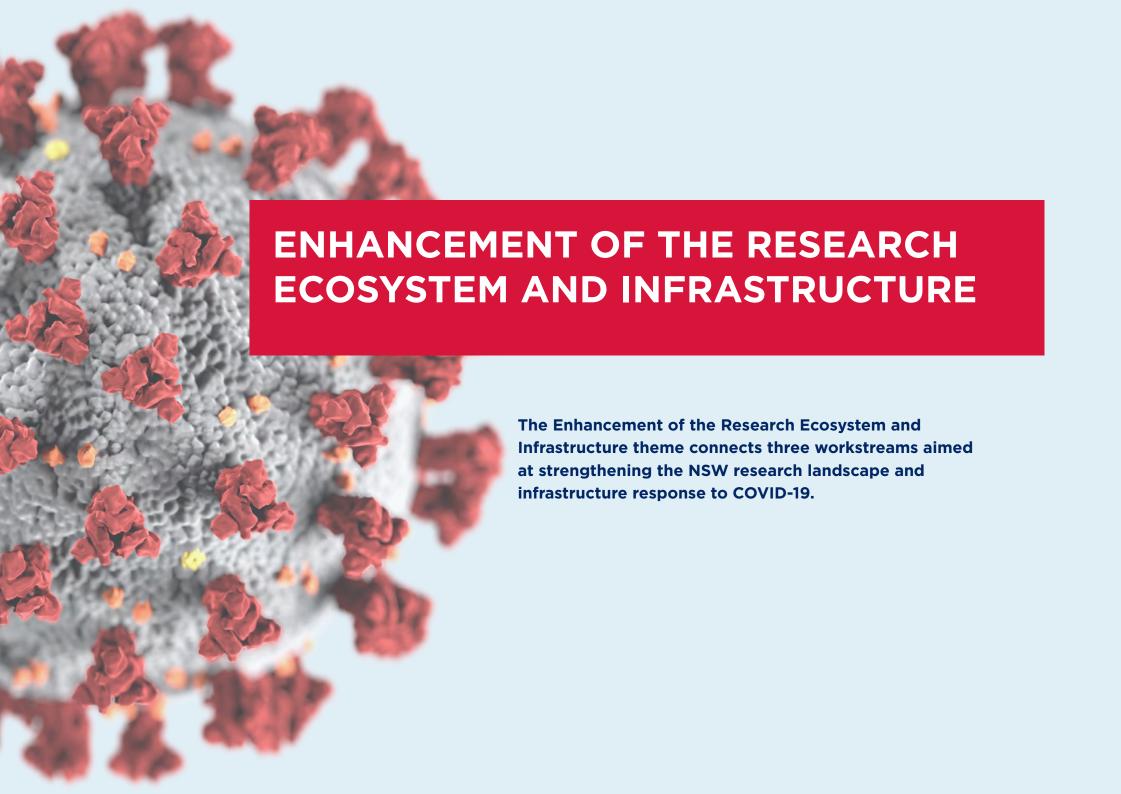
#### PAYBACK METRIC OF IMPACT

- 16 instances when detection of COVID-19 in wastewater identified areas to target increased community testing to confirm transmission
- Example 1: Oran Park cluster (99,000) -Detection in sewage on 2 October 2020 led to media alert on 6 October. Testing rates climb from 1 per 1,000 to 6.8 per 1,000 by 15 October 2020. A total of 25 cases were detected in that cluster by 25 October 2020.
- Example 2: Northern Beaches cluster (69,000) -Detection in sewage on 16 December 2020, the same day as 2 confirmed cases. Media issued and testing increased from 1 per 1,000 to over 90 per 1,000 by 20 December 2020. Cluster totalling 92 cases on 11 January 2021. Detections in sewage continued approximately 2.5 weeks after the last case was identified.
- community detection to inform changes in
- Messages encouraging testing following a detection of COVID-19 in sewage have been translated into 17 languages and disseminated via Western Sydney LHD, South Western Sydney Department of Community Services, GP
- Contributed to the National Wastewater Testing

- · 25 sewage treatment sites in Sydney with sizes of
- 36 additional network sites added to the original 25 sites in Sydney to breakdown the larger catchments to approximately 100,000 per site to increase specificity of data • 130 routine sites in NSW total

- · 88% of NSW covered by sewage surveillance, an increase from 5% coverage when 3 regional sites commenced SARS-CoV-2 surveillance in July 2020
- 21.5 FTE Sydney Water staff
- 9 field staff, 1 Project Manager and 2 Reactive Network
- 9 laboratory staff
- •1 Network specialist
- Large pool of staff trained as back ups
- 20.5 FTE new staff recruited to

NB: Data required for the economic analysis is still being collected. This data includes both the cost of delivering the Sewage Surveillance Program and the value of some of the benefits, hence, it is not estimated in this report. See Appendix C for detail on what the economic analysis will contain in the Final Report.



### **CLINICAL TRIALS**





The Office for Health and Medical Research published a COVID-19 Clinical Trial Guidance Document. A first version was published on 25 March 2020, and an updated version on 9 September 2020. This document aimed to supplement high level guidance published by the Commonwealth Department of Health, providing further operational detail to minimise the adverse impacts of the COVID-19 pandemic on clinical trials in NSW. Key principles include:

- For urgent clinical trials related to COVID-19 and for existing trials incorporating COVID-19 elements, every effort should be made to introduce process flexibilities that expedite these trials whilst protecting participants.
- Emphasis on minimising trial burden and disruption to health-related services in NSW whilst also maintaining the safety of trial participants, site, sponsor and vendor staff, and the validity of trials.
- Participants are at the centre of clinical trials and should be kept engaged and informed in relation to clinical trial changes.

As reported in the rapid translation and communication section, the Clinical Trial Guidance webpage had been visited a total of 4,689 times as of 31 January 2020.

"We worked collaboratively with all the sector stakeholders, our public hospital researchers and clinical trials groups, as well as our Government stakeholders including the Commonwealth to develop this guideline to support clinical trials to remain open during COVID-19."

Manager, clinicaltrialsNSW, Office for Health and Medical Research

### The NSW Health COVID-19 Therapeutics and Research Advisory Group (TRAG)

The TRAG has been formed to provide strategic expert advice to NSW Health and the NSW Government on the development and testing of treatment therapies for people infected with COVID-19 or at heightened risk of infection. It may also provide advice on the early deployment of COVID-19 treatments that have been evaluated in clinical trials both in Australia and internationally. A list of members is available in Appendix B.

To date, the TRAG has provided advice on feasibility of trials, protocols and therapeutic proposals, and priorities for clinical enabling infrastructure.



### The NSW Health COVID-19 Vaccine Advisory Group (VAG)

The VAG has been formed to provide strategic expert advice to NSW Health and the NSW Government on the development and testing of candidate COVID-19 vaccines for the prevention of COVID-19. It may also provide advice on the early deployment of COVID-19 vaccines that have been evaluated in clinical trials. A list of members is available in Appendix B.

To date, the VAG has provided advice on the COVID-19 Research Grants, priorities for clinical trials, and a vaccine production proposal.



### Waratah Vaccine Trial Alliance

The Waratah Vaccine Trial Alliance is a collaboration of clinical vaccine trial researchers, consumers, and other stakeholders, established to facilitate rapid conduct of COVID-19 specific and related vaccine trials of both pharmaceutical industry sponsored and investigator-initiated vaccine candidates. Current participating urban hospital sites include: the Sydney Children's Hospitals Network (SCHN); Westmead Hospital; St Vincent's Hospital; and Prince of Wales Hospital.





### **Adaptive Platform Trials Network**

The NSW Adaptive Platform Trials (APT) component of the workstream aims to build capacity to conduct adaptive clinical trials for the treatment of COVID-19 while linking NSW researchers to a global network of experts.

The **three** platforms reach across the ICU, hospital and community settings and offer an alternative to traditional trials by evaluating more than one COVID-19 treatment at a time. Investment in statistical support infrastructure has also been made to optimise the value obtained from the platforms. Reflecting international best practice, this investment places NSW at the forefront of innovative trials in Australia moving into the post-COVID-19 recovery period.

The NSW Adaptive Platform Trial Network includes:



#### REMAP-CAP (A Randomised, Embedded, Multi-factorial, Adaptive Platform Trial for Community-Acquired Pneumonia)

REMAP-CAP is a well-established international platform evaluating treatments to optimise ICU care of patients with CAP.

REMAP-CAP implemented the Pandemic Appendix to include additional domains for COVID-19 therapies. There are 17 sites participating in REMAP-CAP in NSW.



#### ASCOT (Australasian COVID-19 Trial)

ASCOT is an international clinical trials platform that will generate clinical evidence about treatment for COVID-19 that can be applied to reduce mortality or the need for mechanical ventilation in hospitalised but not yet critically ill patients with COVID-19. There are 17 sites participating in ASCOT in NSW.



#### **BEAT-COVID-19**

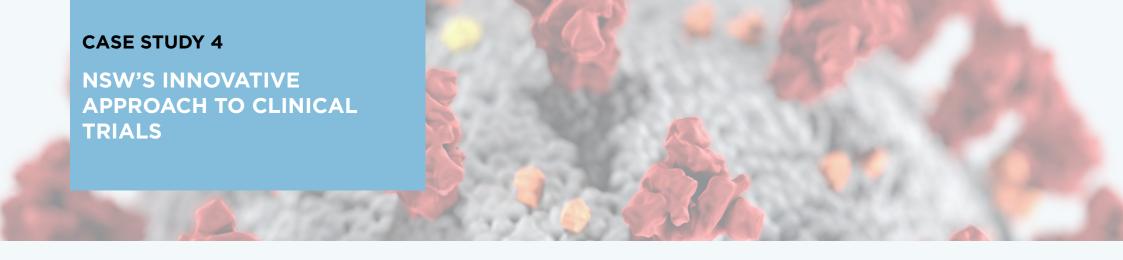
BEAT-COVID-19 is an emerging NSW platform evaluating interventions for the treatment of COVID-19 in high risk, older people who are living in the community or in aged care facilities. It has been designed to harmonise with the similar UK PRINCIPLE trial.

The Health and Clinical Analytics team at the University of Sydney provides statistical support across the three platforms.

Investment in cutting-edge trial infrastructure is likely to enhance NSW's reputation as an international destination for large scale and high impact clinical trials. Importantly, by capitalising on this opportunity to invest in APTs, NSW is well-positioned to reap ongoing benefits when APT capacity and infrastructure is re-focused toward non-COVID-19 research.

"Traditional ways of conducting clinical trials typically address only one or two narrowly defined questions, and many are inconclusive. By taking an adaptive platform approach, we can efficiently address multiple clinical questions, simultaneously evaluate and compare a range of treatments, in a broad variety of patient groups. APTs enable us to use data to learn quickly about what works, what doesn't, and in whom, benefiting those participating in the platform, as well as future patients."

Director of Health and Clinical Analytics, School of Public Health, University of Sydney/
Sydney Children's Hospitals Network



COVID-19 presented an opportunity to invest in the capacity to design and implement Adaptive Platform Trials (APTs), supporting innovation in clinical trial design and delivery in NSW. Unlike traditional trials, in APTs researchers evaluate data as it accumulates so clinicians can optimise management decisions as soon as possible, without having to await the trial's conclusion. Innovation in trials will give NSW residents access to rapidly evolving COVID-19 treatments and strengthen the overarching NSW clinical trials ecosystem.

### **Benefits of investing in Adaptive Platform Trials**

APTs enable multiple interventions to be evaluated simultaneously and sequentially under a single coordinated platform. This means that effective treatments can be identified and deployed faster to NSW patients compared with traditional clinical trial methods, improving patient outcomes and reducing the need for multiple traditional trials.

Using APTs, the commercial development pathway can also be reduced, as progression through the pathway can occur seamlessly rather than through multiple trials across consecutive clinical stages. These innovative approaches to trial design can improve equitable access to novel therapeutics for patients.

### **Building the NSW Adaptive Platform Trials network**

The collaborative work undertaken through the APTs has connected researchers in NSW with established, international adaptive platforms. Trials such as REMAP-CAP demonstrate the ability of their platform infrastructure to rapidly pivot when COVID-19 emerged.

"The nurses and doctors, who were under incredible COVID pressure, were able to pivot quickly to include COVID therapeutic assessments in an adaptive platform, so (a) our COVID patients were getting access to these trial drugs, which was really difficult in the early days of COVID and (b) they could provide data to help make evidence-based decisions about how we treat COVID longer term."

(Manager, clinicaltrialsNSW, Office for Health and Medical Research)

### Critical facilitation role played by the Office

The Office for Health and Medical Research Clinical Trials workstream played an essential liaison and facilitating role, proposing and securing funding agreements, progressing operating plans, and agreeing on how funding would be used to enhance long-term infrastructure for NSW.

### **EXPEDITING STATEWIDE ADMINISTRATIVE PROCESSES**



### **Monitoring and remediation**

During the COVID-19 pandemic the Office for Health and Medical Research's Research Ethics and Governance Unit undertook multiple engagements with the research community, including a presentation on reporting and monitoring to local health district Research Directors, a presentation at an Association of Regulatory and Clinical Scientists (ARCS) conference, and publication of COVID-19 reports on the NSW Health and Medical Research website. The Unit also fielded a survey of Research Directors to better understand what was being done in each district to prioritise COVID-19 related applications.

Figure 1. Monthly NSW COVID-19 research approvals



The Research Ethics and Governance Unit fulfilled a continuous monitoring role to ensure timely processing of both COVID-19 and non-COVID-19 related ethics applications and applications for Site Specific Assessments (SSAs).

Remediation was not necessary for ethics applications, as all local health districts prioritised COVID-19 ethics applications and processed them within reasonable timeframes.

Remediation action for SSAs was taken at five different sites during September and October 2020. This involved the Research Ethics and Governance Unit contacting the impacted research offices individually to facilitate the resolution of governance issues and to offer help and guidance. All the research offices dramatically improved performance and met their KPIs after remediation. For example, one research office showed a high processing time of 33 days in August 2020, significantly over the benchmark of 15 days. This triggered remediation in the monthly monitoring system which commenced in September and was completed in October 2020. The office's performance rapidly improved immediately after the remediation, with the average SSA review time decreasing to 18 days in September, 10 days in October, 4 days in November and 1 day in December 2020.

As a consequence of strong performance, no applications needed to be re-allocated during 2020.



### BENCHMARK: number of applications in 2019 (non-COVID-19)

**ETHICS APPLICATIONS PROCESSED** 

1,931

SITE **APPLICATIONS PROCESSED** 

2,261

Number of applications 1 Jan 2020—31 Jan 2021

COVID-19 related studies		Non-COVID-19 related studies	
ETHICS APPLICATIONS PROCESSED	222	ETHICS APPLICATIONS PROCESSED	2,076
SITE APPLICATIONS PROCESSED	404	SITE APPLICATIONS PROCESSED	3,024



TIME TO APPROVAL

**APPLICATIONS PROCESSED** 

### **NSW BENCHMARKS**

Ethics approvals — 45 days Site approvals — 15 days

**COVID-19 related studies** 

Non-COVID-19 related studies

16 **MEAN ETHICS** DAYS APPROVAL

**MEAN ETHICS** APPROVAL

31 **DAYS** 

MEAN SITE **APPROVAL** DAYS

**MEAN** SITE **DAYS APPROVAL** 

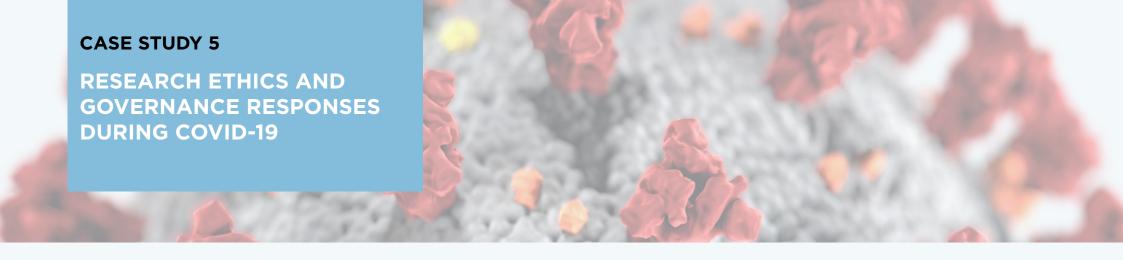


Pathway created for efficiencies in future emergencies and business-asusual procedures

- eSignatures used in place of wet signatures
- Conducting meetings through Zoom allowed flexibility and greater frequency of meetings

"Ethics and governance management can only contribute a fraction of the path to keep research going in NSW, but by smoothing the way, we were always open for business. In NSW we managed to do more research in 2020 compared with past years."

> **Senior Policy Officer, Research Ethics and Governance Unit,** Office for Health and Medical Research



A high volume of studies had to vary or suspend their research in early 2020 due to directives such as physical distancing. At the same time, an unprecedented pressure was placed on the system to rapidly approve COVID-19 research submissions.

### **Guidelines operationalised the messaging for Research Offices** in NSW

The Office for Health and Medical Research published guidelines, providing Research and Governance Officers with advice on potential issues arising and strategies to facilitate rapid commencement of COVID-19 studies. Each local health district tailored their own strategy, consulting with the Office as required. Innovations included holding frequent remote meetings and using electronic signatures to expedite process. The Office for Health and Medical Research played a role in sharing strategies between Research Offices across NSW.

A key enabler of success was early, frequent and clear communication between Research Offices and the research community, facilitating planning of ethics and governance for studies during development.

### Monitoring statewide research ethics and governance activity

REGIS is the statewide workflow management system which captures all research ethics and governance activity. The Office for Health and Medical Research added new fields to REGIS in April 2020, enabling real-time monitoring for COVID-19 and non-COVID-19 research. This showcased high performing local health districts and alerted the Office for Health and Medical Research if any district required remediation.

### Proactive approach taken by Sydney Local Health District (SLHD)

SLHD's Ethics Committee had a highly effective response to the research challenges presented by COVID-19. They were proactive early in the pandemic, putting together an effective working party to develop guidance to ensure clinical trials could continue safely, informed by local and international guidelines. Initial out of session Ethics Committee meetings became regular virtual meetings held weekly for nine months. This enabled SLHD to review a large proportion of ethics proposals from across NSW. Early communication from researchers informed the committee about future submissions to be expected, enabling planning. Rapid turnaround times were facilitated by committed and experienced people on both the committee and in the Research Office, along with support for research from the LHD Chief Executive.

"It required a lot of effort from the office staff and reviewers on the committee. A lot of it is due to the culture, expertise and commitment of people involved, all working to get things done and approved. We were going to be looking at the studies anyway; this was just doing it more quickly".

(Deputy Chairperson SLHD Ethics Review Committee, Chairperson of the Clinical Trials Subcommittee)

The Office for Health and Medical Research was valued by SLHD as a regular contact and source of information about initiatives and other relevant guidance throughout 2020.

### **INDUSTRY SCHEMES**







### **Triage and referral service**

During the COVID-19 pandemic, the Industry

Schemes workstream fulfilled a critical triage and referral role between key industry stakeholders with COVID-19 related requests or proposals and relevant policy teams within NSW Health. From January to October 2020 the team processed:

- 47 procurement related requests
- 59 research and development related requests
- 33 other requests.

This included triage and referral of services of a ventilator manufacturer which later became an integral aspect of the NSW Health COVID-19 response.

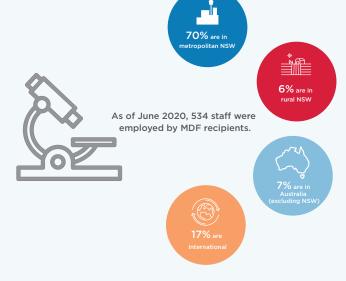
Due to its success, this triage and referral service has developed into a formalised and more general Health and Medical Research Concierge accepting requests from organisations globally and providing advice or referrals as appropriate.

### **Supporting Medical Device Fund recipients**

The Medical Devices Fund (MDF) supports development and commercialisation of competitive technology in the medical device industry. The MDF also seeks to bring local innovation to market and improve the uptake of cost-effective technology by the health system, boosting economic growth and improving patient outcomes.

Due to the threat COVID-19 presented to small or start-up businesses such those funded through the MDF. the NSW Medical Devices Fund COVID-19 Relief Package was established.

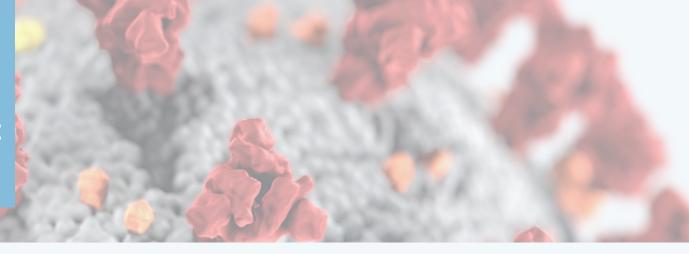
- Four MDF firms left vulnerable from the pandemic received assistance through the COVID-19 Relief Package to ensure viability to support the COVID-19 recovery period (\$2.01M)
- No MDF recipients permanently shut down due to COVID-19.
- To date, three MDF recipients have contributed to producing COVID-19 related technology or products:



- CleanSpace Halo is a reusable respirator used in healthcare settings for pandemic preparedness. As a result of COVID-19, the device was successfully deployed to a number of Australian hospitals.
- Atomo Diagnostics is transforming rapid diagnostic testing (RDT) through the design and manufacture of innovative blood-based medical devices and currently offers diagnostic test solutions for screening for COVID-19 at the point of care.
- SpeeDx specialises in molecular diagnostic solutions and has partnered with Nepean Hospital to develop a risk-based COVID-19 management test.

### **CASE STUDY 6**

MDF GRANT RECIPIENT
SUCCESSFULLY PRODUCES
MEDICAL TECHNOLOGY DEVICE
LOCALLY TO RESPOND TO THE
GLOBAL COVID-19 PANDEMIC



### CleanSpace respirators developed with the support of the Research Concierge

Prior to the COVID-19 pandemic, the Medical Devices Fund (MDF) awarded CleanSpace two rounds of funding (2015 and 2019) to support the development of their innovative workplace respiratory protection equipment. The CleanSpace technology is a lightweight personal respirator, originally developed for industrial use, providing protection from dust particles. CleanSpace had approached NSW Health via the MDF looking for a healthcare application, as they had predicted that in the event of a pandemic there would be a shortage of disposable masks for healthcare workers.

### Pandemic-ready with high market value

With the prior year's investment and support from the MDF, CleanSpace was ready to support the response when the COVID-19 pandemic emerged.

In March 2020, the Office for Health and Medical Research introduced CleanSpace to NSW Health Procurement and NSW Treasury via the Office's Research Concierge service. Through this introduction, respirators were deployed across a number of Australian public hospitals and were particularly useful for anaesthetic, intensive care, head/neck surgical and emergency teams.

This deployment across Australian hospitals was in parallel to distribution in Japan, Singapore, Malaysia, Taiwan and Korea, as well as US and European hospital facilities, who accelerated their roll out of CleanSpace respirators during the pandemic.

In October 2020, CleanSpace listed on the Australian Stock Exchange following a \$131.4 million Initial Public Offering at \$4.41 per share. Upon closing on their opening day, CleanSpace was trading 48% higher at \$6.50 per share, signifying the value the Australian market could see at that point in time in their innovative technology.

## **Economic benefits for NSW from the global success of CleanSpace**

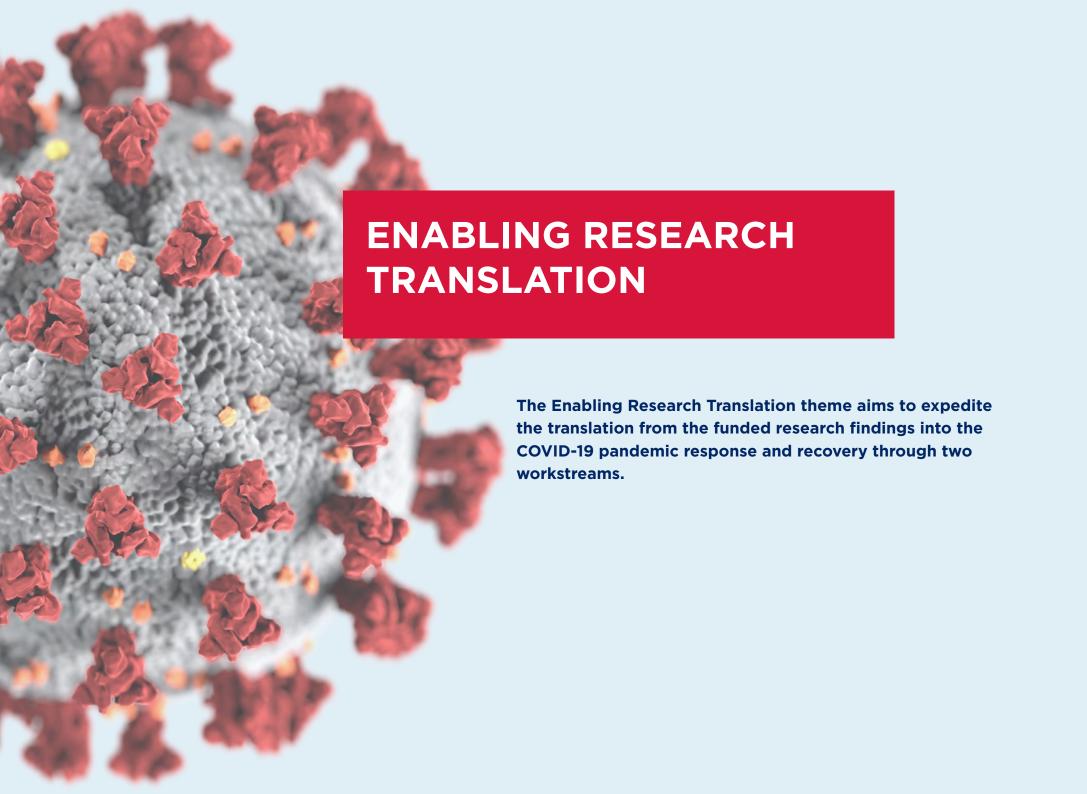
NSW reaps the benefits of the global success of CleanSpace, as the company's headquarters are in NSW, the Intellectual Property remains in NSW, and the manufacturing is also in NSW, thus creating a local ecosystem around their technology. International expansion and subsequent sales attract revenue back into NSW and create local employment opportunities, which are important for the NSW economy to support the COVID-19 recovery.

CleanSpace is a prime example of how the MDF provides support, opportunities and goes on the journey with funding recipients, which fosters the medical devices innovation ecosystem in NSW.

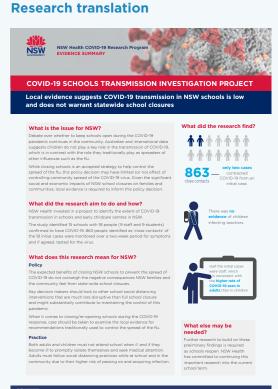
"If you invest in the right people and the technology has a market demand, like CleanSpace, they will flourish and seize the opportunity to make a difference ... and they will always acknowledge the support that they received from government, particularly from NSW Health.

That's a really big lesson for us."

(Director, Enterprise and International Partnerships,
Office for Health and Medical Research)



# **RAPID TRANSLATION AND COMMUNICATIONS**



The Rapid Translation service provides rapid research synthesis of COVID-19 Research Program outputs and targeted dissemination to key decision makers. The service is provided as needed by the Evidence and Evaluation Unit (EEU) in the Centre for Epidemiology and Evidence (CEE).

A workflow and template has been established for rapid translation of research findings to ensure there is no unnecessary delay between delivery of research outcomes and application to policy and practice. This involved development of a standard process for generating synthesis of COVID-19 research products, with a target turnaround time of 3-5 business days between delivery of research outcomes

and development of a synthesised document to assist in translation to policy and practice.

Communication and rapid translation outputs include external-facing project snapshots and project stories published on webpages, as well as internal evidence summaries with policy recommendations.



#### **Communications**

Throughout the COVID-19 pandemic, NSW Health has communicated key activities and research outcomes publicly, including through the NSW Health and Medical Research website and social media accounts.

As of 31 January 2021:

- the website has had a total of 41,025 hits on pages related to COVID-19; overall, this has formed 22.3% of total activity on the site
- the highest volume of activity on COVID-19 related webpages on the site was in May 2020 (12,035 views, 46.9% of total views)
- the COVID-19 Research Program webpage has been visited a total of 28,683 times
- the Clinical Trial Guidance webpage has been visited a total of 4,689 times.



NSW HEALTH AND MEDICAL RESEARCH WEBSITE

**40** COVID-19 related stories, project stories, project snapshots and media releases published.

**NSW HEALTH WEBSITE** 

Additional 4 stories related to COVID-19 research projects published.

#### **PUBLICATIONS WITH THE HIGHEST NUMBER OF VIEWS**

#### "First COVID-19 research grants announced" – July 2020 (1,391 views)

Media release announcing that the first round of projects to receive funding under the \$25 million COVID-19 Research Grants program had been announced and listing the seven projects worth \$3.3 million being funded through the program.

#### "The analytical tool that could take the ambiguity out of COVID-19 test results" – August 2020 (1,142 views)

Project story detailing the work being undertaken by NSW Health Pathology as a Round 1 COVID-19 Research Grant recipient (Improved Confirmatory Diagnosis of SARS-CoV-2 infection using Protein Mass Spectrometry).

#### "Blood pressure drugs may bring clarity to new COVID-19 treatment" – June 2020 (936 views)

Story about the 'Controlled evaLuation of Angiotensin Receptor Blockers for COVID-19 respiraTory Disease' (CLARITY) study which aims to examine the effectiveness of angiotensin II receptor blockers (ARBs) on improving the outcomes of people who tested positive for COVID-19 disease.

@NSWMedResearch TWITTER ACCOUNT

8 COVID-19 related stories shared

#### **PUBLICATIONS WITH THE HIGHEST NUMBER OF VIEWS**

"Surveying the behaviours of a population in a pandemic will reveal data to refine COVID-19 response and help understand the wider health implications. A @NSWHealth grant to the @SaxInstitute will drive this vital collection of information #C19RP" – October 2020 (41,488 views)

A story detailing the work being undertaken by the Sax Institute 45 and Up COVID Insights project (Round 1 COVID-19 Research Grant recipients).

"For Aboriginal people, the pandemic is just one of many reasons preventative health care services may not be accessible. Together with @NSWHealth and Aboriginal communities, @UniNewEngland Prof Kim Usher is looking to change that" – September 2020 (39,714 views)

A story detailing work being undertaken by the University of New England as a result of Round 1 COVID-19 Research Grant funding through the 'Impact of COVID-19 on Indigenous Australians' preventive health behaviours: A mixed methods study' project.

"Difficult' samples create confusion in COVID-19 diagnosis, but a new testing approach using mass spectrometry and supported by a NSW Health COVID-19 Research Grant might help solve the problem" – August 2020 (32,544 views)

Project story detailing the work being undertaken by NSW Health Pathology as a Round 1 COVID-19 Research Grant recipient (Improved Confirmatory Diagnosis of SARS-CoV-2 infection using Protein Mass Spectrometry).

## **NEXT STEPS**

A Final Impact Evaluation Report for the NSW Health COVID-19 Research Program will be developed at the conclusion of the COVID-19 Round 2 Research Grants. The Final Report will include analysis of additional contributions the Program has made to the COVID-19 response and recovery, with a focus on impacts across multiple domains and value for money that have emerged since February 2021.



#### **Contribution to Knowledge Generation**

- While this report includes preliminary outcomes from Round 1 COVID-19 Research Grants and Emergency Response Priority Research, finalisation of funded research (including Round 2) will enable further knowledge generation impacts to be reflected, including publication and citation numbers and instances of new insights, tools or methodologies. Additional translation and communication activities will be identified in the Final Report, including number of evidence summaries, instances of evidence translation, and COVID-19 related stories published on public websites or social media.
- Further development of the Adaptive Platform Trials infrastructure will enable ongoing knowledge generated within the NSW clinical trials ecosystem to be reported.



#### **Contribution to Clinical Care**

- Finalisation of funded research projects will enable assessment of the extent to which funded research has contributed to clinical care to support the NSW response or recovery.
- If data is available, the Final Report will assess the extent to which there has been change in the total number of clinical trials in NSW, including active COVID-19 related clinical trials and non-COVID-19 related clinical trials compared to pre-COVID-19, and the number of COVID-19 clinical trials in NSW compared to COVID-19 clinical trials in the other Australian states.



#### **Contribution to Policy and Programs**

- Finalisation of funded research projects will enable assessment of the extent to which the research has contributed to policy and programs in NSW.
- The Final Report will identify instances where clinical trials infrastructure and services have supported ongoing non-COVID-19 trials and impacted on equity of access to COVID-19 and/or non-COVID-19 clinical trials.
- If innovations associated with expedited ethics/SSA processes are hardwired for future public health emergencies or business-as-usual, these changes will be reflected in the Final Report.



#### **Contribution to the Community and Health Outcomes**

- Finalisation of Round 1 and Round 2 of the COVID-19 Research Grants and the Emergency Response Priority Research workstream will enable assessment of impacts the funded research has had on community and health outcomes.
- The Final Report will also reflect the number of MDF recipients who have remained in operation during and post the COVID-19 pandemic, and how this has led to local jobs saved and instances of benefits for patients, the health system and NSW community.



#### **Contribution to Economic Benefits**

- The two rounds of COVID-19 Research Grants, as well as the research funded through the Emergency Response Priority Research workstream, are expected to result in economic benefits through employment of research staff, revenue from commercialised knowledge generated, and leveraged funding from outside NSW. The extent to which this occurred because of the Program will be assessed in the Final Report.
- Where data is available, economic activity resulting from the Enhancement of the Research Ecosystem and Infrastructure theme will be assessed, such as job creation, sustainment of highly skilled employment opportunities in NSW, or additional investment attracted into NSW.

In addition, the Final Report will identify the value for money of selected projects, such as the Sewage Surveillance Program, by applying the HMRI's research impact assessment framework (FAIT). By conducting deep dives on selected projects, the Final Report will identify quantifiable metrics of impact, the contribution to economic benefits of the research investment, and compelling narratives that showcase how the research has led to translation and positive outcomes for NSW.

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# APPENDIX A - PROGRAM LOGIC MODEL

Need		High-level aims	Detailed aims	Activity	Outputs	End user	Impa	
							Short term	Medium and long term (Note these overlap with short term)
was a need identified by NSW to create research evidence to the the state's response to the -19 pandemic.	ing schemes	Workstream 1. COVID-19 Research Grants: to create knowledge and innovations for the pandemic response	Invest in COVID-19 research funding to maximise rapid translation and impact in the short, medium and long term	Develop and administer funded COVID-19 research projects	1. Funded grants and clinical trials by priority and ERPR; recipients report results rapidly using templates. Example metrics for outputs:  # projects funded  # % projects funded by priority area  # % projects by setting  # % projects reporting milestones  \$ spent	Two broad groups of end users:  1. End users for the evaluation: NSW Health Secretary, Ministry Executive, and NSW Treasury.	Contribution to Knowledge Generation #I: New COVID-19 related research innovations via workstreams 1, 2, 3, 4 and 5 #2: New COVID-19 related research knowledge to the NSW COVID-19 response via workstreams 1, 2, 3, 4 and 5 #3: Rapid translation of findings i.e. direct link between research product and end	NOTE: Many of these impacts will accrue beyond the life of the evaluation and some may be aspirational. They are provided to: i) document the path to anticipated impacts and demonstrate the long-term view of the Program, and ii) list impacts that could be modelled/simulated for anticipated cost/benefits (Note, however, this is currently out of scope for
that need a NSW Health Research Program ('the was rapidly designed and ed to: the NSW research ecosystem or research.  ching purpose of the Program	Research fundi	Workstream 2. Emergency Response Priority Research (ERPR): to create evidence for urgent public health management	Facilitate the priority projects focused on public health	Ensure appropriate governance in place, ensure ethics requirements are met, monitor progress, facilitate reporting and dissemination	# % projects reporting milestones  \$ spent  2. Application of Workstream 6's Rapid Translation Synthesis platform to project outputs (i.e. examples of expedited translation from 1-page Evidence Summaries for research findings)  3. Series of new products (application form, reporting template, program logics designed to encourage translation)	Other leadership groups across NSW including Public Health Emergency Operations Centre/Public Health Response Branch, State Health Emergency Operations Centre, Critical Intelligence Unit, Senior Executive Forum, and Health	users - time between discovery and utilisation via workstreams 1, 2, 3, 4 and 6  #4: First analysis of effectiveness from COVID-19 research initiatives, including programs that address equity issues via workstreams 1, 2, 3, 4, 5 and 6  #4a: Key learnings as to what worked/did not work from funded COVID-19 initiatives (including translation). Initial recommendations for health sector preparedness for i) another emergency and/or ii) consideration for post-COVID-19 business as usual via workstreams 1, 2, 3, 4, 5 and 6  Contribution to Clinical Care	the evaluation).  Contribution to Knowledge Generation #1: Analysis of effectiveness from Program initiatives, key learnings on programs that demonstrated cost-effectiveness; insights on programs that may be suitable for scale-up; insights on programs that addressed equity issues; recommendations for preparedness for the next pandemic/emergency; understanding why/how successful translation occurred via workstreams 1, 2, 3, 4 and 5 but mostly workstream 6
research evidence to guide ogram development oth the NSW COVID-19 recovery for the NSW nd economy.	arch ecosystem and infrastructure	Workstream 3. Clinical Trials: to increase NSW-based participation in clinical trials in the COVID-19 environment	Clinical trials initiatives to:  1. Implement an adaptive clinical trials platform across NSW for robust and rapid assessment of potential COVID-19 therapeutics  2. Encourage NSW-based participation across multiple sites in high profile industry-sponsored national and international trials  3. Develop statewide accessible clinical trials enabling infrastructure  4. Foster collaboration across, and develop maturity of the sector	1. Establish the Vaccine and Therapeutic Advisory Groups and commence meeting schedule 2. Implement an adaptive clinical trials platform across NSW for robust and rapid assessment of potential COVID-19 therapeutics 3. Encourage NSW-based participation across multiple sites in high profile industry-sponsored national and international trials 4. Develop statewide accessible clinical trials enabling infrastructure	1. Development of adaptive platform clinical trial infrastructure and framework across three settings (ICU, hospital and community) 2. Recommendations from VAG and TAG sent to decisions maker in public or private sector 3. Enabled COVID-19 and non-COVID-19 clinical trials in NSW	2. End users for research and infrastructure outputs (use of outputs by these end users facilitate 'impact'):  • Ministry of Health, including the Chief Health Officer and Public Health Emergency Operations Centre/Public	#5: New clinical practice/technologies via workstreams 1, 2, 3, 4 and 5 #6: Identification of technologies and models of care for COVID-19/COVID-19 via workstream 3  Contribution to Policies and Programs #7: New, confirmed and/or adapted health and industry policies/programs as a result of research evidence generated by this Program via workstreams 1, 2, 3, 4, 5 and 6  #8: New, confirmed and/or adapted health and industry policies/programs to support recovery as a result of research evidence generated by this Program via	<ul> <li>#2: Knowledge about value and affordable research products that did not translate - why they failed to translate and remedies for translation if these products are needed via workstream 6</li> <li>Contribution to Clinical Care</li> <li>#3: Contribution to evidence based, cost effective and affordable research products used in policy and practice (pharma, devices, models of care) via workstreams 1, 2, 3, 4, 5 and 6</li> <li>Contribution to Policies and Programs</li> <li>#4: Monitored and evaluated effect of policy including health benefits (i.e.</li> </ul>
irch ecosystem and infra		Workstream 4. Expediting Statewide Administrative Processes: to expedite Human Research Ethics Committee (HREC) and SSA processes and hardwire innovations into the post-COVID-19 research environment	Speed up ethics approval and site specific authorisation to:  1. Facilitate faster initiation of COVID-19 research  2. Work with LHDs to design framework and processes to monitor and speed up approval for COVID-19 research  3. Investigate opportunities for COVID-19 processes to be retained for general use	Monitor and facilitate LHD/SCHN to expedite ethics and SSA approvals	1. Prioritised HREC approval for COVID-19 research 2. Fortnightly monitoring of HREC and SSA approval times and mechanisms to implement remedies if required. Example metrics for outputs:  • time between COVID-19 research ethics/SSA lodgement and approval, by LHD (See REGIS)  • process time compared between COVID-19 and non-COVID-19 research ethics process times (See REGIS)  3. Innovative processes and structures to expedite HREC and SSA approval times (e.g. trialled HREC speed interventions, reallocation of ethics applications)	Health Response Branch  Minister for Health and Medical Research Researchers and research funders (e.g. NHMRC)  Health services Other NSW Government departments (e.g. Department of Education, Department of Premier and Cabinet)  Australian Government	workstreams 1, 2, 3, 4, 5 and 6  #9: New, confirmed and/or adapted HREC and SSA processes to expedite approval processes that are scalable beyond COVID-19 via workstream 4  #10: Safe access to COVID-19 therapeutics for NSW researchers, health care workers and community, and quality data to inform the NSW COVID-19 response via workstream 3  Contribution to the Community and Health Outcomes  #11: Greater community knowledge about COVID-19: prevention/treatment/management/new policies via workstreams 1, 2, 3, 4, 5, 6 and 7  #11a: Prevention policy and other interventions to reduce transmission  #12: Initial health benefits from technology, treatments and models of care	evaluated COVID-19 policies for real world effectiveness - requires simulation modelling) via workstreams 1, 2, 3, 5 and 6 #5: New capability for adaptive platform clinical trials in NSW via workstream 3 #6: Sustained expediting of HREC and SSA approvals due to new innovative processes and policies developed during COVID-19 via workstream 4  Contribution to the Community and Health Outcomes #7: Health benefits (e.g. quality of life) from technology, treatments and models of care that have been contributed to by the Program. Includes prevention, treatment and management via workstreams 1, 2, 3, 4 and 5
	Resc	Workstream 5. Industry Schemes: to support the medical devices industry during COVID-19 and into the recovery	Support commercialisation of therapies and devices for COVID-19     Support the medical devices industry during COVID-19 and into the recovery period     Assist industry to pivot to address critical supply chain issues	Design and implement the COVID-19 Triage Service, engage across government to support the medical device sector	Operational data from the Triage Service     Designed policy to support early stage and vulnerable MDF recipients     Pivoting manufacturers	Industry (including MDF recipients and biopharmaceutical and devices)  Media Patients and community	(COVID-19 prevention, treatment, management) via workstreams 1, 2, 3, 4 and 5  Contribution to Economic Benefits  #13: Viability of MDF recipients (compared to baseline via workstream 5 survey) via workstream 5  #14: Number of MDF funded companies that are pivoting via workstream 5  #15: Number of MDF funded companies that remain viable via workstream 5  #16: Examples of COVID-19 innovations developed by MDF funded companies via	Contribution to Economic Benefits     #8: Growth of devices and therapeutics industry, workforce, and revenues in NSW     #9: ROI of sustained acceleration of HREC and SSA processes (as noted methods to be developed) via workstream 4     #10: ROI for selected deep-dive research projects and innovations (establish long-term impacts of projects versus total cost) via
	Islation	Workstream 6. Research Translation and Impact Assessment: to expedite the use of research outputs by end users and measure the impact of the Program	Develop resources for rapid research synthesis and a feedback loop between COVID-19 research findings and key decision makers (i.e. link research outputs to end users)     Evaluate the impact of the Program	Design architecture of Rapid Translation Synthesis platform, agreed impact framework and methods for evaluating the Program, understand evaluation end user needs for reporting  Design architecture of Rapid Translation Synthesis platform, agreed impact framework and methods for evaluating the Program, understand evaluation end user analysis to be determined) via workstreams 4 and 1. Research translation process established  2. # Evidence Summaries for rapid translation 3. # Research translation processes facilitated  #17b: Economic benefit of faster translation process established  #17c: Economic benefit of faster translation process established  #17b: Economic benefit of faster translation process established  #17c:	workstream 5 #17a: Economic benefit of faster HREC and SSA approval processes (NB: methods of analysis to be determined) via workstreams 4 and 6 #17b: Economic benefit of faster translation due to Rapid Research Synthesis platform (NB: methods of analysis to be determined) via workstream 6 #18: Value for money for selected deep-dive research projects and innovations via	workstream 6  #11: Contribution to NSW economy (evidenced in state GDP; employment, device industry growth etc) via workstreams 1, 2, 3, 4, 5 and 6  form		
Research tran	Research tran	Workstream 7.  Communications: to communicate and promote the Program's achievements	1. Communicate the activities and achievements of the Program 2. Promote research findings from the Program (i.e. supporting dissemination and translation) 3. Provide a snapshot of all COVID-19 research and assets across NSW (i.e. information and promotion) 4. Assist with communication to LHDs on ethics SSAs (with Workstream 4)	Strategic communication about the Program and wider COVID-19 research across NSW	1. Project snapshots 2. Researcher interviews/news articles 3. Project outcome summaries 4. Reach (webpage visits, impressions, views) 5. Engagement (likes, retweets, comments, shares)		workstream 6 #19: Foster collaboration across and maturity of the clinical trials sector to ensure NSW is a destination of choice for clinical trials Sponsors (COVID-19 and non-COVID-19) via workstream 3	

# **APPENDIX B - ADDITIONAL METRICS**

Table 1. Round 1 COVID-19 Research Grants projects

CHIEF INVESTIGATOR	HOST ORGANISATION	PROJECT TITLE	BUDGET
Dr Linda Hueston	NSW Health Pathology Westmead Institute for Medical Research	Development, evaluation and validation of ELISA assays for both the diagnosis of COVID-19 and utility in seroprevalence in communities	\$389,411
Professor William Rawlinson	NSW Health Pathology The University of Sydney	Improved confirmatory diagnosis of SARS-CoV-2 infection using protein mass spectrometry	\$111,318
Professor Vitali Sintchenko	NSW Health Pathology The University of Sydney	Enhanced genomic tracking of COVID-19 importations and transmissions in NSW	\$471,583
Associate Professor Joanne Bryant	UNSW Sydney	A rapid qualitative assessment of COVID-19 health needs in an urban Aboriginal community	\$152,092
Professor Kathleen Clapham	University of Wollongong	A place-based pandemic response to the strengths and vulnerabilities of Aboriginal communities in southeastern New South Wales	\$793,125
Dr Martin McNamara	Sax Institute	45 and Up: COVID Insights	\$983,920
Professor Kim Usher	University of New England	Impact of COVID-19 on Indigenous Australians' preventive health behaviours: A mixed methods study	\$335,680
TOTAL FUNDING			\$3,237,129

**Table 2. Round 2 COVID-19 Research Grants projects** 

CHIEF INVESTIGATOR/S	HOST ORGANISATION	PROJECT TITLE	BUDGET
Professor Anthony Cunningham	Westmead Institute for Medical Research	Novel diagnostics for evaluating duration of immunity after COVID-19 and for Phase I/II vaccine trials	\$540,384
Associate Professor Fabienne Brilot	Kids Research at SCHN	Ultra-sensitive PC2 serology and rapid viral outgrowth assays	\$567,130
Associate Professor Deepak Bhonagiri	South Western Sydney Local Health District	24/7 eICU model of care for Level 4 ICUs in rural NSW	\$499,696
Dr Shannon Nott Professor Andrew Wilson	Western NSW Local Health District and University of Sydney	Evaluation of the Virtual Rural Generalist Service (VRGS) as an effective, "COVID-19 resilient" model of care	\$500,000
Dr Milena Heinsch	The University of Newcastle	The eCliPSE COVID-19 project: an electronic pathway to care for NSW residents to reduce depression, anxiety, and alcohol use problems in the face of COVID-19	\$459,046
Professor Valsamma Eapen	South Western Sydney Local Health District	A digital solution to address the mental health and financial impacts of the pandemic for children and their parents in the first 2000 days	\$495,000
Scientia Professor Richard Bryant	UNSW Sydney	Rapid evaluation of a scalable program for reducing common mental disorders during COVID-19	\$496,624
Ms Sandra Bailey	Sax Institute	Supporting the mental health of health workers at Aboriginal Community Controlled Health Services in NSW during the COVID-19 pandemic and beyond	\$498,010
Professor Kristine Macartney	NCIRS and Sydney Children's Hospitals Network	Designing and testing COVID-19 vaccine public health messages	\$297,200
Associate Professor Emily Blyth	The University of Sydney	Manufacture of banked SARS-CoV-2 specific T lymphocytes derived from recovered COVID-19 patients to prevent progression to severe COVID-19 in vulnerable individuals	\$423,768
TOTAL FUNDING			\$4,776,858

Table 3. Emergency Response Priority Research projects (as of 31 January 2021)

KEY RESEARCHERS	HOST ORGANISATION	PROJECT TITLE	BUDGET
Scientia Professor John Kaldor Associate Professor Bette Liu	UNSW	COVID-19 NSW outcomes study	\$66,778*
Professor Robert Booy Dr Shopna Bag	University of Sydney, Western Sydney Local Health District	Burden of influenza-like illness (ILI) disease in adults ≥65 years in aged care facilities	\$177,709
Scientia Professor John Kaldor Professor Kristine Macartney	NCIRS	Serosurveillance for SARS-CoV-2 infection	\$476,567
Professor Kristine Macartney	NCIRS	NSW Health COVID-19 schools transmission investigation project	\$293,213
Dr Kaye Power	Sydney Water	Wastewater-based epidemiology for COVID-19 - validation pilot	\$46,000
Dr Philip Britton	SCHN	Surveillance of paediatric COVID-19, Kawasaki disease and PIMS-TS via PAEDS	\$50,000
Dr Louise Causer	UNSW	Retrospective infected health care worker study	\$88,585*
Professor Kristine Macartney Dr Lucy Deng	NCIRS	The Australian First Few 'X' (FFX) Project for COVID-19	Initial costs supported by OHMR - rolled into other support costs
TOTAL FUNDING			\$1,198,852

<sup>\*</sup> estimate of salary support for researchers, to be invoiced by UNSW.

NB. Does not include the ongoing 2021 funding of the Schools Transmission study (\$276,806) or the commenced new study (Safety and effectiveness of the COVID-19 vaccination program; \$610,629), approved 25 February 2021.

#### **Table 4. Emergency Response Priority Research reports and publications**

	REPORT	
SEROSURVEILLANCE FOR SARS-CoV-2 INFECTION	1. Seroprevalence of SARS-CoV-2-specific antibodies in Sydney, Australia following the first epidemic wave 2020 <sup>5</sup>	
NSW HEALTH COVID-19 SCHOOLS TRANSMISSION INVESTIGATION PROJECT	1. Transmission of SARS-CoV-2 in Australian educational settings: a prospective cohort study <sup>6</sup>	
COVID-19 NSW OUTCOMES STUDY	1. Hospital outcomes after a COVID-19 diagnosis from January to May 2020 in New South Wales Australia <sup>2</sup>	
RETROSPECTIVE INFECTED HEALTH CARE WORKER STUDY	1. COVID-19 in healthcare workers in NSW <sup>9</sup>	
	PRESENTATION	
SEROSURVEILLANCE FOR SARS-CoV-2 INFECTION	<ol> <li>Presentation to PHRB leadership, 6 August 2020</li> <li>Presentation to COVID-19 Research Leadership Team, 11 August 2020</li> <li>Australasian COVID-19 Virtual Conference, "Seroprevalence of SARS-CoV-2 antibodies in Sydney, April-June 2020", 10 December 2020</li> </ol>	
RETROSPECTIVE INFECTED HEALTH CARE WORKER STUDY	1. Australasian COVID-19 Virtual Conference, "Lessons from a national First Few "X" household transmission stud 8 December 2020	
THE AUSTRALIAN FIRST FEW 'X' (FFX)	<ol> <li>Presentation to Infectious Diseases Community of Practice and Clinical Council, 19 August 2020</li> <li>Kirby Institute Seminar Series, "COVID-19 and healthcare workers in NSW", 20 October 2020</li> <li>Australasian COVID-19 Virtual Conference, "Investigating healthcare worker infections in NSW: new approache and lessons learned", 10 December 2020</li> </ol>	
NSW HEALTH COVID-19 SCHOOLS TRANSMISSION INVESTIGATION PROJECT	<ol> <li>Presentation to PHRB, 24 June 2020</li> <li>NCIRS seminar series, "Learning together – Transmission of SARS-CoV-2 in NSW educational settings", 22 September 2020</li> <li>Australasian COVID-19 Virtual Conference, "Factors contributing to SARS-CoV-2 outbreaks in four New South Wales educational settings", 10 December 2020</li> <li>Australasian COVID-19 Virtual Conference, "To open or close? COVID-19 in Educational Settings: key learning points", 10 December 2020</li> </ol>	
COVID-19 NSW OUTCOMES STUDY	1. Australasian COVID-19 Virtual Conference, "Hospitalisations following the first wave of COVID-19 in NSW", 10 December 2020	

#### Table 5. VAG and TRAG members

#### **VAG MEMBERS**

- Professor Kristine Macartney (Chair), Director, Australian National Centre for Immunisation Research and Surveillance (NCIRS)
- Professor Peter McIntyre, Senior Professorial Fellow, NCIRS and Professor, Women's and Children's Health, University of Otago
- Professor Tony Cunningham, Executive Director, The Westmead Institute for Medical Research and the Institute's Centre for Virus Research
- Professor Tania Sorrell, Professor and Co-Director, Marie Bashir Institute for Infectious Diseases & Biosecurity, University of Sydney
- Professor John Attia, Assistant Dean Research and Laureate Professor,
   Office of the PVC Health and Medicine, University of Newcastle
- Professor Raina MacIntyre, Program Head, Kirby Institute and UNSW
- Professor Andrew Grulich, Program Head, Kirby Institute and UNSW
- Professor Tom Snelling, Director of Health and Clinical Analytics, School of Public Health, University of Sydney/Sydney Children's Hospitals Network
- Anita van der Meer, Manager, clinicaltrialsNSW, NSW Health, Office for Health and Medical Research

#### **TRAG MEMBERS**

- Professor Garry Jennings AO, Executive Director, Sydney Health Partners (Chair)
- Professor Bruce Neal, Executive Director, The George Institute;
   Professor of Medicine, UNSW
- Professor Tom Snelling, Director of Health and Clinical Analytics, School of Public Health, University of Sydney/Sydney Children's Hospitals Network
- Professor Tania Sorrell, Professor and Co-Director, Marie Bashir Institute for Infectious Diseases & Biosecurity, University of Sydney
- Scientia Professor Guy Marks, University of NSW; Honorary Professor, Woolcock Institute, University of Sydney
- Professor John Simes AO, Director NHMRC Clinical Trials Centre, University of Sydney; ACTA representative
- Professor Tony Kelleher, Professor and Program Head, The Kirby Institute, UNSW
- Ainslie Cahill, Consumer representative, SPHERE
- Megan Ford, Executive Director, Clinical Trials, South Western Sydney Local Health District and Ingham Institute
- Professor Jennifer Martin, Clinical Pharmacologist and Practicing General Physician, School of Medicine and Public Health, University of Newcastle
- Professor Sarah Hilmer, Conjoint Professor of Geriatric Pharmacology, University of Sydney
- Anita van der Meer, Manager, clinicaltrials NSW, NSW Health, Office for Health and Medical Research

## **APPENDIX C - ECONOMIC SCORECARD**

# Proposed economic analysis methods for the Sewage Surveillance Program research impact assessment in the Final Report

Cost study for sewage surveillance

A rapid cost study will be conducted to report the research and development cost of sewage surveillance and the associated implementation cost. The cost study will be constructed at a high level to reflect the resources consumed by sewage surveillance and will be used to report return on investment for the entire Sewage Surveillance Program.

NB: At the time of this report, the costs for the project were still accumulating.

#### **Estimation of benefits**

The NSW Health Critical Intelligence Unit (CIU) has estimated the counterfactual representing the scenario: What if NSW had not implemented its COVID-19 response initiatives? Hence, the counterfactual represents what might have happened had NSW not been successful in managing COVID-19 (Source: Economic implications of health system responses to COVID-19, Critical Intelligence Unit, 17 Feb 2021).

The estimates will support calculation of the total values of benefits for the three variables in the adjacent column.

The actual attribution of benefit to sewage surveillance is unknown. However, from the impacts in the scorecard a case can be made that sewage surveillance made a contribution to NSW's success in managing COVID-19. At this stage it is proposed that the attribution be highly conservative (1% with sensitivity analysis 0.5% to 1.5%) in all benefit instances (benefits = avoided mortality, hospitalisations and lost gross domestic product (GDP)).

Three key benefits that the Sewage Surveillance Program has contributed to will be examined:

- Contribution to avoided mortality due to COVID-19: Had NSW not controlled COVID-19, there
  would have been an expected 5,250 deaths (based on mortality data from the EU and USA);
  instead, we had 56 deaths (Source: CIU). We will apply an average value of a statistical life to
  monetise this estimated benefit.
- 2. Contribution to **avoiding excess COVID-19 related hospitalisations** in NSW (actual hospitalisations in NSW to 19 Sept 2021 were 418 plus 148 ICU admissions): If UK rates of hospitalisation were applied to NSW, the estimated hospitalisations would have been approx. 48,000.
- 3. Contribution to **avoiding an additional downturn in state GDP** because unnecessary lockdowns and unnecessarily extended lockdowns were avoided: The CIU has not estimated this GDP value as yet partly this is likely to be due to the time lag in publishing state GDP. Nonetheless, following the CIU counterfactual methods, we will estimate the actual downturn in state GDP and compare this to the downturn in state GDP that might have eventuated had NSW experienced similar GDP impacts as reported in the UK or EU.

A small (1%) attribution to the Sewage Surveillance Program is proposed across these three benefits. The resulting value will be used in the economic analysis to determine value for money.

