PROTOCOL

COVID Wellbeing: Mapping vulnerability to, and impact of, the COVID-19 pandemic on the mental health and wellbeing of Australian children, young people, and their families

HREC Reference Number: HREC73816
Protocol Version: 6.0
Date: 28th January, 2022

Statement of Compliance

This study will be conducted in compliance with all stipulation of this protocol, the conditions of the ethics committee approval, the NHMRC National Statement on Ethical Conduct in Human Research (2007 and all updates), applicable national and local regulations and in the spirit of the Integrated Addendum to ICH E6 (R1): Guideline for Good Clinical Practice E6 (R2), dated 9 November 2016 annotated with TGA comments.

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PROTOCOL SYNOPSIS

TITLE	COVID Wellbeing: Mapping vulnerability to, and impact of, the COVID-19 pandemic on the mental health and wellbeing of Australian children, young people, and their families
OBJECTIVES	The aim of this research program is to analyse existing data to understand the impact of COVID-19 on the mental health and wellbeing of children, young people, and families, and how pre-pandemic experiences contribute to risk and resilience.
DESIGN	This research program applies statistical methods to existing datasets. The study setting is MCRI, using existing IT infrastructure.
OUTCOMES AND OUTCOME MEASURES	The primary outcome to be explored is the mental health and wellbeing of children, young people, and their families. Mental health and wellbeing has been measured in different ways across the existing datasets, including via the emotions and worries subscales of the Coronavirus Health and Impact Survey (CRISIS).
EXPOSURES	Potential risk and resilience factors prior to the COVID-19 crisis will be explored. Specific exposures of interest include pre-pandemic mental health, psychosocial wellbeing, socioeconomic and demographic circumstances, and health experiences.
POTENTIAL CONFOUNDING FACTORS	Directed Acyclic Graphs (DAGs) will be developed to guide consideration of bias and identify potential sources of confounding, for each analysis.
STUDY POPULATION	We intend to analyse existing data drawn from the Australian child and adolescent population. The number of participants in each data set is variable.
STUDY DURATION	The research program is expected to run from April 2021 to April 2023.
NUMBER OF SITES	The research program site is MCRI.

GLOSSARY OF ABBREVIATIONS

ABBREVIATION	TERM
ATP	Australian Temperament Project
LSAC	Longitudinal Study of Australian Children
CATS	Child to Adolescence Transition Study
MYPS	Mother's and Young People's Study
VAHCS	Victorian Adolescent Health Cohort Study
CAP	The Children's Attention Project
HREC	Human Research Ethics Committee
MCRI	Murdoch Children's Research Institute
NGO	Non-Government Organisation
NHMRC	National Health and Medical Research Council
RCH	Royal Children's Hospital

INVESTIGATOR AGREEMENT

I have read the protocol entitled "COVID Wellbeing: Mapping vulnerability to, and impact of, the COVID-19 pandemic on the mental health and wellbeing of Australian children, young people, and their families".

By signing this protocol, I agree to conduct the study, after approval by a Human Research Ethics Committee or Institutional Review Board (as appropriate), in accordance with the protocol and:

- the principles of the Declaration of Helsinki
- the NHMRC National Statement on Ethical Conduct in Human Research (2007 and all updates)
- the Australian Codefor the Responsible Conduct of Research (NHMRC, 2007 and all updates)
- and in the spirit of the good clinical practice guidelines adopted by the TGA [Integrated Addendum to ICH E6 (R1): Guideline for Good Clinical Practice E6 (R2), dated 9 November 2016 annotated with TGA comments].

Changes to the protocol will only be implemented after written approval is received from the Human Research Ethics Committee or Institutional Review Board (as appropriate), with the exception of medical emergencies.

I will ensure that study staff fully understand and follow the protocol and evidence of their training is documented on the study training log.

Name	Role	Signature and date
Dr Meredith O'Connor	Principle Investigator	 19-03-2021

1. ADMINISTRATIVE INFORMATION

1.1. Sponsor

The sponsor is Murdoch Children's Research Institute. On behalf of the Sponsor, MCRI, the Study Principal Investigator, Dr Meredith O'Connor, will undertake and/or oversee those Sponsor responsibilities delegated by the Sponsor.

Study Sponsor	Murdoch Children's Research Institute
Contact name	Dr Meredith O'Connor
Address	50 Flemington Rd, Parkville, Victoria, Australia

1.2. Expected duration of study

The study is expected to run from April 2021 to April 2023, including time for the publication of the resulting work in peer-reviewed journals.

1.3. Contributorship

Contributors to the project are outlined below. Dr Katherine Lange has been appointed as a Research Officer to support the undertaking of this project. Additional collaborators with specific areas of speciality will be engaged as co-authors on peer-reviewed papers.

Name	Affiliation(s)	Role	Contribution
Dr Meredith O'Connor	Murdoch Children's Research Institute; University of Melbourne	Principle Investigator	Lead the project and establish project management and governance mechanisms
Dr Marnie Downes	Murdoch Children's Research Institute	Investigator	Statistical consultation and oversight
Dr Margarita Moreno-Betancur	Murdoch Children's Research Institute; University of Melbourne; Monash University	Investigator	Statistical consultation and oversight
Prof Craig Olsson	Deakin University; Murdoch Children's Research Institute	Investigator	Content expertise and senior oversight for the research program
Prof David Burgner	Murdoch Children's Research Institute; University of Melbourne	Investigator	Content expertise and senior oversight for the research program
Professor Sharon Goldfeld	The Royal Children's Hospital; Murdoch Children's Research Institute; University of Melbourne	Investigator	Content expertise and senior oversight for the research program
Dr Katherine Lange	Murdoch Children's Research Institute	Investigator	Research Officer undertaking analyses and other research activities for the project
Dr Karen McLean	Murdoch Children's Research Institute	Investigator	Lead a specific analysis on families facing adversity

1.4. Stakeholder involvement

A key internal stakeholder is the Campus-Wide COVID Wellbeing Working Group, which draws together researchers working with longitudinal cohorts to understand impacts of COVID-19 on

psychosocial wellbeing from across the Melbourne Children's Campus. Ongoing collaboration with the Working Group will ensure that redundancy in analyses is avoided, and the benefits of the research maximised. As specific studies are defined within this research program, relevant external stakeholders will be identified and engaged through the investigator team's broad policy networks.

2. INTRODUCTION AND BACKGROUND

2.1. Background and rationale

Children have been spared the worst of the physical impacts of the coronavirus disease (COVID-19). They are at lower risk of becoming infected, symptomatic and transmitting severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). However, the indirect impact of COVID-19 has led to rapid and major upheavals with substantial and pervasive consequences for children's lives.[1] Children are experiencing a range of adversities as a result, including parents struggling with mental health problems and substance abuse, relationship breakdowns, financial stress, and an alarming increase in family violence.[1,2] Exposure to these adversities is expected to have both short and long term consequences for children's social-emotional health and development.[3-5]

Capturing these indirect effects of the pandemic for children and young people is essential. Robust data can help to highlight emerging disparities for marginalised groups, direct services and support to where they are most needed, and justify increased resourcing to support child and adolescent health during the pandemic. Understanding of the adverse impacts being experienced in particular domains, like mental health, can also direct attention to specific mitigating responses.[6] Longitudinal studies established prior to the pandemic can help to inform the targeting of such prevention and intervention efforts, by informing risk associated with pre-pandemic circumstances and health status.[7]

The Melbourne Children's LifeCourse initiative brings together an impressive array of clinical and population-based longitudinal studies from the Melbourne Children's Campus. A number of these cohorts have quickly pivoted to collecting data on the psychosocial impacts of the COVID-19 pandemic. The LifeCourse platform has enabled the rapid sharing of resources and approaches during the design phase of these data collections. As a result, cohorts have generally collected well aligned data from the Coronavirus Health and Impact Survey (CRISIS)[8] tool. The CRISIS tool includes seven domains capturing COVID infection and exposure, life changes, daily behaviours, emotions and worries, media use and substance use.

A strength of these cohorts is that together, they capture the pandemic experiences of children and young people from a range of different backgrounds and circumstances. Importantly, they also include children and young people with different types of health care needs, and so have the potential to inform varying approaches to promoting mental health and wellbeing in the wake of COVID-19 (Figure 1). For example, population-representative cohorts provide insights into the mental health impacts for children and young people in the general community, which is important for informing universal efforts to prevent mental health problems from arising. In contrast, cohorts focused on children with specific ongoing health needs can inform treatment of COVID-related issues in the hospital and other health settings.

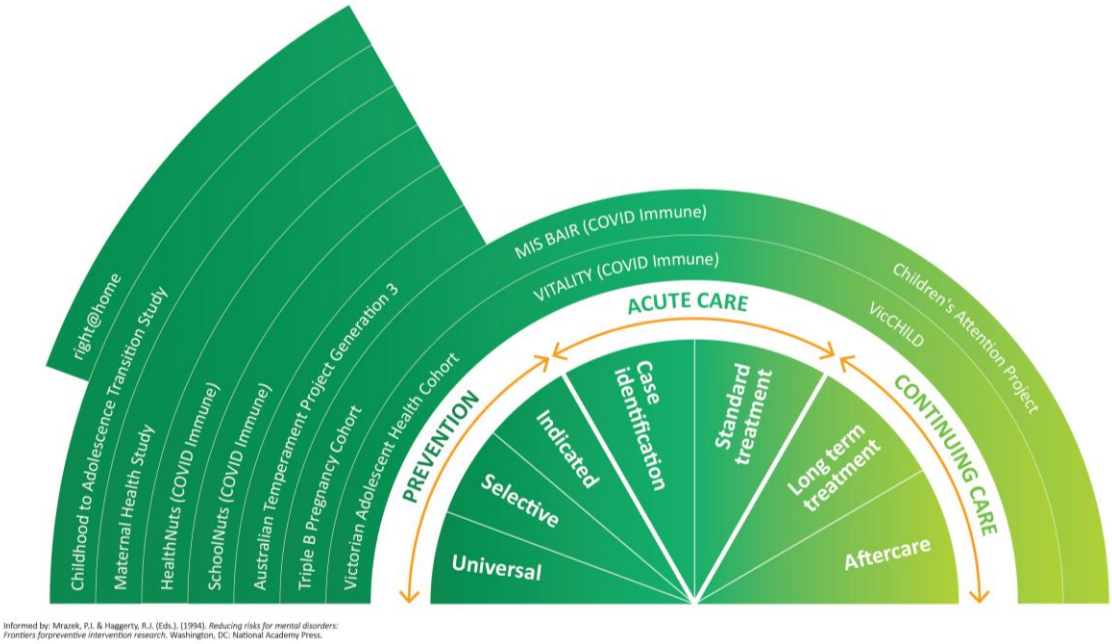

Figure 1. Cohorts capturing the psychosocial impacts of COVID-19 across the continuum of care.

We propose to analyse these aligned data on the impacts of COVID-19 from LifeCourse cohorts to understand:

1) how the pandemic has affected the mental health and wellbeing of children, young people and their families,
2) how pre-pandemic experiences and circumstances shape risk and resilience to these impacts for children and young people, and
3) how the pandemic will continue to shape the future mental health and wellbeing of children young people and their families (in future funded follow-ups).

In this application we seek RCH HREC approval to undertake analysis of existing cohort data to address the first two of these important questions.

2.2. Aim

The aim of this research program is to analyse existing data to understand the impact of COVID-19 on the mental health and wellbeing of children, young people, and families, and how previous experiences contribute to risk and resilience during the pandemic.

3 STUDY OBJECTIVES

3.1 Primary objective

The primary objective of this research program is to generate new knowledge about the outcomes of and influences on mental health and wellbeing during the COVID-19 pandemic and its aftermath.

4 STUDY DESIGN

4.1 Type of Study

This research program will involve analysis of existing datasets. To address the broader aim and objective of this program, specific research questions will be developed, informed by discussion and collaboration with the Campus-Wide COVID Wellbeing Working Group. The Campus-Wide COVID Wellbeing Working Group draws together researchers working with longitudinal cohorts to

understand impacts of COVID-19 on psychosocial wellbeing from across the Melbourne Children's Campus. This collaboration will ensure that redundancy in analyses is avoided (e.g., conducting work already underway by other teams), and the benefits of the research maximised (e.g., by undertaking complementary work that can enhance the impact of other research). As specific research questions are defined, relevant stakeholders will be identified and engaged through the investigator team's broad networks across Victorian and Federal Government.

For each specific research question, the most appropriate dataset(s) will be selected and a data access request submitted through the LifeCourse portal, or via approved processes for external cohorts (e.g., LSAC). Cohorts approve or deny these requests to utilise their data, in line with their specific ethical and governance requirements. The potential datasets to be drawn on include those described below, and others may be added in the future. Each of these cohorts have collected (or are currently collecting) data on the impacts for COVID-19 for participating families. These data have been collected either through standalone modules or by integrating COVID-19 questions into data collections that were planned or underway as the pandemic began, adding to the wealth of existing pre-pandemic data. Together, they capture children and young people with varying health needs across the continuum of care (Figure 1).

4.1.1 Prevention-focused cohorts

4.1.1.1 LSAC Child Health CheckPoint

Longitudinal Study of Australian Children (LSAC) is a nationally representative sample of two cohorts of Australian children – the birth cohort (B-cohort) of 5107 infants, and the kindergarten cohort (K-cohort) of 4983 four-year-olds – each of which commenced in May 2004. A complex survey design was used to select a sample that was broadly representative of all Australian children except those living in remote areas. Data were collected on children's development as well as family and community characteristics. Multiple information sources were used, including parent interview, direct child assessments and observational measures, parent and teacher self-report questionnaires and linkage to administrative datasets. The Child Health CheckPoint is a stand-alone physical health and bio-specimen module offered to the retained B-cohort at Wave 6, and nested between LSAC Waves 6 and 7 in 2015–16. A total of N=1,874 B-cohort families participated. The study child and one of their parents completed a comprehensive health assessment at a CheckPoint Assessment Centre, or if a centre visit was not possible, a shorter home visit was conducted.[9]

4.1.1.2 right@home

right@home is a multi-state nurse home visiting (NHV) randomised controlled trial designed to promote family wellbeing and child development.[10] 722 pregnant women experiencing adversity (≥2 of 10 social risk factors) were recruited between 30 April 2013 to 29 August 2014 from public maternity hospitals in the states of Victoria and Tasmania (Australia). Participants and their children were followed from pregnancy until children turn 6 years of age, including their first year of school. The right@home NHV program is based on the Maternal Early Childhood Sustained Home-visiting program and incorporates additional modules to help parents care for and respond to their children, creating a supportive home learning environment. right@home aims to investigate the effectiveness of the NHV program in improving parent care of and responsivity to the child, and the home learning environment; and longer-term effects on child physical and mental health and language development and maternal parenting and mental health.

4.1.1.3 Child to Adolescence Transition Study (CATS)

The CATS[11] study is a unique longitudinal study of children in metropolitan Melbourne as they approach and transition through adolescence. The study began in 2012 and follows over 1200 children from grade 3 (8-9 years of age) through adolescence. The children are assessed once every year. The study also collected information from teachers through primary school, and parents through to Wave 6 (year 8; 13-14 years). The main focus of the study is on the health and emotional development of children during the middle years of school with the aim of improving our understanding of the many influences that effect the health and emotional adjustment of children as they approach their teens. The study looks at the experiences of children and their families, their changing social context as they move into secondary school and their reactions to the biological changes of puberty. The information collected as part of this large study will help us identify when and how to promote the best health and emotional adjustment in pre-teens.

4.1.1.4 Mother's and Young People's Study (MYPS)

The Mother's and Young People's Study (MYPS) (previously Maternal Health Study) is a multi-wave, prospective cohort study investigating the health and wellbeing of over 1500 first-time mothers and their firstborn children. Women were recruited to the study from six Melbourne metropolitan hospitals between 2003-2005. In the early years of the study the main focus was on women's health and recovery after childbirth. Women taking part in the study completed questionnaires and telephone interviews in early and late pregnancy, and at three, six, nine, 12 and 18 months postpartum, and when their first child was four and ten years of age. Over 800 women in the study have also been followed up after second and subsequent births. Data have been collected on common maternal physical and psychological health problems, including incontinence, sexual health problems, depression, anxiety and intimate partner abuse, and on a range of child health and developmental outcomes. Information has also been collected regarding the social context of women and children, and changing life circumstances as the children grow up. The study aims to improve understanding of social and obstetric factors influencing maternal and child health.

4.1.1.5 Australian Temperament Study Generation 3 Study (ATPG3)

The Australian Temperament Project (ATP) is one of Australia's oldest longitudinal studies of social-emotional development that has followed a representative sample of over 2000 infants and their parents from 4 months (1983) to over 30 years of age. The study has collected detailed age-appropriate survey data on temperament, internalising (depression/anxiety), externalising (violence and addiction) and positive developmental outcomes over 16 waves. Parents, infant welfare nurses, teachers and young people (from 11-12 years) completed questionnaires. In 2011, recruitment commenced of cohort offspring with follow-ups in pregnancy (T3), birth, 8 weeks, 12 months and 4 years of age, combining population surveys with in-depth clinical observations on a broad range of constructs including parent mental health and caregiving, and infant behaviour and attachment security. Bringing together data across three generations, the ATP now provides a rare opportunity to address key questions about how the experiences of one generation may affect the next, from grandparent to parent to child.

4.1.1.6 Triple B Pregnancy Cohort

The Triple B Pregnancy Cohort Study (Bumps, Babies and Beyond) is an Australian study of 1,623 families.[12] The project is a longitudinal birth cohort which examines a wide range of biopsychosocial factors that relate to the health and development of Australian children and families. Importantly, the project has a key focus on examining the impacts of alcohol, tobacco and other drug use in pregnant women and their partners during the prenatal period on infant development and family functioning.

4.1.1.7 Victorian Adolescent Health Cohort Study (VAHCS)

2000 Stories is a landmark longitudinal study spanning more than 20 years, composed of the Victorian Adolescent Health Cohort Study (VAHCS) and the Victorian Intergenerational Health Cohort Study (VIHCS). The VAHCS was established in 1992, with a group of around 2000 Year 9 students (14 – 15 years of age) recruited across Victoria, Australia. Aspects of teenage health and behaviour investigated include mental health, personality and behaviour, school, family, and drug and alcohol use. This information has been used to improve the health of future generations by influencing policy and informing prevention programs. The VIHCS, launched in 2006, is one of the first prospective multi-generational studies in the world to look at how a parent's (VAHCS participant) lifestyle, health and behaviour before pregnancy (including the teenage years), as well as during and after pregnancy, might influence their child's health and development. It is one of the first longitudinal studies of childhood psychosocial development to be embedded within an existing longitudinal study of parent development and aims to understand the processes that might influence many aspects of health and wellbeing across generations.

4.1.1.8 SchoolNuts (COVID Immune)

SchoolNuts is a cross-sectional population-based study that aims to measure the prevalence of food allergy in the early adolescent age group, as well as to understand risk factors for recurrent and severe accidental food ingestion reactions and to determine clinical predictors of food challenge outcomes. 9,630 children aged 10-14 years have been recruited from randomly-selected schools across Melbourne. Participants have completed surveys on allergic disease status, food allergy-specific quality of life, pubertal development and risk-taking behaviour. Parents of participating children have completed questionnaires on family history of allergic disease and environmental exposures. Participants suspected of having a food allergy have attended a hospital clinic for allergy testing and treatment. COVID Immune is a new cohort which brings together four pre-existing cohorts – including SchoolNuts, HealthNuts, MIS BAIR, and VITALITY – and includes a focus on the psychosocial impacts the pandemic.

4.1.1.9 HealthNuts (COVID immune)

The HealthNuts study of 5,300 children is the world's first comprehensive population-based study of food allergy with an objective measurement of true food allergy. The study will enable researchers to better understand the natural history of allergic disorders including food allergy, asthma, eczema and hay fever and the risk factors for developing these conditions in the first six years of life. The study will have important implications for clinical guidelines and public health policy. HealthNuts is part of the COVID Immune collaboration.

4.1.1.10 Millennium Cohort Study (MCS)

The Millennium Cohort Study (MCS) is a nationally-representative cohort of children born in the UK between September 2000 and January 2002.[13] Families were selected through Child Benefit Records, and a disproportionately stratified clustered sampling design was used to over-represent children living in Wales, Scotland and Northern Ireland, disadvantaged areas, and, in the case of England, areas with high proportions of ethnic minority groups. 18,818 infants were enrolled onto the study, with 18,296 singletons present at 9 months. Interviews were carried out by trained interviewers in the home with the main respondent (usually the mother). COVID focused data collections were undertaken via online surveys. Ethical approval for data collection was gained from the National Health Service Research Ethics Committee, and can be freely accessed for bona fine researchers. We have previously shown the potential to draw the MCS together with Australian cohorts to explore development over a range of settings.[14]

4.1.2 Acute care cohorts

4.1.2.1 Vitality (COVID Immune)

VITALITY is a double-blind, randomised, placebo-controlled trial assessing the role of postnatal vitamin D supplementation for the prevention of infant food allergy. Recruitment began in December 2014, and is planning on recruiting 3055 healthy, term, breastfed 6-8 week old infants from council-run immunisation sessions across Melbourne, Australia. Vitamin D is likely to play a role in early infant immune health, with emerging evidence that early life vitamin D deficiency increases the risk of developing childhood diseases such as food allergy, lower respiratory infections (LRIs) and eczema. VITALITY aims to determine if vitamin D supplementation leads to a reduction in challenge-proven food allergy, LRIs, food sensitisation, doctor diagnosed eczema, and vitamin D deficiency in the first year of life; with the ultimate goal being to develop improved public health guidelines for vitamin D supplementation of infants. An economic evaluation of the impact of the intervention from a societal perspective will also be used to model the potential cost-effectiveness of routine infant vitamin D supplementation compared to no supplementation. VITALITY is part of the COVID Immune collaboration.

4.1.2.2 MIS BAIR (COVID Immune)

The Melbourne Infant Study: BCG for Allergy and Infection Reduction (MIS BAIR) study is a randomised controlled trial (RCT) to assess the effect of neonatal BCG (tuberculosis) vaccination on clinical allergy and infection outcomes over the first five years of life. The study is based on the hypothesis that the heterologous effects of BCG on innate immunity and the cellular immune response has a beneficial effect on the developing immune system. The study has both clinical and laboratory components. The clinical outcome measures are respiratory infections, asthma, eczema and allergic sensitisation (measured by skin prick test). A combination of medical records and parent-completed online questionnaires are used to collect extensive and detailed antenatal, perinatal and postnatal data. The laboratory component comprises an extensive collection of biosamples for future immunological and molecular studies. MIS BAIR is part of the COVID Immune collaboration.

4.1.3 Continuing care cohorts

4.1.3.1 VicChild

VicCHILD is the Victorian Childhood Hearing Impairment Longitudinal Databank.[15] It is a Victorian register and research databank of children born with permanent hearing loss. VicCHILD ultimately aims to help children with permanent hearing loss reach their full developmental potentials. Over 850 families have already contributed data to VicCHILD. The information collected and stored is intended to help researchers and health professionals gain a better understanding of the causes and outcomes of childhood hearing loss; help researchers understand why some children with a hearing loss do well, while others face greater difficulties; and improve intervention and treatment.

4.1.3.2 Children's Attention Project

The Children's Attention Project (CAP), commenced in 2011, is a prospective longitudinal study of almost 500 children with and without Attention-Deficit/Hyperactivity Disorder (ADHD) recruited from Grade 1 (6 – 8 years old) classes across socio-economically diverse primary schools in Melbourne, Australia.[16] The study aims to map the course of ADHD symptoms over time and to identify risk and protective factors associated with differential outcomes. CAP is the first Australian longitudinal study of children with and without ADHD and one of the first community-based longitudinal studies of children that meet the full diagnostic criteria for ADHD recruited in the early primary school years.

The study's examination of a broad range of risk and protective factors and ADHD-related outcomes has the potential to inform novel strategies for intervention and prevention.

4.2 Study Setting

The study setting is MCRI, using the existing IT infrastructure of the MCRI.

5 PARTICIPANTS AND RECRUITMENT

5.1 Number of Participants

We intend to analyse existing data sources as described above (section 4.1). The number of participants varies across the datasets, ranging from less than 500 to nearly 10,000 children.

5.2 Consent

For each of the existing datasets described above (section 4.1), participant consent was obtained by the relevant institutions responsible for the data collection. For each specific research question, the most appropriate dataset(s) will be selected and a data access request submitted through the LifeCourse portal (https://lifecourse.melbournechildrens.com/data-access/) or relevant application process for external sources (e.g., LSAC, MCS). Cohort custodians approve or deny these requests in line with their specific ethical and governance requirements. This includes consideration of their specific ethical approvals and participant consent for reuse of their data.

In the case of the COVID Immune cohorts (HREC 66821), there was originally no explicit consent gained for other researchers to use data collected from the original cohorts. This includes key demographic data collected in the original waves that are necessary to characterise the cohorts, including:

- Child sex at birth
- Child has a chronic condition/special health care need (yes/no only, no details about condition)
- Sex of parent completing COVID wave
- Mother's age at COVID wave (years)
- Mother's highest level of education (completed high school vs. post-high school education)
- Main language spoken at home (English vs. Non-English), or Parent's background/country of birth (if main language not available)
- Aboriginal or Torres Strait Islander descent (yes/no only)

However, since the original consent, COVID Immune participants were informed by email that their child's deidentified data from COVID Immune or the original study (i.e., Vitality, MIS BAIR, SchoolNuts, or HealthNuts) may be shared with any current and future funders, research projects, student projects, biobanks, medical journals or data research repositories. For those participants who opted out of sharing deidentified information no data will be shared with or analysed for the COVID Wellbeing study. COVID Wellbeing will receive de-identified data for those participants who did not opt-out. This will allow for COVID Wellbeing to achieve important benefits, including directing attention to specific mitigating responses, highlighting emerging disparities for marginalised groups, directing services and support to where they are most needed, and justifying increased resourcing to support child and adolescent health during and in the wake of the pandemic. The variables of interest are not considered sensitive, and these important benefits far out-weight the very low risk of potential harm associated with secondary analyses of these data.

6 OUTCOMES

6.1 Primary outcome

The primary outcome to be explored is the mental health and wellbeing of children, young people, and their families. Mental health and wellbeing has been measured in different ways across these existing datasets, including via the emotions and worries subscales of the Coronavirus Health and Impact Survey (CRISIS).[8]

7 DATA MANAGEMENT

7.1 Data Storage

We will be provided with secure access to existing (de-identified) datasets. Data will be stored confidentially (de-identified) in electronic form on the MCRI server in a restricted access folder. Only those members of the research team who are authorised users of each dataset will have access to the data. No name-identified disaggregated information will be used in any publications. According to the 2018 Australian Code for Responsible Conduct of Research, research data will be retained for 5 years from the date of publication. We will delete the data permanently once the retention period has ended.

7.2 Data Management Framework

To ensure a systematic workflow, clear storage and labelling of data files, and a transparent record of analysis code leading to study results, we will utilise the Changing Children's Chances Data Management and Research Workflow Framework. This framework was developed for the Changing Children's Chances project (HREC/55470/RCHM-2019) in collaboration with Dr O'Connor, Dr Moreno-Betancur, and with oversight from Prof Sharon Goldfeld. As for the current project, it focuses on secondary data analysis only using similar data sources, thereby providing an efficient framework for the current research program. Dr Meredith O'Connor will take responsibility for oversight of data management and orienting and training the Research Officer (Dr Katherine Lange) in relevant processes and responsibilities defined in this framework.

8 POTENTIAL RISKS RELATED TO STUDY CONDUCT

8.1 Data confidentiality and security

This research program analyses existing data with low risks to participants. The only risk identified is the security of data and potential for re-identification. This will be managed through the protocols defined above in Section 7.

9 STUDY OVERSIGHT

9.1 Governance structure

This project brings together a committed and expert group of investigators with knowledge and experience in investigating psychosocial outcomes over the life course, cohort research, and statistical methods. Dr Meredith O'Connor will lead the project and establish project management and governance mechanisms. Her leadership will be complemented by a strong and diverse group of co-investigators. Professor Olsson and Professor Burgner, who lead the campus LifeCourse initiative, and Professor Sharon Goldfeld, Head of Population Health, will provide senior oversight for the research program. The statistical team includes Dr Margarita Moreno-Betancur and Dr Marnie Downes, who will provide ongoing statistical consultation and oversight. This team will provide conceptual guidance, contribute to research papers, and participate in regular teleconferences and investigator meetings. Collaboration and ongoing discussion with the Campus Wide COVID Wellbeing Working Group will be achieved through ongoing monthly meetings (already established).

9.2 Timeline

An indicative timeline for the research program is provided below.

Table 1. Indicative timeline for the COVID Wellbeing research program.

	2021			2022			
Task	**Apr-Jun**	**Jul-Sep**	**Oct-Dec**	**Jan-Mar**	**Apr-Jun**	**Jul-Sep**	**Oct-Dec**
Ethics approval and amendment							
Data access requests							
Recruitment of Research Officer							
Analysis of data							
Drafting of publications							
Responding to reviewer comments and taking papers to final publication							
Engagement with Campus-Wide COVID Wellbeing Working Group							

10 STATISTICAL METHODS

10.1 Statistical Analysis Plan

The analytic approaches used will depend on the specific research questions. We will draw on existing data and apply robust analytic techniques as appropriate to the research question at hand, and with support of experienced biostatisticians where required. This includes development of Directed Acyclic Graphs (DAGs) to guide consideration of bias, for example potential sources of confounding, for each analysis. As well as rich data on mental health and wellbeing across the cohorts, each cohort also contains rich data on useful confounding adjustment factors such as sociodemographic circumstances.

10.1.1 Handling of missing data

For all analyses, potential selection bias introduced by non-response and attrition will be considered and methods for addressing missing data, such as multiple imputation, applied as appropriate.

11 ETHICS AND DISSEMINATION

11.1 Research Ethics Approval

This protocol and any subsequent modifications will be reviewed and approved by the HREC at RCH. A letter of protocol approval by HREC will be obtained prior to the commencement of the study.

11.2 Modifications to the protocol

This research program will be conducted in compliance with the current version of the protocol. Any change to the protocol document that affects the scientific intent or study design is considered an amendment, and therefore will be written and filed as an amendment to this protocol. All such amendments will be submitted to the HREC, for approval prior to becoming effective.

11.3 Confidentiality

Participant confidentiality is strictly held in trust by the participating investigators, research staff, and the sponsoring institution and their agents. The study data and all other participant information generated will be held in strict confidence. No information concerning the study or the data will be released to any unauthorised third party, without prior written approval of the sponsoring institution.

Authorised representatives of the sponsoring institution may inspect all documents and records that are required to be maintained by the investigator.

11.4 Financial Disclosure and Conflicts of Interest

Funding sources are described in section 10.6. The investigators have no conflicts of interest to declare.

11.5 Dissemination and translation plan

Findings will have important implications for considering mental health and related supports and services for children and young people in the wake of the COVID-19 pandemic. This includes, for example, the domains in which supports may be required, what factors might be targeted for intervention, and which groups may require more intensive supports. To disseminate these findings, our research environment will facilitate the dissemination of findings in high impact peer-reviewed publications, including leading child health, epidemiology and education journals, as well as national and international conferences, seminars and workshops. Summaries of key research findings will be provided in non-technical formats on the LifeCourse website, which is publicly accessible.

11.6 Budget

Research program costs are shown below including support for collection of data on the impacts of COVID-19 for LifeCourse cohorts (already allocated), and staffing costs of a Research Officer.

Item	Cost
Support for COVID data collection costs (including infrastructure)	$336,667
LifeCourse COVID Wellbeing Research Officer (including 27% oncosts) for 12 month 1FTE appointment	$121,538
High-spec computer for the Research Officer to perform analyses	$1,925
Total	**$460,130**

These costs are fully covered by funding received by the Department of Health and Human Services (now managed through the Department of Jobs, Precincts and Regions), Morgan Stanley, and the Vincent Chiodo Charitable Trust.

12 REFERENCES

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