Comprehensive health **I**mplications of corona**VI**rus (COVID-19) exposure in the **C**ommunity (**CIVIC**)

1 ABOUT THE PROJECT

1.1 Title

Comprehensive health implications of coronavirus (COVID-19) exposure in the community (CIVIC)

1.2 Funding

The main funding body for this project is the National Health and Medical Research Council (NHMRC) of Australia through Program Grant 1092642 awarded to Professor Christopher Reid.

1.3 Roles and responsibilities

This study is an investigator initiated and conducted study managed by the Centre of Clinical Research and Education (CCRE), School of Public Health, undertaken at the Healthy Living Clinic, based at Curtin University.

Principal Investigator Professor Christopher Reid
Co-investigators Dr Jacquita Affandi

1.4 Ethics

Ethics approval has been obtained from Curtin University's Human Research Ethics Committee (HREC) : HRE2020-0153. The study will adhere to the Principles of Good Clinical Practice (GCP) and the National Statement on Ethical Conduct in Human Research.

2 Background and Rationale

The World Health Organisation (WHO) has announced that coronavirus (COVID-19) is a pandemic. As of 26 March 2020, there have been 2,799 confirmed cases of COVID-19 in Australia, with 376 new cases reported in the previous 24 hours alone, and a total of 11 deaths (Data from Australian Government, Department of Health).

COVID-19 infection shows no signs of abating soon. Like other diseases associated with the coronavirus family such as Severe Acute Respiratory Syndrome (SARS), COVID-19 is a disease of the respiratory system. However, those with hypertension and cardiovascular disease (CVD) appear to be highly susceptible to its more severe effects, with mortality rates 2-3-fold higher, respectively than the general population (WHO-China Joint Mission report). Recent reports of profound myocarditis and fatal arrhythmias suggest potential critical influence of COVID-19 on the cardiovascular systems [1, 2]. Patients presenting with COVID-19 and pre-existing CVD have an increased risk of severe disease and death. In Wuhan, China, the case fatality rate (CFR) was elevated amongst patients with pre-existing comorbid conditions – 10.5% for CVD, 7.3% for diabetes, 6.3% for chronic respiratory disease, 6.0% for hypertension, and 5.6% for cancer [3].

COVID-19 infection has been associated with multiple direct and indirect cardiovascular complications including myocardial injury, myocarditis, arrhythmias and venous thromboembolism [4]. However, true COVID-19 exposure in the Australian community and its potentially significant cardiovascular implications is currently unclear as testing is not freely available for everyone, including those presenting with symptoms who do not meet current guidelines for testing. Thus there is a high unmet need to collect data from patients in the community in order to understand the long-term impact of COVID-19 infection.

The first wave of the COVID-19 pandemic caused a mental health crisis as it swept through China and Australia should prepare to address similar problems as the number of infections increase. The Australian government has taken a staggered approach to slow down the spread of COVID-19 in order not to overwhelm the hospitals and other public health services. People who have been exposed to COVID-19 or tested positive have been advised to either quarantine or self-isolate for 14 days. A paradoxical effect of the coronavirus containment strategy has resulted in increased cases of anxiety and depression. Psychosocial risk factors, particularly anxiety and depression, can exacerbate cardiovascular risk and increase morbidity and mortality [5-8]. These otherwise modifiable CVD risk factors can be intensified by the effects of COVID-19 in isolation. Currently, China has been implementing emergency psychological crisis interventions to reduce the negative psychosocial impact on public mental health but challenges persist [9].

Australia is in the cusp of COVID-19 infection explosion, thus community data on anxiety and depression must be collected concurrently to lower the long-term risk of CVD. This will assist in decision-making so that public mental health interventions can be formally integrated into public health preparedness and emergency response plans.

Thus, collection of data is needed in order to uncover the true size of the hidden iceberg of potential cases of COVID-19 in our communities. This information can be then turned around rapidly to be used to guide public health planning around testing, quarantine, treatment and recovery which may have an immediate impact on our clinical response to this fast-moving pandemic.

To address these urgent priorities, we have established external partnerships with the Western Australian Health Translation Network (WAHTN), WA Country Health Service (WACHS). Within Curtin University - the Digital Health Cooperative Research Centre (CRC) developing an app to generate high-dimensional dataset for predictive machine learning approaches, and the Centre for Data Linkage (CDL) for data linkage with Medical Benefit Scheme (MBS) and Pharmaceutical Benefits Scheme (PBS) with the Department of Health Services, and the School of Psychology. We will survey the community to advance our understanding of COVID-19 at population level. The use of an app will facilitate prospective collection of data related to COVID-19 and capture the dynamic nature of exposure, onset of symptoms, disease trajectory, and clinical outcomes currently observed.

Our overall goal is to identify cardiovascular risk factors for incidence and outcomes related to COVID-19 across the spectrum of disease presentation and severity to provide a resolution snapshot on the current pandemic as well as develop an infrastructure within infected populations for long-term follow-up and molecular and biomarker studies to prevent the next global outbreak.

There is an urgent need to deploy this survey either via online links, QR codes or the app to maximize the collection of information as the COVID-19 pandemic accelerates and is likely to peak in the coming weeks in Australia.

2.2 Hypothesis

Exposure to COVID-19 will affect long-term cardiovascular risks and health outcomes of the general population.

2.1 Outcomes and Objectives

Primary outcome: Changes in health status, including cardiovascular, physical and mental health, between at the time of survey and follow-up.

Objectives:

1. We will launch an online survey using social media to disseminate the online links, QR codes on brochures, and deploy an app to capture information en masse from the community during the 2020 pandemic using mobile digital technology where applicable. This survey is designed to capture self-reported information from community participants regarding symptoms associated with COVID-19 and cardiovascular risk factors during the current COVID-19 pandemic. Data collected will allow construction of more accurate models of disease incidence and outcomes which can inform risk stratification for testing and algorithms for management (i.e. quarantine and hospitalization). The survey should take approximately 15-20 minutes.
2. We will follow-up participants at 2, 4, 6, 8, 10, 12 weeks and every 3 months up to a year, and annually thereafter (total up to 5 years) with additional surveys to assess their health and well-being. We will link collection of data on lifestyle, diet, health conditions and psychosocial risk factors from community participants in quarantine or self-isolation, with Australian government health datasets. This data will allow us to link the presentation of symptoms with clinical course, including likelihood of testing positive for COVID-19, development of new symptoms, and major cardiovascular and health outcomes.

Secondary outcomes:

A. Anxiety and depression questionnaires will be administered online and through the app to assess psychosocial risk factors during COVID-19 quarantine and self-isolation will be assessed via data linkage to investigate future CVD outcomes.
B. Changes in cardiovascular risk and overall physical and mental health assessments, associated with COVID-19 exposure and isolation using data analytics.
C. Participants will be invited at a later time to participate in physiological cardiovascular risk assessments and biospecimen collection (See section 3.5). This data will allow us

to link with cardiovascular risk factors with COVID-19 exposure using immune and genetic biomarkers.

3 METHODS: STUDY DESIGN, ASSESSMENTS

3.1 Study population

We will recruit community participants who have tested for COVID-19, people who have had COVID-19 risk factors, and those currently or have been in quarantine or self-isolation. We will be launching the online survey using QR codes on brochures, through social media (Twitter, Facebook etc) and via our collaborator's websites (WAHTN, WACHS).

Due to the unprecedented nature of the COVID-19 pandemic, it is difficult to determine the sample size. We estimate a recruitment of between 5,000 – 10,000.

3.2 Study inclusion / exclusion criteria

Inclusion:

Any member of the community above 18 years of age who are or have been:

- placed under quarantine (due to travelling back into Australia,)
- self-isolating (due to being in close contact* with a person who tested positive to COVID-19)
- self-isolating (awaiting COVID-19 test results)
- self-isolating (due to being tested positive to COVID-19 but not requiring hospitalization)
- self-isolating (symptomatic but not meeting criteria for COVID-19 testing)
- tested for COVID-19 but the result was negative
- hospitalised for COVID-19 and now discharged
- been impacted by social distancing guidelines

* 'Close contact' is defined as:
- Health care associated exposure, including providing direct care for novel coronavirus patients, e.g. health care worker, working with healthcare workers infected with novel coronavirus, visiting patients or staying in the same close environment of a novel coronavirus patient, or direct exposure to body fluids or specimens including aerosols.
- Working together in close proximity or sharing the same classroom environment with a novel coronavirus patient.
- Traveling together with novel coronavirus patient in any kind of conveyance.
- Living in the same household as a novel coronavirus patient (includes parents caring for a COVID-19 positive child <18).

Exclusion:

- Unable to read or understand English or with no access to an interpreter.

3.3 Participant recruitment strategies

Recruitment will be carried out in 3 main Phases:

Phase 1: We intend to recruit participants via Curtin media, social media (Twitter, Facebook etc), with links in our collaborators' websites (WAHTN, WACHS), print media and snowball recruitment, advertising through community newsletters, and through a variety of community recruitment strategies.

We will give out brochures containing QR codes which will immediately link to the online survey, and place them in general practice clinics and COVID-19 clinics. We intend to advertise through community newspapers and our network of collaborative research partners. Recruitment strategies will be evaluated, and successful campaigns will be extended.

Phase 2: We will invite previous participants who were involved in our clinical trials and research studies on our clinic database; specifically, participants from the low dose colchicine (LoDoCO2) trial, statins in reducing events in the elderly (STAREE) and prevalence of atrial fibrillation in the community (PACIFIC study). The LoDoCo2 clinical trial participants (n=644; age:35-82 years) are a high-CVD risk cohort with a readily available set of biobank samples. The STAREE participants are a healthy cohort of participants over the age of 70 (currently 1000 participants enrolled in WA, with 100 samples biobanked). The PACIFIC participants are a relatively healthy cohort above the age of 55 (62 participants with biobank samples).

Phase 3: A targeted invitation will be sent to participants recruited from Phase 1 and 2 for follow-up cardiovascular risk assessments.

3.4 Online survey using the REDCAP research data capture system

Participants will be invited to consent and complete an online survey on the REDCAP system using a link on any of our collaborators' wesbites (WAHTN, WACHS), QR codes on brochures or using the specially developed app. Previous clinical trial participants will be invited separately via email or direct mail. In the event whereby participants do not have access to mobile devices, participants may contact the research team to request for a soft copy to be emailed or a hard copy can be mailed directly to their address.

- Participants will read the:
  - Main participant information sheet and complete the consent form which includes consent to medical records, record data linkage follow-up with government health datasets.
  - Questions pertaining to COVID-19 symptoms, exposure and testing, health, lifestyle, medical history questionnaires will be administered.
  - Anxiety and depression questionnaires will be administered.

3.5 Future invitation for cardiovascular risk assessments

Participants will be invited to come into Curtin University for a cardiovascular risk assessment at a later stage when the COVID-19 pandemic has dissipated. The cardiovascular risk assessments will mirror the PACIFIC Study [HRE2018-0296], and include any future assessments derived from outcomes of Phase 1 and 2.

3.6 Follow-up questionnaires

- Participants will be invited to respond to follow-up questionnaires in relation to their health status at 2, 4, 6, 8, 10, 12 weeks, then every 3 months until the 12th month, then annually thereafter (a total of 5 years).
  - The participant will receive an email reminder or the app will ping a reminder to complete a survey asking questions in relation to their general health status, in particular, the diagnosis of cardiovascular disease (to monitor long-term cardiovascular health outcomes). Anxiety and depression questionnaires will also be administered [Depression, Anxiety and Stress Scale (DASS)21].
  - Participants may receive the iECG device, and return in a post-paid envelope.

3.7 Record data linkage

- Participants will be invited to provide consent to link personal information to government health databases to identify participants' future cardiovascular events or death during or after 5 years.
  - The "CIVIC Study" data will be submitted to the Western Australia Department of Health Services Centre for Data Linkage to link data to government health datasets including hospital admissions and discharge data.

- CIVIC Study data will also be linked to the Medical Benefits and Pharmaceutical Benefits database, Primary Health Network Databases and the National Death Index.

4 METHODS: DATA COLLECTION, MANAGEMENT AND ANALYSIS

REDCap database at Curtin University

Data will be entered into a secure Research Electronic Data Capture (REDCap) database housed at Curtin University. REDCap is a web-based application developed by Vanderbilt University to capture data for clinical research and to create databases and projects and is widely used throughout Australia for clinical research.

Curtin University's REDCap (redcap.curtin.edu.au) database is housed inside the Curtin University network and firewall. Access to the platform (redcap.curtin.edu.au) uses a secure-socket-layer to encrypt the web transport layer along with 2-step authentication. This means a person must provide a valid username, password & code each time they log in.

Curtin University's REDCap is backed up eight times a day using an automated process that takes a complete script (data plus schema) of the MySQL database. The database software used is MySQL and the Server runs on Windows Server 2016 Datacenter machine. The backups are kept on the Db Server as encrypted zip files. Curtin University network is backed up using Amazon Cloud Services (AWS). The actual physical location of the data is AWS's Sydney data centre.

Access to REDCap will be limited to approved researchers who are part of the study team and the REDCap administrators who are from the Clinical Trial and Data Management Centre, Western Australian Health Translation Network which is based at Curtin University.

Data storage for data analysis at Curtin University

Identifiable data will be entered into the REDCap database for researchers to be able to follow-up for 2, 4, 6, 8, 10, 12 weeks, every 3 months until the 12th month, and annually thereafter (total of 5 years) and future cardiovascular risk assessments. The collection of follow-up data will allow the progress of the participant's cardiovascular health outcomes to be tracked over time. Only the database manager and relevant key REDCap data personnel will ensure only the non-identifiable data is exported out of this database or used for publications. The sensitive variable date of birth (DOB) will be included. This is important to allow for querying purposes, for example to flag potential duplicate entries. DOB will not be reported but will be used to calculate the variable 'age at diagnosis' which will be recorded as a whole year.

Data for analysis will be exported out of the REDCap database and stored on the secure Research (R drive) at Curtin University where it will be analysed. The R drive is part of Curtin University's four-pronged approach to assist Curtin researchers to comply with the Australian Code for the Responsible Conduct of Research and Curtin's Research Data and Primary Materials Policy.

The Research Drive provides adequate protection against hardware failure. Redundant copies of the data in the Research Drive are stored on two physically separate data centres in Curtin University. The

Research Drive performs periodic virus scanning on data stored in research project folders. The antivirus scans all files less than two gigabytes in size.

Access to project folders on the drive can only be granted by the head of the research group at Curtin University. Only Curtin staff, Curtin students and Curtin associates with a valid Curtin ID can be granted access to a research project folder.

5 REFERENCES

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Participant Information Sheet

Principal Researcher:	Prof Christopher Reid
Associate Researcher:	Dr Jacquita Affandi
Project Title:	Comprehensive health implications of Coronavirus (COVID-19) exposure in the community (CIVIC)

COVID-19 is an infectious disease caused by a newly discovered coronavirus. Most people infected with COVID-19 will experience mild to moderate breathing difficulties and recover without requiring special treatment. However, older people, and those with underlying medical problems like cardiovascular disease, diabetes, chronic respiratory disease, and cancer are more likely to develop seriousillness.

The CIVIC study is designed to investigate the effects that COVID-19 may have on the health of your heart and lungs and other health implications. This will allow us to better inform future health practices in times of outbreaks of severe acute respiratory infections.
This questionnaire is designed to help medical professionals and researchers understand COVID-19. It does not give health advice. Health advice can be found at https://www.health.gov.au/news/health-alerts/novel-coronavirus-2019-ncov-health-alert

We would like to invite you to participate in the CIVIC study if you are 18 years or older and:

- Have had COVID-19 like symptoms such as cough and fever
- Have been tested for COVID-19
- Been in quarantine or self-isolation
- Been impacted by social distancing guidelines

If you agree to participate you will be asked to sign the consent form, or if you are completing online consent by pressing the 'I agree' button.

We are asking you to:

1. Answer an online questionnaire which includes questions about you, your lifestyle, exposure to COVID-19, medical history and current medications. This will take approximately 15-20 minutes.

2. Provide your name, date of birth, email address, suburb and country, and/or phone number so that we may contact you to complete follow-up questionnaires.

3. Provide permission to access some specific health related information about yourself in government health datasets (using data linkage).

We need to find out if COVID-19 exposure is linked to future cardiopulmonary events such as heart attacks and heart failure, respiratory disorders and how this affects the Australian health system. Throughout our lives, information is collected about our health and healthcare. This information is already routinely collected by hospitals, health departments, and other groups or organisations that provide health services.

The collection of this information is usually required by law, and is securely stored by the service or agency that collects it. Health research is very important as it looks at how health care is managed and how services are delivered and used. Data linkage is a way of connecting information held by different groups or services in a way that protects a person's privacy. Being able to link data can be very useful in health research. It can provide a more accurate picture of the overall health and well-being of groups of people.

Data linkage is usually performed by a trusted third party – a Data Linkage Unit – who are specialists in this task but perform no other role in the research. They typically use personal information to perform the linkage between different types of data related to your health, called datasets.

We would like your permission to let us link your data to information in other health databases so that we can collect selected, additional information about you e.g. if you have a cardiovascular event (such as heart attack, heart failure etc) or any other serious health related events. We will collect information about you from the following state and national databases such as the WA Emergency department data collection; WA Hospital morbidity data collection; WA Mortality register; Primary Care databases and the National Death Index Registry.

For example, exposure to COVID-19 may determine different needs for future medical input or medications related to heart health (e.g. worsening of cardiovascular complications) resulting in higher health costs. Thus early identification of cardiovascular risk factors will allow for prompt interventions.

In the future, we may ask you to sign another consent form to allow us to access information held about you from the Medicare Benefit Scheme and Pharmaceutical Benefit Scheme.

WHAT ARE THE POSSIBLE RISKS AND BENEFITS OF BEING INVOLVED IN THIS RESEARCH

- We will ask questions about your feelings regarding Covid-19. If answering these questions is upsetting, we have provided links to organisations which may be of help to you.
    - Lifeline on 13 11 14
    - beyondblue.org.au
    - Mindspot.org.au
    - Centre for Clinical Interventions
    - Your GP

There will be no direct benefits for you taking part in this study. Your participation will contribute to the advancement of research into the COVID-19 virus.

WHAT WILL HAPPEN TO YOUR INFORMATION

By signing the consent form, you give permission for the study's research staff to collect and use your health information for the research project. Any information obtained in connection with this research project that can identify you will remain confidential. The information you contribute for this study will be identified by a unique code, although as we conduct the study, we will use your name, for example, when we contact you (at 2, 4, 6, 8, 10, 12 weeks, then every 3rd month until 12th month, then annually for 4 years = 5 years in total). Only authorised persons, who understand that this information must be kept confidential, will have access to individual contributions, participant names, or email addresses.

All electronic study data will be stored on a secure server at Curtin University. Data will be archived and finally destroyed according to the archiving rules of the University and Health Department Guidelines, Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law.

Information about you may be obtained from your health records held at this and other health services for the purpose of this research. By signing the consent form you agree to the study team accessing health records if they are relevant to your participation in this research project. Your health records and any information obtained during the research project may be checked (to verify the procedures and the data) by the relevant authorities and authorised representatives. Authorised authorities include the Human Research Ethics Committees of the Western Australian Department of Health and Curtin University. If this should occur, these personnel are required to comply with the privacy laws that protect you when dealing with your information. By signing the Consent Form, you authorise release of, or access to, this confidential information to the relevant study personnel and regulatory authorities as noted above.

Results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified. All health results will be presented as group data, meaning individuals cannot be identified. Information about your participation in this research project may be recorded in your health records.

In accordance with relevant Australian, Western Australian, and other relevant laws, you have the right to request access to your information collected and stored by the research team.

Any information obtained for the purpose of this research project that can identify you will be treated as confidential and securely stored. It will be disclosed only with your permission, or as required by law. We will inform you of the project findings when results are published.

WHAT SHOULD I DO IF I WANT TO STOP TAKING PART IN THE STUDY

You may withdraw your consent at any time by emailing civic@curtin.edu.au or phone 1800 971 022 (and choose Option 1).

WHO IS FUNDING THE RESEARCH?

The main funding body for the CIVIC study is the National Health and Medical Research Council of Australia through Program Grant 1092642 awarded to Professor Christopher Reid.

The CIVIC study is run by Centre of Clinical Research and Education (CCRE), School of Public Health, Curtin University. If you require further information or if you have any concerns about this project, you can contact Dr Jacquita Affandi on 1800 971 022 (and choose Option 1) or email at civic@curtin.edu.au, or the Principal Researcher, Professor Christopher Reid on (08) 9266 7123.

WHO HAS REVIEWED THE RESEARCH PROJECT?

Curtin University Human Research Ethics Committee (HREC) has approved this study (HREC number HRE2020-0153). Should you wish to discuss the study with someone not directly involved, in particular, any matters concerning the conduct of the study or your rights as a participant, or if you wish to make a confidential complaint, you may contact the Ethics Officer on (08) 9266 9223 or the Manager, Research Integrity on (08) 9266 7093 or email hrec@curtin.edu.au.

Participant Consent Form

Principal Researcher:	Prof Christopher Reid
Associate Researcher:	Dr Jacquita Affandi
Project Title:	Comprehensive health implications of coronavirus (COVID-19) exposure in the community (CIVIC)

- I have read and understood the purposes of this research as described in the Participant Information Sheet (Version 1.4 dated 08 APR 2020) and agree to participate.
- I understand that my confidential information will not be reported in any way that could identify me.
- I understand that I may be contacted regularly during the COVID-19 pandemic to complete further questionnaires.

This research has been approved by the Human Research Ethics Committee at Curtin University [HRE2020-0153].

☐ I agree to the release of my personal information (including my Medicare number, my full name, date of birth and sex) for linking to the State and National health datasets.

[If hard copy consent]

Name of Participant (please print first, middle and last)

_____ _____ _____

Signature _____ Date _____

[if online consent]

Click "I consent" button

ID no:

The CIVIC study is designed to investigate the effects that COVID-19 may have on the health of your heart and lungs and other health implications. This will allow us to better inform future health practices in times of outbreaks of severe acute respiratory infections. This questionnaire is designed to help medical professionals and researchers understand COVID-19. It does not give health advice.

We are inviting people with at least one of the following to participate in CIVIC

Please select which of the following applies to you:

- ☐ Have had symptoms such as cough and fever in the last 14 days
- ☐ Have been tested for COVID-19
- ☐ Been in quarantine or self-isolation
- ☐ Been impacted by social distancing guidelines

Are you 18 years of age or older ?	☐ Yes ☐ No
Do you reside in Australia ?	☐ Yes ☐ No
Can you read and understand English (or have access to an interpreter)?	☐ Yes ☐ No

Before completing the questionnaire, please read the Participant Information Sheet. Should you require further information please phone 1800 971 022 (and select option 1) to speak to a CIVIC team member, or contact us via civic@curtin.edu.au.

When you have decided that you wish to participate in CIVIC, please sign and date the consent form before proceeding.

ID no:

Participant Consent Form

Principal Researcher:	Professor Christopher Reid
Associate Researchers:	Dr Jacquita Affandi
Project Title:	**C**omprehensive health **i**mplications of corona**vi**rus (COVID-19) exposure in the **c**ommunity (CIVIC)

- I have read and understood the purposes of this research as described in the Participant Information Sheet (Version 1.5 dated 30 APR 2020) and agree to participate.
- I understand that my confidential information will not be reported in any way that could identify me.
- I understand that I may be contacted regularly during the COVID-19 pandemic to complete further questionnaires.

This research has been approved by the Human Research Ethics Committee at Curtin University [HRE2020-0153].

☐ I agree to the release of my personal information (including my Medicare number, my full name, date of birth and sex) for linking to the State and National health datasets. (optional)

[If hard copy consent]

Name of Participant (please print first, middle and last)

_____

Signature _____ Date _____

[if online consent]

Click "I consent" button

- Please read each question carefully and answer ALL of the questions by following the completion instructions provided.
- All information will be strictly confidential
- The purpose of this questionnaire is to obtain information about your lifestyle, health and well-being)

ID no:

CIVIC STUDY

Please fill in your details below:

Date of Birth (Day/Month/Year): _ _ / _ _ / _ _ _ _

Sex (at birth): ☐ Male ☐ Female

Suburb: postcode _____

Country: _____

Ethnic group (check all that apply):

☐ Caucasian/White
☐ Aboriginal/Torres Strait Islander
☐African Descent
☐Arab descent
☐East Asian (origins of: Chinese descent, Japan, Mongolia, Korean descent)
☐South Asian (origins of :India, Pakistan, Bangladesh, Nepal, Bhutan, Nepal, Maldives and Sri Lanka)
☐South East Asian (origins of : Cambodia, Laos, Myanmar, Thailand, Vietnam, malaysia, Brunei, Indonesia, the Philippines, Singapore and East Timor)
☐ Other: _____
☐Unknown

Country of birth: _____

Are you pregnant? ☐ Yes ☐ No ☐ Unknown

If yes – Number of gestational weeks _____

Please tell us how many people live in your household (including yourself)?

Number of people in household >70 years |__|__|
Number of people in household = 18-69 years |__|__|
Number of people in household <18 years |__|__|

Are you currently participating in any other research study? ☐ Yes ☐ No
If yes, please specify : _____

What is your usual occupation?

☐ Healthcare/Medical
☐ Agriculture, Food Production, Farming and Conservation
☐ Architecture, Design and construction
☐ Arts, Advertising, Media & Marketing
☐ Education and Training
☐ Financial, Insurance and Superannuation
☐ Government, Defence and Public Administration
☐ Hospitality, Customer Service and Tourism
☐ Information and Communication Technology
☐ Legal
☐ Manufacturing, Transport and Logistics
☐ Mining, Resource and Energy
☐ Science, Technology and Engineering
☐ Other Industry
☐ Retired/Unemployed
☐ Student

Due to COVID-19, are you or have you been:	
Placed under quarantine (either due to travelling back into Australia or your state)	☐ Yes ☐ No
Self-isolation (due to being in close contact* with a person who tested positive to COVID-19)	☐ Yes ☐ No
Self-isolation (awaiting COVID-19 test results)	☐ Yes ☐ No
Self-isolation (due to being tested positive to COVID-19 but not requiring hospitalisation)	☐ Yes ☐ No
Self-isolation (symptomatic but not meeting criteria for COVID-19 testing)	☐ Yes ☐ No
Hospitalised for COVID-19 and now discharged	☐ Yes ☐ No
Have you been tested for COVID-19	☐ Yes ☐ No
If yes, what date was the specimen collected for COVID-19 testing?	_ _ / _ _ / _ _ _ _
What was the test result?	☐ Positive for COVID-19 ☐ Negative for COVID-19 ☐ Waiting for results
If you had a second test, please check this box	☐
What date was the second specimen collected for COVID-19 testing?	_ _ / _ _ / _ _ _ _
What was the test result?	☐ Positive for COVID-19 ☐ Negative for COVID-19 ☐ Waiting for results
If you had a third test, please check this box	☐
What date was the third specimen collected for COVID-19 testing?	_ _ / _ _ / _ _ _ _
What was the result?	☐ Positive for COVID-19 ☐ Negative for COVID-19 ☐ Waiting for results

* 'Close contact' is defined as:
- Health care associated exposure, including providing direct care for novel coronavirus patients, e.g. health care worker, working with health care workers infected with novel coronavirus, visiting patients or staying in the same close environment of a novel coronavirus patient, or direct exposure to body fluids or specimens including aerosols.
- Working together in close proximity or sharing the same classroom environment with a novel coronavirus patient.
- Traveling together with novel coronavirus patient in any kind of conveyance.
- Living in the same household as a novel coronavirus patient (includes parents caring for a COVID-19 positive child <18).

Since becoming aware of COVID-19, have you had any of the following signs or symptoms?			
History of fever	☐YES	☐NO	☐Unknown
Cough	☐YES	☐NO	☐ Unknown
If yes,	☐YES	☐NO	☐ Unknown
- dry cough	☐YES	☐NO	☐ Unknown
- Cough with thick phlegm	☐YES	☐NO	☐ Unknown
- Cough with blood in phlegm	☐YES	☐NO	☐ Unknown
Sore throat	☐YES	☐NO	☐ Unknown
Runny nose	☐YES	☐NO	☐ Unknown
Ear pain	☐YES	☐NO	☐ Unknown
Wheezing	☐YES	☐NO	☐ Unknown
Chest pain	☐YES	☐NO	☐ Unknown
Muscle aches	☐YES	☐NO	☐ Unknown
Joint pain	☐YES	☐NO	☐ Unknown
Fatigue	☐YES	☐NO	☐ Unknown
Shortness of breath	☐YES	☐NO	☐ Unknown
Headache	☐YES	☐NO	☐ Unknown
Seizures	☐YES	☐NO	☐ Unknown
Abdominal pain	☐YES	☐NO	☐ Unknown
Vomiting / Nausea	☐YES	☐NO	☐ Unknown
Diarrhoea	☐YES	☐NO	☐ Unknown
Eye Infection/ Conjunctivitis	☐YES	☐NO	☐ Unknown
Skin rash	☐YES	☐NO	☐ Unknown
Skin ulcers	☐YES	☐NO	☐ Unknown
Swollen lymph nodes	☐YES	☐NO	☐ Unknown
Are there any other symptoms you want to tell us about?	_____		
	_____		
	_____		

If you are currently suffering from any of the above symptoms, and are concerned for your health, please contact your usual healthcare provider by telephone or visit the https://www.health.gov.au/contacts/national-coronavirus-helpline

Healthy Living Questionnaire

The purpose of this questionnaire is to obtain information about your lifestyle, health and well-being.

Please answer these questions about your lifestyle **PRIOR** to the outbreak of COVID-19.

EXERCISE prior to the outbreak of COVID-19

EXERCISE

MILD EXERCISE: How many days per week did you do mild exercise (e.g. walking)? |__| of 7 days

MODERATE/VIGOROUS EXERCISE: How many days per week did you do moderate/ vigorous exercise (vigorous activity refers to any hard physical effort which makes you breathe much harder than normal)? |__| of 7 days

SITTING/RECLINING: How much time (in hours) did you spend sitting or reclining in a typical day? |__|__| : |__|__| (hh:mm)
Do not include time spent sleeping or driving

SMOKING prior to the outbreak of COVID-19

Did you **ever** smoked tobacco regularly (≥ 5 days/week for at least a year)? ☐ Yes ☐ No

If yes, current or ex-smoker ☐ Current ☐ Ex-smoker

Did you stop smoking within the last year	☐ Yes ☐ No
Number of years a regular smoker:	|__|__|
Age when started smoking regularly:	|__|__|
Number of cigarettes smoked/ day:	|__|__|
Time (minutes) spent smoking e-cigarettes/ day:	|__|__||__| (mins)
Number of cigars smoked/ day:	|__|__|
Number of times pipe smoked/ day:	|__|__|

Healthy Living Questionnaire

ALCOHOL USE prior to the outbreak of COVID-19

Alcohol use: (Please select one only)

- ☐ Current
- ☐ Former
- ☐ Never

If Current or Former:
How often did you usually drink alcohol (please select one only)

- ☐ less than once per week
- ☐ 1-2 days per week
- ☐ 3-4 days per week
- ☐ 5-6 days per week
- ☐ every day

On a day that you drank alcohol, how many standard drinks* did you usually have? (please select one only)

- ☐ 1-2 drinks
- ☐ 3-4 drinks
- ☐ 5-8 drinks
- ☐ 9-12 drinks
- ☐ ≥13 drinks

CAFFEINE USE prior to the outbreak of COVID-19

Caffeine: Did you drink coffee, tea or other drinks containing caffeine? ☐ Yes ☐ No

If yes, how many caffeinated drinks per week did you consume? |__|__| caffeinated drinks per week

MEDICAL HISTORY

HAVE YOU EVER BEEN DIAGNOSED WITH:

High Blood Pressure (*Hypertension*)	☐YES	☐NO	☐Unknown
Cardiac disease, including congenital heart disease *(not hypertension)*	☐YES	☐NO	☐Unknown
Heart failure	☐YES	☐NO	☐Unknown
Coronary artery disease *If yes, select all that apply:*	☐YES	☐NO	☐Unknown
☐ Myocardial infarction (MI) heart attack ☐ Coronary artery bypass grafting (CABG) ☐ Percutaneous coronary intervention (PCI) ☐ Stable angina ☐ Unstable angina ☐ Other types of coronary artery disease (CAD)			
Atrial fibrillation / arryhthmias	☐YES	☐NO	☐Unknown
Stroke *If yes, what type of stroke did you have:*	☐YES	☐NO	☐Unknown
☐ Ischaemic ☐ Intracerebral hemorrhage (ICH); ☐ Transient ischaemic (TIA)			
High cholesterol	☐YES	☐NO	☐Unknown
Family history of heart disease or stroke in a first degree relative *(father, mother, brother or sister age< 65 years)*	☐YES	☐NO	☐Unknown
Lung Disease	☐YES	☐NO	☐Unknown
Asthma	☐YES	☐NO	☐Unknown
Diabetesdiabetes - if yes, do you have complications with your diabetes? eg nervepain in your feet, damage to blood vessels in eyes, gangrene	☐YES	☐NO	☐Unknown
Liver Disease	☐YES	☐NO	☐Unknown
Kidney Disease or kidney failure *If yes:*	☐YES	☐NO	☐Unknown
Are you on dialysis?	☐YES	☐NO	☐Unknown
Cancer	☐YES	☐NO	☐Unknown
Immune disorders	☐YES	☐NO	☐Unknown
Auto-immune disorder (*e.g. Lupus, Coeliac, Multiple Scleorsis*)	☐YES	☐NO	☐Unknown
Neurological disorders (*e.g. Epilepsy, Parkinson's*)	☐YES	☐NO	☐Unknown
Eating disorders	☐YES	☐NO	☐Unknown
Dementia	☐YES	☐NO	☐Unknown
Anxiety	☐YES	☐NO	☐Unknown
Depression	☐YES	☐NO	☐Unknown
Other mental health disorders	☐YES	☐NO	☐Unknown
AIDS/HIV	☐YES	☐NO	☐Unknown
Is there any other medical condition you want to tell us about? specify			

MEDICATIONS

Please enter all your current regular medications that have been prescribed by a doctor

Enter either the brand name or the name of the active ingredient.

For example if you are taking the statin Lipitor then you can write either “Lipitor” or “Atorvastatin”.

If you take no prescription medications please tick this box ☐

ID no:

CIVIC STUDY

DASS21

Name: *Date:*

This survey has 21 statements. Please read each statement and circle a number 0, 1, 2 or 3 which indicates how much the statement applied to you *OVER THE PAST WEEK.* There are no right or wrong answers. Do not spend too much time on any statement.

The rating scale is as follows:

0 Did not apply to me at all
1 Applied to me to some degree, or some of the time
2 Applied to me to a considerable degree, or a good part of time
3 Applied to me very much, or most of the time

1	I found it hard to wind down	0	1	2	3
2	I was aware of dryness of my mouth	0	1	2	3
3	I couldn't seem to experience any positive feeling at all	0	1	2	3
4	I experienced breathing difficulty (eg, excessively rapid breathing, breathlessness in the absence of physical exertion)	0	1	2	3
5	I found it difficult to work up the initiative to do things	0	1	2	3
6	I tended to over-react to situations	0	1	2	3
7	I experienced trembling (eg, in the hands)	0	1	2	3
8	I felt that I was using a lot of nervous energy	0	1	2	3
9	I was worried about situations in which I might panic and make a fool of myself	0	1	2	3
10	I felt that I had nothing to look forward to	0	1	2	3
11	I found myself getting agitated	0	1	2	3
12	I found it difficult to relax	0	1	2	3
13	I felt down-hearted and blue	0	1	2	3
14	I was intolerant of anything that kept me from getting on with what I was doing	0	1	2	3
15	I felt I was close to panic	0	1	2	3
16	I was unable to become enthusiastic about anything	0	1	2	3
17	I felt I wasn't worth much as a person	0	1	2	3
18	I felt that I was rather touchy	0	1	2	3
19	I was aware of the action of my heart in the absence of physical exertion (eg, sense of heart rate increase, heart missing a beat)	0	1	2	3
20	I felt scared without any good reason	0	1	2	3
21	I felt that life was meaningless	0	1	2	3

ID no:

CIVIC STUDY

FOLLOW UP SURVEYS

These are the final questions we have for you today.
We want to know how you would like us to send you the follow-up surveys. Surveys will be sent out every 2 weeks until 12 weeks, then every 3 months until 1 year and then anually. You may opt out of these surveys at any time.
The easiest option is for us to email you the surveys. If you do not have access to email, then we can post paper copies to your residence or we can call you and complete the surveys with you over the telephone.

If you have any questions about the follow-up surveys please call **1800 971 022 (choose option 1)**

Do you have access to emails for future surveys?

☐ YES – I want to use my email address
☐ NO – I do not have access to email

If yes, please enter your email address: _____

If no, how do you want to receive the follow up surveys?

☐ Posted to your residence

Please enter your mail address (future surveys will be posted to you with a reply paid envelope):

_____

_____

_____

☐ Telephone Call

Please enter your phone number:

_____

Do you have a preferred contact time (eg morning or evening):

_____

First Name, Middle Name and Last Name: _____

What is your preferred first name? *We will use this when we send you emails or contact you.* _____

If you have any comments or questions about this survey, please enter them in the box to the right. Or you may send your comments directly to civic@curtin.edu.au

_____

_____

_____

_____

Please return this completed questionnaire including the signed consent form to:

CIVIC Study - CCRE
Curtin University, School of Public Health
Building 400, Kent Street
Bentley WA 6102

Thank you for completing these surveys for the CIVIC study.

If answering any of these questions has been upsetting, please contact your GP or any of these organisations who may be of help to you.

Lifeline on 13 11 14

beyondblue.org.au

Mindspot.org.au

Centre for Clinical Interventions

Follow-up surveys.

If you have any questions about the follow-up surveys please call 1800 971 022 (choose option 1) and tell a member of the team your study ID.

Curtin University Human Research Ethics Committee (HREC) approval number HRE2020-0153

The following questions are for the 2nd week timepoint.

Thank you for you participation in the CIVIC study. The information you have provided is already helping us to understand more about the impact COVID-19 is having on our community – both in terms of health and well-being.

Today's questions are mainly about your feelings and well-being, as well as catching up with your health and changes in exposure to COVID-19. We really thank you for your time in helping with this important research.

Please read each question carefully and answer all of the questions by following the completion instructions provided below.

- All information will be strictly confidential
- The purpose of this questionnaire is to obtain information about your feelings and well-being)
- This survey will take about 10-15 minutes to complete.

We would like to ask you some follow-up questions.

In the last two weeks, have you been:

placed under quarantine (either due to travelling back from interstate or overseas)	☐ Yes ☐ No
in self-isolation	☐ Yes ☐ No
hospitalised for COVID-19 and now discharged	☐ Yes ☐ No
tested for COVID-19	☐ Yes ☐ No

If tested, Date of test: _____
Date of result:_____

No changes ☐

In the last two weeks, have you had any of the following signs or symptoms?	
History of fever	☐YES ☐NO ☐Unknown
Cough	☐YES ☐NO ☐ Unknown
with sputum production (e.g. thick phlegm)	☐YES ☐NO ☐ Unknown
bloody sputum/haemoptysis (e.g. blood in phlegm)	☐YES ☐NO ☐ Unknown
Sore throat	☐YES ☐NO ☐ Unknown
Runny nose (Rhinorrhoea)	☐YES ☐NO ☐ Unknown
Ear pain	☐YES ☐NO ☐ Unknown
Wheezing	☐YES ☐NO ☐ Unknown
Chest pain	☐YES ☐NO ☐ Unknown
Muscle aches (Myalgia)	☐YES ☐NO ☐ Unknown
Joint pain (Arthralgia)	☐YES ☐NO ☐ Unknown
Fatigue / Malaise	☐YES ☐NO ☐ Unknown
Shortness of breath (Dyspnea)	☐YES ☐NO ☐ Unknown
	☐YES ☐NO ☐ Unknown
Headache	☐YES ☐NO ☐ Unknown
Altered consciousness/confusion	☐YES ☐NO ☐ Unknown
Seizures	☐YES ☐NO ☐ Unknown
Abdominal pain	☐YES ☐NO ☐ Unknown
Vomiting / Nausea	☐YES ☐NO ☐ Unknown
Diarrhoea	☐YES ☐NO ☐ Unknown
Conjunctivitis (eye infection)	☐YES ☐NO ☐ Unknown
Skin rash	☐YES ☐NO ☐ Unknown
Skin ulcers	☐YES ☐NO ☐ Unknown
Swollen lymph nodes (Lymphadenopathy)	☐YES ☐NO ☐ Unknown
Bleeding (Haemorrhage)	☐YES ☐NO ☐ Unknown
Any other :	_____
	_____
	_____

In the last two weeks,

Exercise: How many days per week do you do moderate/ vigorous exercise (vigorous activity refers to any hard physical effort which makes you breathe much harder than normal)?

|__| of 7 days
Minutes per day |__|__|__|

Exercise: How many days per week do you do mild exercise (e.g. walking)?

|__| of 7 days
Minutes per day |__|__|__|

How much time do you spend sitting (including driving) or reclining in a typical day (excluding sleeping)?

|__|__| : |__|__| (hh:mm)

Height _____cm

weight _____kg

Smoking: Have you **ever** smoked tobacco regularly (≥ 5 days/week for at least a year)? ☐ Yes ☐ No

If yes, current or ex-smoker ☐ Current ☐ Ex-smoker

Number of years a regular smoker: |__|__|
Age when started smoking regularly: |__|__|

Number of cigarettes smoked/ day: |__|__|

Time spent smoking e-cigarettes/ day: |__|__| : |__|__| (hh:mm)

Number of cigars smoked/ day: |__|__|

Number of times pipe smoked/ day: |__|__|

If an ex-smoker: Did you stop smoking within the last year? ☐ Yes ☐ No

Year stopped smoking _____

In the last two weeks,

Alcohol use: ☐ Current ☐ Former ☐ Never (Please select one only) If current or former

How often do you usually drink alcohol (please select one only)

☐ <once per week
☐ 1-2 days per week
☐ 3-4 days per week
☐ 5-6 days per week
☐ every day

On a day that you drink alcohol, how many standard drinks* would you usually have? (please select one only)

☐ 1-2 drinks
☐ 3-4 drinks
☐ 5-8 drinks
☐ 9-12 drinks
☐ ≥13 drinks

Caffeine: Do you currently drink coffee, tea or other drinks containing caffeine? ☐ Yes ☐ No

If yes, number of caffeinated drinks per week? |__|__| caffeinated drinks per week

The following questions are asking about your feelings and wellbeing.

Sleep Condition Indicator (SCI) 2-item version

Please read each statement and choose the option which indicates how much the statement applied to you. There are no right or wrong answers. Do not spend too much time on any statement.

	Score				
	4	3	2	1	0
Thinking about a typical night in the last month,					
1. how long does it take you to fall asleep?	0-15 min	16-30 min	31-45 min	46-60 min	>61min
2. if you then wake up during the night, how long are you awake for in total? (add all the wakenings up)	0-15 min	16-30 min	31-45 min	46-60 min	>61min
3. how many nights a week do you have a problem with your sleep?	0-1	2	3	4	5-7
4. how would you rate your sleep quality?	Very good	Good	Average	Poor	Very poor
Thinking about the past month,					
5. affected your mood, energy, or relationships?	Not at all	A little	Somewhat	Much	Very much
6. affected your concentration, productivity, or ability to stay awake	Not at all	A little	Somewhat	Much	Very much
7. troubled you in general	Not at all	A little	Somewhat	Much	Very much
Finally					
8. how long have you had a problem with your sleep?	I don't have a problem/<1 mo	1-2 mo	3-6 mo	7-12 mo	>1 yr

PHQ-9 questionnaire

Please read each statement and choose the appropriate box which indicates how much the statement applied to you *over the last 2 weeks*. There are no right or wrong answers. Do not spend too much time on any statement.

	Not at all	Several days	More than half the days	Nearly every day
1. Over the *last 2 weeks*, how often have you been bothered by any of the following problems?				
a. Little interest or pleasure in doing things	☐	☐	☐	☐
b. Feeling down, depressed, or hopeless	☐	☐	☐	☐
c. Trouble falling/staying asleep, sleeping too much	☐	☐	☐	☐
d. Feeling tired or having little energy	☐	☐	☐	☐
e. Poor appetite or overeating	☐	☐	☐	☐
f. Feeling bad about yourself or that you are a failure or have let yourself or your family down	☐	☐	☐	☐
g. Trouble concentrating on things, such as reading the newspaper or watching television.	☐	☐	☐	☐
h. Moving or speaking so slowly that other people could have noticed. Or the opposite; being so fidgety or restless that you have been moving around a lot more than usual.	☐	☐	☐	☐
i. Thoughts that you would be better off dead or of hurting yourself in some way.	☐	☐	☐	☐
2. If you checked off any problem on this questionnaire so far, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?	Not difficult at all ☐	Somewhat difficult ☐	Very difficult ☐	Extremely difficult ☐

GAD-7 questionnaire

Please read each statement and choose the appropriate box which indicates how much the statement applied to you *over the last 2 weeks*. There are no right or wrong answers. Do not spend too much time on any statement.

Over the last 2 weeks, how often have you been bothered by the following problems?	Not at all sure	Several days	Over half the days	Nearly every day
1. Feeling nervous, anxious, or on edge	0	1	2	3
2. Not being able to stop or control worrying	0	1	2	3
3. Worrying too much about different things	0	1	2	3
4. Trouble relaxing	0	1	2	3
5. Being so restless that it's hard to sit still	0	1	2	3
6. Becoming easily annoyed or irritable	0	1	2	3
7. Feeling afraid as if something awful might happen	0	1	2	3

If you checked off any problems, how difficult have these made it for you to do your work, take care of things at home, or get along with other people?

Not difficult at all ☐

Somewhat difficult ☐

Extremely difficult ☐

Very difficult ☐

Wellbeing Scale

Below are some statements about feelings and thoughts. Please choose the box that best describes your experience of each over the last 2 weeks.

	None of the time	Rarely	Some of the time	Often	All of the time
1. I've been feeling optimistic about the future	☐	☐	☐	☐	☐
2. I've been feeling useful	☐	☐	☐	☐	☐
3. I've been feeling relaxed	☐	☐	☐	☐	☐
4. I've been dealing with problems well	☐	☐	☐	☐	☐
5. I've been thinking clearly	☐	☐	☐	☐	☐
6. I've been feeling close to other people	☐	☐	☐	☐	☐
7. I've been able to make up my own mind about things	☐	☐	☐	☐	☐

Response scale: None of the time (1), Rarely (2), Some of the Time (3), Often (4), All of the time(5)

If answering these questions is upsetting, we have provided links to organisations which may be of help to you.

- **000** for emergency services (police, ambulance, firefighters)
- **Mental Health Emergency Response Line** (staffed by mental health professionals, provides expert and accurate telephone response to acute mental health issues)
  - Metro residents: 1300 555 788
  - Peel Residents (1800 676 822)
  - TTY (1800 720 101)
- **Rurallink**: specialist after hours mental health telephone service for the rural communities of Western Australia
  - Rurallink: 1800 552 002
  - TTY: 1800 720 101
- **Lifeline** on 13 11 14 (free crisis support 24/7)
- **Suicide Call Back Service**: 1300 659 467 (free counselling 24/7)
- **Suicide crisis text line** 0477 13 11 14 (crisis support via text)
- **National sexual assault, domestic family violence counselling service (1800respect.org.au):** 1800 737 732
- **beyondblue.org.au** 1300 22 4636 (for information and support 24/7)
- **Mindspot.org.au** 1800 61 44 34 (free online assessment and treatment for anxiety and depression)
- **Centre for Clinical Interventions** (www.cci.health.wa.gov.au, for online information about mental health problems and their treatment)
- **Headtohealth.gov.au** for a range of high quality digital mental health resources