Explanatory Statement

Title	**The Optimising Isolation, Quarantine and Distancing Study for COVID19 (Optimise COVID19 Study)**
Principal Investigators	Professor Margaret Hellard, Dr Katherine Gibney, Dr Alisa Pedrana, Prof Mark Stoove, Prof Lisa Gibbs, Dr Angela Davis, Dr Nick Scott, Prof Dean Lusher, Prof David Wilson, Assoc Prof Joe Doyle, Dr Freya Shearer, Dr. Nic Geard, Prof Sophie Hill.
Associate Investigators	Prof Jodie McVernon, Dr Karen Block, Prof David Anderson, Prof Allen Cheng, Ms Ali Coelho, Prof Sally Green, Mr Danny Vadasz, Dr Brett Sutton, Prof Alex Collie
Location	Burnet Institute, 85 Commercial Road, Melbourne, Victoria, Australia 3004

1. Introduction

You are invited to take part in this research project because you have expressed interest in participating in our study to understand your experience and views of **home-based isolation or quarantine as a person who either (i) received a positive test result for COVID-19 or (ii) have been notified as a close contact of someone with confirmed COVID-19** during the COVID-19 respiratory virus outbreak. This Explanatory Statement gives you information about research project. It explains what is involved to help you decide if you want to take part. Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Participation in this research is voluntary (if you don't wish to take part, you don't have to). If you decide you want to take part in the project, you will be asked to complete the following study activities. **An initial interview will occur** over the phone with one of the project researchers, this will also include completion of a registration form. You will then be asked to complete a retrospective **diary** about your health and contacts in the past 2 weeks, an **online questionnaire**, and asked to complete an electronic **daily diary** entry for 14 days. Following the initial daily diary for 14 days, you will then receive notification to complete follow up diaries (single day) 4 times/month for 12 months (average once weekly). You will be asked to also repeat a monthly online questionnaire for12 months.

In doing so you are telling us that you:

- understand what you have read;
- consent to take part in the research project;
- consent to be involved in the procedures described;
- consent to the use of your personal and health information as described.

You now have a copy of this Explanatory Statement to keep and print for yourself. We will require you to provide verbal consent prior to the **study procedures** taking place.

2. What is the purpose of this research project?

The purpose of this project is to find out how members of the public experience COVID-19 and the measures taken to prevent infection and how experiences change over time. The researchers are interested in hearing about: what kind of information you were given, your understanding of the home isolation/quarantine process, what issues you faced during the period, what services or support you were provided with and how you accessed products and services. We will also ask about how your living situation, work, responsibilities, physical health, mental health and lifestyle have been affected by COVID-19 and preventative measures such as physical distancing. The information gathered in this research project will be used to inform a strategic approach in how to continue to ensure new infections are reduced, while understanding the economic, physical and social impacts that self-isolation and physical distancing have on individuals.

3. What does participation in this research project involve?

a) Questionnaires and daily diaries

Participation in this study involves completing the following online questionnaires and diaries. You will be sent online access to the questionnaire and diary surveys and asked to capture the details as listed in the table. If you are not comfortable or not able to complete the surveys yourself online, you will have the option to be assisted by a researcher over the phone.

Enrolment interview including retrospective diary	**Baseline questionnaire**	**Daily diary**	**Follow up questionnaires**
Day 0	**Day 0**	**Initial ;Daily for days 1-14 Follow up diary (single day) 4 times/month for12 months**	**Day 30 and repeated every month for up to 12 months**
Phone	Online (option for phone)	Online (option for phone)	Online (option for phone)
Key people form			
Retrospective diary - Symptoms - Diagnosis - Testing - Isolation / quarantine - Communication - Movements		Daily respiratory/COVID symptoms Testing Diagnosis Isolation/quarantine	COVID health and exposure - Symptoms - Diagnosis - Testing - Isolation / quarantine - Access to services and information
	Topics included in questionnaire: Living situation Work, study & responsibilities Lifestyle, social engagement & support Physical health & healthcare utilisation Mental Health & wellbeing COVID health Attitudes and experiences of government measures to prevent COVID	Daily documentation of social contacts: - Demographics of contact - Relationship to contact - Location of contact - Type /Purpose of contact - Length of contact Mood	Topics included in questionnaire: Change in living situation Change in work, study or responsibilities Lifestyle, social engagement & support Changes to physical health or healthcare COVID-related health and isolation Mental health & wellbeing Attitudes and experiences of government measures to prevent COVID

Expected to take approximately 30 minutes	Expected to take 30 minutes if self-completed	Expected to take 5-10 minutes for each day	Expected to take 20 minutes if self-completed
Reimbursement for your time: $55 at baseline		$15/for initial 14 day daily diaries (minimum 10 days completion) Thereafter $10 per month ($2.50 per diary).	$25 per follow up survey completed

The overall study will take place over 15 months. Individuals will be recruited to participate at different times in the study. Depending on when you are recruited, you will be asked to repeat a fortnightly daily diary and monthly questionnaire for up to 12 months. A researcher will confirm the expected follow up required for you.

If you meet certain criteria during the observed follow up period (e.g. recently diagnosed with COVID-19, newly notified as a close contact of someone with confirmed COVID-19), then a researcher will invite you to complete another 14-day daily diary.

We may also ask you if you are willing to be contacted about participating in a qualitative interview to better understand peoples experience of isolation and quarantine. Some participants will be contacted separately about this; it is optional to participate in the interview which may take place either via telephone/zoom, depending on preference. The interview will take approximately an hour, it will be audio recorded and then after it is typed up (transcribed) the audio will be destroyed. The interview will be viewed by staff that have been trained to perform the transcription duties of the project compliant with Burnet Institute confidentiality policies. A pseudonym will be allocated to you, so that your real name and identity isn't known. All interview transcripts will be stored under the requirements of Burnet Institute's security requirements; on a secure password protected server.

We will ask if you are happy to be contacted in the future by a member of the study team who is working on research studies in COVID-19 exploring types of diagnostic tests, blood & swab collection would be involved. This is optional and will not impact your involvement in this study.

Will I be reimbursed for being in the study?

You will be reimbursed for your time in completing the project questionnaires and diaries as detailed above (see section 3a for summary of reimbursement schedule). You will receive your reimbursement twice a month via electronic gift card vouchers which can be used across a range of retailers.

b) Nomination of people who have a key role in your life (key people)

To better understand how the community is responding to COVID-19 and the measures to prevent infection, we would like to ask you to nominate people you consider to have a key role in your life on a daily or weekly basis. These may include your family, friends, neighbours, co-workers, or others. Some of these people may also be in self-isolation or quarantine since your positive test result. Our research is interested seeing how people's social connections affect their health and wellbeing as well as how they influence how COVID-19 might spread through a community. We would like to ask some of your key people to also be involved in completing similar surveys to what is outlined for your involvement in the study. We will ask you to provide a name and contact number for these people so that we can contact them to invite them to participate. These details will only be used for this purpose, and no other personal information from your study participation will be shared with anyone. Each key person nominated will have the right to refuse participation, this will not affect your study participation. If they refuse, we will not contact them again, their details will be retained until the completion of the study.

4. What are the possible benefits?

Possible benefits to you include having a say in the development of research and programs to promote the health of the general public and improve our national response to epidemics of novel diseases such as COVID-19.

5. What are the possible risks?

You may feel uncomfortable talking and answering questionnaires about your experience of quarantine. However, you are free to not answer any question you don't feel comfortable answering. The researcher will make themselves available before and after the interview (within work hours) to answer any questions that may arise or any concerns you have.

We would encourage you to answer truthfully and please be assured that all your responses will remain confidential and will not be passed to any authorities. However, you should be aware that should you become involved in a criminal or civil case, in certain limited circumstances, a court of law may be persuaded to order disclosure of particular information relating to you which would otherwise remain confidential.

You are free to stop participating if you become upset or distressed as a result of your participation. If this happens, please notify the researcher as soon as possible, and they will discuss with you the option of arranging for counselling or other appropriate support if you wish. The researcher will give you advice and information about several free options for support after the interview and help you to choose the best option for you and help you make contact.

6. Do I have to take part in this research project?

Participation in any research project is voluntary (if you do not wish to take part, you do not have to). If you decide to take part and later change your mind, you are free to withdraw from the project at a later stage. If you decide to withdraw, please notify a member of the research team as soon as possible. If you withdraw, you will not be contacted for any further participation, but it will not be possible to remove any data that we have previously collected about you.

7. How will I be informed of the results of this research project?

At the end of the study period, we will remove all your identifiable information. The findings will report on summary data that can't identify any single person. If you're interested in the results, you can find them on the Optimise Study website (www.optimisecovid.com.au). or a short summary can be mailed to you.

8. What will happen to information about me?

It is anticipated that the results of this research will be published and/or presented in a variety of forums, including to the Government. In any publication and/or presentation, information will be provided in such a way that you cannot be identified.

Your personal information and survey data will be stored in a password-protected database on a secure server at the Burnet Institute. The database for the study has been designed and supported by SNA toolbox, to review the Privacy Policy and terms of use of how data is collected, used and stored (https://www.snatoolbox.com/). Members of the software service providers are part of the study team. A unique identification number will be assigned to you at the start of the study and this will help us link the information you provide over time. This information will be re-identifiable: the code is used so that the research team can identify you if necessary; for example, to contact you for follow up questionnaires.

Restricted members of the study team have access to your personal data. They will only use personal data to contact you and your key people for the purposes of recruitment and follow up. Optimise researchers will have access to your de-identified data as well as your postcode. De-identified data means all personal information (name and email) is replaced with a unique ID. Any summaries that may be produced will not contain any identifying information.

To help us map your social network over time, we need to retain and store your personal details and the links to the people you nominated and any other contacts until the end of the study. These data will be stored separately from your de-identified survey data to help protect your privacy and confidentiality. Documentation that captures your verbal consent will be stored separate from your data. All data collected will be retained for 7 years and then destroyed.

Any information obtained for the purpose of this research project that can identify the participant's will be treated as confidential and securely stored. It will be disclosed only with your permission, or to comply with the law.

9. Can I access research information kept about me?

In accordance with relevant Australian and/or Victorian privacy and other relevant laws, you have the right to access the information collected and stored by the researchers about you. Please contact one of the researchers named at the end of this document if you would like to access your information. Furthermore, in accordance with regulatory guidelines, the information collected in this research project will be kept for at least 7 years.

10. Is this research project approved?

The ethical aspects of this research project have been approved by the Alfred Hospital Ethics Committee. This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)* produced by the National Health and Medical Research Council of Australia. This statement has been developed to protect the interests of people who agree to participate in human research studies.

11. Who can I contact?

For further information:
If you want any further information concerning this project, you can contact one of the Principal Researchers:

Professor Margaret Hellard, (03) 9282 2163, margaret.hellard@burnet.edu.au

Dr Katherine Gibney, (03) 9035 3958, katherine.gibney@unimelb.edu.au

Study team contact details: email: optimise@burnet.edu.au
Text: 0447 045 460
Phone (03) 9282 2182

For complaints:

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

Position	*Complaints Officer, Office of Ethics & Research Governance, Alfred Health*
Telephone	*03 9076 3619*
Email	*research@alfred.org.au*

Please quote the following project number: 333/20