Participant Information and Consent Form

Short Name of Study	The OUTPOST Study – Pandemic Preparedness
Full Name of Study	OUTcomes Post COVID (OUTPOST): Pandemic Preparedness study
Principal Investigators	Prof Andrew Lloyd, Prof Lena Sanci
Co-investigators	Dr Ruby Biezen, A/Prof Lucette Cysique, Dr Miranda Smith
Research Team	Hayley Ivanusic, Natali Coric, Jia Shing See, Oonagh Macken
Study Sponsor	Department of Health and Aged Care
Sites' Name	University of Melbourne, University of New South Wales

What am I being invited to do?

You are invited to take part in this research project because you registered your interest in joining after seeing an ad for the **OUTPOST Study – Pandemic Preparedness**.

The study plans to enrol up to 100 people ≥18 years of age, with **flu-like symptoms confirmed to have acute COVID, Influenza or Respiratory Syncytial Virus (RSV) infection**. We will follow participants with periodic online questionnaires, blood sampling and smart watch tracking for 12 weeks. Participants will be recruited from social media across metropolitan Melbourne and Sydney.

Please read this information and feel free to ask any questions. Contact details for the study are provided below. You can take some time to make up your mind and decide if this study is right for you. You can also talk to someone you trust, like a family member, friend, or your General Practitioner (GP).

What is the purpose of this study?

This study is looking at people who develop flu-like symptoms due to COVID-19, Influenza (the flu) or RSV (another cause of flu-like symptoms). We will follow participants for 12 weeks to demonstrate how comprehensive samples and information on mild infections can be tracked to gain detailed understanding of infection and recovery.

As colds and flu-like illnesses are common in the community, we are recruiting people like you through social media.

This study will help us further develop an existing research platform that could be used in case of a pandemic.

Do I have to take part and can I change my mind?

Taking part is up to you

You will only have the option to take part in the study if you have **tested positive for acute COVID, Influenza or Respiratory Syncytial Virus (RSV) infection, and that you have not previously been enrolled in the OUTPOST main study**. You get to decide whether you take part in this study. You can say yes or no.

Your decision won't affect your relationship with any of the institutions involved (the University of Melbourne, the University of NSW, Kirby Institute, APPRISE, or your general practice).

You can change your mind at any time

If you do take part, you can stop at any time. If you want to stop, please contact the study investigators. Details for the study contacts are provided below. You do not have to tell us why.

Once you stop taking part, we will not collect any more information about you. We will keep the information we have already collected to make sure the results of the study can be measured properly.

The study might stop for other reasons

We might need to stop the study while you are taking part. If this happens, we will explain the reasons to you.

We may also ask you to stop taking part in the study if it is no longer in your best interest. If this happens, we will discuss this with you.

What do I have to do if I take part?

If you take part in this study, you will be expected to remain engaged for 12 weeks and complete all components of the study at each of three timepoints: baseline, 6 weeks and 12 weeks.

Figure 1 contains an overview of the study activities across the three timepoints.

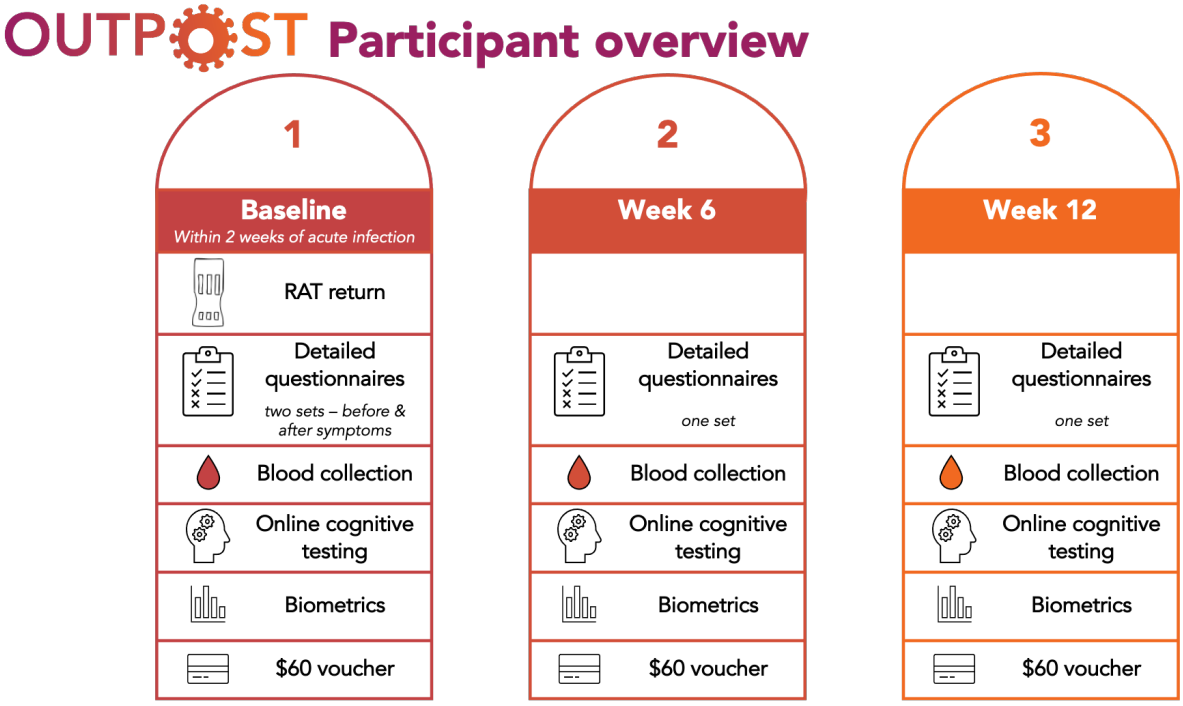

Fig 1. Activities at each time point – baseline, week 6 and week 12.

We will ask you to return your positive Rapid Antigen Test (RAT).

At each timepoint (during your acute infection, 6 weeks after your acute infection, and then 12 weeks after your acute infection), there will be three activities we need you to do:

1. Complete a set of questionnaires. Each set takes about 20-30 minutes to complete.
2. Get a blood sample taken – this will be done at your nearest participating pathology lab.
3. Complete a 25 minute online cognitive test (to assess your thinking and memory).

We will also request that you wear a smart watch which will monitor some key body functions (heart rate, blood oxygen level and respiratory rate, sleep-wake patterns, and step counts) for 12 weeks with an off day for battery recharge. Finally, we will request that you check your blood pressure lying down and standing up at each of the same study time-points. We will provide you with the equipment to monitor your body functions including those listed above and blood pressure. You will need to download an application which you can upload your study data through a secure web portal.

If you have ongoing symptoms at 12 weeks, you will be invited to complete a semi-structured interview by telehealth with a skilled researcher to better understand your ongoing health issues. If required, we will also facilitate an appointment with the GP of your choice to undergo a standard clinical visit and potentially some tests.

We will ask you to provide details of the GP you mostly attend for general health issues. We will contact your GP if you have a positive test and if you require any further investigations

for ongoing health issues. If you do not have a regular GP, you can leave this section of the initial survey blank, although we may contact you to select a GP if you have ongoing health issues needing attention. To contact your GP, we need to collect three points of identification from you so your GP can accurately find you in their clinic record system. This includes your name and date of birth, plus a residential or email address or phone number.

The table below outlines in detail what you need to do in this study.

Please note, once you enter the study you will be assigned an anonymous study identity (ID) number so your name and personal details such as date of birth, address, and phone number will be kept confidential and available only to the researchers analysing the study data. Only the study manager and lead researchers will know how to connect your ID number to your contact details in case we need to contact you. This would be to notify you and your GP of test results, to complete missing information from your survey, or to deliver your gift voucher as a thank you for participation. For more information, please contact the study co-ordinator via the details below.

What part of the study?	What do I have to do?
Initial screening (online)	We will ask you a few questions and if you are interested in the study, we will register you for a Rapid Antigen Test (RAT). You will be assigned a unique study ID. We will need to collect your name, your postal address and your email so we can deliver the RAT test kit (which includes two triple combination tests for COVID, flu and RSV) to your home address via Express Post.
RAT self-test (at home)	You need to complete the triple RAT test for COVID, Influenza (flu), and RSV soon after you receive the kit. Instructions are provided with the testing kit. After completing the RAT, you will record your results by using a unique link that will be sent to you by email. If your test is positive for any of the viruses, you will need to upload a photo of the test results for verification. You may be required to take a second RAT if the first is uncertain, or negative. **You will be offered enrolment into the study if either of the two tests is positive.** You will need to return your positive RAT testing kit via courier, which we will arrange on your behalf. **If both your RAT results are negative, you will not continue with the study**.
Eligibility screening (online)	If you test positive, we will ask you a few questions to make sure you are eligible for the study.
Consenting to take part in this study (online)	If you are eligible and happy to take part in this study, you will be asked to sign the e-consent form.

Baseline	**Detailed questionnaires (online):** We will ask you to complete two sets of questionnaires online at the start of the study (link will be provided via email). These questionnaires will take about 20-30 minutes each to complete. You will have two weeks to complete these questionnaires at baseline. One set of questionnaires will ask about your health *prior to* your recent acute infection. The other set will focus on health symptoms *since* your current infection and how they are affecting you (such as fever, cough, fatigue, brain fog, breathlessness, and sleep disturbance). We will also ask you brief questions about your mood. We will ask you to complete a short questionnaire about your medical history. **Blood collection (at a nearby pathology centre):** We will send you a blood collection form to enable collection of ~35ml of blood (equivalent to 2 tablespoons) once you are able to (1-2 weeks after the onset of acute infection). We will provide you with detailed instructions once enrolled. **Online cognitive testing (online):** At your convenience and on a laptop or desktop computer, you will complete an online cognitive testing that lasts about 25 minutes to assess how fast you can respond to a stimulus or how many things you can remember. We will ask you to do as best as you can on each task. You will be able to take a break if needed. We will provide you with detailed instructions once enrolled. **Biometrics via smart watch:** We will ask you to wear a smart watch which will monitor your heart rate, blood oxygen, respiratory rate, sleep-wake patterns, and step counts. We will provide you with a device and detailed instructions once enrolled. **Standing up test of blood pressure (at home)** We will ask you to complete a quick test which assesses your blood pressure variations when lying down and standing up. We will provide you with a blood pressure machine and detailed instructions to complete this component once enrolled. **$60 voucher:** At the completion of all components at each timepoint, you will receive a $60 gift voucher.

Week 6 and Week 12	**Detailed questionnaires (online):** We will ask you to complete a set of questionnaires online at each timepoint (link will be provided via email). These questionnaires will take about 20-30 minutes to complete. You will have two weeks to complete these questionnaires. The questionnaires will focus on health symptoms since the previous timepoint and how they are affecting you (such as ongoing fever, cough, fatigue, brain fog, breathlessness, and sleep disturbance). We will also ask you brief questions about your mood. **Blood collection (at a nearby pathology centre):** We will send you a blood collection form to enable collection of ~35ml of blood (equivalent to 2 tablespoons) at each timepoint. **Online cognitive testing (online):** At your convenience and on a laptop or desktop computer, you will be able to complete an online cognitive testing that lasts about 25 minutes to assess how fast you can respond to a stimulus or how many things you can remember. We will ask you to do as best as you can on each task. You will be able to take a break if needed. **Biometrics via smart watch:** We will ask you to continue wearing a smart watch which will monitor your heart rate, blood oxygen, respiratory rate, sleep-wake patterns and step counts. **Standing up test of blood pressure (at home)** We will ask you to complete a quick test which assesses your blood pressure variations lying down and standing up. **$60 voucher:** At the completion of all components at each timepoint, you will receive a $60 gift voucher
Semi-structured interview (by telehealth)	If you have ongoing symptoms at 12 weeks after your infection, we will invite you to participate in an interview to better understand your symptoms. This interview will be conducted via telehealth by trained study personnel and will last between 30-45 minutes. The study coordinator will arrange an appointment at a convenient time for you.
Clinical visit (at your nominated GP)	If you have ongoing symptoms at 12 weeks, we will also ask you to complete a health check at your nominated GP to help

	you, and the study investigators, to understand why your symptoms are persisting. We will ask your GP to review the history of your illness, do a physical examination, and to arrange laboratory investigations. The study coordinator will facilitate an appointment at a convenient time for you and your GP.

Please note: If you would prefer to complete the questionnaires via phone (at the start of the study and/or at any of the study follow-ups), or require any assistance in completing the questionnaires online, please contact the study researchers via the contact details below, and we will call you at a time convenient for you.

Payment for your time and expenses

To recognise your time, travel costs and any inconvenience, we will offer you a $60 gift voucher when you have completed all components at each time point (baseline, 6 weeks and 12 weeks): questionnaire, blood sample, online cognitive testing and continual monitor of your biometrics.

If we require you to have any tests with your doctor, we will re-imburse your doctor for any out-of-pocket costs for the consultation so you will not be charged for the appointment.

What are the benefits of taking part?

There may be some benefits from taking part in this study. These include knowing which (if any) virus is making you sick, and may assist you to seek antiviral treatment if necessary, and to take precautions to prevent spreading to others. If you develop persistent symptoms, the study will may assist you in getting timely and appropriate assessments with your GP.

Although not a direct benefit to you, by taking part, you will also help the researchers understand more about cold and flu-like infections in the community and their longer-term impacts. This knowledge will help plan for better health services and pandemic response in the future.

What are the risks and discomforts of taking part?

Taking part in this study involves minimal risks. You may feel uncomfortable taking the nose swab for the RAT, but following our study instructions will minimise this possibility. The completion of the questionnaires may wear you out, but you will be able to complete them at a convenient time at home, and on several separate occasions if needed. Some of the items on the questionnaires and questions during the interview will cover symptoms that may raise some anxiety and possibly some distress (e.g., about mental health and everyday

function). We will make sure that you can discuss any worries that you may have with the trained study personnel.

You may encounter discomfort or bruising with blood sample collection. All samples will be collected by trained technicians who can easily treat any acute issues.

If you have any concerns during the study, we recommend that you contact the study investigators via the details below, and you may also contact your GP. We may follow up with your GP regarding your concerns. If you are experiencing any distress while participating in this study, we have provided a list of contacts of well-recognised services for mental health assistance below. This list will also be accessible via the study website. If you report a high level of mental health distress, we will notify your GP. Your GP will then ensure appropriate further steps are taken.

If you are experiencing any distress while participating in this study, please consider contacting any of the following services for help.

The following services are available 24/7:

- Lifeline - 13 11 14
- Suicide Call Back Service - 1300 659 467
- Beyond Blue - 1300 224 636
- Standby Support After Suicide - 1300 727 247
- 13YARN - 13 92 76
- Nurse-on-Call - 1300 60 60 24
- The hospital emergency department nearest to you

Other resources for support

- Talk to someone you trust
- Talk to your General Practitioner (GP)
- Contact your local Employee Assistance Program (EAP) (these have counsellors)

In the instance where you may have trouble taking the nose swab or completing the questionnaires, we would ask that you let the study coordinator know as soon as possible.

Confidentiality

All the answers you make to our questionnaires, and all your test results, will be kept in a secure password-protected data repository at the University of Melbourne under your anonymous study ID number. Samples derived from your blood samples will also be stored under the same anonymous study ID number in secure freezers at UNSW. The list

connecting your ID number to your name, address and phone number will be kept in a separate secure server that only the study manager and lead researchers can access for the purposes of communicating with you about test results, your gift vouchers and any questionnaires that are not completed.

Only the research team can access your smartwatch data (oximetry, respiratory rate, sleep-wake, step counts; no GPS data will be collected) through a secure web portal dedicated to wearable research data management.

The online cognitive test uses the 'Test Many Brains Project' cognitive test platform (https://www.manybrains.net/about-us) with an agreement with the University of New South Wales where only de-identified data is jointly shared on secured repositories (UNSW REDCap and Test Many Brains Project server). De-identified data means that no personal information is stored, and the data is only linked to your anonymous ID number. We have chosen The Many Brains Project for this project because it is a non-commercial entity which has developed online cognitive testing for the benefit of the researchers and research participants. The Many Brains Project is a 501(c)3 non-profit that promotes the values, techniques, and tools of open, participant-centered brain science. The Many Brains Project (1) provides access to high quality cognitive tests and (2) supports the development of infrastructure, software, and research initiatives that emphasize open science solutions, participant-centered research, and help further the science of the mind / brain and brain health.

If I take part, what will happen to my information?

The information collected about you and your symptoms will be stored in a password-protected database that will only be accessible to the research team.

Collecting your information

If you consent, we may collect further information about your medical history including medical diagnoses, hospitalisations, and treatments relevant to the study through your medical record from your GP and/or directly from you.

Keeping your information safe

To keep your information safe, we will:

- follow all relevant privacy requirements
- keep it on a secure, password protected server which is only accessible to named researchers at the University of Melbourne
- take steps to prevent anyone from accessing information that identifies you unless they need to, for example, to conduct an audit

- give it a code and keep it separate from anything that could easily identify you, like your name or contact information.

You can ask us to tell you what information we have collected about you as part of this study. If your information is not correct, you can also ask us to change it.

We will keep your information for 15 years. After this, we will dispose of all data in keeping with University of Melbourne policy.

Sharing your information with others

We will share some of your information with others.

Sharing information with your GP: We will inform your GP that you are taking part in this study. Your GP will also be provided with a copy of your RAT results. They will add this information to your medical records. If we find out information relevant for your ongoing care, we will share this information with your GP so you can receive the care you need.

Getting more information

If you would like to know more about how we will collect, store, and share your information and samples as part of this study, please visit the study website bit.ly/outpost-study or study contact via the details below.

How may my information be shared in the future?

We will ask you to consider sharing your information and samples for future research. Sharing information with others can help make all research more effective and impactful.

When we share your information, we will take steps to make it impossible for anyone to link the information back to you. This includes removing information that could identify you, like your name or contact information.

You can choose the kinds of research for which we share your information and samples:

- Any future research
- Research studies that are related to this health condition
- Research studies that are being done in Australia
- Research studies that are being done by non-commercial organisations, like universities and public research institutes.
- Research studies that are being done by non-commercial organisations, like universities and public research institutes and/or commercial organisations such as pharmaceutical or medical device companies.

If you agree to share your information, you will not be told about the future research studies. However, you will be able to see the types of research studies with which we have shared information on our website.

If you change your mind, you have the option to ask us to stop sharing your information. However, if your information has already been shared, it may not be possible to retrieve or destroy it.

Who is running and paying for this study?

This study is being conducted by Prof Andrew Lloyd, Prof Lena Sanci, A/Prof. Lucette Cysique, Dr. Ruby Biezen, Dr. Miranda Smith who are investigators from the Department General Practice and Primary Care and Department of Infectious Diseases at the University of Melbourne and the Kirby Institute at the University of New South Wales.

This study is being funded by the Australian Government Department of Health and Aged Care through the Australian Partnership for Preparedness Research on InfectiouS disease Emergencies (APPRISE).

Who has approved this study?

The Human Research Ethics Committee at the University of Melbourne has approved this study. This committee makes sure that this study meets Australian ethical standards for research that involves people.

Complaints about how this study is being run

This project has human research ethics approval from The University of Melbourne [Project ID 36808].

If you have any concerns or complaints about the conduct of this research project which you do not wish to discuss with the research team, you should contact the Research Integrity Administrator, Office of Research Ethics and Integrity, University of Melbourne, VIC 3010. Tel: +61 3 8344 1376 or Email: research-integrity@unimelb.edu.au.

All complaints will be treated confidentially. In any correspondence, please provide the name of the research team and/or the name or ethics ID number of the research project.

Where can I find more information?

Thank you for taking the time to read this information about our study. You can contact a member of the study team at any time to ask questions using the following contacts:

Email: outpost-study@unimelb.edu.au

You can also visit our website https://www.apprise.org.au/outcomes-post-covid-the-outpost-study/ for more information.

For Consent of Participation

Consent to take part in this study

By signing this consent form, I acknowledge that:
• I freely agree to take part in this study, across the 3 timepoints at baseline, 6 and 12 weeks to complete the following:
  ○ Questionnaires (online)
  ○ Blood collection
  ○ Neuro-cognitive testing (online)
  ○ Monitor biometrics (heart rate, respiratory rate, and sleep and activity patterns)
• I understand that I can stop taking part in the study at any time
• I have read, or have had read to me, the information provided about this study and understand what is involved
• I have had the opportunity to consider the information, ask questions and am satisfied with the answers I received
• I understand after completing all activities at each time point, I will receive $60 gift voucher
• I understand that the research team will have access to my biometrics data through a secure web portal dedicated to wearable research data management
• I give permission for the researchers to contact my general practice to access any relevant data including my data from the Australian Immunisation Register should it be required
• I have been informed that the confidentiality of the information I provide will be safeguarded subject to any legal requirements; my data will be password protected and accessible only by the named researchers.
• I understand that if I experience persistent symptoms at 3 months, I will be invited to participate in an interview and a clinical visit at my nominated GP, I can accept or decline my participation.
• I understand that only my deidentified cognitive test data for the online cognitive study will be shared with the secured 'Test Many Brains Project' (https://www.manybrains.net/about-us)

Consent to optional parts of the study	Yes	No
I agree to my information and samples being stored and shared for any future research	☐	☐
OR		
I agree to my information and samples being stored and shared for only:		
a. Research studies that are closely related to this one	☐	☐
b. Research studies that are being done in Australia	☐	☐
c. Research studies that are being done by non-commercial organisations	☐	☐
d. Research studies being done by both commercial and non-commercial organisations	☐	☐

Short Name of Study	The OUTPOST Pandemic Preparedness study
Full Name of Study	OUTcomes Post Infection (OUTPOST): Pandemic Preparedness Study
Principal Investigators	Prof Andrew Lloyd, Prof Lena Sanci
Co-investigators	Dr Ruby Biezen, A/Prof Lucette Cysique, Dr Miranda Smith
Research Team	Hayley Ivanusic, Natali Coric, Jia Shing See, Oonagh Macken,
Study Sponsor	Department of Health and Aged Care
Site Name	University of Melbourne, University of New South Wales

Person taking part in the study:

Signature: _____

Date: _____

Name: _____

Email: _____

Mobile: _____

For Withdrawal of Participation

Short Name of Study	The OUTPOST Study
Full Name of Study	OUTcomes Post COVID (OUTPOST): a prospective cohort study
Principal Investigators	Prof Andrew Lloyd, Prof Lena Sanci
Co-investigators	Dr Ruby Biezen, A/Prof Lucette Cysique, Dr Miranda Smith
Research Team	Hayley Ivanusic, Natali Coric, Jia Shing See, Oonagh Macken,
Study Sponsor	Department of Health and Aged Care
Site Name	University of Melbourne, University of New South Wales

Declaration by Participant/Representative

I wish to withdraw myself from participation in the above research project and understand that such withdrawal will not affect my relationship with the University of Melbourne or the University of New South Wales.

Person taking part in the study:

Signature: _____

Date: _____

Name: _____

Email: _____

Mobile: _____