Participant Information and Consent Form	
Short Name of Study	The OUTPOST Study: a pilot study
Full Name of Study	OUTcomes POST COVID: The OUTPOST Study - pilot phase
Principal Investigators	Prof Andrew Lloyd and Prof Lena Sanci
Study Sponsor	Department of Health and Aged Care
Site Name	University of Melbourne

What am I being invited to do?

As the OUTPOST research team, we invite you to take part in a pilot study to understand the best methods to recruit participants with acute respiratory infection in the community. This pilot forms part of a larger long-term study. You have been invited to take part because your general practice is a partner in this pilot study.

Around 100 people will take part in this pilot study. They will be from 2-3 general practices across Victoria.

Please read this information and feel free to ask any questions. Contact details for the research team are provided on page 7 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 local doctor.

What is the purpose of this study?

We want to find people with acute COVID-19 infection in the community and follow them to see what happens in the longer-term.

This pilot study will explore the best ways to get people to join the study. As most COVID infections occur in the community, we are recruiting people like you from your general practice or family doctor.

This pilot study will help us understand:

- If the research methods to find and enrol participants are effective,
- If our methods and instructions to diagnose the infection are appropriate, and
- If the questionnaires to document symptoms are acceptable to participants.

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

Taking part is up to you

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 your GP, your practice or any of the institutions involved (the University of Melbourne, the Kirby Institute and the Doherty Institute).

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 researcher via the details 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 pilot study, you will be expected to remain engaged for the 6 weeks. We will ask you if you would like to continue into the main study when it is ready in 2024. At that time, we will give you more information about the main study so you can make your decision.

The table below outlines what you need to do in this study. Please note, once you enter the study you will be assigned an anonymous identity (ID) number so your name and personal details such as address, and phone number will be kept confidential 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 (name/address and phone number) in case we need to contact you. This would be to notify you of test results, to complete missing information or to deliver your gift voucher as a thank you for participation. For more information, please contact the researcher via the details on page 7.

What part of the study?	What do I have to do?
Eligibility screening	We will ask you a few questions to make sure you are eligible for the study.

Consenting to take part in this study	If you are eligible and happy to take part in this study, you will be asked to sign a consent form.
Self-swabbing	After consenting to the study, we will send you a testing kit, including information resources about common viruses such as COVID-19, Influenza A and B, and RSV. When you receive the testing kit (or at 72 hours after symptom onset, whichever is later), you will need to do a nose swab and return it to the laboratory for testing via courier (instructions in the pack).
Baseline questionnaire (at the start of the study)	We will ask you to complete a set of questionnaires online at the start of the pilot study (link will be provided). These questionnaires will take around 30mins and ask about any symptoms you may? have and how they are affecting you.
Follow-up questionnaire (at 6 weeks)	We will ask you to complete the same set of questionnaires online at the end of the pilot study (link will be provided). These questionnaires will take around 30mins and ask about any symptoms you may have and how they are affecting you.
Workshop	You may be invited to participate in a workshop at the end of the pilot study to discuss your experience of the study. This will include your thoughts on how you were recruited to the study, the self-swabbing process and completing the questionnaires.

Please note: If you would prefer to complete the questionnaires via phone (at the start of the study and the end of the 6 weeks), please contact the researcher via the contact details on page 7 below and we will call you at a time convenient for you.

Payment for your time and expenses

You will need to spend a total of about an hour in the 6 weeks taking part in this study. To recognise your time and any inconvenience, we will offer you a $30 gift voucher.

If you are invited to and participate in the 1.5-hour workshop at the end of the pilot study, a further $50 gift voucher will be given in compensation.

What are the benefits of taking part?

You will have some benefits by taking part in this study. These include getting a test that can identify a range of viruses which may be causing you to feel sick. Your GP will be told about these results which may help them understand your condition better. By taking part, you will also help the researchers understand more about COVID infections in the community. This knowledge may help other people in the future.

What are the risks and discomforts of taking part?

We believe any risks in taking part in this pilot study are minimal. You may feel uncomfortable taking the nose swab. Some of the items on the questionnaires might cover sensitive topics (e.g. your mental health) which may cause you some anxiety and possibly some distress. We will make sure that you can discuss any worries that you may have with the researcher you are in contact with. In the instance where you may have trouble taking the nose swab or completing the questionnaires, we would ask that you let the researcher you are in contact with know as soon as possible. A break or rest may also help to reduce anxiety.

If you experience any concerns during the study, we strongly recommend that you contact the research team via the details on page 7 below, and/or contact your GP. We may follow up with your GP regarding your concerns. Furthermore, if we find that you report a high level of distress, your general practice/GP will be notified. Your general practice/GP will then ensure appropriate further tests and/or treatment are undertaken.

Breach of confidentiality

All the answers you make to our questionnaires, and your test results, will be kept in a secure locked data repository at the University of Melbourne under your anonymous ID number. 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 voucher and any questionnaires that are not completed.

For those participating in the workshop, you will be reminded that you must keep what you hear in the workshop confidential and not share it with others.

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

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. The self-swabbing sample will be couriered to a diagnostic pathology laboratory where genetic material of respiratory viruses including COVID-19, Influenza A or B, RSV or rhinovirus may be detected. The genetic material of the virus will be stored for future research, such as surveillance of the number and spread of these infections in the community.

Collecting your information

If you consent to the study, we will collect information for the study through your medical record from your general practice, your GP and directly from you.

We may also collect information for this study from other services such as the Australian Immunisation Register. We will only collect this data through your general practice upon your consent.

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.

Keeping your samples safe

We will keep your respiratory sample safe by:

- keeping them securely at the Victorian Infectious Disease Reference Laboratory
- Your sample will be provided with a code with your ID number. This code will be kept separate from anything that could easily identify you, like your contact information.

If you do have a virus on your nasal swab, we may send your samples to other laboratories for the virus in your sample to be analysed.

We will keep any leftover samples that have not been used up in the study for 15 years. After this, we will destroy them.

Sharing your information with others

We will share some of your information with others.

- **Sharing information with your GP**: we will tell your GP that you are taking part in this study. Your GP will also be provided with a copy of your respiratory virus test 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.
- **Legal requirements to share your information**: some information needs to be shared with others by law. In this study we will test for respiratory viruses including SARS-CoV-2, Influenza A and B, and RSV. If any results are positive, we will notify the required public health authorities.
- **Sharing information with other researchers:** we may share certain information from this study so that other researchers can use it in the future. These researchers may be in Australia or overseas. We will only share information that has been aggregated, that is, joined together with information from others before sharing, to ensure anonymisation.

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 <link> or contact the researcher via the details on page 7.

How may my information and samples be shared in the future?

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

When we share your information and samples, we will take steps to make it difficult for anyone to link the information back to you. This includes removing information that could easily identify you, like your name or contact information. There is still a very small chance that someone could identify you again.

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 and samples, 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 and samples. However, if your information or samples have already been shared, it may not be possible to retrieve or destroy them.

Who is running and paying for this study?

This study is being run by researchers from the Department General Practice and Primary Care, University of Melbourne and the Kirby Institute, 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

If you have any complaints about how this study is being run, please contact:

Manger, Human Research Ethics, Research Ethics and Integrity, University of Melbourne.

Tel: +61 3 8344 1376 or Email: research-integrity@unimelb.edu.au

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:

Dr Ruby Biezen, Research Fellow (University of Melbourne)

Phone: +61 3 9035 4886 Email: ruby.biezen@unimelb.edu.au

You can also visit our website/scan the QR code below to find more information.

<QR code>

Signature Page

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Full Name of Study	OUTcomes POST COVID: The OUTPOST Study - pilot phase
Principal Investigators	Prof Andrew Lloyd and Prof Lena Sanci
Study Sponsor	Department of Health and Aged Care
Site Name	University of NSW and University of Melbourne

Consent to take part in this study

By signing this consent form, I acknowledge that:

- I freely agree to take part in this study
- 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 give permission for the researchers to contact my general practice to access 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.

Consent to optional parts of the study	**Yes**	**No**
I agree to my information and samples being collected, stored and shared for any future research **OR** I agree to my information and samples being collected, 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	☐	☐
	Yes	**No**
I agree to be contacted to participate in the workshop after the pilot study	☐	☐

Person taking part in the study:

Signature: _____ Date: _____

Name: _____

Parent/Guardian/Carer of participants under 17 years of age taking part in the study: (for participants 12-17 years only)

Signature: _____ Date: _____

Name: _____

Email: _____

Mobile: _____