Participant Information Sheet/Consent Form

Adult providing own consent

Title	Victorian Critical Vaccinees Collection
Short Title	VC2
Protocol Number	75984
Project Sponsor	The University of Melbourne
Coordinating Principal Investigator	Professor Sharon Lewin *(The University of Melbourne)*
Principal Investigator	Professor Sharon Lewin

Part 1 What does my participation involve?

1 Introduction

You are invited to contribute to the Victorian Critical Vaccinees Collection (VC2), a biobank of samples and health data to support research into the long-term impact of novel (new) vaccines. We are inviting you because you are planning to, or are about to, receive a vaccine for a current critical/pandemic outbreak. We would like to ask you to provide blood and saliva samples at several timepoints before and after your vaccination.

This Participant Information Sheet/Consent Form tells you about the research project. It explains why we are collecting samples and clinical information. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or your local doctor.

Participation in this research is voluntary. If you don't wish to take part, you don't have to. You will receive the best possible care whether or not you take part.

If you decide you want to take part in the research project, you will be asked to sign the consent section. You may be given an option to read and sign this consent form on an electronic platform. The format and information will not change, all that is different is your consent, signature and date will be captured electronically and not a "wet" (ink) signature on paper. You will be able to keep a copy of this document once you have signed.

By signing the consent form you are telling us that you:

- Understand what you have read
- Consent to take part in the research project
- Consent to have the samples collected as described
- Consent to the use of your personal and health information as described.

You will be given a copy of this Participant Information and Consent Form to keep.

2 What is the purpose of a biobank?

The aim of this research project is to create a biobank. A biobank is a stored collection of human biological samples (e.g. blood, saliva) and/or their products (e.g. limited personal health information, DNA). Biobanks are an important resource for medical researchers to improve the understanding of diseases and to help find better ways to prevent or treat them.

3 What is the purpose of this research?

The Victorian Critical Vaccinees Collection (VC2) will create a biobank of samples (blood, saliva) and limited personal health information from a variety of people in Victoria who are receiving novel vaccines during a current infectious disease critical/pandemic outbreak. We will collect samples at several timepoints before and for up to 2 years after your initial vaccine.

Victorian medical researchers who want to answer important questions about the safety and effectiveness of the vaccines will be able to apply to access the stored samples. This will allow researchers to investigate:

- how your immune system responds to the novel vaccines, including the type and size of the immune response and how long it lasts;
- whether your genes play a role in how your immune system responds to the vaccines;
- why some people develop side effects;
- the impact of vaccination in context of the level of critical/pandemic disease in the community.

Rapid advances in technology make it impossible to predict what new tests or studies may be possible in the future. Therefore, when a researcher wishes to use any samples from the biobank, a Human Research Ethics Committee will review their application and decide if their research can proceed.

This project has been funded by the Department of Jobs, Precincts and Regions of the Victorian Government. It was initiated by the Coordinating Principal Investigator, Professor Sharon Lewin.

The project will be conducted at four sites:

- Austin Health;
- Western Health;
- Monash Health; and
- The Peter Doherty Institute for Infection and Immunity (Doherty Institute), The University of Melbourne.

It will be co-ordinated through the Doherty Institute.

4 What does participation in this research involve?

If you agree to take part in this research project, you will be asked to read this Participant Information and Consent Form and confirm that you understand what it says. You can ask any questions you have about this research. When you are satisfied that you fully understand this project, you will be asked to sign and date this form or provide electronic consent.

Participation in the VC2 study requires up to 7 visits over 2 years. You will not be required to attend the Doherty Institute. There will be an electronic questionnaire sent to you for all visit timepoints.

Baseline:

This visit can take place up to 60 days before the date of your first vaccine. The visit can even take place on the day of your first vaccine, but all procedures will need to be completed before vaccination.

This visit is expected to take less than 1 hour and will occur remotely. The following activities will be undertaken:

- collection of demographic and contact information (including name, telephone number, address, email, age, gender and ethnicity);
- a questionnaire which asks about:

- height, weight and waist circumference;
- limited past and current medical history. The information we are seeking is mainly focused on any health issues you may have/had that may impact on how you react to the novel vaccine;
- any current medications (if any) that you may be taking;
- previous pandemic related illness history, including whether you have ever tested positive to the virus of interest or the date of your last test and result;
- a self-assessment of your current health.

- research samples. You will be sent a pathology pack so that you can visit the closest Melbourne Pathology collection centre (Dorevitch Pathology for regional Victorians):
  - blood sample - 89mL or approximately 4½ tablespoons collected in approximately 10 blood tubes;
  - saliva sample – 2mL.

Day 0 is the day of your planned vaccination.

Visit 2: 4 to 15 days after first vaccine dose

This visit is expected to take no more than 15 minutes and will occur remotely. You will receive a SMS reminding you about this visit.

The study activities that will be undertaken at this visit are:

- follow-up questionnaire which asks:
  - if you had any vaccine doses since you completed the previous questionnaire;
  - if you experienced any side-effects;
  - any change in your medical history since last visit;
  - any changes in your medications;
  - a self-assessment of your current health.
- research samples:
  - blood sample - 45mL (less than 2½ tablespoons) collected in approximately 5 blood tubes;
  - saliva sample – 2mL.

Visit 3: 7 to 0 days before 2nd vaccine dose

This visit is only applicable to participants who are receiving a 2-dose vaccination course.

This visit will take approximately 30 minutes and will occur remotely. You will receive a SMS reminding you about this visit.

The study activities that will be undertaken at this visit are;

- follow-up questionnaire;
- research samples. You will be sent a pathology pack so that you can visit the closest Melbourne Pathology collection centre (Dorevitch Pathology for regional Victorians):
  - blood sample - 45mL (less than 2½ tablespoons) collected in approximately 5 blood tubes;
  - saliva sample – 2mL.

Visit 4: 4 to 15 days after second vaccine dose

This visit is only applicable to participants who are receiving a 2-dose vaccination course.

This visit is expected to take no more than 15 minutes and will occur remotely. You will receive a SMS reminding you about this visit.

The study activities that will be undertaken at this visit are:

- follow-up questionnaire;
- research samples:
  - blood sample - 45mL (less than 2½ tablespoons) collected in approximately 5 blood tubes;
  - saliva sample – 2mL.

Month 6
This visit will occur approximately 6 months after your day 0 vaccine dose.

This visit is expected to take no more than 15 minutes and will occur remotely. You will receive a SMS reminding you about this visit.

The study activities that will be undertaken at this visit are:

- follow-up questionnaire;
- research samples. You will be sent a pathology pack so that you can visit the closest Melbourne Pathology collection centre (Dorevitch Pathology for regional Victorians):
  - blood sample - 45mL (less than 2½ tablespoons) in approximately 5 blood tubes.

Month 12
This visit will occur approximately 12 months after your day 0 vaccine dose.

Study activities for this visit are identical to month 6.

Month 24 – End of study
This visit will occur approximately 24 months after your day 0 vaccine dose.

Study activities for this visit are identical to month 6.

Unscheduled Visit
An unscheduled visit may occur for the following reasons:

1. if you decide to receive an additional vaccine for the current outbreak, that is in line with the directive from ATAGI or the local health department (for example in the case of COVID-19 where additional vaccinations were recommended after the initial 2 vaccines during the pandemic)
2. Another outbreak has been declared and you decide to be vaccinated for the new outbreak (for example monkeypox outbreak was declared during the COVID-19 pandemic period).

We would like you to consider providing a blood sample before and after your additional vaccine dose, as well as answering additional questionnaires.

Unscheduled visits are voluntary and not part of the main collection visits of the study.

Other information
This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way and avoids study doctors or participants jumping to conclusions.

There are no additional costs associated with participating in this research project, nor will you be paid. All tests required as part of the research project will be provided to you free of charge.

You will not receive any payment for parking or travel for study visits.

We will provide you with a $100 gift voucher after month 12 study activities have been completed. A further $50 gift voucher will be provided once month 24 study activities have been completed.

5 What do I have to do?
We would like you to commit to complete the required 7 visits over a 2-year period as described. This means completing questionnaires, as well as providing blood and saliva samples.

If restrictions are put back in place in Victoria or you are required to quarantine, it may be possible to arrange a home visit to avoid unnecessary travel.

If at any stage you decide that you no longer would like to participate in this study, then please let the study team, listed in Section 21, know, and you will stop receiving SMS reminders and emails.

There are no lifestyle restrictions for taking part in this research.

6 Can I participate in other research studies during this research project?

You can participate in other research projects, as long as they do not exclude you from participating in this research project. If the other research project does not allow you to participate in any other concurrent study, then you will need to consider all your options before choosing which research project you continue with.

7 Other relevant information about the research project

This project will seek to collect samples from up to 1000 Victorian people as they get vaccinated with various novel vaccines for infectious diseases causing critical/pandemic outbreaks. There is a large network of recruiting sites to ensure that a diverse group of participants are enrolled including:

- **Healthy people from the general population**;
- **Healthcare workers**. These individuals are at high risk of exposure to any infectious viruses that cause critical/pandemic outbreaks in the community. Some people in this group may have an enhanced vaccination response;
- **People who have previously had infection with the virus causing the current critical/pandemic outbreak**. These individuals may also have an enhanced vaccination response, though this may differ depending on the time since infection and how sick they were;
- **People living with HIV**. These individuals may have been included in vaccine licencing studies, but in relatively small numbers. There is some evidence that there may be heightened susceptibility to severe pandemic related illnesses in people living with HIV, but little data on the response to vaccination;
- **People over 65**. These individuals may not respond as well to vaccination as younger groups due to age-related declines in immune function. This decline in immune response may result in an altered and less long-lasting vaccine response;
- **People with underlying immunosuppression or chronic conditions**. These individuals are likely to have a lower immune response to vaccination. However, it is unclear whether novel vaccines might be able to generate some response and in which situations;
- **People with chronic kidney disease and other significant illness**. These individuals may experience lower immune function depending on their disease stage and treatment.
- **Pregnant women**

By collecting samples from a range of people belonging to one (or more) of these subgroups, detailed research will be enabled to understand the response to vaccines. The study samples will be processed for storage at expert laboratories with quality-assured processes. Storage will be done in keeping with international best practice, ensuring that samples are of the highest possible quality for research.

A researcher will only be able to access the samples after their project has been reviewed by an expert panel comprising researchers from a wide range of disciplines and organisations, including community representation. They will also be required to have approval from a Human Research Ethics Committee for their project. They will not be given any identifying information about you such as your name or address.

The collection of blood samples enables different types of studies to be done. Blood cells can be analysed to assess their function and to understand what targets they respond to. The liquid component of blood can be studied to assess antibody types and levels, along with study of other blood components such as clotting factors and enzymes. DNA can be extracted from blood cells for studies to understand the genetic influences on vaccine responses.

Saliva samples contain certain types of antibodies that exist on the surfaces of the mouth, one of the mucosal surfaces that form an important barrier to many viruses that cause diseases in humans.

What is genetic research?

Genetic research involves looking into the genes in your body. Genes are the material (called “DNA”) inside each of your cells that gives the recipe for how each cell is made. Genetic

research can help answer important questions about your immune response. For example, why do some people respond to a treatment (or vaccine), while others do not, or why do some people experience a side effect and others do not? Genetic research can also uncover what part of the immune system responds to the virus or the immunization for a specific outbreak.

It is important to understand that the results from any genetic research will not indicate whether you have a disease or disorder, or whether you will develop one in the future.

If you consent to genetic testing, then some of the blood we collect will be set aside for researchers to use in genetic research.

What is the potential impact on my family if I take part?
There is no potential impact on your family members by taking part in this genetic research project. No information about your family is being collected.

8 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 any stage. We will make a project withdrawal form available on the project website.

If you do decide to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your relationship with the Doherty Institute.

9 What are the possible benefits of taking part?

It is unlikely that you will receive any benefits from taking part in this research as your samples may be stored for a long time. Your samples may contribute to investigations into the impact of novel vaccinations pandemic outbreaks but may not be used for months or years.

10 What are the possible risks and disadvantages of taking part?

Having a blood sample taken may cause some discomfort, bruising, minor infection or bleeding. If this happens, it can be easily treated.

Genetic testing involves the study of genetic material (typically DNA) that is shared with your blood relatives. Genetic research is undertaken for many reasons, including discovering more accurate ways of predicting disease within a group of people, or in people where there is strong family history or predisposition of disease.

In this case genetic testing may be performed to look at genes that are associated with your immune response to the novel vaccine. Genetic testing can include targeted investigation of genes associated with the immune response, or more general approaches including whole genome sequencing. Whole genome sequencing looks at your entire genome, approximately 23,000 genes. If this is done, it is possible that additional findings may occur – these are changes in genes unrelated to your current health but which may be important for future medical care. We specifically ask for your consent to contact you if any additional findings are made. You may or may not wish for the study team to do this.

11 What will happen to my test samples?

The blood and saliva samples taken as part of this study will be strictly used for research purposes and be stored in the biobank for future use.

Your samples will be stored at the Doherty Institute, 792 Elizabeth Street Melbourne VIC 3000, along with samples of many other people. The custodian of the biobank is Professor Sharon Lewin.

Your blood and blood products will not be sold by the University of Melbourne.

12 How long will my samples be stored?

Currently it is planned to store your samples indefinitely until they are used for research or until quality checks show they have deteriorated and are no longer suitable for research. Any sample which needs to be disposed of will be handled according to human tissue disposal regulations.

Your samples will be stored initially as re-identifiable samples. This means that your samples will be identifiable by a code; they can be identified as yours even though the biobank staff do not know your identity. You can have them destroyed by contacting the Doherty Institute Principal Investigator, in writing at:

Professor Sharon Lewin
The Doherty Institute
792 Elizabeth Street
Melbourne VIC 3000
Email: sharon.lewin@unimelb.edu.au

The Doherty Institute Principal Investigator will then contact the biobank and request that your samples are destroyed.

13 Will I be given the results of the research project?

You will not routinely be given results from the use of your biospecimens because your identity will not be disclosed to researchers who are given authorisation to use your samples. We will develop a process for providing any potentially medically relevant genetic results if you consent to this. We will post regular updates on the website www.VC2.org.au. These updates will include all projects using de-identified specimens from the bank, which may or may not include yours.

14 Will drug or biotechnology companies be able to use my sample for profit in the future?

No.

15 Is other information about me collected?

The health information we will collect and store in a databank for this research project will include some basic information about you including your age, gender, ethnicity, weight, past medical history, risk factors for acquiring the current outbreak-causing disease, medication history, your vaccination details and any side effects. We may also store information about any additional health issues that may impact your vaccination response. This information will be provided by you at your study visits.

We will collect your name, phone number, email address and street address. This identifying information will only be used for study conduct purposes - to send you SMS reminders about any upcoming visits, questionnaires, blood collection tubes and Melbourne Pathology request slips. This information will be stored in the databank, and only a limited number of staff will have access to this information. Once the study has been archived, then this identifying information will be deleted and there will be no link to identify your stored samples.

Part 2 How is the research project being conducted?

16 How is the VC2 biobank operated?

Details of the governance of the research project are available in the Research Protocol, which has been made available to the Human Research Ethics Committee of your institution. We will also provide details of who is involved and the processes for sample access on our website www.vc2.org.au. The research project is overseen by Victorian infectious disease researchers from a variety of organisations and will also include community representation. All research approved for the use of VC2 specimens must abide by the National Statement on the Ethical

Conduct of Research Involving Humans from the NHMRC.

17 What will happen to information about me?

By signing the consent form you consent to the study doctor and relevant research staff collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential.

Any identifiable information about you will only be accessed by study staff for the purpose of conducting this study.

The database (REDCap) used in this study will manage both the online questionnaires and SMS reminders as well as study information collected at face-to-face visits. The database will be housed within the University of Melbourne's secure computer complex. Personal information (i.e. first name, surname, phone number and email address) will be collected and retained in this database and will specifically be used to send SMS reminders and questionnaires electronically. Your identifying information will not be retained by researchers after the collection of data is complete. When the data collection is complete (that is, at the end of the study), all identifying information will be removed from the database. Any analysis will be on a dataset that does not include any information from which you could be identified (known as de-identified data). This de-identified electronic data will be kept in password-protected files on a secure Melbourne University network drive. Only researchers directly involved in this study will have access to this data. The de-identified data will be kept indefinitely and may be provided to researchers whose applications for specimen use are approved (as described below).

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.

In the future, your health information and samples may be given to researchers as part of the search for a genetic cause of the disease caused by the virus or for other research purposes. The samples will be labelled only with a unique study ID and not with any personal identifiers (e.g. name, telephone number). It will be possible to re-identify the samples as yours using your study ID. Only study investigators involved in this project will have access to the code used to create your study ID. Once the study has been archived, only one study staff member involved in the VC2 study at the Doherty Institute will be able to link your study ID to you.

In accordance with relevant Australian and/or Victorian privacy and other relevant laws, you have the right to request access to your information collected and stored by the study team. You also have the right to request that any information with which you disagree be corrected. Please contact the study team member named at the end of this document if you would like to access your information.

It is anticipated that the 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, except with your express permission.

18 Complaints and compensation

If you suffer any injuries or complications as a result of this research project, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical treatment. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

19 Who is organising and funding the research?

This research project is being conducted by a multi-site team of researchers led by Professor Sharon Lewin at The University of Melbourne, The Peter Doherty Institute for Infection and Immunity.

By taking part in this research project you agree that samples of your blood or saliva (or data generated from analysis of these materials) may be provided to The University of Melbourne, Doherty Institute.

You will not benefit financially from your involvement in this research project even if, for example, your samples (or knowledge acquired from analysis of your samples) prove to be of commercial value to The University of Melbourne.

In addition, if knowledge acquired through this research leads to discoveries that are of commercial value to The University of Melbourne, the study doctors or their institutions, there will be no financial benefit to you or your family from these discoveries.

The University of Melbourne will receive a payment from The State of Victoria, Department of Jobs, Precincts and Regions for undertaking this research project.

No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

20 Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of Austin Health.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

21 Further information and who to contact

The person you may need to contact will depend on the nature of your query.

If you want any further information concerning this project or if you have any medical problems which may be related to your involvement in the project (for example, any side effects), you can contact any of the following people:

Clinical contact personnel

Name	Jenny Tran
Position	Clinical Research Assistant
Telephone	0422 203 031
Email	VC2-biobank@unimelb.edu.au

Name	Barbara Scher
Position	Clinical Research Manager
Telephone	0422 203 031
Email	VC2-biobank@unimelb.edu.au

For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

Complaints contact person

Position	Manager, Human Research Ethics, Research Ethics and Integrity
Telephone	(03) 8344 2073
Email	HumanEthics-complaints@unimelb.edu.au

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:

Reviewing HREC approving this research and HREC Executive Officer details

Reviewing HREC name	Austin Health and Human Research
HREC Executive Officer	HREC Executive Officer
Telephone	(03) 9496 4090
Email	research@austin.org.au

Consent Form

Title	Victorian Critical Vaccinees Collection
Short Title	VC2
Protocol Number	75984
Project Sponsor	The University of Melbourne
Coordinating Principal Investigator	Professor Sharon Lewin *(The University of Melbourne)*
Principal Investigator	Professor Sharon Lewin

Consent Agreement

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the biobank described in the project.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the project without affecting my future health care.

"Unscheduled" sampling (pre and post additional vaccine doses):		
I consent to undergo sample testing before and after any additional vaccines for specific critical/pandemic outbreak whilst participating in this study	☐ Yes	☐ No
Participant initials	_____	

I understand that I will be given a signed copy of this document to keep.

Storage and use of samples for research:		
I consent to the storage of blood and saliva taken from me for use, as described in Section 7 of the Participant Information Sheet, in:		
- research projects related to this critical/pandemic outbreak	☐ Yes	☐ No
- other infectious disease research projects	☐ Yes	☐ No
- any other future research	☐ Yes	☐ No

Use of samples for genetic research:		
I consent to my samples being used for genetic research, as described in Section 7 of the Participant Information Sheet for:		
- research projects related to this critical/pandemic outbreak	☐ Yes	☐ No
- other infectious disease research projects	☐ Yes	☐ No
- any other future research	☐ Yes	☐ No

Receiving information from genetic research:	
If research with my DNA reveals some other medical condition relating to me for which treatment is available or pending I wish to be informed	☐ Yes ☐ No

Declaration by Participant – for participants who have read the information

Name of Participant (please print) _____

Signature _____ Date _____

Declaration by Study Doctor/Senior Researcher†

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Name of Study Doctor/
Senior Researcher† (please print) _____

Signature _____ Date _____

† A senior member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature.