Insert Header with institution's name or institution's letterhead

Participant Information Sheet/Consent Form

Interventional Study - *Adult providing own consent*
Participants not receiving influenza vaccination

[Insert site name]

Title	Does repeated influenza vaccination constrain influenza immune responses and protection?
Short Title	HCW Cohort Study
Protocol Number	[redacted]
Project Sponsor	Melbourne Health
Coordinating Principal Investigator/ Principal Investigator	[redacted]
Associate Investigator(s)	[redacted]
Location	[*insert name of hospital*].

Thank you for taking the time to read this Information Statement and Consent form. This document is 8 pages long. Please make sure you have all the pages.

Part 1: What does my participation involve?

1 Introduction

You are invited to take part in this research project because you work at [*insert name of hospital*]. This project will examine the immune response to influenza vaccination among hospital workers.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the tests involved. 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.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

- Understand what you have read
- Consent to take part in the research project

- Consent to have the tests that are described
- Consent to the use of your personal and health information as described
- Consent to storage and use of samples for future related research

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

2 What is the purpose of this research?

The purpose of this project is to examine the immune response to influenza vaccination among hospital staff by comparing antibody levels between staff who are often vaccinated and staff who are less frequently vaccinated for influenza.

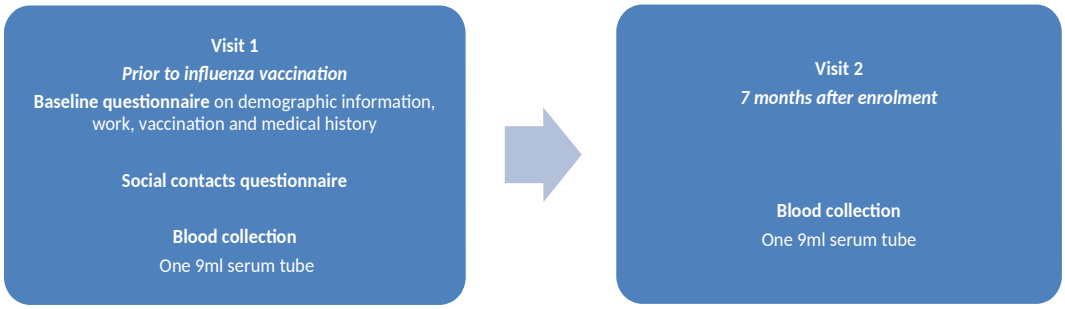
People who are vaccinated against influenza develop antibodies which protect against the virus. When a vaccinated person is exposed to influenza, these antibodies latch onto the virus and remove it from the body. Previous research studies have shown protection against influenza by measuring antibody levels in blood. However, antibody levels are variable and may drop within a year after vaccination.

There is little published information on the differences in antibody levels among hospital workers who are often vaccinated and those who are less frequently vaccinated for influenza. The findings from this study may provide information contributing to this area of research.

In addition, we are interested in studying the immune response to COVID-19 infections among healthcare workers and enhance our understanding of the SARS-CoV-2 virus, which is the virus that causes COVID-19 disease.

3 What does participation in this research involve?

Participation in the study will involve two visits where you will have 9mL of blood (approximately 1½ teaspoons) taken to measure antibody levels on two occasions. You will also be asked to complete 2 to 3 questionnaires to collect information about you and about your daily social interactions.



The total time commitment for participating in this study is approximately 4 hours per year for [*insert number of years depending on year of enrolment*] years.

There are no costs associated with your participation in this research project. All tests required as part of the research project will be provided to you free of charge. Each time you are seen for a blood sample, you will be given [redacted]

3.1 Monitoring flu-like illness

Approximately two weeks after enrolment in the study you will begin receiving weekly SMS and/or email reminders to complete a weekly online survey of flu-like illness. If you meet the criteria for flu-like illness, you will be sent daily symptom surveys via SMS and/or email. You will also be asked to collect a nasal and a throat swab for testing for influenza and other respiratory viruses. Nasal swabs involve inserting a swab into each nostril and rotating the swab against the inside of the nose for 3 seconds. Throat swabs involve rubbing the swab at the back of your throat. Detailed instructions on how to collect the swabs, as well as a swab kit will be provided upon enrolment to the study.

3.1.1 If you test positive for influenza

If you are identified to have tested influenza A positive, the site manager will contact you to organise collection of additional blood samples. Three 9ml blood samples will also be collected approximately 7 and 14 days post-illness onset. An additional two 9 ml blood samples will be collected approximately 7 months after the first visit.

3.1.2 If you test positive for SARS-CoV-2

If you test positive for SARS-CoV-2, a member of the study team may call you to ask if you would be willing to provide additional swab and blood samples. You do not have to provide these additional samples if you do not feel comfortable doing so.

Additional nose, throat and rectal swabs may be requested to help us understand how long people remain infected with the SARS-CoV-2 virus. We will mail or deliver swabs and instructions to your home so that you can collect these extra swabs while you are in isolation at home. We will also need to ask you for your home address to be able to deliver these swabs.

Additional blood samples may be requested to help us understand the immune response to SARS-CoV-2 infections. Six additional 9ml blood samples will be collected at up to 5 visits occurring approximately 3, 7, 14, and 30 days after you developed symptoms and at the end of the flu season, around November.

4 What do I have to do?

To participate in this study, you must be:

- aged between 18 and 60 years;
- a current staff, student, volunteer or honorary member at [*insert hospital name*] eligible for the hospital's free vaccination program;
- willing to provide a current mobile phone number for SMS reminders during the study period;
- able and willing to complete the informed consent process;
- available for follow-up over the next 7 months;
- able and willing to provide follow up blood samples up to 7 months post-enrolment

You will not be able to participate in this study if you have received immunosuppressive treatment within the past 6 months or are contraindicated for influenza vaccine (e.g. you are currently ill or have a fever above 38°C).

5 Other relevant information about the research project

Six hospitals in Australia will participate in this study. [*Insert hospital name*] is one of the participating hospitals. A total of 250 staff at [*insert hospital name*] will participate in this study. Overall, 1500 healthcare workers across 6 hospitals will participate in the study.

This research has been funded by the US National Institutes of Health [redacted]

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 any stage. 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 [*insert hospital name*].

7 What are the alternatives to participation?

You do not have to take part in this research project. This is a research study and does not constitute treatment or therapy.

8 What are the possible benefits of taking part?

We cannot guarantee or promise that you will receive any benefits from this study. This study may be able to provide previously unknown information about influenza antibody levels in hospital workers. This information is useful for influenza vaccination programmes in hospitals. You will be able to find out how well your body has responded to vaccination using one measure of antibody response.

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

Blood samples will be collected as part of the study. There are no major risks associated with giving blood. Most people feel uncomfortable when the needle is put in their arm to take blood. It is possible there may be some bruising, swelling, or bleeding where the needle enters the skin.

If you develop flu like symptoms during the study period, you will be asked to collect a nasal and throat swab. Instructions on how to do this, as well as a swab kit will be provided upon enrolment to the study. There is minimal risk involved in collecting a these swabs, though it can cause some discomfort.

10 What will happen to my test samples?

By consenting to take part in this study, you also consent to the collection, storage and use of the blood samples and any swabs collected during the study period. These samples will be sent to [redacted] During and after the study, you retain the right to have the sample material destroyed at any time by contacting the principal investigator.

If you provide a swab, this will be sent to [redacted] to test for influenza, as well as other respiratory viruses. If your swab is positive for influenza, the sample will then be sent to the [redacted] for further testing to identify the influenza strain, including genetic testing of the viruses.

11 What if new information arises during this research project?

Sometimes during the course of a research project, new information about the risks and benefits of the project may become available. If this happens, the study coordinator will tell you about it and discuss with you whether you want to continue in the research project. If you decide to withdraw you will be free to do so at this time. If you decide to continue in the research project you will be asked to sign an updated consent form.

12 What if I withdraw from this research project?

If you decide to withdraw from the project, please notify a member of the research team before you withdraw. This notice will ensure the study team do no try to contact you for follow-up. If you do withdraw your consent during the research project, the research team will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law.

Part 2: How is the research project being conducted?

13 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 for the purpose of this research project *and for the future research described in Section 16* 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.

Additional information on current and previous influenza vaccination years will be collected [*insert name of department that holds vaccination records*]. The study data will be collected, stored and archived together with your original consent form in [redacted]

[redacted]

[redacted]

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. You will be able to obtain a copy of any publications from the study website [*insert url*].

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 research 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.

14 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.

15 Who is organising and funding the research?

This research project is being conducted by [redacted], in collaboration with [*enter department and hospital name*]. The research project is funded by the US National Institutes of Health. No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

16 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 Melbourne 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.

17 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 the coordinating principal investigator [redacted] or any of the following people:

Study coordinator

Name	*[Name]*
Position	*[Position]*
Telephone	*[Phone number]*
Email	*[Email address]*

Clinical contact person

Name	*[Name]*
Position	*[Position]*
Telephone	*[Phone number]*
Email	*[Email address]*

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

Name	*[Name]*
Position	*[Position]*
Telephone	*[Phone number]*
Email	*[Email address]*

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 name	Melbourne Health
HREC Executive Officer	[redacted]
Telephone	[redacted]
Email	[redacted]

Reviewing HREC approving this research and HREC Executive Officer details

Local HREC Office contact (Single Site - Research Governance Officer)

Name	*[Name]*
Position	*[Position]*
Telephone	*[Phone number]*
Email	*[Email address]*

Consent Form - *Adult providing own consent*

Title	Does repeated influenza vaccination constrain influenza immune responses and protection?
Short Title	HCW Cohort Study
Protocol Number	[redacted]
Project Sponsor	Melbourne Health
Coordinating Principal Investigator/ Principal Investigator	[redacted]
Associate Investigator(s) *(if required by institution)*	[redacted]
Location *(where CPI/PI will recruit)*	*[Location where the research will be conducted]*

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 research 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 study without affecting my future health care.
- I understand that I will be given a signed copy of this document to keep.

Declaration by Participant – for participants who have read the information

Name of Participant (please print) _____

Signature _____ Date _____

Declaration - for participants unable to read the information and consent form

See Note for Guidance on Good Clinical Practice CPMP/ICH/135/95 Section 4.8.9, witness * required

Witness to the informed consent process

Name (please print) _____

Signature _____ Date _____

* Witness is not to be the investigator, a member of the study team or their delegate. In the event that an interpreter is used, the interpreter may not act as a witness to the consent process. Witness must be 18 years or older.

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.

Consent to use of samples for future research

I consent to the storage and use of blood and swabs taken from me for use, as described in the relevant section of the Participant Information Sheet, for:

- This specific research project
- Other research that is closely related to this research project
- Any future research.

Name of Participant (please print) _____

Signature _____ Date _____

For participants unable to read the information and consent form

See Note for Guidance on Good Clinical Practice CPMP/ICH/135/95 Section 4.8.9, witness * required

Witness to the informed consent process

Name (please print) _____

Signature _____ Date _____

* Witness is not to be the investigator, a member of the study team or their delegate. In the event that an interpreter is used, the interpreter may not act as a witness to the consent process. Witness must be 18 years or older.

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.

Form for Withdrawal of Participation - *Adult providing own consent*

It is recommended that this form NOT be included as part of the PICF itself, but that it be developed at the same time and made available to researchers for later use, if necessary. Note that a participant's decision to withdraw their separate consent to the use and storage of tissue will need to be documented separately and linked to the PICF used for that purpose.

Title	Does repeated influenza vaccination constrain influenza immune responses and protection?
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Coordinating Principal Investigator/ Principal Investigator	[redacted]
Associate Investigator(s) *(if required by institution)*	[redacted]
Location *(where CPI/PI will recruit)*	*[Location where the research will be conducted]*

Declaration by Participant

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine treatment, my relationship with those treating me or my relationship with *[Institution]*.

Name of Participant (please print) _____

Signature _____ Date _____

In the event that the participant's decision to withdraw is communicated verbally, the Study Doctor/Senior Researcher will need to provide a description of the circumstances below.

Declaration by Study Doctor/Senior Researcher†

I have given a verbal explanation of the implications of withdrawal from the research project 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 withdrawal from the research project.

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