

45 and Up Study Participant Information Sheet

Effectiveness of standard dose influenza vaccine in preventing cardiovascular hospitalisations

October 2022

Principal Investigator: Professor Raina MacIntyre

This research project is in addition to the main 45 and Up Study. Participation is voluntary. Participation in this project does not change your involvement in the main 45 and Up Study. Information collected by this research project will become part of the 45 and Up Study in future.

What is the purpose of this research project?

This project will estimate the effectiveness of the standard dose influenza vaccine in preventing hospitalisation for heart disease in people aged 50 years and over. There is growing evidence that having the flu may increase the risk of having a heart attack or heart failure, so getting an annual vaccine may reduce the risk of being hospitalised for heart disease. The researchers want to know whether individuals who received a flu vaccine in 2017 were less likely to be hospitalised for influenza-related heart disease during the flu season (May-September) of that year.

Who is conducting this research project?

The research project is being carried out by the University of New South Wales, Kirby Institute, Biosecurity Program with the following researchers:

- **Prof C Raina MacIntyre**, Biosecurity Program, The Kirby Institute, UNSW Sydney
- **Dr Aye Moe**, Biosecurity Program, The Kirby Institute, UNSW Sydney
- **Mallory Trent**, Biosecurity Program, The Kirby Institute, UNSW Sydney
- **Abu Muhammad Zubair Akhtar**, Biosecurity Program, The Kirby Institute, UNSW Sydney

Research Funder: This research is being funded by Sanofi Pasteur, Australia.

Why have I been invited to participate in this research project?

The researchers are looking for three groups of people: 1) those who may have been hospitalised

for cardiovascular disease during 2017; 2) those who may have been hospitalised for gastrointestinal disease in 2017; and 3) those who were not hospitalised at all in 2017. This is so that things like whether people have been vaccinated for influenza can be compared between the three groups. When you joined the 45 and Up Study, you agreed to be followed through your health records. It is based on these health records that you have been invited to participate in this research. When you joined the 45 and Up Study, you agreed to receive invitations to participate in other research projects such as this.

Do I have to participate in this research project?

Participation in this research project is voluntary. If you do not want 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 decide you want to take part in the research project, please:

- Read this information carefully (ask questions if necessary)
- Read and complete the online consent form that follows this information
- Contact the 45 and Up Study to obtain a copy of your consent form if desired.

This information is also available on the Sax Institute's website at:

www.saxinstitute.org.au/resource/influenza-vaccine-PIS to view or print.

What does participation involve?

If you agree to participate you will be asked to:

- **Complete an online questionnaire** about your hospitalisation and vaccination history in 2017. You will only be asked to complete this survey once. The survey should take approx. 5-10 minutes to complete.
- **Provide your doctor's contact details and approval to contact them.** The UNSW research team will use the details provided to contact your doctor to verify the details provided in your questionnaire on vaccination in 2017. We will not collect any other information from your healthcare provider.

Are there risks to me in participating in this research project?

You may feel some discomfort in disclosing medical information and/or having the study team contact your medical provider. Participation in this study is voluntary and you may withdraw at any time. After verifying your vaccination status with your medical provider, their contact details and any identifying information about you will be destroyed. All data will be analysed and stored in a non-identifiable format where your identity will be unknown. Further information about how your data will be used can be found below. If you have concerns, please contact the 45 and Up Study Infoline 1300 45 11 45, or email 45andUp@saxinstitute.org.au

Will I benefit from this research project?

There will be no immediate personal benefit to you for your participation in this research project. The research project will improve our understanding of the role of influenza vaccination in the prevention of cardiovascular hospitalisation.

Will taking part in this research project cost me anything, and will I be paid?

There are no costs associated with participating in this research project, nor will you be paid.

What information will the researchers receive about me from the Sax Institute?

By agreeing to be a part of this research project, you agree to the Sax Institute providing the research project researchers with:

- Information relevant to this research project that you have previously provided to the 45 and Up Study

- Questionnaire data and/or information that you provide as part of this research project
- Your GP/clinic contact details and information from your doctor about whether you received a flu vaccine in 2017 and the type of vaccine received
- Your email address or address (*only if you would like to receive a copy of the study results*).

What will happen to information about me?

By signing the consent form, you consent to the research team collecting and using information about you for the research project. The research team will store the data collected from you for this research project for a minimum of 7 years after the completion of the research. The information about you will be stored in a non-identifiable format where your identity will be unknown. Information collected from you will be stored within the Sax Institute's SURE workspace, which is hosted in a tier-3+ (i.e. best available) data centre in Sydney.

The information you provide is personal information for the purposes of the Privacy and Personal Information Protection Act 1998 (NSW). You have the right of access to personal information held about you by the University, the right to request correction and amendment of it, and the right to make a complaint about a breach of the Information Protection Principles as contained in the PPIP Act. Further information on how the University protects personal information is available in the [UNSW Privacy Management Plan](#)

The information will also become part of the 45 and Up Study resource. It will be stored by the Sax Institute for the life of the 45 and Up Study plus 7 years and combined with other information from the 45 and Up Study. All future research projects using this information will require approval from a relevant human ethics committee and the Sax Institute.

How and when will I find out the results of the research project?

The research team intend to publish and/or report the results of the research. All information will be published in a way that will not identify you.

If you would like to receive a copy of the results you can let the research team know by inserting your email or mailing address in the consent

form. The researchers will only use these details to send you the results of the research.

What if I want to withdraw from the research project?

If you do consent to participate, you may withdraw at any time. You can do so by contacting the 45 and Up Study. Your decision not to participate or to withdraw from the research project will not affect your relationship with UNSW Sydney, the 45 and Up Study, or the Sax Institute. If you decide to leave the research project, the researchers will not collect additional information from you. You can request that any identifiable information about you be withdrawn from the research project. It may not be possible to withdraw information that has already been used for research or publication. Withdrawal from the research project will not withdraw you from the overall 45 and Up Study.

What ethics approval does this research project have and how can I contact them?

This research project has been approved by the UNSW Human Research Ethics Committee [approval #HC210980] and the NSW Population and Health Services Research Ethics Committee [approval 2021/ETH11664 / 2021.55].



What if I have a complaint or any concerns about the research study?

If you have a complaint regarding any aspect of the study or the way it is being conducted, please contact the UNSW Human Ethics Coordinator:

Complaints Contact

Position	Human Research Ethics Coordinator
Telephone	+ 61 2 9385 6222
Email	humanethics@unsw.edu.au
HC Reference Number	#HC210980

What should I do if I have further questions about my involvement in the research project?

If you require further information regarding this research project or if you have any problems accessing the online consent or survey, please contact the 45 and Up Study team on 1300 45 11 45 or email 45andUp@saxinstitute.org.au If required, the Study team can provide contact information for the researchers involved in this project.



About the 45 and Up Study

The 45 and Up Study is the largest general population program of health-related research ever conducted in Australia. More than 267,000 people aged 45 and over are part of the Study, and are being followed over time through routine follow-up questionnaires and linkage to health and other records.

The 45 and Up Study has been approved by the University of New South Wales Research Ethics Committee. Study participants have also given permission to be invited to participate in further research projects. Each of these research projects has been through a stringent review process prior to approval. **Participation in these research projects is optional.**

Study governance

The 45 and Up Study is owned and managed by the Sax Institute in collaboration with major partner Cancer Council NSW, and partners the Heart Foundation and the NSW Ministry of Health.

About the Sax Institute

The Sax Institute is an independent, not-for-profit organisation whose mission is to improve health, health services and programs by increasing the use of research in policy making. We want to achieve wiser decisions for a healthier Australia. The Sax Institute's objectives are to: generate new research for use in policy; improve policy makers' access to existing research; and develop and test innovative new ways to increase the use of research evidence in policy making. See www.saxinstitute.org.au for more information.

Confidentiality

The 45 and Up Study, and any research projects from it, is bound by Commonwealth and State privacy legislation and guidelines: Privacy Act 1988 (Cth), Health Records and Information Privacy Act 2002 (NSW); and the NSW Health Privacy Manual for Health Information. The 45 and Up Study has strict procedures and systems to safeguard participant confidentiality. The Study is also bound by strict scientific ethical accountability to the University of New South Wales, Sydney NSW 2052:

Telephone: (02) 9385 6222

Email: humanethics@unsw.edu.au

Contact the Sax Institute about the 45 and Up Study

For any questions, comments, or complaints about the 45 and Up Study or this research project, to withdraw consent for participation, or for further communication, please contact us by:

Telephone: 1300 45 11 45 (toll-free Study Infoline)

Email: 45andUp@saxinstitute.org.au

Or in writing addressing your correspondence to:
Dr Martin McNamara, Chief Investigator,
45 and Up Study, GPO Box 5289, Sydney NSW 2001.

Thank you. We could not conduct the 45 and Up Study without the generosity of our participants. We are immensely grateful to all of you.