Wellness and Flu Injection Response (WeFi)

**PARTICIPANT INFORMATION STATEMENT**

This Participant Information Statement tells you about the research study. Knowing what is involved will help you decide if you want to take part in the research. Please read this sheet carefully and ask questions about anything that you want to know more about or do not understand.

1. What is this study about?

You are invited to take part in a research study examining the relationship between health biobehavioural and psychosocial factors and responses to the influenza vaccination (flu shot). These factors are being examined as they have been identified as affecting the immune response. You will be asked about your health and behaviours, as well as how you react to your flu shot and whether you experience any flu-like symptoms this winter.

1. Who is running the study?

The study is being carried out by Dr Kate Edwards, Associate Professor in Exercise Physiology, The University of Sydney; Professor Robert Booy, Head of the Clinical Research team at the National Centre for Immunisation Research and Surveillance (NCIRS) & Professor of Paediatrics and Child Health, Children’s Hospital, Westmead; and Ms Erika Goldbaum, doctoral candidate at The University, under the supervision of Dr Edwards.

1. What will the study involve for me?

If you agree to take part, you will complete a short (5-10min) questionnaire about health behaviours (such as sleep and exercise habits) and psychosocial factors (such as stress) while at the University flu shot clinic.

Links to online follow-up surveys will be sent to an email address you provide. Tomorrow and for the next three mornings, you will be asked to complete a 1-2-minute online questionnaire to record a few of your behaviours and any adverse events you have experienced following the vaccination. Beginning two weeks after the flu shot, you will be asked to complete a 1-2-minute online survey asking whether you experienced any flu-like symptoms. This will repeat fortnightly for six months.

1. How much of my time will the study take?

In total, you are asked to complete three types of online questionnaires over 6 months. The first questionnaire is estimated take 5-10 minutes, with follow-ups about adverse events and flu symptoms each estimated at 1-2 minutes time. The total time estimate is less than 45 minutes.

1. Who can take part in the study?

Adults (at least 18 years old) who (1) are eligible for a flu shot as part of the University of Sydney employee health program and (2) have not previously received the influenza vaccine this year are eligible.

1. Do I have to be in the study? Can I withdraw from the study once I've started?

Being in this study is completely voluntary and you do not have to take part. Your decision whether to participate will not affect your current or future relationship with the researchers or anyone else at the University of Sydney.

If you decide to take part in the study and later change your mind, you are free to withdraw at any time up to the point that we have analysed and published the results. You can do this by contacting the research team at [shs.exvax@sydney.edu.au](mailto:fhs.exvax@sydney.edu.au) from the address at which we have contacted you and stating your desire to withdraw.

If you decide to withdraw from the study, we will not collect any more information from you. Because the follow-up surveys are sent automatically, there may be a slight delay in when we stop contacting you. We will check for messages at least once before each survey send-out and endeavour to keep unwanted contact to no more than one message.

1. Are there any risks or costs associated with being in the study?

There are no anticipated risks associated with the questionnaires.

*Please note: if you experience any side-effects from your flu shot which warrant medical attention, contact your GP or other health professional.*

1. Are there any benefits associated with being in the study?

There are no direct health benefits to being in this study. This study has the potential to improve understanding of vaccination responses, which may help improve future vaccination campaigns.

Any participant completing the final survey, regardless of any prior missed follow-up surveys, may opt-in to a random draw to win one of 10 $50 Coles vouchers. Winners will be notified electronically and have one week to accept (by contacting study team and stating acceptance). Unclaimed prizes will be entered into another random draw for all non-winning opt-in participants, with the same acceptance rules, and the cycle repeating until all vouchers have been claimed.

1. What will happen to information about me that is collected during the study?

Your information will be stored securely in password-protected files on secure servers and your identity/information will be kept strictly confidential, except as required by law. Any identifying information will be removed from the data you provide and stored separately from the data. Data will be retained for 5 years and then destroyed according to University protocol. Your information will only be used for the purposes outlined in this Participant Information Statement, unless you consent otherwise.

Study findings may be published, but you will not be individually identifiable in these publications*.*

1. Can I tell other people about the study?

Yes, you are welcome to tell other people about the study.

1. What if I would like further information about the study?

If you have any questions or would like to know more at any stage during the study, please feel free to email the study team at [shs.exvax@sydney.edu.au](file:///C:\Users\egol4196\Dropbox%20(Sydney%20Uni)\Erika%20PhD\Flu%202020\fhs.exvax@sydney.edu.au) or call Erika Goldbaum on 8627 1866*.*

1. Will I be told the results of the study?

You have a right to receive feedback about the overall results of this study. You can tell us that you wish to receive feedback by ticking the relevant box in the final survey. This feedback will be in the form of a short one-page summary. You will receive this feedback after the study is finished.

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

Research involving humans in Australia is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this study have been approved by the HREC of the University of Sydney [2019/711]. As part of this process, we have agreed to carry out the study according to the *National Statement on Ethical Conduct in Human Research (2007).* This statement has been developed to protect people who agree to take part in research studies.

If you are concerned about the way this study is being conducted or you wish to make a complaint to someone independent from the study, please contact the university using the details outlined below. Please quote the study title and protocol number.

The Manager, Ethics Administration, University of Sydney:

* **Telephone:** +61 2 8627 8176
* **Email:** ro.humanethics@sydney.edu.au
* **Fax:** +61 2 8627 8177 (Facsimile)

***This information sheet is for you to keep***