SHIVERS-II

Participant Information Sheet for the SHIVERS-II Influenza Cohort Study in 2020

Locality: Wellington **Lead Investigator:** Sue Huang **Phone:** 04 529 0600

What information is included in this participant information sheet?

This sheet is to give you information to help you decide whether you want to continue as a SHIVERS-II participant in 2020. It includes the reason why we are doing the study, what we are asking you to do, the risks and benefits of the study, and what happens when the study is finished. Please read over this sheet carefully and discuss with your family, whānau, friends, or healthcare providers before deciding whether or not to continue with the study. It is entirely up to you to decide if you want to continue to take part in SHIVERS-II. You can stop taking part in the study at any time – no reason needs to be given. Stopping the study will not affect your current or future health care.

What is the SHIVERS-II Influenza Cohort Study?

SHIVERS-II aims to better understand the immunity or protection people have against the flu (through infection or vaccination). Findings of SHIVERS-II will help the New Zealand government make choices about flu vaccine recommendations and make decisions about how to reduce the impact of the spread of the flu in the community. The study will also provide information that can be used to improve flu vaccines in the future and better prepare for flu pandemics.

SHIVERS-II is an observational study. **No medications or interventions are tested in this study**.

What are we asking you to do in this study?

Study activities will be very similar to previous years with minor changes. If you want to continue in the SHIVERS-II study, you will be asked to do the following activities:

Consent: In the study continuation message that you receive, there is a link to an online consent form. If you have difficulties with this link, you can go to http://shivers.org.nz/ to find a consent form to print out, sign and return electronically (details are on the consent form). If you want a hard copy consent form, you can call or email us and we will mail it to you with a pre-paid envelope included.

Continuation questionnaire: When you complete the online consent, you will be automatically directed to the online continuation questionnaire, which will take less than 10 minutes to complete. If you have not done this in a few days, we will remind you by email/text or phone including a link to the questionnaire. You will be asked to update those details including contact information, vaccination and health and influenza-like illness status. We might check your GP, your workplace influenza vaccination records and NZ health registries for details necessary for the study.

Regular surveys: Early in the year, we will start sending weekly emails or text messages to ask whether or not you had a flu shot and if you have been sick with cough, fever or other respiratory symptoms. We may send messages twice a week during an active period of the flu activity.

Nose or Throat swab: If you get sick with a flu-like illness, such as cough and fever, study nurses will set up a time to take a nasopharyngeal, nose, or throat swab from you to test for flu and other respiratory viruses. If the swab shows no flu virus then we'll let you know, and there is nothing that needs to be done further. If your swab shows positive for the flu virus, we'll work with you to collect a blood sample.

Blood sample collection schedule: Over the study, we will need to collect a blood sample from you a few times:

- ***Post-vaccine blood***: If you have a flu shot, a blood sample will be collected 3-6 weeks after the vaccination.
- ***Post-flu blood***: If your swab is positive for the flu virus, a pair of blood samples will be collected from you. The first blood will be taken 1-2 weeks after illness onset and another 3-6 weeks later.
- ***Annual blood***: It will be collected outside of the flu season (i.e. post-season) for each participant.
- We will provide information how to have your samples collected by text/email and on our study website (http://shivers.org.nz/).
- At the collection centre, a phlebotomist (a person trained to collect blood) will take about 15 mL or one tablespoonful of blood from you. We may ask for recollection in cases where samples are not sufficient for testing.
- You are welcome to perform a karakia at any sample collection.

Household transmission sub-study: If you are interested in involving you and your household members in this sub-study, here is a brief summary of the activities:

- ***Routine survey and the first visit***: You will be asked one extra question in your regular email or text messages whether any of your household member is sick with a flu-like illness. If so, study nurses will set up a time to visit

your household member who is sick, explain study details, obtain the consent and then take nose/throat swab(s) from your household member with flu-like illness to test for flu and other respiratory germs.

- ***Inviting all household members***: Only when the swab of your household member is positive for the flu virus, all household members are then invited into the study. For those consented household members, nurses will take a pair of blood (one at initial visit and another 4-6 weeks later). Household members will monitor for flu-like symptoms for up to 21 days and nurses will take respiratory samples from your household member(s) who is(are) sick. More details will be provided in a separate participant information sheet for this sub-study.

Thank you voucher: You will receive a $30 gift card after each blood sample to recognize your time and effort.

What are the benefits of taking part in this study for me? SHIVERS-II will find out if you were ill from the flu or another respiratory virus during the winter. In the household flu transmission study, we will find out about how flu spread in your household (if participating). The study will contribute to knowledge about the body's immune responses to the flu and how the virus spreads.

Who is involved in running the SHIVERS-II study?
The Institute of Environmental Science and Research (ESR) is the leading agency for the SHIVERS-II study. It is a member of SHIVERS (Southern Hemisphere Influenza and Vaccine Effectiveness Research and Surveillance) project family. SHIVERS is a long series of research on influenza virus and vaccine and this study is the second in its series (SHIVERS-II).

Here are some other important details of SHIVERS-II:

- SHIVERS-II is being funded by the United States National Institutes of Health (US NIH) through the St. Jude Center of Excellence for Influenza Research and Surveillance (SJCEIRS) in Memphis.
- SHIVERS-II is multi-agency collaboration including your general practice (GP) and others in Wellington, Compass Health, ESR, the Universities of Auckland and Otago, Regional Public Health, the Capital Coast District Health Board, the Malaghan Institute and SJCEIRS.
- The New Zealand Health & Disability Ethics Committee has approved SHIVERS-II (NTX11.11.102.AM49).

What testing is done on my samples? And where?
Blood samples and swabs will be sent to ESR's National Influenza Centre at Wallaceville, Upper Hutt.

- Swabs will be tested for flu and other respiratory viruses at ESR.
- Blood samples will be tested for antibodies, other immune cells, and specific genes that associate with immune responses. Some of these immune tests will be done at Wallaceville and at the Malaghan Institute of Medical Research in Wellington. A small amount of your samples will be sent to SJCEIRS in Memphis for more complex testing that cannot be performed here. None of these tests being done would be important for your healthcare.
- Your samples may be tested to help in the response to public health issues, such as understanding the body's immune response to a new influenza virus.
- Your samples will be stored securely for 10 years after the study ends, and then will be disposed of safely.
- You may hold beliefs about a sacred and shared value of all or any tissue samples removed. The cultural issues associated with sending your samples overseas and/or storing your tissue should be discussed with your family/ whānau as appropriate. There are a range of views held by Māori around these issues; some iwi disagree with storage of samples citing whakapapa and advise their people to consult before participating in research where this occurs. However, it is acknowledged that individuals have the right to choose.

How is my privacy protected? What happens to the information you provide?
Your test results and information are confidential:

- Your GP will receive the results done on your swab which may show if a virus has caused your flu-like symptoms. Swab results will be sent to your GP about two weeks after the swab is taken.
- Your GP will not receive the results done on your blood samples as these results are not for clinical purposes. The blood tests need to use samples across a number of years, and therefore the results may not be available for several years.
- Your samples will be labelled with a unique study number without any identifiable information when sent overseas, so that you cannot be identified.
- We need to use your personal information (name, date of birth and contact details) to get in touch with you and to ensure that your GP can provide you with results from the tests being done in the study. In addition to study researchers having access to this information, only the study funder and their agents, the ethics committees that approved the study, and regulatory agencies could access study records for the sole purpose of checking the accuracy

of the recorded information.

- Study communications will mainly be electronic (email, text messages, and online surveys), and the study cannot guarantee the security of electronic responses to study communications.
- You have the right to ask for your personal study information and to ask for that information to be corrected, if you find an error.
- If you decide to withdraw from the study, we may process the information collected up to the point when you withdraw.
- The SHIVERS-II study staff will request information from NZ health registries, practice medical records to validate or complete missing information on your vaccination and respiratory illness/conditions and non-health related information such as demographics. Additionally, we may check your workplace influenza vaccination records to validate or complete missing influenza vaccination information.
- You can also contact us to get the overall SHIVERS-II results. It may be many years before these results are available.
- Study results will be grouped together on all participants without any of your personal information to be provide to health authorities, publish them in medical journals, and make them available on the SHIVERS-II website (http://shivers.org.nz/). Information collected for the study on participants will be posted on the study funder website (US NIH). **No personal identifiable information will be published.**
- All study records are confidential. They will be stored securely at ESR and will be destroyed 10 years after the study ends.

What if something goes wrong?

There are very few risks associated with this study. Taking swabs and blood samples are common and safe procedures. Nose/nasopharyngeal swabs may cause brief pain, itchy nose, eye watering, or sneezing. Throat swabbing could cause some discomfort, coughing, or gagging. The risk from blood collection is usually minor, such as redness or bruising around the site where the blood is taken. The procedure may also cause infection and some discomfort. We minimize risks by having trained staff take your samples.

If you were injured in this study, which is unlikely, you would be eligible to apply for compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery. If you have private health or life insurance, you may wish to check with your insurer that taking part in this study will not affect your coverage.

Who can I talk to about this study?

- If you any questions about the study, you can contact Dr. Sue Huang at 04 529 0600 or email ShiversProject@esr.cri.nz.
- If you want to talk to someone who isn't involved with the study, you can contact a Health and Disability Advocate. Freephone 0800 555 050.

We thank you for your time and consideration of taking part in this important population health study.