

**Participant Information Sheet/Consent Form**

**Interventional Study** -*Adult providing own consent*

**Box Hill Hospital**

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| **Title** | A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Safety, Tolerability, and Immunogenicity of Respiratory Syncytial Virus Prefusion F Subunit Vaccine When Coadministered With Seasonal Inactivated Influenza Vaccine in Adults ≥65 Years of Age |
| **Project Sponsor** | Pfizer Australia Pty Limited |
| **Principal Investigator** | Prof Christopher Gilfillan |
| **Location**  | Box Hill Hospital – Arnold Street, Box Hill VIC 3128, Australia |

**Part 1 What does my participation involve?**

1. **Introduction**

You are being invited to take part in this research project because you are a healthy man or woman aged 65 years or older. The research project is testing a new vaccine called Respiratory Syncytial Virus vaccine (RSVpreF for short) which may help protect older people against RSV infection.

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

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 and vaccines that are described
* Consent to 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 this research?**

Respiratory Syncytial Virus (RSV) is a common type of virus (germ) that can cause respiratory tract infections ranging from mild cold-like symptoms to severe lower respiratory tract disease, such as pneumonia. Older adults may develop severe RSV infection, and this can trigger other underlying heart or lung conditions. Individuals with severe RSV infection may need to be hospitalised and may need help breathing. For adults, treatment is generally supportive, and there is no specific medicine against RSV infection recommended for adults.

As RSV and influenza (flu) infections mostly occur in the autumn and winter months, it is possible that in the future, RSVpreF and flu vaccine may be given at the same time. Therefore, the purpose of this research is to find out whether RSVpreF can be given at the same time as your annual flu vaccine or whether they should be given on different days.

RSVpreF is an investigational vaccine. This means that it is not an approved vaccine to protect against RSV infection in Australia.

This research is being conducted by Pfizer Inc and sponsored in Australia by Pfizer Australia Pty Limited.

**3 What does participation in this research involve?**

Participation in the study involves 3 visits to the study doctor over a 2-month period. Each visit is about 1 month apart.

If you agree to participate you will be asked to sign the consent form and then the study doctor will check if you meet the study requirements. Once it has been confirmed you meet the study requirements, you will be assigned by chance (like flipping a coin) to 1 of 2 study groups. Both groups receive a total of 3 injections via the intramuscular route (injection into the muscle in your upper arms) across two vaccination visits during the study. At Visit 1, one group will receive the flu vaccine and RSVpreF on the same day followed by the placebo a month later at Visit 2. The other group will receive the flu vaccine and a placebo at Visit 1 followed by RSVpreF a month later at Visit 2. The only difference between the study groups is the visit order in which you will receive RSVpreF or placebo in the left arm.

You have a 50% chance of receiving RSVpreF at Visit 1 and placebo at Visit 2, and a 50% chance of receiving placebo at Visit 1 and RSVpreF at Visit 2. The placebo injection looks like the RSVpreF vaccine but does not contain any active ingredients.

All participants will receive the flu vaccine at Visit 1 in the right arm, and RSVpreF vaccine in the left arm at either Visit 1 or Visit 2, the difference between the two groups is whether these vaccines are given together or 1 month apart.

This diagram shows when and where you will receive your study vaccines.



On the days you receive injection(s), you will be asked to wait at the study site for at least 30 minutes for observation.

You will be participating in a double-blind study. This means that neither you, nor the study doctors, nor the study team will know which group you are in and whether you receive RSVpreF or placebo at Visit 1 or at Visit 2. However, if needed, your study doctor can find out which study vaccine you received at each visit.

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.

In this research study, you will have certain tests, procedures, and assessments. A brief overview of the study procedures done at each visit is shown below. The study doctor may ask you to come in for additional tests, procedures, and assessments, if necessary, to protect your health.

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| --- | --- | --- | --- |
|  | Visit 1Vaccination 1Day 1 | Visit 2Vaccination 2Month 1 | Visit 3Follow-upMonth 2 |
| Review, sign, and date this document |  |  |  |
| You will be asked to provide demographic information, such as your sex, race, ethnicity, and date of birth. |  |  |  |
| You will be asked questions about your past and present health, including any medicines you may be taking, and vaccinations received. |  |  |  |
| Site staff will measure your temperature. |  |  |  |
| Site staff will perform clinical assessment of your health and if needed a physical examination. |  |  |  |
| If needed, the study doctor/nurse will discuss birth control methods (men only). |  |  |  |
| Confirm you are eligible for the study. |  |  |  |
| The study doctor/nurse will take a blood sample to measure your immune response to the vaccine. | 30 mL(about 6 teaspoons) | 30 mL(about 6 teaspoons) | 30 mL(about 6 teaspoons) |
| You will be given training on using the e-diary and reporting post-vaccination reactions. |  |  |  |
| You will be given your vaccine injection(s). You will need to wait in the clinic for 30 minutes following each injection. |  |  |  |
| You will be asked to postpone any non-study vaccinations for 2 to 4 weeks either side of your study vaccinations (except if medically needed).  |  |  |  |
| You will be asked to complete the e-diary questions. | for 7 days | for 7 days | return e-diary |

**Electronic Diary (E-diary) Completion**

* At Visit 1, you will be given an electronic diary (“**e-diary**” for short, a device that looks like a smart mobile phone), or if you wish, you can download the e-diary application (‘app’) to your own smart phone if you have one. The e-diary has questions related to any potential side effects after your vaccination. The study team will provide training on how to use the e-diary.
* At Visit 1, you will be given a **digital thermometer**, and a **measuring device** to take home. You will be shown how to use them.
* At home, every evening for 7 days after each vaccination visit (Visit 1 and Visit 2), you will need to complete the e-diary questions. On the evening of your vaccination and each evening for 6 more days (7 days in total), you will take your temperature under your tongue and use the measuring device to measure any redness or swelling on your **left arm** where you were given the RSVpreF/placebo vaccination, and enter these measurements in the e-diary. You will also need to answer some other yes/no questions in the e-diary about symptoms you may have after the vaccination in your left arm. You do not need to measure any injection site reactions in your right arm where you received the flu vaccine, nor report them in the e-diary. It is very important that you complete the e-diary every evening as instructed. If you do not, your study doctor or nurse will contact you to check how you are doing.
* You will need to keep the e-diary charged up when you are not using it (just like you would with your mobile phone).
* If you have any severe symptoms after your vaccination, any redness or swelling that is 21 or bigger on the measuring device, or a temperature of 39°C or higher, you must contact your study doctor or nurse who will review your symptoms and if needed will arrange an extra visit at the study site. At this extra visit you will have a clinical assessment of your health, the area around your left arm vaccination site will be assessed, your temperature measured, and you will be asked about your symptoms and health.
* You will need to bring the e-diary or your mobile phone with the ‘app’ installed to all study visits.
* You will need to return the e-diary or delete the ‘app’ from your mobile phone at the final Visit 3.

**Blood Samples**

* You must provide blood samples in order to take part in this study. Each sample is 30 mL (6 teaspoons) and these will be taken before vaccination at both Visit 1 and Visit 2 and again at Visit 3. The total volume of blood samples during the study will be about 90 mL (about 18 teaspoons).
* The blood will be collected from a vein in your arm to test your immune response (antibody levels) before your vaccinations and about 1 month after your second vaccination. This will tell the research team how well your body has responded to the RSVpreF vaccine and flu vaccine. The sample may also be used to develop and/or evaluate the test procedures used to measure the response to the vaccines, as well as for other exploratory purposes.

**Costs and Reimbursement**

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

You may be reimbursed for any reasonable travel, parking, meals, and other expenses associated with the research project visit.

**Local Doctor Notification**

If you decide to participate in this research project, the study doctor will inform your local doctor.

**4 What do I have to do?**

If you agree to participate it is important that you tell the study team:

* If you have ever taken part in any other RSV study or received a RSV vaccination or have been in any other study in the past 28 days or are currently involved in any other study.
* About your health, past and present including medical conditions and procedures, surgeries, and allergies.
* About changes in your health, if you have to visit a healthcare provider, any doctor or nurse appointments, or any hospital admissions or emergency department visits.
* About your current and recent medication use, any new medications, and any change in existing medication use.
* About vaccinations you have had recently, including your most recent flu vaccination; if you have any new vaccinations or plan to receive any other vaccinations.
* If you do not understand anything about the study.
* If you are not able to comply with the study requirements.
* If you cannot attend an appointment, and you are likely to be going away for a long period during the study.
* If your e-diary device or ‘app’ is not working properly.
* If you wish to take part in another research study.
* Tell other doctors, nurses, and healthcare providers about your participation in this study by showing the information card provided to you by the study team.

**Use of Birth Control (for male participants only)**

The effects of the investigational RSVpreF vaccine used in this study on sperm, a pregnancy, a foetus, or a nursing child are not known.

**If you are female** and of childbearing potential, you cannot be in this study. All women in this study are expected to be postmenopausal, therefore are not required to use birth control.

**If you are male** and able to father children and you are sexually active with a woman of child-bearing potential, you must use birth control consistently and correctly for at least 28 days after you receive your last study vaccination. The study doctor will discuss with you the methods of birth control that you should use while you are in this research study and will help you select the method(s) that is appropriate for you. The study doctor will also check that you understand how to use the birth control method and may review this with you at the first two research study visits.

Birth control methods, even when used properly, are not perfect. If your partner becomes pregnant during the study, or you want to stop your required birth control during the study, you should tell the study doctor immediately. You will not be allowed to donate sperm for at least 28 days after your last study vaccination.

Please also tell the doctor who will be taking care of your partner during the pregnancy that you took part in a study.

The study doctor will ask if your partner or your partner’s pregnancy doctor is willing to provide updates on the progress of the pregnancy and its outcome. If you/your partner agrees, this information will be provided to Pfizer for safety follow-up. Your partner will be provided with a separate pregnancy data release form for signing if your partner agrees to this.

**5 Other relevant information about the research project**

About 2230 healthy adults aged 65 years and older will take part in this study. The study is taking place at about 30 research sites across Australia. It is expected that about 100 people will take part at this site.

**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 routine treatment, your relationship with those treating you or your relationship with Eastern Health.

**7 What are the alternatives to participation?**

There is currently no RSV vaccine available in Australia. This study is for research purposes only. If you choose not to take part in the study, you may still receive your annual flu vaccine from your regular healthcare provider or pharmacist. Your study doctor will discuss these options with you before you decide whether or not to take part in this research project. You can also discuss the options with your local doctor.

**8 What are the possible benefits of taking part?**

We cannot guarantee or promise that you will receive any benefits from this research; however, possible benefits may include more frequent contact with healthcare providers. Also, information learned from the study may help other people in the future.

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

Medical treatments or vaccines often cause side effects. You may have none, some or all of the effects listed below, and they may be mild, moderate or severe. If you have any of these side effects, or are worried about them, talk with your study doctor. Your study doctor will also be looking out for side effects.

There may be side effects that the researchers do not expect or do not know about and that may be serious. Tell your study doctor immediately about any new or unusual symptoms that you get.

Many side effects go away shortly after vaccinations are given. However, sometimes side effects can be serious, long lasting or permanent. If a severe side effect or reaction occurs, your study doctor may need to stop your vaccinations. Your study doctor will discuss the best way of managing any side effects with you.

**RSVpreF study vaccine**

Pfizer’s investigational RSV vaccine is being assessed in clinical studies that have included more than 11000 healthy adults 18 years of age and older who have received the vaccine.

The known side effects of this RSV vaccine are similar to those commonly observed with other vaccines.

The frequencies of events are still being estimated because many studies of RSVpreF are still ongoing. Based on data from a large completed study in adults 18 years and older, the following local reactions and systemic events were reported by RSVpreF recipients.

**Very common (occurring in more than 1 in 10 people):** injection site pain or tenderness, headache, fatigue (tiredness), diarrhoea, joint aches, and muscle aches or pain.

**Common (between 1 in 10 and 1 in 100 people):** injection site swelling, injection site redness, feeling sick (nausea), being sick (vomiting), and increased body temperature (fever).

The events were mostly mild or moderate, and generally of short duration (1 to 3 days).

There may be other risks that currently are unknown because the study vaccine is investigational.

As with any vaccine given by injection, **very rarely** people may have an allergic reaction **(frequency cannot be estimated based on available data)**. The allergic reaction could be minor (rashes) or more severe including:

* + - * Swelling of the face or lips (oedema)
			* Wheezing (bronchospasm)
			* Difficulty in breathing (dyspnoea)

If you have symptoms of an allergic reaction, you should seek medical attention immediately. A severe allergic reaction (anaphylactic shock) may occur and could be life-threatening.

It is important that you report all symptoms and side effects that you experience as soon as they occur, whether or not you think they are caused by the study vaccine.

**Flu Vaccine**

Your study doctor will tell you which flu vaccine you will be given, and the possible side effects associated with this flu vaccine. The most common side effects with flu vaccine in adults 65 years of age and over include injection site pain, fatigue/tiredness, headache, and muscle aches. These are not all of the possible side effects of flu vaccine. You can ask your study doctor about other side effects that may occur.

**If you are allergic to eggs, egg products or chicken proteins, have had an allergic reaction to a previous dose of flu vaccine, have ever had Guillain-Barre syndrome (severe muscle weakness) or have problems with your immune system, you must not take part in this study.**

**Placebo Injection**

Everyone taking part in this study will receive placebo either at Visit 1 or at Visit 2. You may experience injection site reaction(s), including pain, swelling, and/or redness or bruising.

**Blood Draw**

Having blood taken may cause faintness, inflammation of the vein, pain, bruising, or bleeding at the site of puncture. There is also a slight chance of infection. If this happens, it can be easily treated.

**10** **What will happen to my test samples?**

Your blood samples will be processed and frozen at the study site before being shipped to Pfizer’s Vaccine Research Laboratory (Pearl River, New York, USA) for analysis. Additional samples may be collected if a replacement sample is needed.

Your blood samples will be used only for scientific research. Each sample will be labelled with a barcode so that the laboratory scientists testing the samples will not know who the sample has come from. Some of the samples may be stored for future testing and may be kept for up to 15 years after the study ends, at which time they will be destroyed. In addition to testing for this study, any leftover samples after the study is complete may be used for additional research related to the development of products. No testing of your DNA will be performed.

You will be asked to provide consent for the storage and use of any remaining blood samples (for example, after all study-related testing has been undertaken) for future unspecified research.

The samples will remain the property of Pfizer and may be shared with other researchers as long as confidentiality is maintained, and no testing of your DNA will be performed. You will not be told of additional tests, nor will you receive results of any of these tests. You may request that your samples, if they can be identified, be destroyed at any time. Any data already collected from those samples will still be used for the study. However, we cannot guarantee the destruction of samples because, for example, the samples may no longer be traceable to you or the samples may have been used up.

**11 What if new information arises during this research project?**

Sometimes during the course of a research project, new information becomes available about the vaccine that is being studied. If this happens, your study doctor will tell you about it and discuss with you whether you want to continue in the research project. If you decide to withdraw, your study doctor will make arrangements for you to end your participation in the safest way. If you decide to continue in the research project, you will be asked to sign an updated consent form.

Also, on receiving new information, your study doctor might consider it to be in your best interests to withdraw you from the research project. If this happens, he/she will explain the reasons.

**12 Can I have other treatments during this research project?**

If you agree to participate in the study, you should not receive:

* any non-study RSV vaccines (approved or investigational) at any time prior to the study, or during the study.
* any other investigational vaccines or medications within 28 days prior to the study, or during the study.
* any medications that affect your immune response (such as oral corticosteroids), blood or plasma transfusions, immunoglobulin, or fever or other pain medications taken prior to study vaccinations to prevent symptoms related to vaccinations, unless advised by your doctor.

Whilst you are participating in this research study, you may not be able to take some or all of the medications, treatments or vaccines you have been taking. It is important to tell your study doctor and the study staff about any treatments, medications or vaccines you may be taking, including over-the-counter medications, vitamins or herbal remedies, acupuncture or other alternative treatments. You should also tell your study doctor about any changes to these during your participation in the research study. Your study doctor should also explain to you if any of your treatments, medications or vaccines need to be stopped for the time you are involved in the research study.

**13 What if I withdraw from this research project?**

You may withdraw from the study at any time at your own request, or you may be withdrawn at any time at the discretion of the investigator for safety, behavioural, compliance, or administrative reasons. If you decide to leave the study, you will be asked by the study team why you would like to withdraw.

If you decide to withdraw from the project, please notify a member of the research team before you withdraw. This notice will allow that person or the research supervisor to discuss any health risks or special requirements linked to withdrawing.

If you do withdraw your consent during the research project, the study doctor and relevant study staff will not collect additional personal information from you (unless you have told the study team that you agree to provide new information or samples), 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. You should be aware that data collected by the Sponsor up to the time you withdraw will form part of the research project results. If you do not want them to do this, you must tell them before you join the research project.

If you stop taking part in the research project and you do not tell the study team, your contact information may be used by the study team to contact you, your family or your personal doctor.

If you have questions regarding or wish to withdraw your consent to the processing of your personal information, please contact the study staff.

**14 Could this research project be stopped unexpectedly?**

The study doctor may also decide to take you off the study vaccine and/or remove you from the study (even if you do not agree) in the following situations:

* You are unable or unwilling to follow the instructions of the study;
* The study doctor decides that the study is not in your best interest or that you are no longer eligible to be in the study; or
* The study is stopped by the study Sponsor, Human Research Ethics Committee (HREC) (a group of people who review the study to protect your rights), or by a government or regulatory agency.

**15 What happens when the research project ends?**

A description of this clinical trial will be available on http://www.ClinicalTrials.gov. The study results, when available, may also be found onwww.pfizer.com and https://www.clinicaltrialsregister.eu/.

These websites will not include information that can identify you. At most, the websites will include a summary of all results. You can search these websites at any time.

The website(s) mentioned in this section are in English only. If you need assistance to understand the content in a different language, please ask a member of the study team.

The Sponsor will provide the study doctor with information about the study results when all participants have completed the study. At that time, some of your individual study results will be given to you or your doctor (if different from the study doctor) in accordance with applicable law, but will not be given to your family, your employer, or any insurance company.

Because this is an investigational vaccine study, RSVpreF will be given to you only during this study and not after the study is over.

**Part 2 How is the research project being conducted?**

**16 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.

In order to conduct the study and comply with legal and regulatory requirements, your study team will collect information about you. Information about you may include personal information that directly identifies you, demographics, and sensitive information such as your medical history and data from this study (including diagnoses, treatment, date of birth, race, and ethnicity). If required by this study, the study team may also collect biological samples from you.

Your name will be removed from your information and/or your biological samples before it is sent outside the study site and replaced with a unique code. This information is referred to as “Coded Information.” The study site will keep the link between the code and your name confidential. The Sponsor’s employees and those with whom the Coded Information is shared are required to protect the Coded Information and will not attempt to re-identify you. Data generated using biological samples will be handled in the same way as the Coded Information, unless otherwise stated in this consent document.

The Sponsor may use your Coded Information and biological samples to support future research. At this time, we do not know the specific details of these research projects; however, the Coded Information and biological samples, if collected as part of the study, could be used in combination with data from other sources, not related to this study. Reasonable safeguards will be taken to protect the Coded Information and biological samples used in any future research and may include: (a) limiting access to individuals bound by duties of confidentiality; (b) taking steps to minimise the risk of re-identification; and (c) obtaining approval of ethical review boards. Furthermore, if your Coded Information and biological samples that are collected as part of the research project are anonymised such that they can no longer be linked to you, they may be used for future research purposes.

Information may be collected from electronic devices if the participant uses a mobile application or other digital tool during the study. The participant should review this consent document as well as the terms and conditions and privacy policy of any digital tool or mobile application used in the study to understand further how information collected through those digital tools and applications may be used.

Under certain circumstances, information that identifies the participant by name may leave the study site in connection with the study and be sent to a vendor contracted by the Sponsor, in order to support the use of digital tools (for example, electronic diary, electronic consent, mobile applications) in the study. The people and/or organisations contracted by the Sponsor to provide these services must keep your personal information private, and they will not share with the Sponsor any information that can directly identify you.

The site will retain your information for the period necessary to fulfil the purposes outlined in this consent document and/or for the maximum period permitted by applicable law, which could be at least 15 years after the end of the study. The Sponsor will retain your Coded Information for the period necessary to fulfil the purposes outlined in this consent document, indefinitely or for the maximum period permitted by applicable law after the end of the study.

Some of the people and/or organisations using your information may be based in countries other than Australia. Data privacy laws may be different or less protective in these countries than in Australia; however, the Sponsor will remain responsible for information about you that is transferred and used.

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.

Information about you may be obtained from your health records held at this and other health services for the purpose of this research. By signing the consent form, you agree to the study team accessing health records if they are relevant to participation in this research project.

Your health records and any information obtained during the research project are subject to inspection (for the purpose of verifying the procedures and the data) by the relevant authorities and authorised representatives of the Sponsor, Pfizer Incand Pfizer Australia Pty Ltd, the institution relevant to this Participant Information Sheet, Eastern Health, or as required by law. Your information may also be accessed and used by: people and/or organisations providing services to or collaborating with the Sponsor. By signing the Consent Form, you authorise release of, or access to, this confidential information to the relevant study personnel and regulatory authorities as noted above.

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 permission.

Information about participation in this research project may be recorded in your health records.

Any information obtained for the purpose of this research project and for the future research described 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.

In accordance with relevant Australian and/orVictorian 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.

**17 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.

There are two avenues that may be available to you for seeking compensation if you suffer an injury as a result of your participation in this research project:

* The pharmaceutical industry has set up a compensation process, with which the Sponsor of this research project, Pfizer Australia Pty Limited, has agreed to comply. Details of the process and conditions are set out in the *Medicines Australia Guidelines for Compensation for Injury Resulting from Participation in a Company-Sponsored Clinical Trial*. In accordance with these Guidelines, the sponsor will determine whether to pay compensation to you, and, if so, how much. A copy of the Guidelines is available to you from the research staff on request. If you have any questions about the Guidelines, please contact the Manager of Eastern Health Office of Research & Ethics on (03) 9895 3398.
* You may be able to seek compensation through the courts.

**18 Who is organising and funding the research?**

This research project is being conducted by and funded by Pfizer Incand sponsored in Australia by Pfizer Australia Pty Limited.

Pfizer may benefit financially from this research study if, for example, the study assists Pfizer to obtain approval for a new drug/device.

By taking part in this research study, you agree that samples of your blood (or data generated from analysis of these materials) may be provided to Pfizer. Pfizer may directly or indirectly benefit financially from your samples or from knowledge acquired through analysis of your samples.

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 Pfizer.

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

Eastern Healthwill receive a payment from Pfizer Australia Pty Limited 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).

**19 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 Monash Health Human Research Ethics Committee (NHMRC 2018).

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.

**20 Further information and who to contact**

The study team will work with you to answer any questions that you may have about the study.

You will be given a card with important emergency contact information, including a 24-hour phone number. Show this card to any healthcare provider if you seek emergency care during this study. This card includes information about the study that will help the healthcare provider treating you.

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

If you want any further information concerning this study or if you have any medical problems which may be related to your involvement in the study (for example, any side effects), you can contact the principal study doctor on (03) 9092 6753or any of the following people:

**Clinical contact person**

|  |  |
| --- | --- |
| Name | Vanessa James |
| Position | Study Coordinator |
| Telephone | (03) 9194 7573 |
| Email | vanessa.james@monash.edu |

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 | Eastern Health Office of Research and Ethics |
| Position | Manager |
| Telephone | (03) 9895 3398 |
| Email | ethics@easternhealth.org.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 | Monash Health Human Research Ethics Committee |
| HREC Executive Officer | Ms Deborah Dell, Interim Director, Research Operations |
| Telephone | 03 9594 4611 |
| Email | research@monashhealth.org |



**Consent Form -** *Adult providing own consent*

**Box Hill Hospital**

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| --- | --- |
| **Title** | A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Safety, Tolerability, and Immunogenicity of Respiratory Syncytial Virus Prefusion F Subunit Vaccine When Coadministered With Seasonal Inactivated Influenza Vaccine in Adults ≥65 Years of Age |
| **Project Sponsor** | Pfizer Australia Pty Limited |
| **Principal Investigator** | Prof Christopher Gilfillan |
| **Location**  | Box Hill Hospital – Arnold Street, Box Hill VIC 3128, Australia |

**Declaration by Participant**

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 give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to Eastern Healthconcerning my health and treatment for the purposes of this project. I understand that such information will remain confidential.

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 healthcare.

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

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|  | Name of Participant (please print) |  |  |  |  |
|  |
|  | Signature |  |  Date |  |  |
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Under certain circumstances (see Note for Guidance on Good Clinical Practice CPMP/ICH/135/95 at 4.8.9) a witness\* to informed consent is required.

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|  | Name of Witness\* to Informed Consent Process (please print) |  |  |
|  |
|  | Signature |  |  Date |  |  |
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\* 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.

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|  | Name of Study Doctor/Senior Researcher† (please print) |  |  |
|  |  |
|  | Signature |  |  Date |  |  |
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† 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.



**Optional Future Research –** *Adult providing own consent*

**Box Hill Hospital**

|  |  |
| --- | --- |
| **Title** | A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Safety, Tolerability, and Immunogenicity of Respiratory Syncytial Virus Prefusion F Subunit Vaccine When Coadministered With Seasonal Inactivated Influenza Vaccine in Adults ≥65 Years of Age |
| **Protocol Number** | C3671006 |
| **Project Sponsor** | Pfizer Australia Pty Limited |
| **Principal Investigator** | Prof Christopher Gilfillan |
| **Location**  | Box Hill Hospital – Arnold Street, Box Hill VIC 3128, Australia |

I consent to the storage and use of any remaining blood samples (for example, after all study related testing has been undertaken) to be used 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.

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|  | Name of Participant (please print) |  |  |
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|  | Signature |  |  Date |  |  |
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|  | Name of Witness\* to Informed Consent Process (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.

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|  |
|  | 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*

**Box Hill Hospital**

|  |  |
| --- | --- |
| **Title** | A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Safety, Tolerability, and Immunogenicity of Respiratory Syncytial Virus Prefusion F Subunit Vaccine When Coadministered With Seasonal Inactivated Influenza Vaccine in Adults ≥65 Years of Age |
| **Protocol Number** | C3671006 |
| **Project Sponsor** | Pfizer Australia Pty Limited |
| **Principal Investigator** | Prof Christopher Gilfillan |
| **Location**  | Box Hill Hospital – Arnold Street, Box Hill VIC 3128, Australia |

**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 Eastern Health.

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|  | Name of Participant (please print) |  |  |  |  |
|  |
|  | Signature |  |  Date |  |  |
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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.

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**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.

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|  | 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.