Participant Information Sheet

The purpose of this pilot study is to test the processes for a new trial that will be running during winter 2017-18 looking at a combination of a new vaccine against flu together with the current seasonal flu vaccine in adults aged 65 years and over.

RIVET
Re-inventing Influenza Vaccine Efficacy Trials

There are two parts of the immune system that can protect us against flu infections.
The standard vaccine only stimulates one part of the immune system to produce antibodies.
Next year we will start testing a new flu vaccine that stimulates both parts of the immune system (T cells as well as antibodies) to see if this means that people get a flu-like illness less often. We will test this in a trial called INVICTUS.

This year we are running RIVET, a pilot study of the follow up processes for the INVICTUS Trial
To be eligible you must usually receive the usual seasonal flu vaccine but not have had it yet
To ensure we test our process fully we will be in regular contact with people taking part for the whole of the winter period and we will ask you to share your experience with us in the end.

We will be asking volunteers to help develop the processes for the main trial by:

Letting us know you are interested in taking part by calling or returning a reply slip to the research team

We will then book you an appointment at your home with a study team member at a time that works for you

Your first appointment should take no longer than 45 min and we will:

- Answer any questions you may have about taking part
- Sign a consent form with you to say you are happy taking part and you understand what is involved
- Take your pulse and temperature
- Ask you some questions about yourself and your medical history
- Provide you with a thermometer and tape measure
- Ask you to let us know when you receive your flu jab

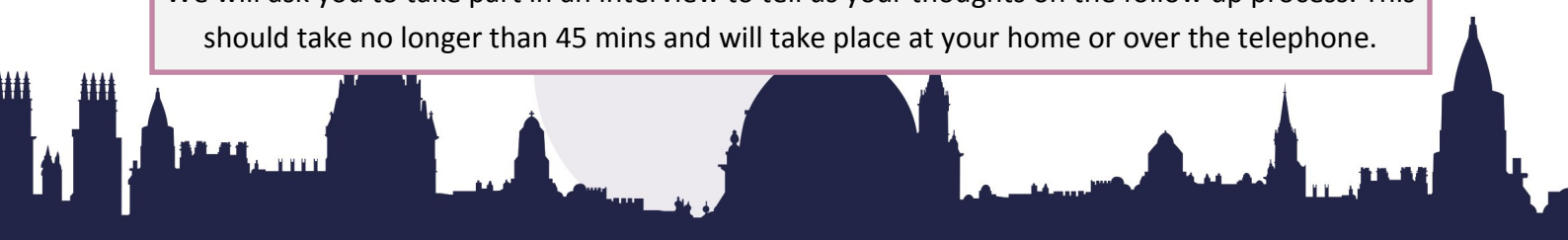
Once you have received your routine flu jab from your GP practice you will complete a diary for 1 week following your routine flu vaccination appointment telling us about any flu-like symptoms

We will contact you at regular intervals throughout the winter season (Aprox. Oct - Apr) via your preferred contact method

If you have any flu-like symptoms at any point throughout the winter season you will need to let us know and complete a diary card telling us how you feel until you feel completely better

We will ask you to take part in an interview to tell us your thoughts on the follow up process. This should take no longer than 45 mins and will take place at your home or over the telephone.

RIVET Phase 2 PIS V1.1 21/09/2016 REC Ref: 16/SS/0160



Here are a few more details for you about the RIVET Study

Will I be paid for taking part in this study?

You will be reimbursed for your participation with a gift voucher worth a total of £100 on completion of all the follow up processes and the qualitative interview that takes place at the end of the study. This is to cover any costs incurred due to your participation and most importantly to thank you for taking part in this study.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the research team who will do their best to answer your questions. You can contact us here: Sarah Tearne (Sarah.tearne@phc.ox.ac.uk)

If you suffer a reaction after your flu jab from your GP practice, please contact your GP practice directly.

Can I take part?

Participation is entirely voluntary. If you wish to take part you need to be eligible for the usual seasonal flu vaccine but not have had it yet and aged 65 years or over.

Will my taking part in this study be kept confidential?

All information collected about you during the research will be kept strictly confidential in accordance with the Data Protection Act. Only the research team will have access to the data. Responsible members of the University of Oxford may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations. All identifiable information will be removed from the transcription of your interview and will be stored securely on a server at the University of Oxford.

What will happen if I don't want to continue with the study?

You can withdraw from the study at any time. You do not need to provide us with an explanation for withdrawing. If you withdraw none of your medical or legal rights will be affected now or in the future. As long as you agree the information already collected may still be used. If you withdraw after the audio from the interview has been transcribed, any data collected as part of the interview will be kept on a secure server and hard copies filed in a secure room accessed only by authorised personnel only at the Department of Primary Care Health Sciences of the University of Oxford.

What are the risks and benefits of taking part?

There are no risks to taking part in this study. There are no added benefits from taking part in this study either. You will be helping the researchers ensure that their trial processes for INVICTUS are efficient and appropriate.

Who is organising and funding the research?

This study is being funded by Vaccitech.

Who has reviewed the study?

All research is reviewed by an independent group of people called a Research Ethics Committee, who protect your safety, rights, wellbeing and dignity. This trial has been ethically reviewed by South East Scotland Research Ethics Committee reference number: 16/SS/0160.