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 recruitment processes for the INVICTUS Trial

To ensure we test our process fully we will ask you to follow the INVICTUS recruitment process as closely as possible and will ask you to share your experience with us in the end in a focus group.

During this pilot study, participants will not receive a flu vaccine

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

Letting us know you are interested in taking part by calling the research team

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We will then book you an appointment with the trial team at a local surgery

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Prior to your appointment (at least 24 hours), you will receive an appointment confirmation letter and the Participant Information Sheet for the RIVET study via the post.
We will also send you the Participant Information Sheet for the main INVICTUS trial.

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At your appointment 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
- Go through a mock version of the INVICTUS recruitment procedures and so ask you some questions about yourself and your medical history
- Take your temperature, pulse, blood pressure, height and weight

This appointment should take no longer than one hour

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We will ask you to take part in a focus group on the same day to tell us your thoughts on the follow up process. This should take no longer than two hours.

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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 £75 at the end of the day, once the mock recruitment visit and focus group have concluded. This is to cover any costs incurred due to your participation in the study 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@phc.ox.ac.uk

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 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 focus group has been transcribed, any data collected as part of the focus group discussion will be kept.

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 the trial procedures 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 reference number: 16/SS/0160.