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ECLIPSE

Exploring **C**o-infection with **L**ive Attenuated **I**nfluenza Vaccine and **P**neumococcu**S** in healthy old**E**r adults

Participant Information Sheet – Group B

We are inviting adults, aged 18 to 49 and 60 to 80, to take part in a study which will look at how the nasal influenza vaccine affects the immune system. This will help us to have a better understanding of the immune response in the nose for developing tests, treatments and vaccines going forward.

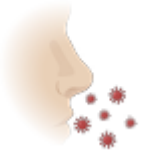
You have been invited to take part in this study because you have responded to advertisement or previously agreed to be approached for future research.

Before you decide that you would like to take part in this study, it is important for you to understand what the study is about and what participation would involve. Please take the time to read the information carefully and discuss it with others if you wish. Thank you for taking the time to consider volunteering for this study. If you have any questions, please contact the study team.

Contact the local study team at: Centre for Clinical Vaccinology and Tropical Medicine
Churchill Hospital, Headington, Oxford, OX3 7LE

Tel: 01865611400 Email: info@ovg.ox.ac.uk

Study Overview



Condition Studied:
Upper Respiratory Tract Infection

Vaccine:
Nasal Flu Vaccine

Study length:
31 days

Number of visits:
5 +/- 1

Can I take part?

YOU MUST:
- Be aged 18-49 or 60-80
- Be in good health
- Live near or around study site

YOU MUST NOT:
- Be under Consultant/Hospital care
- Have had your flu/pneumococcal vaccines this year
- Have a problem with your immune system
- Be a current smoker

Contents

Summary

What is this study?

In the study, we hope to understand the way the body reacts to a combination of the flu (influenza) virus and *Streptococcus pneumoniae* (Spn, pneumococcus) bacteria. We will look at combining the two germs to see if it will help us understand respiratory infections, and the immune system cells in the nose. Pneumococcal bacteria can cause chest infections such as pneumonia, more often in young children and older adults. The information gained by doing the study could help us develop new treatments and vaccines for the influenza virus and pneumonia.

This combined model has been well tested in younger adults, and we want to compare these results with a group of older adults aged 60-80 years (Group A). The primary goal of this study is to understand if this would be safe and easy to study in this age group.

As safety is extremely important in this study, we would be using a nasal vaccine for the flu called the Live Attenuated Influenza Virus (LAIV) that it is indicated for vaccination of children and adolescents in the UK. LAIV mimics the way the immune system responds to the virus without causing flu illness. We have chosen 'pneumococcal serotype 6B' for the pneumonia germ, as it has been shown to be safe and well tolerated in older adults. Pneumococcal serotype 6B mostly affects the upper airways and can be easily treated with antibiotics to take in the event of a chest infection. There would be a study doctor available to call to discuss any concerns related to the study throughout your journey in the trial.

The study is split into Group A and Group B. This leaflet discusses Group B; you should have also received a separate leaflet about Group A if eligible (aged 60-80 years old).

Who are we?

The Oxford Vaccine Group are researchers at the University of Oxford. We have been studying lung infections using healthy volunteers for over ten years to provide world-leading research into the pneumococcus using methods called an Experimental Human Pneumococcal Challenge (EHPC) model. More than 2000 participants have already been safely studied using our methods.

What is the purpose of this study?

By using a live attenuated (virus that do not cause illness) influenza vaccine, we hope to copy the immune response to the influenza virus in the nose. Both pneumococcus and influenza virus are common germs worldwide. They cause infections with symptoms that range from mild colds and ear infections to serious pneumonia and sepsis. When someone is exposed to both, which is very common in winter, it might affect how likely they are to develop infection or how serious their symptoms will be. It is important to understand this relationship better so that future studies on treatments or vaccines can be carried out.

Pneumococcus has already been safely used in studies where people had a small amount of bacteria put in their nose (challenged), stay in their own homes and attend the study site for regular visits (outpatient

challenge studies). There is no need to self-isolate following any study visits. It has been combined safely with the influenza vaccine and extensively studied in a healthy population.

Who can take part in the study?

For this group (Group B) we are looking for up to 20 healthy volunteers (up to 10 younger and 10 older adults). We will check that you are in good health to take part by asking questions about your medical conditions.

You are potentially eligible if:

- You are 18-49 OR 60-80 years old
- You are able to consent for yourself
- You speak English fluently
- (if applicable) For participants who could potentially become pregnant: Use contraception for the duration of the study and have a negative pregnancy test at the screening visit and LAIV vaccination visit.

You are not eligible if any of the following apply to you:

- You are already taking part in another clinical trial
- You have medical conditions that severely affect your health, and you need follow up in hospital
- You have had the flu vaccine/pneumococcal vaccine already this year (you may be eligible next winter if we are still recruiting)
- You are a current smoker (including vaping), or recently gave up smoking (in the last six months)
- You take recreational drugs
- You are on any medication that might impact the study results, such as: medicines that suppress the immune system, or long-term antibiotics
- You are allergic to penicillin or amoxicillin
- You work in healthcare or have a direct caring role to people at high-risk of infection: i.e., under five or extremely clinically vulnerable.

Do I have to take part?

No. Taking part in this study is entirely voluntary. If you decide to participate, you can withdraw from the study at any time. This will not affect your healthcare.

What happens if I choose to take part?

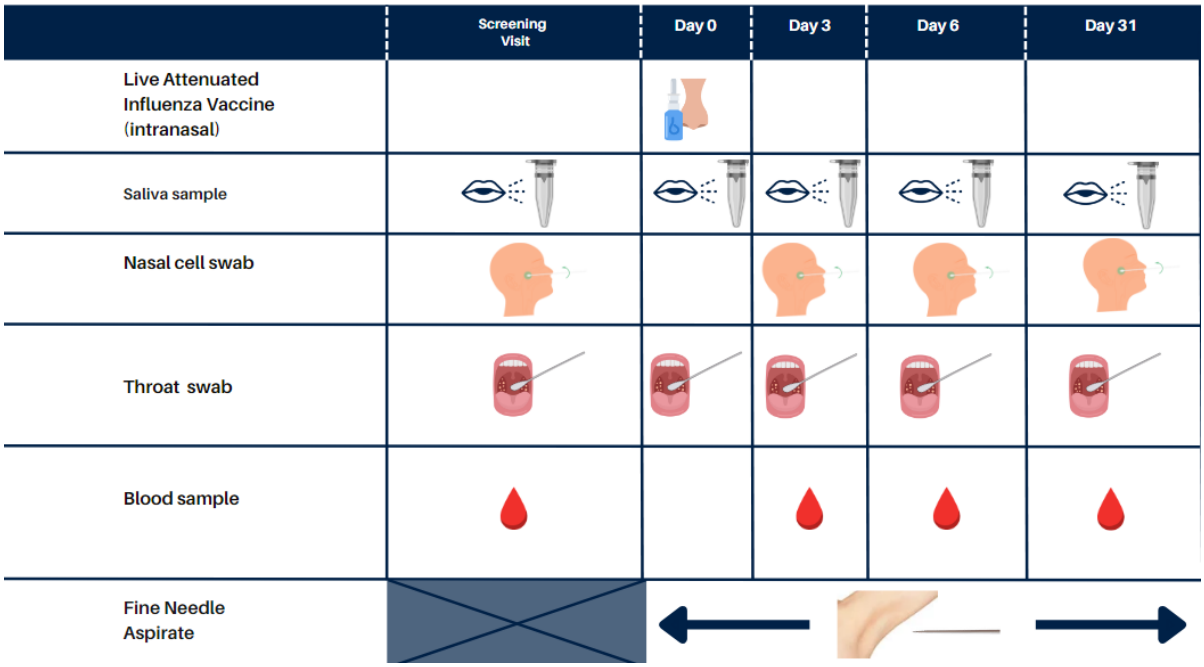
If you choose to take part in the study, we will ask you to meet the research team in-person. At this visit, we will check if you are suitable, and you will be given the opportunity to ask questions. If you are happy to proceed, we will ask for your written signed consent.

Following this, you will have a clinical examination and tests. The study involves further four in-person visits depending if you have the baseline samples done separately to the screening visit (plus one optional fine

needle aspirate visit). These are spaced out over approximately five weeks with most of the visits happening in the first three weeks. During the study, everyone will receive the nasal flu vaccine on day 0.

Timeline of study visits and procedures

GROUP B LAIV Only



**The baseline samples may be done at a later timepoint than the screening visit, this is to make sure the baseline samples are done no more that 7 days before the LAIV is given.*

What happens at each visit?

Screening visit

A member of the research team will discuss the study with you individually or in a group session. You will have the opportunity to ask questions and discuss the study directly with a researcher in private following the presentation. We will ask you questions to assess whether you are eligible to take part in the study. **This will take about an hour and a half.**

We will ask routine questions about your medical health, your vaccination history and medications you are taking. We will take your blood pressure, heart rate and temperature, and we will carry out a brief

examination. There are tests done to make sure you are fit and well this includes: blood tests, an ECG (for the older adult group), a urine sample (where relevant), and a COVID 19 test.

There are other tests done for research purposes including: nasal cells, nasal wash, throat swabs, saliva, and a blood test. These baseline samples may be done on a date separate to the screening visits due to them needing to be obtained no more than a week ahead of the inoculation.

If we need further information about your medical history to confirm your eligibility, we may access your electronic patient record or request your GP to complete a screening eligibility letter or provide your medical summary before screening visit.

During your screening, you will be asked to provide your national insurance number, or passport number, if you do not have a national insurance number. This will be entered on to a national database, called The Over-volunteering Prevention Service (TOPS). This database helps keep participants safe by stopping any volunteers taking part in too many clinical trials. If you do not want your information added to TOPS, you would not be able to take part in our study. If you withdraw from the study before you receive a vaccine, the database will show that you never received a dose. Only the study staff and other medicines research units can use the database. We may call other units, or they may call us, to check your details.

Data entered by us into TOPS is based on whether you receive a vaccine or not. If you receive a vaccine, this data will be retained in TOPS. If we need to contact you about the study after it has ended but we are unable to, because you've moved or lost contact with your GP, the TOPS database may be able to help us.

Further information can be found at:

https://www.hra.nhs.uk/about-us/committees-and-services/the-over-volunteering-prevention-system/

If, for any reason, the study team find you could not take part in the study this will be discussed with you.

Once the study team have confirmed your suitability for the study, we will contact you to arrange a date for your vaccination day. Your participation in this study is at the researchers' discretion.

Day 0: LAIV (flu) vaccine visit

We will check you are happy to continue and that you are feeling well before we give you the vaccine.

You will be asked to sit slightly reclined for 15 minutes and then the LAIV will be introduced to both nostrils by dripping in a small liquid sample with a dropper. You will be asked not to swallow so the fluid stays in the nose for as long as possible. The overall visit takes around one hour.

You will go home with a study pack including:

- A thermometer to check your temperature at home
- A study contact card
- Nose/saliva sampling swabs, instructions and storage bags

At home you will keep a symptom diary for 21 days (Day 0 to Day 20). You should inform the study team about any moderate/severe symptoms as soon as possible. Details on clinical symptom definitions will be given to you to help with filling out the diary. On home sampling days you will record your sample on electronic record (or a paper diary) and contact the team via phone or text.

Whilst at home, you will take some samples from your own nose and saliva (we will train you on how to do this and send you a video to refer to) and store them in the freezer. You may be asked to take photos of the sample label every time you collect a home sample. We will ask you to bring these samples and the photos to the clinic at your next follow-up appointment.

Follow-up visits

You will return to the clinic for further checks on your vital signs, to review any symptoms you might develop and more nose, throat and blood tests at several timepoints after flu vaccination as shown in the table above. In total you will have five visits (or six visits with an optional Fine Needle Aspirate visit – see below)

We will collect your symptom diary (described above) at the last follow up visit.

Fine Needle Aspiration visit (Optional)

A subgroup of 10 participants across group A and B of the study will be offered a procedure, called a fine needle aspirate (FNA), to take cells and fluid from a gland (lymph node). **This is an optional part of the study**, and you do not need to have this to take part. More details about the procedure are below. This can be done as a separate visit or combined with another visit after anytime between day 0 and day 31.

What other medical matters are relevant to the study?

Post study vaccination: If you are eligible for a seasonal influenza and COVID-19 vaccine you should have these after the study. Depending on vaccine availability we may be able to offer you the seasonal COVID-19 and influenza vaccines. This would occur at the end of the final study visit (Day 31). The seasonal vaccines will be given as per national guidance. The intention is that your participation in this study does not compromise your access to annual vaccinations.

Private Insurance: If you have private medical insurance or travel insurance, participation in a study will often not affect your cover for any conditions unrelated to the study; however, to be certain, you must tell your insurer you are planning to participate.

Contraception: The study vaccine is not recommended during pregnancy. It is therefore a requirement of participation that volunteers who could become pregnant must use contraception during the study. Unless you are post-menopausal or have had a permanent sterilisation procedure, you will be required to use one of the contraception methods listed below and to have a pregnancy test at screening and before vaccination.

Female participants where any of the following apply will not be required to use contraception:

1. Post-menopausal
2. Surgical sterilisation (bilateral tubal occlusion, total abdominal hysterectomy etc)
3. Complete abstinence from sexual intercourse which could result in pregnancy (please note this must be in line with participants' normal lifestyles, and declarations of abstinence during the study will not be sufficient)
4. Sole sexual partner is a vasectomised male
5. Exclusive sex with a female partner(s).

Acceptable contraception methods include:

1. Oral, injected or implanted hormonal contraceptives that prevent ovulation
2. Intrauterine device (IUD)
3. Intrauterine system (IUS)
4. Barrier methods of contraception (condom or occlusive cap with spermicide

Male participants in the study are not required to use barrier methods (condoms) for the purpose of contraception. There is no evidence that the vaccine can be shed into semen.

Pregnancy: There is a moderate amount of safety data for live attenuated influenza vaccine in pregnancy, with no evidence that it is harmful. However, if you were to become pregnant during the study, you should tell us immediately. With your consent we would continue to follow-up for safety reasons up to birth or end of pregnancy.

What samples do we collect from you?

We collect nose, throat, saliva, urine (women of childbearing potential) and blood samples to look at the germs and your immune response. There will be an option to have the fine needle aspirate in up to 10 people across the study.

- **Nasal wash:** We gently squirt a little salty water into your nose. After a few seconds the water runs out into a sample bowl. This will tell us about the germs in your nose and your immunity.

- **Throat swab**: We take a small cotton swab and wipe the back of your throat in a circular motion. This is to test for germs in your throat.

- **Nasal Cells:**

Nasal cells may be collected by either or both of the two methods below (Nasal curette and/or Nasal swab)

Nasal Curette: We insert a very small and narrow plastic spoon (about the size of a toothpick) into the inner surface of the nose that is withdrawn in a sweeping motion to collect small cells. We will perform this twice on each nostril.

Nasal swab: We use a small cotton swab and wipe the back of your nose to collect cells.

- **Blood samples:** We take blood samples from a vein in your arm (using a needle). We will take up to 80mL (about the same as five tablespoons) during a visit. This amount of blood is safe to have taken in one go, and your body will replace this blood quickly. This is to look at your immune response.

- **Fine Needle Aspirate (Optional)**

This procedure is optional. This involves using ultrasound to identify a lymph node (a gland with a role in the immune system) in your armpit. We will then take a sample of the lymph node using a needle, we use the ultrasound machine help guide us to the right place. This can be done on both armpits. This visit could be combined with another visit, or done as a separate visit anytime between Day 0 and Day 31.

What samples do you need to take yourself at home?

- **Nasosorption:** This is a small strip that we put into the entrance of your nose. It is absorbent and will soak up some of the slime coating your nose. This is one of the samples we will ask you to take at home.

- **Saliva:** You will be asked to collect saliva by either rubbing a sponge on a stick against your gum lines for up to two minutes or by dropping saliva directly into a container.

We will provide you with a step-by-step guide to explain how to obtain home samples and on what days. We will ask you to obtain nasosorption and saliva samples at home, provide you with containers and you will store them in the fridge until your next study visit.

What are the benefits of the study?

Participants will not receive any direct benefit to taking part in this study. However, you will be a valuable part of a research study that we hope will eventually lead to the development of new methods to prevent or treat respiratory infections.

How much will I get paid?

Study participants would be reimbursed for their time, travel, and the inconvenience of taking part in the study. The maximum reimbursement for any volunteer who completes the whole study is up to £700 for Group B. All participants will be reimbursed based on the following figures:

Study Procedure	**Reimbursement**
Time per visit (Screening, Inoculation)	£60
Time per visit (Follow up)	£40
Travel expenses per visit	£30
Sample collection per visit	£20
Full Diary completion	£30
Home Samples	£20/each
FNA (if applicable)	£150

You may also receive additional reimbursement for any unscheduled visits (£90/visit) if requested by the study team.

The sum reimbursed is on a pro-rata basis, so, if for example, you choose to withdraw halfway through the study, or do not complete all study procedures, we would calculate your reimbursement based on the visits you have attended and samples that have been obtained.

Reimbursements will be made at set timepoints through the study, Screening, 31 days after vaccination. The reimbursement is not taxed and should not affect any benefits you receive.

Payments are made directly by bank transfer. For this reason, we require participants to provide their bank details at the screening visit. Bank details are kept confidential. Personal information such as your name, bank details and national insurance number may be shared with the University finance team to process or verify your reimbursement payments. Financial auditors may also audit the records where this information is held. All confidential data will be stored according to the UK General Data Protection Regulation.

What are the potential risks of the study?

Influenza Vaccine: There are some symptoms that commonly happen after taking this medicine, such as: headache, stuffy nose, nose bleeds, rash, sore muscles, and fever. In very rare cases it can cause a severe allergic reaction.

Blood sampling: The risks associated with blood sampling are minimal, but this may cause temporary pain, bruising and/or bleeding to your arm. The blood sampling will be performed by trained healthcare professionals. In the rare circumstance that we notice anything unusual or medically significant about your blood test results then we would let you know and ask your permission to inform your GP.

Nasal sampling: There are limited risks related to these samples. During a nasal wash, you may swallow a small amount of salty water, however, this is harmless. The nasal cell sample is slightly uncomfortable and may make your eyes water briefly. Sometimes a small amount of blood can be seen on the sample probe, however, it is rare for it to cause a nosebleed.

Throat swabs: These samples may make you feel some discomfort.

Fine Needle Aspirate: This is usually well tolerated, causing only mild pain when having an injection to numb the area. It may cause pain, bruising and bleeding. Rarely, it may cause infection.

Incidental medical findings

Since we carry out several medical tests throughout the study, it is possible that we detect previously unknown health issues (*e.g.,* high blood pressure, abnormal blood results such as infection with hepatitis B or C and human immunodeficiency virus, HIV). This will be discussed with yourself and with your permission, your GP informed for ongoing follow up.

In the UK, healthcare professionals are legally obliged to report any new suspected cases of hepatitis B and hepatitis C to the UK Health Security Agency (UKHSA). If you are found to have hepatitis B or C, we will be required to send a report to the UKHSA, including your name and personal contact information. It's important to note that you cannot opt out of this.

What will happen to the samples collected in the study?

The samples taken in this study will be stored and processed in the Oxford Vaccine Group, University of Oxford, Oxford University Hospitals NHS Trust and across other sites and other collaborators outside the UK (Nosevacc consortia).

Samples will be taken to look at your immune response to the virus as well as the bacterium and whether you are carrying either in your nose after exposure. These experiments may involve the extraction of molecules, such as DNA, which make up the genes in your cells. These tests can be used to see if there are genetic factors that affect protection or susceptibility to these bacteria or viruses.

The blood samples we collect to assess your eligibility and safety will be processed in an NHS laboratory and results from these samples are connected to your NHS record. Your details and results from these samples are safeguarded under the NHS Trust's data protection policy and will only be accessed during the study by the researchers to assess your safety and eligibility.

We will also ask for your consent to retain leftover samples to be used for future ethically approved research in the UK and overseas. This consent will be requested separately. If you consent, samples are anonymised and will be transferred to a research tissue bank at the end of the study. You can decide whether or not you agree to genetic material being stored, however, your DNA is unique to you so it can never be completely anonymous. These samples will be transferred to a research tissue bank held at the University of Oxford. The stored samples will be analysed, as and when new technology becomes available, or when new scientific questions arise relating to protection and susceptibility of disease and carriage. If you agree, these samples would be stored indefinitely.

What if there is a problem?

A research doctor is available to contact twenty-four hours a day, seven days a week by phone. You will be asked to contact us as soon as possible if you are unwell or if you develop any symptoms including, but not exclusive to, sore throat, earache, headache, fever, cough or breathlessness. We would also like to know about any new health or medication changes. Any medical care you need will be provided by the NHS.

The investigators recognise the important contribution that volunteers make to medical research, and will make every effort to ensure your safety and wellbeing. The University of Oxford, as the research sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your taking part in this study. If something does go wrong, you are harmed during the research, and this is due to someone's negligence, then you may have grounds for a legal action for compensation. While the Sponsor will cooperate with any claim, you may wish to seek independent legal advice to ensure that you are properly represented in pursuing any complaint. The study doctor can advise you of further clinical action and refer you to a doctor within the NHS for treatment, if necessary. NHS indemnity operates in respect of the clinical treatment provided.

What if I change my mind or want to stop?

If you do start the study, you are free to stop at any time and without giving a reason. If you decide not to take part, or to withdraw from the study, this won't affect your future healthcare. In case of withdrawal, we will ask to let the study team know and the study team will advise you if any safety follow-up is required.

If you decide to stop or lose capacity to consent to being in the study, we will only continue to use the samples that have already been taken and information that we have already collected from you – no further samples or data will be collected. You are free to request that your samples are destroyed at any time during or after the study. You will be paid for the visits completed up to that point.

The study team may stop your involvement in the study for the following safety reasons:

- If you develop a condition that is in the exclusion criteria
- If you start a new medication that is prohibited
- If you are unable to follow study instructions or the team are unable to contact you.

In these cases, the participant would be withdrawn from the study. Identifiable data or tissue already collected with consent would be retained and used in the study, unless you request that we destroy your samples that haven't been analysed yet. No further data or tissue would be collected or any other research procedures carried out on or in relation to the participant

Would my taking part in this study be kept confidential?

All information that is collected about you during the research will be coded with a study number and kept strictly confidential. Any information about you that leaves the clinic would have your name and address removed so that you could not be recognised, except for your signed consent for, letters sent to your GP and some blood samples sent to NHS labs (which may contain your NHS number). To enrol into this study, you are required to consent for us to contact your GP.

We will write to your GP and consultant (if appropriate) to inform them when you enrol in the study and when you complete it, so they can update your medical records accordingly. Your GP may also be asked to share information about your medical history and give access to any other medical records as required to ensure there are no medical reasons that would prevent you from taking part. We would only notify your GP of the results of any medical tests with your permission.

Responsible members of the University of Oxford, the relevant NHS Trusts involved in the research may also be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations. No one else will be told that you are involved in the study.

What will happen to my data?

General Data Protection Regulation (GDPR) requires that we state the legal basis for processing information about you. In the case of research, this is 'a task in the public interest.' The University of Oxford, based in the United Kingdom is the Sponsor for this study and the 'data controller' and is responsible for looking after your information and using it properly. Your personal information will be kept confidential and handled in accordance with data protection laws in the UK. We will be using information from you and your medical records to undertake this study.

We will use the minimum amount of personally identifiable information.

We may disclose your personal data to our third-party service providers to carry out activities specifically for the purpose of this research study and as explained in this information sheet, for example text messaging service providers/companies to send study-related text messages to you. Any third-party service providers are required to take appropriate security measures to protect your personal data in line with University of Oxford policies. We do not allow our third-party service providers to use your personal data for their own purposes, but rather to only process your personal data for specified purposes and in accordance with our instructions.

Study data may be stored electronically on a secure server by the University IT team, and paper notes will be kept in a secure location at each study site or as outlined in local SOP's. We will store the research data and any research documents with personal information, such as consent forms, securely for up to 25 years after the end of the study, or as per national regulatory requirements. Anonymised research data may be kept indefinitely. Your email address is required for the electronic diaries, in order for them to function. Only designated site staff and the data manager(s) will have access to view your email address and you will need to consent to this. It will not be possible to identify you in any publication or report.

If you withdraw from the study, we will keep the information about you that we have already obtained, including blood samples and symptom diary data, but if you prefer you can request for the samples to be destroyed (if they have not already been analysed).

Data will be collected and held by the Oxford Vaccine Group. It will be accessible to staff at the Oxford Vaccine Group, responsible staff from the University of Oxford, regulatory authorities, independent auditors which may be appointed by Sponsor and funder in collaboration, who may monitor/audit the data collection process. We will use your name, date of birth, NHS number, home address, and contact details, to contact you about the research study and, if you agree, to access your medical records to assess eligibility.

Data may be transferred outside of the UK e.g., where data protection laws may differ from the UK. Data that are transferred elsewhere will be pseudo-anonymised (meaning any identifiable information will be replaced in a way that does not allow you to be directly identified).

We may need to view your ID (driver's licence, passport or national ID card) and will record either your national insurance or passport number for TOPS database registration and payment processing. This will be taken at the screening visit. We will securely retain this information until the end of the study. Your bank details will be stored for a minimum of 7 years in line with Oxford University financial policy If you only complete online screening (before informed consent) your data will not be kept beyond the end of the study.

At the completion of the study, unless you consent otherwise (e.g., if you request to be informed of other studies), your personal details will not be used to contact you other than in exceptional circumstances concerning your safety. If you consent to take part in another study carried out by <<insert study site>> personal information and medical information including blood test results may be accessed to avoid unnecessary repetition.

If you agree to future contact (e.g., to be informed of other studies) we will continue to store your consent form within the study records and personal information (e.g., name, DOB and contact details) in a password protected database. This will be archived on a university server with restricted access and kept indefinitely, or until the study team feel that it would no longer be required, at which point it will be deleted. This will be held separately from the study data and you can request at any time to have your details removed. If you have not consented to being approached for future studies, your contact details and consent form will be destroyed after 25 years or as per national regulatory requirements.

General Data Protection Regulation (GDPR) provides you with control over your personal data and how it is used. When you agree to your information being used in research, however, some of those rights may be limited in order for the research to be reliable and accurate. Further information about your rights with respect to your personal data is available at https://compliance.web.ox.ac.uk/individual-rights

You can find out more about how we use your information by contacting info@ovg.ox.ac.uk

What happens at the end of the study?

The results of this research study may be presented at scientific meetings or conferences and published in a scientific medical journal. This can take approximately two years after the study is completed. Your individual results would not be identifiable nor would you be identified in any report or publication. Once results are publicly available, we will send you a Results letter including a lay summary of the results and a link to the publication. The results of this research study may be presented at scientific meetings or conferences and published in a scientific medical journal. This can take approximately two years after the study is completed.

How have patients and the public been involved in this study?

The Oxford Vaccine Group Patient Public Involvement (PPI) group have reviewed the main participant-facing documents associated with this study (participant information sheet, informed consent form and advertising materials).

Who has reviewed this research study?

This research has been looked at by an independent group of people, called a Research Ethics Committee, to protect participants' interests. This study has been reviewed and given favourable opinion by East Midlands – Leicester South Research Ethics Committee.

Who is organising and funding the study?

The study is sponsored by the University of Oxford. The study is being conducted by the Oxford Vaccine Group including scientists, doctors, nurses who investigate infectious diseases and vaccines.

Funding has been received from the Horizon Europe Guarantee Extension under UK Research and Innovation. The funder will have no influence on study decisions or the results from the study.

What if I wish to complain?

If you wish to report a concern about any aspect of the study, you can contact your local study team at 01865611400 and info@ovg.ox.ac.uk. You may also contact the sponsor, the University of Oxford, RGEA (Research Governance and Ethics Assurance) office on 01864 616480, or email at rgea.complaints@admin.ox.ac.uk. Reporting a concern will not affect the medical care you receive now or in the future.

What should I do if I am interested in taking part?

You do not need to make a final decision straight away. If you are interested in taking part in this study or have any questions, you can:

- Complete the online screening questionnaire: Online Screening Questionnaire
- Contact the research team by the phone number or e-mail address: 01865 611400 and info@ovg.ox.ac.uk

If your response reaches us after the study has finished recruitment, we will let you know. Thank you for taking the time to read this information sheet and for considering taking part in this study.

Yours Faithfully,

Dr Katrina Pollock
Oxford Vaccine Group, University of Oxford
Centre for Clinical Vaccinology & Tropical Medicine (CCVTM),
Churchill Hospital, Oxford, OX3 7LE