



ECLIPSE

Exploring Co-infection with Live Attenuated Influenza Vaccine and Pneumococcus in healthy older adults

Participant Information Sheet – Group A



This study will help us develop new treatments and vaccines. It will look at how the body reacts to the *Live Attenuated Influenza* vaccine (LAIV) and *Streptococcus pneumoniae* bacteria (pneumococcus) being used together and given through the nose.

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.

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Study Overview



Condition Studied:
Upper Respiratory Tract



Inoculation:
Streptococcus pneumoniae
(Spn, pneumococcus)



Vaccine:
Nasal Flu



Study length: 31 days
(optional 60 days)



Number of visits:
9 +/- 2

Can I take part?



YOU MUST:

- Be aged 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



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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 or 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 beneficial 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 A; you should have also received a separate leaflet about Group B.

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?

We are looking for up to 60 healthy volunteers. We will check for reasons that may put you at higher risk of becoming seriously ill. If we find any reason that you may be at higher risk of infection, then we will not invite you to take part.

You are potentially eligible if:

- You are 60 to 80 years old
- You are able to consent for yourself
- You speak English fluently

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 have a direct caring role to people at high-risk of infection, such as children under the age of 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 first 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 eight in-person visits, and two optional visits, first for a procedure, called a fine needle aspirate, to take cells and fluid from a gland (lymph node). The second optional visit is for nasal biopsy where a sample of tissue from your nose is taken.

These visits will be spaced out over approximately five weeks. If you consent to the additional optional nasal biopsy, the length of your participation in the study will increase to up to 9 weeks.

During the study, everyone will be exposed to both the pneumococcus and the influenza vaccine through drops in the nose. Everyone receives the pneumococcus bacteria on Day 0.

Approximately 3 days prior to receiving the pneumococcus challenge (Day -3) you will receive either saline or the nasal flu vaccine (LAIV). Finally, 3 days post challenge with pneumococcus (Day 3) you will receive either saline or LAIV, depending on which one you had received previously on Day -3. See example below.

- Day -3: Saline and Day 3: nasal flu vaccine
OR
- Day -3: Nasal flu vaccine and Day 3: saline

But you will not know which order you received the saline or the nasal flu vaccine, until the end of the study (called 'blinded'). The study team will know what you have had, but as the actual procedure is the same for both times, you will not know.

At the end of the study, you will receive an "Unblinding Letter", to let you know when you had LAIV and when you had saline. You will not need to self-isolate after the pneumococcus challenge, but we will ask you questions to check that you do not share a house with anyone who might be vulnerable to infection.

Timeline of study visits and procedures:

GROUP A - Spn + LAIV/SALINE

Screening Visit	7 days prior to Day 0	3 days prior to Day 0	Day 0	Day 2	Day 3	Day 7	Day 9	Day 28
<i>Streptococcus pneumoniae</i> inoculation								
Saline OR Live Attenuated Influenza Vaccine (intranasal)		Saline OR 			Saline OR 			
Saliva sample								
Nasal samples								
Throat swab								
Blood sample								
Fine Needle Aspirate								



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.

If you are happy to take part in the study, you will be asked to complete a quiz to show us you know what the study involves. You will then be asked to sign a consent form. 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. If applicable, we may ask you if there is any possibility of pregnancy. We will take your blood pressure, heart rate and temperature, and take blood tests, do a physical examination, and perform an ECG. This is all done to make sure you are fit and well.

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 a medical summary before the 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.

During this visit, we will give you a 24hr contact letter to have a friend or relative who lives nearby you to sign up as 24h contact. We will need this information to have a way of contact you if we are unable to get in touch with you. We will ask for this person to provide their name, telephone number, address, e-mail address and sign the form to give consent. The 24h contact letter contains a brief explanation on the study and how the personal information of this person will be used.

Data entered by us into TOPS is based on whether you receive a vaccine or not. If you receive a vaccine, these details 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 have 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 finds 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 at screening, we will contact you to arrange a date for your baseline assessment (Day -7). If more than 90 days have elapsed from your screening visit to



enrolment, we will repeat your face-to-face screening visit including some of the tests. Your participation in this study is at the researchers' discretion.

Day -7: Baseline assessment

We will check your vital signs, do a physical examination and then take some of the baseline samples. This includes:

- Nasal samples
- Nasal wash
- Throat swabs
- Saliva
- Blood sample
- COVID19 test

We need to get our baseline samples shortly before receiving the flu vaccine or saline (between one to six days prior). This is so we can check that you don't already have pneumococcal germs in your nose.

If you do have pneumococcal bacteria in your nose, we can delay your enrolment into the study and repeat the baseline assessment in a month's time.

Day -3 and Day 3: Vaccination with LAIV/saline

During the Day -3 visit you will be allocated to either have saline or the flu vaccine into your nose. We will ask you to wear a blindfold or close your eyes while we do this. The researchers will know which one you have had, but this will be hidden from you. This makes sure that the study results aren't influenced by what you expect might happen. The overall visit takes around one hour.

You will either have:

- Day -3: Saline and then Day 3: flu vaccine
- OR
- Day -3: Flu vaccine and then Day 3: saline
-

We will check you are happy to continue and that you are feeling well before we give you the vaccine. The overall visit takes around one hour.

Day 0: Pneumococcal challenge

We will check you are happy to continue and that you are feeling well prior to challenge. Another blood test will be taken.

You will be asked to sit in a reclined position during the procedure and for 15 minutes after inoculation. The bacteria will be introduced to both nostrils by dripping in a small liquid sample with a pipette. You will be asked not to swallow, touch your face and sniff so the fluid stays in the nose for as long as possible. We can provide extra pillows if needed to make you more comfortable. The overall visit takes around one hour and a half.



You will go home with a study pack including:

- A course of antibiotics to keep with you in case you are unwell. You will be instructed **when** to take them
- A thermometer to check your temperature at home
- A safety information sheet
- A study contact card
- Nose/saliva sampling swabs, instructions and storage bags

At home you will keep a symptom diary for 21 days (Day -3 to Day 17). 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 an electronic record (or a paper diary)..

Whilst at home, you will take some samples from your own nose and saliva (we will train you how to do this and send you a video to refer to) and store them in the freezer. We will ask you to bring these samples and your sample logging form to the clinic at your final study visit.

Follow-up visits

We will ask you to return to follow-up clinics for further checks on your vital signs, to review any symptoms you might develop and more nose, throat and blood tests. These return visits will take place at several timepoints after vaccination and pneumococcus inoculation, as shown in the table above. In total, you will have 9 or 10 visits, if you have the optional fine needle aspirate visit. You may be asked to come in for extra visit(s) if needed for safety reasons.

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 all groups 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. This can be done as a separate visit or combined with another visit after anytime between day -3 and day 28. You will be provided with a separate information sheet about the procedure, and you can decide at any time before D28 if you wish to have this additional sample taken.

Nasal Biopsy Visit (Optional)

A subgroup of 10 participants across group A and B of the study will be offered a procedure, called a nasal biopsy. An Ear, Nose, and Throat (ENT) specialist doctor will take a small sample of tissue from the inside of your nose. This is to look at your immune response to germs at the site of infection. You will be provided with separate information about the procedure and can decide at any point in the study if you wish to have this



additional sample taken. As the biopsy can be taken between day 14 and day 60, if you do decide to have this sample being taken, the length of your participation in the study will increase.

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 28). 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. If you would like to take the opportunity to take the seasonal vaccines, please let the team know.

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.

What samples do we collect from you?

We collect nose, throat, saliva, and blood samples to look at the germs and your immune response.

- **Nasal wash:** We gently squirt saline 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.
- **Nasosorption:** This is a small strip that we put into the entrance of each of your nostrils. It is absorbent and will soak up some of the secretions coating your nose. This is one of the samples we will ask you to take at home.
- **Nasal Cells:** Nasal cells may be collected by either or both 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 80 mL (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: 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 to 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 -3 and day 28.
- **Nasal biopsy: This procedure is optional.** An Ear, Nose, and Throat (ENT) specialist doctor will take a small sample of tissue from the inside of your nose. This is to look at your immune response to germs at the site of infection. You will be provided with separate information about the procedure and can decide at any point in the study if you wish to have this additional sample taken. As the biopsy can be taken between day 14 and day 60, if you do decide to have this sample being taken, the length of your participation in the study will increase.

What samples do you need to take yourself at home?

- **Nasosorption:** This is a small strip that we put into the entrance of each of your nostrils. It is absorbent and will soak up some of the secretions 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 freezer until your final study visit

What are the benefits of taking part in 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 reimbursed?

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 £1,060 for Group A. 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
Nasal Biopsy (if applicable)	£160

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, after the screening visit, 7 and 28 days after inoculation. 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?

Challenge with pneumococcal bacteria: Because the germs we expose you to are live, there is a very small risk of infection to you or to your close contacts. However, this pneumococcus bacterium has been given in previous studies to healthy adults, and older adults, with no serious side effects. However, you may have cold-like symptoms such as, headaches, earaches, a cough or a fever.

We provide a safety pack as described in the *Day 0: Pneumococcal challenge* section and you will have 24-hour access to the research team by phone. The pack includes clear safety precautions, and instructions on what to do if you feel unwell. Everyone who tests positive for pneumococcus will take a course of antibiotics at the end of the study, or if they feel unwell, on the advice of a study doctor.

Influenza Nasal Vaccine: There are some symptoms that commonly happen after taking this vaccine, 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 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 sampling is slightly uncomfortable and may make your eyes water briefly. Sometimes a small amount of blood can be seen on the sample swab, 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 or damage to underlying structures. Further information on potential risks associated with the procedure can be found in the 'FNA Participant Information Sheet and Informed Consent Form' document.

Nasal biopsy: the procedure itself may be uncomfortable and may cause minor bleeding and short-term pain in the nose. For more details, please refer to nasal biopsy participant information sheet.

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 the 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 will follow local sample labelling requirements (which may include personal identifiers). Results from these samples are connected to your NHS record, which is connected to the local hospital trust. 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 transferred at the end of the study to a research tissue bank held at the University of Oxford.

You can decide separately whether or not to agree to your genetic material being stored, as your DNA is unique to you so it can never be completely anonymous. These samples will also be transferred to the University research tissue bank. 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 24 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.

If a person in your household develops similar symptoms, the study team cannot give guidance on managing any symptom or treatment. Household members who show the appropriate symptoms should seek medical assistance (if required) from their GP or from their local hospital, and to provide advice about the fact that a member of their household has been involved in this study.

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.

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. You can choose to stop study assessments/investigations but continue with study follow-up visits for us to monitor your safety. In case of withdrawal, we will ask you to let the study team know (you don't have to provide a reason). The study team will advise you if any safety follow-up is required and may recommend that you take a course of antibiotics if you have received pneumococcus inoculation.

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 kept strictly confidential. To enrol into this study, you are required to consent for us to contact your GP.

We will write to your GP to inform them when you enrol in the study and when you complete it, so they can update your medical records accordingly. We will inform the GP of any vaccinations offered to you during the course of the study and if you were given optional seasonal Flu or COVID-19 vaccinations. 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, where data protection laws may differ. Data that is 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 the Oxford Vaccine Group 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?

Soon after the study is finished, we will send you an “Unblinding Letter”. This lets you know which day you had LAIV and which day you had saline. Your individual test 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 coordinated 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
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