Oxford Vaccine Group
University of Oxford
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PARTICIPANT INFORMATION SHEET

LEGACY03: Lymph node flu & COVID-19 vaccine responses in younger or older adults

You are invited to take part in a study to investigate how lymph nodes respond to seasonal influenza (flu) and COVID-19 vaccines and how these changes with age.

The study is being run by the Oxford Vaccine Group, which is part of the University of Oxford.

Before you decide on whether to participate in this study, it is important that you take the time to understand why the research is being done and what it would involve. Please read this information sheet carefully. If you have any further questions about the study, please do not hesitate to contact us (contact details are below and at the end of the leaflet).

If you are interested in taking part in this study, then please complete the online pre-screening questionnaire at: https://trials.ovg.ox.ac.uk/trials/legacy03

If you have further questions about the study that you would like to discuss with our team, please contact us at:

Email: info@ovg.ox.ac.uk

Tel: 01865 611400

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Summary

Who can take part?	Adults in generally good health • Aged 18 to 45 years • Aged 65 years or over
Study injections (vaccines) being used	Seasonal influenza (flu) vaccine: Adjuvanted quadrivalent influenza vaccine COVID-19 booster vaccine (Moderna COVID-19 vaccine): Spikevax recommended variants e.g., bivalent Original/Omicron BA.4-5/Spikevax XBB
Procedure	Lymph node cell sampling using fine needle aspiration (FNA) of both armpits on two occasions • 1 week OR 2 weeks OR 4 weeks after study injections (as randomised by the study team) and then • 12 weeks after study injections
Study Aims	• To test immune responses to the vaccines using both blood and lymph node samples. Cells from lymph nodes can be sampled using a small needle, fine needle aspiration (FNA). To compare responses in older people with those in younger people
Chief Investigator	Dr Katrina Pollock
Principal Investigator	Dr Katrina Pollock
Study Site	Oxford Vaccine Group, University of Oxford Centre for Clinical Vaccinology and Tropical Medicine Churchill Hospital, Headington, Oxford, OX3 7LE
What happens in the study?	• Volunteers will attend a screening visit, to decide their eligibility to take part, and to obtain their consent • At the next visit, the study injections will be given; one dose of seasonal flu vaccine and one dose of COVID-19 vaccine booster • All participants will have Fine Needle Aspiration (FNA) sampling (a procedure that involves taking cells and fluid from a lymph node) of both armpits after study injections (allocated to be 1-, 2- or 4-weeks after study injections and then 12 weeks after study injections) • All participants will be followed up for 3 months • Participants will attend a total of 7 study visits (1 screening, 1 vaccination, 2 FNAs and 3 follow up visits). • Participants will receive 1 to 2 phone calls dependent on group • Each in person study site visit (7 in total) will include a blood test • The safety of participants will be closely monitored throughout the study
Reimbursement	Screening visit: £110 Study Injections (vaccination) visit: £110 FNA visits: £150 per visit Follow up visit: £90 per visit Diary card: £30 per diary

	Total reimbursement (7 visits not including phone calls): £820
Risks of participation	After **FNA**, there may be some mild discomfort, or bruising. Bleeding and infection are unlikely but may occur as with any minor procedure. These risks are described below (page 3). Anyone taking regular blood thinning medication, including aspirin, will not be able to take part. After **study injections (vaccination),** short-lived symptoms may occur, such as fatigue and discomfort of the arm. A full discussion of risks, including potential rare but serious reactions, can be found on page 10.
Benefits of participation	By participating in this study, you will receive flu and COVID-19 vaccines. You will be helping research into understanding how immune responses to vaccination change with age. You will also be helping in the development of new vaccines that can be used in people of different ages.

What is the purpose of this study?

As we age, our risk of severe disease from infections such as flu and COVID-19, increases. Unfortunately, as we age, our immune system also changes and we respond less well to vaccines. It is therefore important to understand how age changes the immune system. By understanding these changes, we can design vaccines which will offer greater protection to those most vulnerable to diseases such as flu and COVID-19. Conversely, we can also design vaccines better suited for younger people.

This study will test the responses of cells in lymph nodes before and after immunisation with flu and COVID-19 vaccines and compare between older and younger adults.

We are researching how lymph nodes respond to vaccines and how this changes as we age. Lymph nodes are small bean shaped organs present all over the body. After a vaccine is given in the arm, the lymph nodes in the armpit swell in response. Inside the lymph nodes are cells that make antibody in response to the vaccine. Antibodies protect us from infection after we have had a vaccine.

Cells from lymph nodes can be sampled using a small needle. This is called fine needle aspiration (FNA) and it is a well-established test in the clinic; in research it enables direct testing of immune cells. This information will help researchers design future vaccines, and decide how they are given to different populations, for example older people, to offer the best protection against disease.

What is fine needle aspiration (FNA)?

Fine needle aspiration (FNA) involves taking cells and fluid from a lymph node (gland).

You will have an examination to feel for lymph nodes (glands) in your armpit. An ultrasound scan will look closely for your lymph glands. Once a suitable gland has been identified, the area will be cleaned and numbed using local anaesthetic. Using the ultrasound scan for guidance, a needle will be used to collect a small amount of fluid and cells from the gland. You should not feel any pain but may feel some pressure. This procedure will then be repeated on your other armpit. The whole visit can take up to 90 minutes, but the FNA procedure itself takes only a few minutes.

FNA is commonly performed in outpatient clinics to help diagnosis in patients with different health conditions, for example for lumps or swollen glands. It will be performed by a doctor trained in the technique.

FNA is a safe and well-tolerated procedure but, as with any medical intervention, it carries some risks:

• Pain: The FNA should not be any more uncomfortable than a blood test. Any tenderness afterwards will resolve. You can take a simple painkiller like paracetamol if you need it; avoid taking aspirin, as this may increase the risk of bruising.

• Bleeding: The needle used is fine but bleeding under the skin may sometimes occur after the FNA. It usually stops quickly by itself. Any bruising will fade within 2 weeks.

• The risk of bleeding is higher if you are taking any medications that make your blood thinner such as warfarin, aspirin or clopidogrel. If you regularly take any of these medications you will not be able to participate in the study. If you take any aspirin or blood thinning medication in the 7 days before the FNA procedure please let us know.

• Infection after FNA is rare. If you get redness, pain and/or tenderness in the days afterwards you may need antibiotic treatment.

If the doctor is not able to collect enough sample, he/she may decide to repeat the FNA with your permission.

Study visits

Please see the final page for a summary image of the visits.

Visit	**What to expect**
Pre-screening phone call	This is a phone discussion about your medical history and to answer your questions about the study. We will ask you to complete a consent form to retrieve a summary of your medical and vaccination records. This information will be kept confidential.
Screening visit	• Discussion of study • Sign consent form • Identity check • Review of medical history • Physical examination, including “vital signs” (temperature, pulse, blood pressure) • Blood test (and urine pregnancy test, if appropriate)
Study injection (Vaccination) visit	• Vital signs ((temperature, pulse, blood pressure) • Blood test (and urine pregnancy test, if appropriate) • Ultrasound scan of both armpits • Vaccination in each arm (study injections) • Set up eDiary after study injections
FNAs	• Vital signs ((temperature, pulse, blood pressure) • Fine needle aspiration (FNA) and ultrasound scan of both armpits • Blood test
Follow up visits	• Blood test • Review for serious medical events
Phone call	• Review for serious medical events

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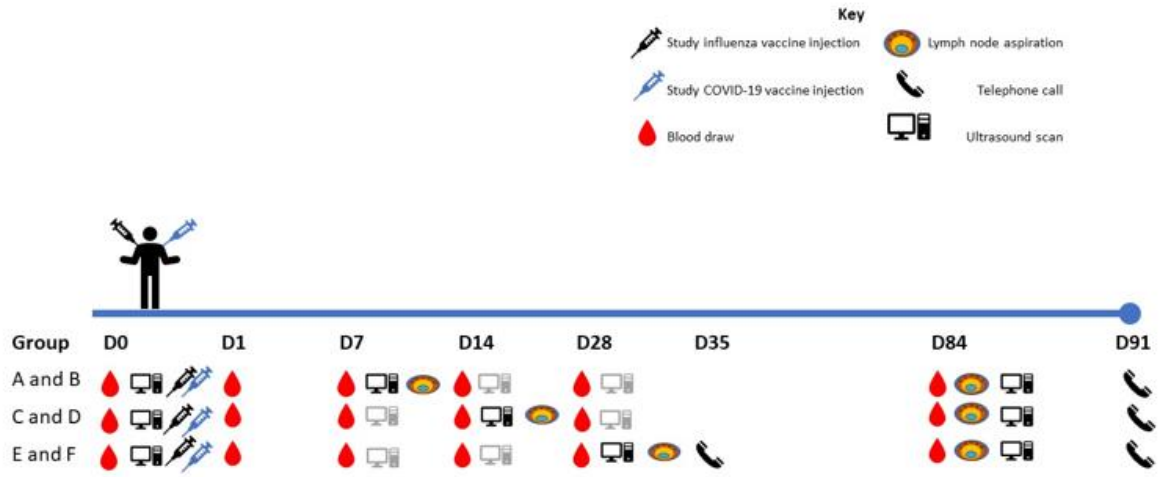
What happens in the study?

1. Recruitment and eligibility screening

We wish to recruit up to 48 people to take part in this study at the Oxford Vaccine Group, University of Oxford. Participants should be in generally good health and aged either between 18 and 45 years or 65 years and over. Volunteers will be asked to complete an initial online questionnaire, followed by a phone call from the study team, to assess whether they are eligible to take part. After this, volunteers will be invited to attend a screening visit which will include a medical assessment. Those who are eligible will then be invited to attend their study injections (vaccination) visit.

2. Allocation to a study group

The timing of the first FNA will depend on which study group you are in. This will be decided by randomisation once we know that you are eligible to take part. This first FNA may be scheduled at 7 days OR 14 days OR 28 days after study injections (vaccination). There is an equal chance of being allocated to each of these three alternatives.



Ultrasound images in grey are dependent on site-staff capacity and may not be required

3. Study visits

All participants in the study will be given one dose each of seasonal flu and COVID-19 vaccines, one in each arm.

Lymph node samples will be taken from both armpits.

Participants will attend a total of 7 study visits (1 screening, 1 vaccination, 2 FNAs and 3 follow up visits) and will receive 1 to 2 phone calls dependent on group as outlined above.

All participants will be followed up for 3 months after vaccinations.

All follow up visits will include a blood test, to assess the immune response. In addition to visits, participants will be asked to complete a short diary for 7 days after vaccination.

Who is sponsoring, organising and funding the research?

The study is organised and sponsored by the University of Oxford. The study is funded by the Medical Research Council and UK Research and Innovation.

How long would I be in the study?

If you are eligible to take part, we will enrol you into the study for 3 months starting from your study injections (vaccination) visit. You can, if you decide to (for whatever reason), withdraw from the study at any time (see What happens if I do not wish to carry on with the study? Page 11).

Can I take part?

To take part in the study, all the following **must apply** to you**:**

You must

Be aged EITHER between **18 to 45 years** OR **65 years or over** at the time of your screening visit
Be **in good health** without serious or unstable ongoing medical conditions
Be able and willing to **comply with all study requirements** including attending all follow up visits
Be willing to **allow your past medical and vaccination history to be checked by the study team** (either by allowing us to discuss your medical history with your GP, or by giving us a medical history summary)
Be willing to **register with TOPS** (The Over-volunteering Protection System)
Agree to **refrain from blood or blood product donation** during the study
Tell us about any **vaccinations** you may have received recently or expect to receive soon including flu vaccine
Have received a primary (two dose) schedule of any MHRA, UK authorised or licenced COVID-19 vaccine
Contraception
(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 study injection (vaccination) visit

You must NOT have

Current and Past Medical Problems
A **serious long-term illness** *e.g.*, a condition that requires hospital or specialist follow-up
A **body mass index (BMI) above 35**
A history of a **blood transfusion** or **immunoglobulin infusions** within 3 months of the study
Regular **anticoagulant** (blood-thinning) **medication** (*e.g.,* warfarin, edoxaban)
A history of **immune system disorders or immune therapy** currently affecting immune function
A history of a **severe allergic reaction to a vaccine or local anaesthetic, including hypersensitivity**
A history of **angioedema**
A history of **cancer that is ongoing**
A **serious ongoing mental health condition** if this may affect your participation in the study

A history of either a **major blood clot**, **blood clotting disorder**, or **bleeding disorder including thrombosis with thrombocytopenia syndrome** (TTS, also known as VITT)
A history of **capillary leak syndrome**
An intake of more than **42 units of alcohol per week** on average (The NHS recommends the following calculator: https://alcoholchange.org.uk/alcohol-facts/interactive-tools/unit-calculator)
Injected recreational drugs within the last 5 years
A history of **hepatitis B**, **hepatitis C** or **HIV infection**
A history of serious pericarditis, myocarditis or other **heart inflammation**
Other Clinical Trials
You must NOT participate in **another clinical trial** that involves receiving a drug or vaccine in the 30 days before the study starts and for the duration of the study
(If applicable) Pregnancy/Breast Feeding During the Study
You must NOT be pregnant or breastfeeding during the study

If you are unclear whether you might be eligible to be involved in the study, you can contact the study team (details at the end of this information sheet).

Which study injections (vaccines) are being used?

In this study you will receive two vaccines, an mRNA COVID-19 booster vaccine and a seasonal flu vaccine. The study injections (vaccines) chosen for the study are licensed for use in adults, and the seasonal flu vaccine is recommended for older adults.

The COVID-19 booster vaccine is Spikevax recommended variants e.g., bivalent Original/Omicron BA.4-5 and Spikevax XBB (Moderna Biotech UK Ltd), whichever is recommended for use routinely. The vaccine is given as an injection into the upper part of the arm. Data from clinical trials and from post-marketing authorisation show the original vaccine to be safe and effective. The Spikevax vaccine can cause the following side effects; pain at the injection site (92%), fatigue (70%), headache (65%), myalgia (62%), arthralgia (46.4%), chills (45.4%), nausea/vomiting (23%), axillary swelling/tenderness (20%), fever (16%), injection site swelling (15%) and redness (10%). These are more common in younger people. Very rarely the vaccine has been associated with heart conditions called myocarditis and pericarditis, facial swelling, nerve conditions such as pins and needles, facial paralysis (very rarely) and widespread skin conditions called erythema multiforme, and urticaria. Women have reported temporary changes in menstrual bleeding in some cases.

The flu vaccine is adjuvanted Quadrivalent Influenza Vaccine (Surface Antigen, Inactivated) (Seqirus UK limited). It is licensed for use in individuals aged 65 years and over and has been trialled in adults of this age and in children. In adults, common adverse reactions were injection site pain (up to 30%), fatigue (around 15%) and headache (around 10%). Most were mild or moderate. Very rarely the vaccine has been associated with nerve disorders such as Guillain-Barré syndrome which affects muscles, generalised rashes, kidney disorders, blood disorders and allergy.

Very rarely vaccines can be associated with allergic reactions, please let the study team know if you have had an allergic reaction to a vaccine or if you are allergic to eggs.

Both vaccines have been very widely used in millions of people and they have a well understood safety profile. As they are quite new types of vaccine, we are required to report any unusual side effects to the MHRA. Please let the study team know if you have any concerns.

Do I have to take part?

No. It is up to you to decide whether to take part. Your decision will not result in any penalty, or changes to your standard medical care. If you do decide to take part, you will be given this information sheet to keep (it will be sent electronically but you can request a paper copy) and you will be asked to sign a consent form.

What will happen if I decide to take part?

Online pre-screening questionnaire and medical records consent

If you decide that you would like to take part in this study, then you will need to complete a short set of online questions that cover some of the key criteria for participation in the study. If the study is right for you at this point, we will contact you to provide further instructions on the next steps. In addition, we will ask you to provide consent for the study team to access your medical records via the electronic patient records or through your GP. This consent is only to allow access to your medical records, and not the consent for enrolment into the study. If you choose to participate in the study, a separate consent will be taken (see below).

Pre-screening phone-call

If you express an interest in taking part, and if the study is right for you from the pre-screening questionnaire, a member of the study team will contact you by telephone to discuss the study and answer any questions you may have. We would also ask you a few more detailed questions to assess your eligibility.

If you remain interested, and if the study is right for you, we will arrange for you to come to our clinic for a screening visit.

Screening visit

This may take place up to 4 months before the study injection (vaccination) day. This, and all other study visits, will take place at the Oxford Vaccine Group, University of Oxford.

At the screening visit, you will meet with study staff, who will discuss this information sheet with you and would provide an opportunity for you to ask any questions you might have about the study and what's involved. You may take as much time as you feel necessary before making any decision on whether to take part. If you then decide to take part, and the study team consider that you have understood the information, you will be asked to sign the study consent form.

This will be followed by a physical examination, which will include the doctor listening to your heart and lungs with a stethoscope and examining your abdomen. Your vital signs (blood pressure, pulse, and temperature), weight and height will be measured. A blood sample will be taken (approximately 10 mL). If applicable, a urine sample may also be taken to perform a pregnancy test.

Study Injection (Vaccination) visit

If you qualify to be in the study after the screening visit eligibility checks, we will arrange for you to attend the study injection (vaccination) visit. First, we will check there have been no new problems since your screening visit. Your blood pressure, pulse and temperature (vital signs) will be checked, and a blood sample taken (approximately 50ml). If appropriate, you will have a urinary pregnancy test before study injections. You will have an ultrasound examination of both armpits.

You will then be given a single dose each of seasonal flu and mRNA COVID-19 vaccines vaccine, one in each arm. Overall, the study injections (vaccination) visit will each take about two hours.

Electronic diary 'eDiary' *(to be completed at home)*

During the study injections (vaccination) visit you will be given access to an online symptom eDiary. This will be set up using your personal e-mail address. We will ask you to record if you have any symptoms of pain, swelling and/or tenderness you may experience in your armpits in the 7 days following study injections (vaccination). If you forget to fill in the diary, you will receive automatic reminders; you may also be contacted by a member of the study team. The diary will be checked for completion at your day 7 visit.

FNAs (see page 3-4, *What is fine needle aspiration?*)

FNAs will be performed, at either 7 days OR 14 days OR 28 days and 84 days (12 weeks) after the study injections (vaccination visit). These visits will take about 90 minutes. We will ask about any recent serious medical problems. You will have a blood test (approximately 45ml) and you will have an ultrasound examination and FNA of both armpits.

Follow up visits

After study injections, you will attend the clinic for several follow up visits, as shown in the diagram above. These visits will take about 30-45 minutes. The visits are for us to check if you are experiencing any problems after the study injections and review your injection and FNA sites. At each visit you will have a blood test (approximately 50 mL).

During the study, you may also be asked to attend for an extra visit, for example, if a blood test needs to be repeated.

What other medical matters are relevant to the study?

Other vaccinations or medications during the study

If during the study you require any vaccinations for health, travel, or occupational reasons, you should inform the study team beforehand. We ask you not to receive any other vaccines within 30 days (before and after) of receiving the study injections. If you are prescribed any new medications during the study, please inform the study team.

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 should tell your insurer you are planning to participate.

Contraception

It is a requirement of participation that volunteers who could become pregnant use contraception (exceptions to this are below).

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

- Post-menopausal
- Surgical sterilisation
- Complete abstinence from sex with a male partner

Acceptable contraception methods include:

- Oral, injected or implanted hormonal contraceptives that prevent ovulation
- Intrauterine device (IUD)
- Intrauterine system (IUS)
- Sole sexual partner is a vasectomised male

Note that barrier methods of contraception such as condoms, are not sufficiently reliable.

Male participants in the study are not required to use barrier methods (condoms) for the purposes of contraception as the risks of vaccine excretion are negligible.

Pregnancy

If you were to become pregnant during the study, you should tell us immediately. There are no safety concerns but we should not take unnecessary blood from you during pregnancy and so would discontinue your involvement.

What should I avoid during the study?

Blood donation

Under current UK regulations, participants must refrain from blood donation during their involvement in the study. However, you will be able to restart blood donation once the last study visit has been completed.

Taking part in other clinical trials

You should not take part in other clinical trials in which drugs or vaccines are administered, or which involve repeated blood sampling, whilst participating in this study as this may affect the results of this study.

Are there any risks from seasonal flu and COVID-19 vaccines?

Potential risks are summarised below:

Vaccine site - 'local' reactions

As with any vaccine, you may experience some discomfort at the injection site. Usually this is mild, but some individuals experience more significant pain which might interfere with their usual activities. Post-vaccination arm pain usually resolves completely within a few days, although it may occasionally persist up to a week or even longer.

Other less common, but possible, symptoms around the injection site might include redness, swelling, itchiness or a feeling of warmth.

General reactions

During the first 24-48 hours after study injections (vaccination), you may experience flu-like symptoms such as muscle aches, joint aches, feverishness, chills, headache, nausea, tiredness and feeling generally unwell. We would expect these symptoms to resolve within a few days.

Are there any other potential risks from taking part in the study?

Fine needle aspiration (FNA) sampling

FNA sampling is described on page 3, *What is fine needle aspiration (FNA)?* It may cause pain, bruising and bleeding. Rarely, it may cause infection.

Blood samples

Blood sampling may cause slight pain and occasionally bruising. Occasionally, people feel light-headed, nauseous or faint. At most visits we will take about 50ml of blood, which should be well tolerated by healthy adults. The **total** amount of blood we will take from each participant over the whole study period is approximately 300 mL. For comparison, a **single** donation to the NHS blood bank would be approximately 470 mL.

What if we find something unexpected

Since we carry out several medical tests throughout the study, we may possibly detect previously unknown health issues (*e.g.,* high blood pressure, abnormal blood results). If abnormal results or undiagnosed conditions were to be found during the study, these would be discussed with you and, if you agreed, your GP would be informed. We would refer any newly diagnosed conditions to your GP.

Sometimes incidental medical findings require your GP to carry out further investigations, such as blood tests, scans or referral to specialists.

What are the advantages of taking part?

By participating in this study, you will receive flu and COVID-19 vaccines.

Will I be paid for taking part in this study?

Study participants will be reimbursed for their time and inconvenience. The reimbursement provided are considered to be reasonable amounts to cover the costs of participating in this research. There should not be any consequences for tax or benefit purposes.

Reimbursement for all participants will be based on the following figures:

- Screening visit: £110
- Vaccination visit: £110
- FNA visits: £150 x 2 = £300
- Follow up visit: £90 x 3 = £270
- Full completion of the Diary card: £30

The sum reimbursed is based on the number of visits you attend. If you choose to withdraw part-way through the study, we will calculate your reimbursement based on the visits you have attended. The reimbursement for a volunteer who completes all the study visits is £820.

Payments are made directly by bank transfer in instalments during the study. For this reason, we require participants to provide their bank details at the screening. 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 (see below).

If we ask you to attend any additional (unscheduled) visit, you would be reimbursed for this at the rate appropriate for the type of visit.

What happens if I don't want to carry on with the study?

At any time during the study, you are entirely free to change your mind about taking part, and to withdraw from the study. This would not result in any penalty. Unless you state otherwise, any blood taken whilst you have been in the study would continue to be stored and used for research, as detailed below. You may request that your blood samples are destroyed at any time during or after the study. For safety, if you withdraw, we may still ask to follow up any medical problems you might have experienced whilst in the study.

In exceptional circumstances, your participation in the study might also be stopped early by the study doctor or the sponsor of the study.

What will happen to any samples I give during the study?

Your samples will be assigned a code and will only be identifiable by this code number. The tissue, and blood samples collected during this study will be analysed in the University of Oxford research laboratories. We may also send de-identified samples to other researchers working with us on this research project. This may include researchers in other countries, including outside of the European Union. All samples you provide will be tested in a de-identified form. However, as your DNA is unique, samples can never be completely anonymous.

If you choose to take part in this study, we will be asking for your separate permission to store your samples that remain after the study is over (including cells and DNA), in a collection of samples called the Oxford Vaccine Centre Biobank. Details of this will be provided in a separate booklet after you are enrolled into this study, and you are free to decline the Biobank and continue to take part in this study if you wish. If you consent to your samples being stored as part of the Biobank, a copy of your informed consent form for the Biobank (which contains your personal information) will be kept, in the same way as your consent form for the study. If you do not wish for your samples to be stored in the Biobank, they will be destroyed 12 months after the end of the study.

The following tests will be performed on your blood samples:

- Blood tests for blood cell counts and liver and kidney function.
- Blood tests for Hepatitis B, Hepatitis C and HIV (at the screening visit).
- A blood test for glucose (at the screening visit).
- A blood test for HLA typing, a genetic test of components of the body's immune system.
- Tests of immune responses following study injections (vaccination) looking at your antibodies and immune cells.
- If you opt in, bloods samples in this study will be stored in the Oxford Vaccine Centre Biobank and may be used in future vaccine research studies.
- If you opt in, blood samples taken in this study may be used for research involving the creation of specific antibodies called 'monoclonal antibodies.'

Detailed immunological tests will be performed on your lymph node samples. These will include RNA sequencing analyses, which show which proteins the cells are making and indicate the activity of the cell's genes.

Will any genetic tests be done?

We will do genetic tests on your blood and lymph node samples to look at the patterns of genes that regulate your own individual immune response. This will help us to work out which aspects of the immune response to vaccines are due to genetic differences between individuals. We will also try to identify and study the genes that appear to be important in your immune response to the study injections (vaccination). Other genetic tests may be done if you consent to your samples being stored in the Biobank (as described in more detail in the Biobank leaflet). You will not receive the results of any genetic tests performed.

What if something goes wrong?

The investigators recognise the important contribution that volunteers make to medical research and make every effort to ensure your safety and well-being. The University of Oxford, as the 'research sponsor', has arrangements in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this study.

In the event of harm being suffered, 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 action and refer you to a doctor within the NHS for

treatment, if necessary. If you are referred to the NHS during the study, then NHS indemnity operates in respect of the clinical treatment which may be provided.

Complaints statement

If you wish to complain about any aspect of the way in which you have been approached or treated during the course of this study, you should contact the research investigators at info@ovg.ox.ac.uk or 01865 611400. Alternatively, you may contact the sponsor organisation of this study (University of Oxford) at the Research Governance, Ethics and Assurance (RGEA) team office on 01865 616480 or email rgea.complaints@admin.ox.ac.uk.

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 form and letters sent to your own GP. 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. 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?

United Kingdom data protection regulation 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 'data controller' and is responsible for looking after your information and using it properly. 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. 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 who may monitor/audit the data collection process, and inspectors from the regulatory agencies. The database servers are held by the sponsor. We will keep identifiable information about you such as contact details for a minimum of 5 years after the study has finished. The need to store this information for longer will be subject to ongoing review. De-identified research data will be stored indefinitely.

A photocopy of your ID (driver's licence, passport or national ID card) and either your national insurance or passport number for TOPS database registration (see below) and payment processing will be taken at the screening visit. We will securely retain copies until the end of the study. Your bank details will be stored for a minimum of 7 years in line with financial requirements. If you only complete online screening or telephone screening (before informed consent) your data will only be kept to the end of the trial.

At the completion of the study, unless you consent otherwise (*e.g.,* if you request to be informed of other trials), your personal details will not be used to contact you other than in exceptional circumstances concerning your safety. If you agree to future contact, your details will be held separately from the study data and you can request at any time to have your details removed.

UK data protection regulation 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 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

TOPS database registration

Volunteers participating in this study must not be enrolled in another study that involves receiving investigational medications or vaccines at the same time. To check this, you will be asked to provide your national insurance or passport number. This will be entered on to a national database which helps prevent volunteers from taking part in too many clinical trials. More information can be found at *www.tops.org.uk*.

What will happen to the results of the research 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 2 years after the study is completed. Your individual results would not be identifiable, nor would you be identified in any report or publication. If you contact the researchers in the future, you can obtain a copy of the results.

The de-identified research data from this study will be shared with the collaborating partners who are organising and funding this research work. Data from this study may be used to file patents or licence vaccines in the future or make profits in other ways. You would not be paid for any part of this. Data from this study may be used as part of a student post-graduate degree, for example a MD or PhD.

Who has reviewed the study?

This research has been checked by an independent group, the Research Ethics Committee, who protect participants' interests. This study has been reviewed and approved by North East – Newcastle & North Tyneside 2 Research Ethics Committee.

Further information and contact details

We hope this information sheet has given you enough information to decide whether to volunteer for this study. If you would like further information about participating in research, please visit the following website: http://www.nhs.uk/conditions/Clinical-trials/Pages/Introduction.aspx

For independent advice about participating in this study, you may wish to contact your GP.

If you are interested in taking part in this study, then please complete the online pre-screening questionnaire at: https://trials.ovg.ox.ac.uk/trials/legacy03

If you have further questions about the study that you would like to discuss with our team, please contact us at:

Email: info@ovg.ox.ac.uk

Tel: 01865 611400

Thank you for your interest in taking part in this study.