Oxford Vaccine Group
University of Oxford
Centre for Clinical Vaccinology and Tropical Medicine,
Churchill Hospital, Headington, Oxford OX3 7LE
Telephone: 01865 611400 info@ovg.ox.ac.uk www.ovg.ox.ac.uk

PARTICIPANT INFORMATION SHEET:

Evaluating COVID-19 Vaccine Boosters (COV-BOOST)

Summary of Major Changes to COV-BOOST patient information sheet (to be used as a front sheet for the revised main patient information sheet Version 5.0, 13th December 2021)

Thank you for taking part in the COV-BOOST trial.

This page provides a summary of the main changes to the trial. For further information please see page 2 onwards.

- The final follow up visit for the trial was previously scheduled to be one year after participants received a vaccination on the study in June 2021. Given the need to generate data on the immune response to booster vaccination following the emergence of the omicron variant, this final currently planned follow up visit will be brought forwards to approximately 8 months after vaccination and will be held in February or March 2022. This will allow data to inform JCVI decision making and planning in spring and early summer 2022.

- Participants that received Valneva vaccine or CureVac vaccine will only need to be contacted by telephone for the 8 month follow up visit. If you received one of these vaccines you will not have to travel to your local site for this visit. If this applies to you, as there is no blood test or travel required for the telephone call, you will be reimbursed £20 for your time, rather than the £45 that participants attending their study site receive for their time, travel and the inconvenience of having blood tests.

- Now that all participants have been unblinded it will no longer be necessary for you to attend a visit at your study site if you have a positive, laboratory confirmed test for COVID-19. We would however like you to continue informing your trial team if you have a positive test.

PARTICIPANT INFORMATION SHEET:

Evaluating COVID-19 Vaccine Boosters (COV-BOOST)

We are recruiting people who received their first COVID-19 vaccination in December 2020, January or February 2021. Please register your interest if you would like to take part!

Contents

Participation could really make a difference during a public health emergency.

Have you had both doses of a COVID-19 vaccine? Did you have the second one more than 12 weeks (84 days) ago? Thank you for reading this, your help, whatever your final decision, is very much valued. We would like to invite you to take part in our study, Evaluating COVID-19 Vaccine Boosters (COV-BOOST). Before you make any decision, it is important you take the time to understand why we are doing this research and what it would involve. Please read the following information carefully and consider discussing it with friends, relatives or others as you wish.

Summary of the first part of the trial which recruited people during June 2021.

In the first part of the trial we studied using 7 different COVID-19 vaccines as a booster dose, plus 3 of these vaccines used at a half of a standard dose, compared to a control group. People in the control group received a vaccine against the meningococcal bacterial infection which causes meningitis and sepsis (Men ACWY) which is commonly used for teenagers. There were 2883 participants in total.

The study is being run in 3 different groups (A-C). Participants in each group will either receive one of 2 different COVID-19 booster vaccines or the Men ACWY vaccine (except Group B who will receive one of 3 different COVID-19 booster vaccines or the men ACWY vaccine). Some people in each group will receive one half of a standard dose of one of the vaccines.

As new SARS-CoV-2 vaccines become available, more vaccines may be included in the trial and so the total number of participants may increase (these will be in later stages of the trial).

- Within each group, participants will be allocated, at random, (rather like a flip of a coin) to receive a single dose of one of the COVID-19 booster vaccines or the control vaccine (MenACWY).
- Four of the booster vaccines are currently approved by the MHRA for NHS use to prevent COVID-19 when used as a 2 dose regimen, 1 is under review for approval by the MHRA, 1 is still in clinical trials but may be available in the UK in 2022 if approved by the MHRA and 1 (CureVac) is no longer in development.
- Between 4 and 6 routine blood tests will be taken over the course of a year to look at the immune responses to the vaccine depending on the group you are in. You may also be asked for a nasal fluid sample and a saliva sample at each visit. You might also be asked to attend for a repeat blood test at a prearranged time that suits you if there were any safety concerns.
- Participants will need to complete an online diary for up to 28 days following vaccination. You will be provided with a diary card (electronic, but for those who are unable to use electronic diary cards, a paper version will be made available), with instructions on use.
- The trial will take one year to complete per participant (from the time the first dose of booster vaccine is given).
- We would not be offering diagnostic COVID-19 testing as part of this trial, but it is important that participants in this trial access COVID-19 testing outside of the trial following normal government guidance.

- You would not know which vaccine you had received until the end of the trial. If you become eligible for a booster vaccination via the NHS during the course of the trial, we can find out whether you received a COVID-19 vaccine or the control vaccine (MenACWY). If you had not received a COVID-19 vaccine and you are eligible for one during any future NHS deployment, we will ensure you are able to receive one.

Summary of the trial change in October 2021 – boosters for stage 1 control cohort participants

Participants who were in the control group (received MenACWY) were invited to attend a visit to have additional immunology and safety bloods taken and be randomised to receive an active COVID-19 vaccine (either a full dose or half dose of the Pfizer vaccine, or a half dose of the Moderna vaccine). They were then asked to attend a subsequent visit 14 and 28 days later for follow up immunology bloods to check their immune response, with further safety bloods at day 28.

What is the purpose of this research trial?

There are now a number of vaccines that have been approved in the UK to prevent COVID-19 and other vaccines that are still in UK clinical trials, which may be approved later in the year. Millions of people have now received their first 2 vaccinations, which we call a "prime-boost" course. There were 2 vaccines used by the NHS to deliver an initial prime-boost during the first part of the NHS immunisation campaign: ChAdOx1-nCov19 (commonly known as the "Oxford vaccine" or 'AstraZeneca Vaccine'), and BNT162b2 (commonly known as the "Pfizer vaccine").

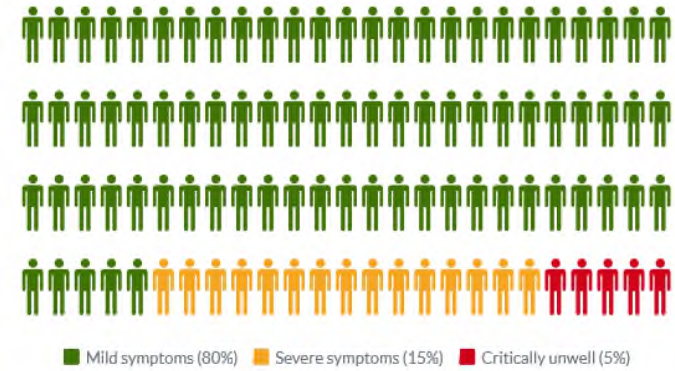
Whilst these have been shown to be highly effective at preventing severe disease due to COVID-19, we don't know how long the immune protection from vaccination will last. In addition, variants of the virus which causes COVID-19 (SARS-CoV-2) have emerged with mutations which might make the immune response from vaccination less effective. It is therefore likely that additional, "booster" vaccinations might be needed for high risk groups after a period of time to provide added protection. This study is trying to find out which vaccines against COVID-19 are effective and safe as a booster vaccination, depending on which vaccine was used to provide the initial prime-boost course. The study will also help to determine whether half doses of some COVID-19 vaccines are sufficient to increase immunity when given as a 3rd dose booster. Being able to give people a half dose means that health services would be able to vaccinate twice as many people with the same amount of vaccine available, so this is another important question. We will be enrolling men and women 30 years old or over who received their initial prime-boost course of vaccination against COVID-19 in December 2020, January or February 2021.

What are the vaccines against?

These vaccines are against the new coronavirus SARS-CoV2 that causes the disease COVID-19.

Common symptoms of COVID-19 include fever, tiredness, dry cough, and changes to taste and smell. Whilst about 80% of infected people have no or mild symptoms and will recover

from the infection without needing special treatment, approximately 10-15% of cases (2-3 in 20) progress to develop severe symptoms, and about 5% (1 in 20) become critically ill.



There are some treatments that have been shown to be effective in reducing the severity of disease and the risk of death; but at present there is no cure. Older people and those with underlying medical conditions are more likely to develop serious illness. It has also been seen that people of some ethnic groups (Black and Asian) might be at a greater risk of severe illness. More than 2.5 million people globally have died from COVID-19 so far. Some people also have symptoms that last a long time after they have recovered (commonly referred to as "long-COVID"). This is why effective vaccines are so important.

What vaccines are being used in this trial?

The twelve vaccines / doses received in the study are shown below.

ChadOx1 nCoV-19 (AstraZeneca/Oxford)
BNT162b2 (Pfizer/BioNTech)
BNT162b2 (Pfizer/BioNTech) Half dose
mRNA-1273 (Moderna)
mRNA-1273 (Moderna) Half dose
NVX–CoV2373 (Novavax)
NVX–CoV2373 (Novavax) Half dose
VLA2001 (Valneva)
VLA2001 (Valneva) Half dose
CVnCoV (Curevac)
Ad26.COV2.S (Janssen)
MenACWY (Control vaccine)

ChAdOx nCoV-19 (AstraZeneca/Oxford): Common use under emergency provision

This is the vaccine that is commonly known as the "Oxford vaccine". It has been tested in more than 20,000 people worldwide as part of the COVID-19 vaccine trials, and millions of members of the public have also been vaccinated. It has been found to be both safe, and effective in preventing COVID-19.

ChAdOx1 nCoV-19 is made from a virus (ChAdOx1), which is a weakened version of a common cold virus (adenovirus). This has been genetically changed so that it is impossible for it to grow in humans. Added to this virus are genes that make proteins from the COVID-19 virus (SARS-CoV-2) called Spike glycoprotein (S), which play an essential role in SARS-CoV-2 infection. By vaccinating with ChAdOx1 nCoV-19, the body recognises and develops an immune response to the Spike protein that helps stop SARS-CoV-2infections.

BNT162b2 (Pfizer/BioNTech): Common use under emergency provision

This is the vaccine commonly known as 'The Pfizer vaccine.' This is a messenger RNA (mRNA) vaccine. This vaccine uses a small amount of the genetic coding material (mRNA) of the SARS-CoV-2 spike (S) protein packaged inside very small fatty particles (lipid nanoparticles). When these are injected into your body, your cells take up these fatty particles, and then start producing the SARS-CoV-2 spike protein. Your immune system then "sees" these spike proteins and makes a protective immune reaction against them. The original mRNA that has been taken into your cells is broken down within a few days and cannot be incorporated into your own genetic code.

This vaccine has been tested in more than 40,000 people worldwide and subsequently given to tens of millions of people, and has been shown to be both safe, and effective.

mRNA-1273 (Moderna): Common use under emergency provision

This is the vaccine commonly known as "The Moderna vaccine". This is also a messenger RNA (mRNA) vaccine which works in a similar way to BNT162b2 (The Pfizer vaccine).

This vaccine has been tested in more than 30,000 people worldwide and subsequently given to tens of millions of people, has been shown to be both safe, and effective.

NVX–CoV2373 (Novavax): Being assessed by regulators for use under emergency provision

This is the vaccine commonly known as "The Novavax vaccine". This is a protein vaccine, which contains a slightly modified version of the SARS-CoV-2 spike protein, alongside an adjuvant called "Matrix M1", which helps the body to produce a stronger immune response.

This vaccine has been tested in more than 20,000 people worldwide and has been shown to be both safe, and effective.

VLA2001 (Valneva): Undergoing phase III clinical trials

This vaccine contains a killed version of the SARS-CoV-2 virus which causes COVID-19 disease. In addition, it contains an adjuvant called CpG 1018 which helps the body to produce a stronger immune response to the vaccine. When the body sees the killed version of the SARS-CoV-2 virus, it produces antibodies against it which prepare the body for when it encounters a live version of the virus in the future.

The Valneva vaccine produced strong immune responses in a phase I study of more than 150 healthy volunteers, and is currently being tested in a large, phase III study involving 4000 participants.

CVnCoV (Curevac): No longer in development

This vaccine is an mRNA vaccine much like the Pfizer and Moderna vaccine. It works in a similar way be delivering short lasting genetic material which enables the body to make the spike protein and develop a protective immune response against it.

This vaccine produced a strong immune response to more than 250 volunteers in a phase I trial and currently a phase 2/3 study is enrolling up to 35,000 participants.

Ad26COV2.S (Janssen): Approved for common use under emergency provision

This is the vaccine that is commonly known as the "Janssen Vaccine", or in the USA as the "Johnson and Johnson Vaccine". This vaccine is an adenovirus vector vaccine much like the Oxford/AstraZeneca vaccine. It contains an adenovirus which has been modified so that it cannot replicate or cause infection in humans, and contains the genetic material for the S glycoprotein found on the outside of the SARS-COV-2 virus. Like the other vaccines, once the body has been exposed to this protein it is able to develop an immune response against it which helps protect the body from infection.

This vaccine has been trialled in over 60,000 people and administered to over 7 million people in the USA and been found to be both safe and effective in protecting against COVID-19.

Men ACWY: Common use with full regulatory approval

This is a vaccine against the meningococcus bacteria which causes meningitis and sepsis. It is a licensed vaccine which is currently delivered to teenagers as part of the routine UK immunisation schedule. It has been used for many years and has been proven to be a highly safe and effective vaccine against meningococcal infection.

None of these vaccines contains a live version of the SARS-CoV-2 coronavirus and therefore cannot give you COVID-19. The potential side effects of these vaccines are discussed in more detail in the section 'What are the risks of taking part in this trial'.

Do I have to take part?

No. It is up to you to decide whether or not to take part. If you do decide to take part, you will be given this information sheet to keep (or be sent it electronically) and will be asked to sign a consent form. You are free to withdraw at any time and without giving a reason, but you may be asked to come for an extra visit for a follow up appointment for safety reasons.

Am I suitable to take part?

Adults that are aged 30 years and over who received their first dose of COVID-19 vaccination in either December 2020, January or February 2021 and who are 84 days post second vaccination are able to take part. Due to the NHS deployment timelines, some sites may need to invite people who have been prime-boosted with their second dose of Oxford/AstraZeneca vaccine with a minimum of 70 days from their second dose. In order to be enrolled in the trial:

- You must be willing to tell the trial staff about your medical history, and you may be asked to allow the trial staff to check this with your General Practitioner (GP). Bear in mind that we would also notify your GP if you joined the trial (even if we did not need to check your medical history with them in advance).
- If you are able to become pregnant you must be willing to practice continuous effective contraception during the first 3 months of the trial and have negative pregnancy tests on the days of vaccination
- You must agree not to donate blood during the trial

You cannot take part in this trial if you:

- Are not at least 84 days post your second COVID-19 vaccine (as above, some sites may allow participants who are 70 days post second dose of the Oxford/AstraZeneca vaccine).
- Have participated in another research trial involving an investigational product in the past 12 weeks. This does not exclude participants in trials of AZD1222 (ChAdOx1 nCOV-19) who were originally recipients of the control vaccine and who received AZD1222 (ChAdOx1 nCOV-19) or BNT162b2 as part of the "national schedule" with AZD1222 (ChAdOx1 nCOV-19) or BNT162b2 dose 1 from mid-Dec 20 through end February 21 and then AZD1222 (ChAdOx1 nCOV-19) or BNT162b2 second dose 12 twelve weeks later (this is allowed by the COV001 and COV002 protocols)
- Have any vaccine (licensed or investigational) in the 30 days before or after this trial vaccine. The exceptions to this are the seasonal influenza vaccine and the pneumococcal vaccine (known as Pneumovax, which is routinely given to over 65-year olds). If you are offered these by your GP or your place of work, we ask that you have these at least 7 days before or after you receive either of the two trial vaccine doses.
- Have received a transfusion of any blood products, or immunoglobulins (antibodies) in the 3 months before having the trial vaccine
- Have immunosuppression or immunodeficiency – this includes being on medications that reduce the immune system such as methotrexate and steroid tablets
- Have ever had a severe allergic reaction (anaphylaxis)
- Have an allergy to any of the component of the COVID vaccines used in this study, including polyethylene glycol/macrogol (PEG). PEGs are a group of known allergens commonly found in medicines, many household products and cosmetics, and are contained in the BNT162b2 (Pfizer/BioNTech) vaccine. Known allergy to PEG is very rare.
- Are pregnant, or intend to become pregnant during the first 3 months of the trial
- Have a current diagnosis of, or are having treatment for, cancer. Exceptions to this are certain skin cancers and pre-cancer of the cervix.
- Have a bleeding disorder
- Continuously take medicines that reduce your blood clotting, such as coumarins and related anticoagulants (i.e. warfarin) or novel oral anticoagulants (i.e. apixaban, rivaroxaban, dabigatran and edoxaban)
- Have a history of serious blood clots known as "cerebral venous sinus thrombosis" or a history of blood clotting disorders accompanied by low platelets.
- Have current alcohol or drug dependency
- Have severe and/or uncontrolled cardiovascular disease, respiratory disease, gastrointestinal disease, liver disease, renal disease, endocrine disorder or neurological illness
- History of active or previous auto-immune neurological disorders (e.g. multiple sclerosis, Guillain-Barre syndrome, transverse myelitis). Bell's palsy will not be an exclusion criterion

To assess if you are eligible to be involved in the trial you can complete the online eligibility questionnaire as described below.

What will happen if I decide to take part?

Online questionnaire – *5-20 minutes*

If you decide you would like to participate in this trial there is a two-part online questionnaire to check initial eligibility.

Part-One

The first part broadly checks whether you can or cannot take part in the trial. The information you provide will not be stored unless you progress to part two.

Part-Two

If you are found to be eligible on completing the first part, you will be asked to give your consent to:

- Provide us with details of your medical history and allow us to store this information. Some participants will be advised they are unable to take part on the basis of this additional information
- Have a researcher contact you by phone to clarify the medical information given (if needed)
- Provide details of your registered GP, and consent for the trial team to contact them if needed
- Provide us with information about yourself such as your date of birth and address

If you do not consent to these things, then you would not be able to join the trial. If you consent and the second part of the questionnaire does not identify any obvious reason why you should not participate, we will review the information you provide, and a trial doctor or nurse may telephone you to go through this in more detail if required.

If, after this process, you are eligible to join the trial, you will be invited to an in-person screening and vaccination visit.

IMPORTANT: If you develop a fever or cough, or loss of sense of smell or taste, or become unwell then you must contact the study team on 01865 611400 for advice before attending any visit.

Please note that it may not be possible to enrol everybody that wishes to take part in the trial and passing through the screening process does not guarantee participation in the trial. In the case that you are not enrolled in the trial, your data would not be stored beyond the end of the trial.

What should I do if I am offered an NHS booster vaccination during the study?

Now that data is available and the data safety monitoring committee have made a decision on which vaccines provided an appropriate immune response, participants will be informed about which vaccine they received and whether further vaccination is required at this stage or after further data safety monitoring committee meetings when new data become available. If you become eligible to receive a booster vaccination from the NHS please follow the advice provided by your study team. If you are not sure what to do please contact your study team who can provide further information.

Enrolment on the Study

Screening and vaccination visit - *1.5 hours (review of medical history, vital signs, blood test, receive vaccine, up to 30 minute observation in clinic after the vaccine)*

Screening component

If you qualify to be in the trial, we will ask you to attend on the vaccination day (Day 0). We will outline the nature of the trial either through a video presentation or in person, and this will explain what to expect by taking part, the risks involved and what side-effects you might expect to experience. There will be an opportunity to ask any questions you may have about the trial, and if you decide to take part we will ask you to sign a consent form.

There may be additional stages of the trial added at a later time point if more vaccines become available. As long as no new information that would affect your involvement in the trial comes to light, we will not ask for you to consent again when these additional stages are added.

If you sign the consent form a member of the medical team would check details of your medical history, and may perform a physical examination; which could involve listening to your heart and lungs with a stethoscope, examining your abdomen as well as feeling for lymph nodes around your neck and in your armpits.

We will measure and record your:

- Height
- Weight
- Temperature
- Blood pressure
- Pulse rate
- Respiratory rate
- Non-invasive blood oxygen level (saturations)
- Pregnancy test (women only)

Blood samples will be taken just before vaccination to check later for:

- Your baseline antibody test before any booster vaccine
- Whether you are anaemic or have any other blood, kidney or liver abnormalities. Sometimes these blood tests need to be repeated, and we would ask you to come for an extra visit to have these taken. It is possible that these tests could reveal unexpected findings which might be of significance to your health. If that is the case, or if the results indicate that it would not be safe to carry on in the trial we would let

you know this. Additionally, regardless of whether you continue in the trial, we may ask for you permission to contact your GP or a specialist so that any further required treatment or investigation can be organised.

We would also (in some participants) ask to take a nasal fluid sample which are is to look at immune responses in the lining of the airways. This is not a test which would have clinically interpretable results; thus you would not be given these results.

Vaccination

Once your eligibility and consent are re-confirmed, you will be randomly allocated to receive one of 7 COVID-19 vaccines, or the control (Men ACWY) vaccine. You will not be told which specific vaccines you are going to receive, or whether you are in one of the groups receiving a half dose. You will only be told this at the end of the trial. The only exception to this would be if you were to become eligible for a booster vaccine on the NHS and we had to find out whether you received the control vaccine, or if you were to become ill and it was felt to be medically necessary for you to know which vaccines you had received.

We will give you an injection with the vaccine into your arm. We will need to keep an eye on you for 15 – 30 minutes after the vaccine has been administered.

<u>Follow-up after vaccination</u>

Electronic Symptom Diary "e-diary" *– Completed at home*

We will give you a thermometer, tape measure and an "e-diary" account to record all your symptoms, your temperature and your vaccination site every day for 7 days after vaccination.

After these 7 days, and for the next 3 weeks, we will ask you to record if you feel unwell or if you take any new medications. The research staff will monitor the e-diary and may telephone you to ask for more information.

You will also be asked to record in the diary any medical conditions for which you see a doctor/dentist until three months after your vaccine, and any serious medical illnesses or hospital visits you may have over the course of the trial.

Follow-up visits – 30 minutes (vital signs, blood tests, nasal fluid test and saliva test (for some participants) and check for side effects or new health problems)

Following vaccination, we will ask you to attend a series of short follow-up visits to ensure everything is fine, to check your symptoms and to have blood tests done as well as nasal fluid tests and saliva tests for some participants.

Note: due to the high number of planned volunteers in this trial, visits may take longer than the estimates given here

Participants who were in the control group (received MenACWY) will be invited to attend additional visits. Participants in the general cohort will attend a visit to have additional immunology and safety bloods taken and be randomised to receive an active COVID-19 vaccine (either a full dose or half dose of the Pfizer vaccine, or a half dose of the Moderna

vaccine). They will then attend a subsequent visit 14 and 28 days later for follow up immunology bloods to check their immune response, with further safety bloods at day 28.

Participants in the Immunology cohort will do the same, but will also be asked to collect samples from their nose and provide a sample of saliva at the vaccination visit and 28 days later, similar to previous visits. All unblinded control participants will also have an additional blood test at day 0 and 14 to test for a blood protein called "Troponin", which can be used to indicate inflammation in or around the heart. This will be measured before and after immunisation to learn about whether levels are affected by vaccination.

Pregnancy will not be an exclusion from vaccination at these visits, as the vaccines being administered are all in current use for pregnant women in the general population without safety concerns.

Participants in the active vaccine groups will be informed of their active vaccine but not which vaccine was received until the end of the study. If the independent data review committee recommends that any vaccines have not provided an adequate boost then everyone in that group (or groups) will receive further information that they should receive an NHS 3rd dose booster and that they may continue in the trial for safety monitoring (a specific new approved letter will be produced in the event of this situation arising).

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

In the unlikely event of you having a problem with your arm where the vaccination was given, we might ask to photograph your arm. Consent for this is included when you are enrolled to the study. You would not be identifiable in these photographs, as only the vaccination site and your unique trial number would be visible. These photographs could be shown to other professional staff, used for educational purposes, or included in a scientific publication.

How many visits will I have to attend?

The number of visits you attend will be the same regardless which vaccines you are randomly assigned to. However, each vaccine group will also have an 'immunology' cohort who will have some extra visits and blood tests and nasal fluid and saliva tests; enrolment to this cohort is limited to the first 25 participants from each vaccine group. The purpose of this will be to better understand the response of the immune system to the vaccine. Participants who are not in the 'immunology' cohort will be in the 'general' cohort. If you are in the general cohort, you will have 4 visits, whilst if you are in the immunology cohort you will have 6 visits.

All participants will have the following visits:

General cohort (Regular frequency sampling cohort)

The table below represents the visit schedule for participants in the general cohort:

Visit schedule for participants in the general cohort				
Trial timeline	**Day 0**	**Day 28**	**Day 84**	**Day 242**
Vaccination	Yes			
Blood tests	Yes	Yes	Yes	Yes
Nasal fluid test &/or Saliva test	No	No	No	No

Immunology cohort (More frequent sampling cohort)

The table below represents the visit schedule for participants in the immunology cohort:

Visit schedule for participants in the immunology cohort						
Trial timeline	**Day 0**	**Day 7**	**Day 14**	**Day 28**	**Day 84**	**Day 242**
Vaccination	Yes					
Blood tests	Yes	Yes	Yes	Yes	Yes	Yes
Nasal fluid test	Yes	No	No	Yes	No	Yes
Saliva test	Yes	No	No	Yes	No	Yes

Participants that originally received MEN ACWY will attend the following additional visits:

Trial timeline	Booster Visit	14 Days Post Booster Visit	28 Days Post Booster Visit
Vaccination	Yes		
Blood tests	Yes	Yes	Yes
Nasal fluid test*	Yes	No	Yes
Saliva test *	Yes	No	Yes

**Only participants in the immunology cohort will have nasal fluid and saliva tests.*

Should you be unable to attend a scheduled visit (for example because you are self-isolating or quarantining), then a researcher might do this visit over the phone with you instead (as long as it was on the correct schedule).

Also, regardless of which group or cohort you are in, if you were to test positive for COVID-19 outside of the trial, we would ask you to inform us of this. You would need to follow current government guidance for people with positive COVID-19 tests.

What things should I consider before taking part in this study?

If you are of female sex and able to have children, you must be willing to practise continuous effective contraception during the first 3 months of the trial; methods of effective contraception are listed in the eligibility questionnaire.

Blood Donation

Under current UK regulations, participants will not be able to donate blood during the course of the trial.

Private Insurance

If you have private medical or travel insurance you are advised to contact your insurance company before participating in this trial, as involvement may affect the cover provided.

Are there things I will be asked to avoid doing during the trial?

You should not donate blood during the trial or take part in other studies that involve blood sampling or the administration of drugs or vaccines, including trials testing other preventive interventions for COVID-19.

If during the trial you require any other vaccinations for health, travel, or occupational reasons, you should inform the trial team beforehand. We will discuss with you the most appropriate time to receive them.

What are the risks of taking part in this trial?

The risks and side effects of the proposed vaccinations and trial procedures are detailed here:

Blood samples

Drawing blood may cause slight pain and occasionally bruising at the site where the needle enters. Some people feel light-headed or even faint when having blood taken. During the course of the trial we will need to take between 20ml and 67ml of blood at a single visit. The total amount we will take over the period of the trial will be (approximately) 174ml if you are in the general cohort, or (approximately) 311ml if you are in the immunology cohort. An additional 27-67ml would be taken at the COVID-19 pathway visit if you were to develop confirmed COVID-19 during the study, and up to an additional 164ml if you were in the control arm immunology cohort attending for a booster vaccination after being unblinded. If repeat bloods are requested for safety reasons at a visit this will be up to 7ml. These amounts over the course of the year, should be below the limit of 470mL every 3 – 4 months for blood donations to the National Blood Transfusion Service.

If abnormal results or undiagnosed conditions are found during the course of the trial these will be discussed with you and, if you agree, your GP (or a hospital specialist, if more appropriate) will be informed. Any newly diagnosed conditions will be looked after within the NHS. Participants will not be informed of the results of their levels of post-vaccine immunity against the COVID-19 virus as these are not clinically validated tests.

Nasal fluid samples

This will involve insertion of a small bit of soft synthetic material about 2cm into your nostril and leaving it in there, pressed up against the inside of your nose for about one minute. This can cause some eye-watering but should not cause any damage to your nostrils. Some people might have more sensitive nostril linings and this might rarely cause a small amount of bleeding.

Saliva samples

We aim to collect 1-1.5mls saliva using a funnel and collection tube. Participants may find the saliva collection process unsavoury as it is involves drooling and spitting into a collection device. We would ask participants who are giving saliva samples not to eat, drink, smoke, chew gum, brush their teeth or use mouthwash for at least 30 minutes prior to their appointment.

Vaccination Side Effects

Common side effects

People very often have tenderness, pain, warmth, redness, itching, swelling or bruising or less commonly have a small lump in their arm where they have been vaccinated.

Other common systemic side effects

Some people can develop these symptoms after vaccination. They usually last for less than a week after you are vaccinated (more commonly 24-48 hours afterwards).

- Fatigue
- Headaches
- Flu-like symptoms, such as high temperature, sore throat, runny nose, cough and chills
- Muscle aches
- Joint aches
- Feeling unwell (malaise)
- Feeling sick or nauseated or vomiting

Other less common side effects:

- Abdominal pain
- Decreased appetite
- Feeling dizzy
- Swollen lymph nodes (glands)
- Excessive sweating, itching skin or rash

These symptoms can be reduced by use of paracetamol around the time of immunisation and over the next 24 hours. We would not routinely recommend the use of ibuprofen or other anti-inflammatory medication at this time.

After immunisation with the BNT162b2 (Pfizer/BioNTech) vaccine, difficulty sleeping has been observed in fewer than 1 in 100 people, and weakness of the muscles on one side of the face has been observed in fewer than 1 in 1000 people.

Data from studies comparing mixed prime-boost regimes of COVID-19 vaccination (e.g. Oxford/AstraZeneca followed by Pfizer) have found this may increase the risk of side effects following the second vaccine. It is possible that by receiving a COVID-19 booster vaccine in this study which is different to your original prime-boost regime, this might increase the side effects following vaccination.

Serious Reactions

With any vaccination there is a small risk of rare serious adverse events, such as an allergic reaction. These may be related to the immune system or to the nervous system. Severe allergic reactions to vaccines (anaphylaxis) are rare (approximately 1 per million vaccine doses) but can be fatal. In case of this unlikely event, medication for treating allergic reactions is available and the researchers are appropriately trained in the management of anaphylaxis.

These are new vaccines, and there may be side effects that we are not yet aware of. Further information about vaccine safety is being actively gathered as the vaccines are being used in the UK and globally. You will be informed of any significant change in the vaccine safety profile.

You will be provided with a 24h trial mobile number. If you experience unexpected events or become in any way concerned you can use this to contact one of the trial doctors at any time. We will ask you to record these symptoms in the e-diary too.

Recently there have been reports of a very rare condition involving blood clots and unusual bleeding after vaccination. This is being carefully reviewed but the risk factors for this condition are not yet clear. Although this condition remains extremely rare there appears to be a higher risk in people shortly after the first dose of the AstraZeneca (AZ) or Janssen

vaccine. Around 4 people develop this condition for every million doses of AZ vaccine doses given. This is seen slightly more often in younger people and tends to occur between 4 days and 2 weeks following vaccination. This condition can also occur naturally, and clotting problems are a common complication of COVID-19 infection. An increased risk has not yet been seen after other COVID-19 vaccines but is being carefully monitored. We do not know whether the risk of clots following vaccination with the Oxford/AstraZeneca or Janssen vaccine will be affected by receiving a first dose after already having had 2 doses of a different COVID-19 vaccine. As the risk of these clots may be higher in younger people, we are not enrolling adults aged under 30 years in this study. Following discussion with the MHRA and JCVI, research studies (including Cov-Boost) are continuing to give the Janssen and Oxford/AstraZeneca vaccines to people aged between 30 and 40 years. As a trial participant you have 24 hour access to the study team in case of medical emergency. The study team will explain to you the symptoms that you should look out for.

Although serious side effects are very rare, if you experience any of the following from around 4 days to 4 weeks after vaccination you should seek medical advice urgently:

- a new, severe headache which is not helped by usual painkillers or is getting worse
- a headache which seems worse when lying down or bending over
- an unusual headache that may be accompanied by:
    - blurred vision, nausea and vomiting
    - difficulty with your speech
    - weakness, drowsiness or seizures
- new, unexplained pinprick bruising or bleeding
  shortness of breath, chest pain, leg swelling or persistent abdominal pain

Theoretical risks - Could immunisation make COVID-19 disease worse?

In the past, experimental vaccines were developed by different research groups against the SARS virus, which is in the same family as the COVID-19 virus and also infects the lungs. In some cases, animals that received certain types of experimental SARS vaccines appeared to develop *more severe* lung inflammation when they were later infected with SARS compared with unvaccinated animals. There has also been one report of this increased disease-associated inflammation being seen in a mouse study for a vaccine against MERS-CoV (another related virus), but this has not been observed in any other reported animal studies, and has not been seen in any of the trials of the vaccines being used in this trial. Importantly, this has not been seen to date in any of the human studies of these vaccines.

Will I be protected against COVID-19 from having the vaccines in this trial?

If you participate in this trial we do not know the additional amount of protection you will receive. The vaccines in this trial have been shown to be protective against COVID-19 when given in the normal way, prior to any previous vaccination against SARS-CoV-2. We do not know whether having an additional dose of the same, or a different vaccine would give you additional protection against getting COVID-19, which is why we are doing this trial. This study will answer the question of whether giving an additional booster vaccine provides further protection; and if so, whether it matters which type of vaccine is given as a booster depending

on which type of vaccine was used for the original prime-boost vaccination course. The answers to these questions, which you would be helping us to provide, are really important for future UK and global vaccine use in populations. You will not know whether you have received a COVID-19 vaccine, or the control vaccine (Men ACWY). You should still continue to follow up-to-date national guidelines regarding social distancing and other coronavirus precautions as appropriate.

If you find out that the type of booster vaccine I receive does not give good protection against COVID-19, will you give me another vaccine?

This study is being overseen by an independent data safety monitoring board and a steering committee, who will evaluate part-way through the trial whether there are signs that any of the vaccine combinations are not giving a good enough immune response. If they were to find any sign that any of the different combinations of vaccine were significantly less effective than other combinations, the independent data safety committee could decide that people in specific groups should receive an NHS booster vaccine, if they are eligible to receive one.

What if I am eligible for routine immunisation against COVID-19, or become eligible whilst enrolled in the trial?

Participation in this trial means that, unless the trial team specifically advise otherwise, you will not need to receive an additional booster in any NHS deployment unless you are in the control group.

Following the announcement of an NHS booster vaccination campaign for COVID-19, we will contact participants to inform them of whether they received an active COVID-19 vaccine 3rd dose as part of the study, or whether they received the control vaccine (MenACWY).

Participants in the control group will be invited to attend additional visits to receive an active COVID-19 vaccine and attend additional visits as discussed in the section titled *Enrolment on the study.*

Participants who received an active vaccine will be informed which vaccine they received and whether any further booster doses are required at that stage.

What are the advantages of taking part?

We anticipate that participating in the trial will mean that you gain some additional protection against the coronavirus if you were to be randomised to receive one of the COVID-19 vaccines (but cannot guarantee this). This would not be the case for the control group who receive the MenACWY vaccine, however these participants will later be offered a COVID-19 booster once a national NHS booster campaign is announced, even if they would otherwise not be eligible via the NHS. It is possible that you could gain this protection sooner than you otherwise would have by waiting for booster vaccinations to be recommended by the NHS. Most importantly, the information gained from the trial will make a valuable contribution to the pandemic response.

What should you do if you believe you may have developed COVID-19 during the trial?

A common and expected side effect of COVID-19 vaccines is fever. If you develop fever in the first 48 hours post-vaccination only, you would not need to self-isolate unless you had other symptoms of COVID-19. If your fever continued (or you had another episode of fever)

after 48 hours then you would need to follow the current government advice. We would also ask you to record any fever that you have in your e-diary. If the fever didn't continue, then it is likely that it was a vaccine effect and you can carry on as normal.

Excluding the above, if you develop symptoms that meet the UK government COVID-19 testing criteria, then you must arrange an NHS test as soon as possible, following the normal routes. If this test is positive, you would need to follow government guidance regarding self-isolation as usual. We would also ask you to contact the trial team on 01865 611400. If you test positive on an alternative route such as via work or a commercial test then please let the trial team know as well. We may ask you to forward on your test result to us.

Now that all participants have been unblinded, if you have a positive test we will no longer invite you for a visit to our clinic which previously involved a review by a doctor, a blood test, and a nose and throat swab. If you have attended a visit because you tested positive previously, this swab would have looked for SARS-CoV-2 but would not be processed immediately – we will not inform you of the result as it would be a repeat of the positive result you already had. We may have to inform Public Health England of the results of this swab and convey to them details about you including your name as a legal public health requirement.

If you are unwell and unable to contact the trial team directly then contact the NHS 111 service or phone 999 if you are severely unwell.

If you are admitted to hospital during the trial then you should inform the medical or nursing staff that you are taking part in this trial. We will provide a contact card for you to give to these staff which will have a link to a website for them to fill in details about your admission. We would also like you to let us know (if you are able) that this has happened.

Do I get access to extra medical treatment from being in the trial?

It is important that you understand that if you do become seriously unwell and need to be admitted to hospital, the standard referral routes within the NHS will be used. Participants will be treated the same way as the general population in this context of the COVID-19 pandemic. We are unable to offer extra medical support outside what is available within the NHS for the general public.

Will I be compensated for taking part in this trial?

Once enrolled you will be compensated for your time, the inconvenience of having blood tests and procedures, and your travel expenses. The total amount compensated will be approximately **£180-£270** depending on the total number of visits attended. Additional visits will be paid at a rate of £45/visit. Please ask the study team if you would like more information on how and when you will be reimbursed. Those who attend for final screening and vaccination visit (Day 0) but are not eligible to proceed further in the trial, will be reimbursed for their time.

Trial reimbursement will be made by bank transfer throughout the trial, so please bring your bank details with you to your screening visit (no cash payments can be made). Should you decide to withdraw from the trial before it is completed, payment will be *pro rata* (you will receive a proportion of the total amount).

Participants that previously received MEN ACWY and return to the study site for an active COVID-19 vaccine and additional follow ups will receive £45 per visit to cover their time, the inconvenience of having blood tests and procedures, and their travel expenses.

Participants that attend a telephone call for their final visit will receive a reimbursement of £20 for their time. Participants that attend their study site for their final visit will receive a reimbursement of £45 for their time, travel and the inconvenience of having blood tests and procedures.

What if the area I live in, or where the trial is, goes back into lockdown or high level restrictions?

Travel for visits for trial purposes are exempt from government restriction, as it is considered an essential journey.

What if new information becomes available?

Sometimes during a trial, new information relevant to the trial becomes available. If this happens, we will tell you about it and discuss whether you want to, or should, continue in the trial. If you decide to continue to take part, you may be asked to sign an updated consent form. On receiving new information, we may consider it to be in your best interests to withdraw you from the trial. Your participation in this trial may also be stopped at any time by the trial doctor or the Sponsor for other reasons.

Will I be given proof of immunisation?

Your GP will be informed that you have taken part in the trial. Following unblinding, we are currently working with the NHS, NIHR and Department of Health to establish a process for information to be uploaded to the NHS app.

What will happen if I do not want to carry on with the trial?

If, at any time, after enrolment, you change your mind about being involved with this trial you are free to withdraw without giving a reason. If you withdraw we would not usually perform any more research procedures; although occasionally we might need to offer you a follow up visit for safety purposes, for example for blood tests. You would not have to agree to this. Your decision will not result in any penalty. Unless you state otherwise, any samples taken whilst you have been in the trial will continue to be stored and used for research as detailed above. You are free to request that your samples are destroyed at any time during or after the trial. Your data would be managed as laid out in the section 'What will happen to my data'. If you choose to withdraw from the trial, your standard medical care will not be affected.

Compensation for study-related injury

Your participation will be covered by the NHS Indemnity Scheme, which will cover any study-related injury or clinical negligence

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 Hospital Southampton NHS Foundation Trust, 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 trial.

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 trial doctor can advise you of further action and refer you to a doctor within the NHS for treatment, if necessary. NHS indemnity operates in respect of the clinical treatment which may be provided if you needed to be admitted to hospital.

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 trial, you should contact the research investigators who will do their best to address your concerns by sending us an email to info@ovg.ox.ac.uk .

Would my taking part in this trial be kept confidential?

All information that is collected about you during the course of the research will be coded with a trial number and kept confidential. The information is available to the trial team, authorised collaborators, ethical review committees, Oxford Vaccine Group, government regulatory agencies and the Sponsor (University Hospital Southampton NHS Foundation Trust) who can ask to access the trial data. Responsible independent monitors may be given access to data for monitoring and/or audit of the trial to ensure we are complying with regulations. They are bound by the same confidentiality rules. The electronic diary is sent to you by email to complete online. University of Oxford will host the trial database and your email address will be stored on a secure University of Oxford server, access to the diary system is password controlled and only trial site staff and sponsor and University of Oxford IT management can view the email address.

Every effort will be taken to maintain confidentiality. Information about you may be stored electronically on a secure server, and paper notes will be kept in a key-locked filing cabinet or restricted access office at Oxford Vaccine Group. Trial results will be published in a scientific journal but nothing that could identify you will be included in any report or publication. Your de-identified data collected in the trial may also be used in future research projects that may take place in hospitals, universities, non-profit institutions or commercial laboratories worldwide. We would not share anything that could identify you.

If you are not enrolled on the trial, either because you were not eligible after screening or there was not capacity to enrol you, then any data collected will be kept until the end of the trial.

What will happen to my data?

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.' University Hospital Southampton NHS Foundation Trust 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 in order to undertake this trial and will use the minimum personally-identifiable information possible. We will keep identifiable information about you such as contact details for 5 years, but with a review of this every 5 years after the trial has finished. This includes a copy of your consent form. The

need to store this information for longer will be subject to ongoing review, taking into account the value of retaining this information for participant safety (e.g. to inform participants of unexpected safety signals emerging from post-licensing surveillance), as a resource for the participants (e.g. if they wish to check which vaccines they have received in the study) and any regulatory requirements. De-identified research data will be stored indefinitely. If you have agreed that samples can be retained for future research then your personally identifiable information will be kept with restricted access solely for the purposes of sample management for a minimum of five years after the last sample has been either used or disposed of in order to meet regulatory requirements. Samples will be provided for future research only in a form that does not identify you. The University of Oxford are storing the trial data on behalf of the study Sponsor, University Hospital Southampton NHS Foundation Trust. Research data will be stored securely at the University of Oxford indefinitely following removal of identifiable information. If you agree to your details being held to be contacted regarding future research, we will retain a record of this consent until such time as your details are removed from our database but will keep this separate from your research data.
The trial team will use your name and contact details, to contact you about the research trial, and make sure that relevant information about the trial is recorded for your care, in relation to your health during the trial and to oversee the quality of the trial.

At the completion of the trial, 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 exceptional circumstances concerning your safety. If you consent to take part in another trial carried out by the Oxford Vaccine Group, personal information and medical information including blood test results may be accessed to avoid unnecessary repetition.

Your bank details will be stored securely in line with the trial site financial policies.

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 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://www.uhs.nhs.uk/Media/UHS-website-2019/Patientinformation/Visitinghospital/Your-personal-data-and-your-rights.pdf

Note that in order to check that we are conducting the trial to high standards we will be engaging trial monitors, who will have access to your data (including personal identifying information). They will not be retaining data beyond the end of the study. Minimal information about you (not including any identifiable information) may also be shared with third parties such as Public Health England or laboratories undertaking analysis of your blood samples (including, but not limited to, Oxford Immunotec and Nexelis) to help us conduct this research. Retention of data by these third parties will be as per PHE/local policies. Anonymised reports on safety information related to any of the study vaccines will be shared with the relevant vaccine manufacturer.

Some participants will have signed up to NHS Digital's *'Sign up to be contacted for coronavirus vaccine studies'* service. Further information regarding how we will inform NHS Digital of your

enrolment in this trial, will be supplied in a Supplementary Privacy Notice for volunteers who are enrolled in the trial.

Involvement of the General Practitioner (GP)/Family doctor (GP)

In order to enrol into this trial, you will be required to sign a form documenting that you consent for us to contact your GP if we need to. This is in case we need to contact your GP to check there are no medical reasons that they are aware of that would make your participation inadvisable. Your GP may be asked to share information about your medical history and give access to any other medical records as required. The researchers will not enrol you in the trial if your GP has relevant concerns about your eligibility or safety.

If you are enrolled in the trial we will write to your GP to let them know this. This will be done regardless of whether we check any medical information with them. It is important to do this so that your medical records are kept up to date.

If you have up to date copies of your medical records or GP summary records please bring these to your screening visit.

What will happen to any samples I give?

If you consent, some of your leftover blood samples can be stored and used for future infectious disease or vaccine-related research at the in the Oxford Vaccine Group Biobank or Bioresource. This is optional; your participation in this trial will not be affected by your decision whether to allow storage and future use of your leftover samples. Upon your request at any time, your remaining blood samples will be destroyed.

Your trial samples will be analysed in the Oxford Vaccine Group research laboratories or other specialist laboratories. Tests to look at the response of your body to the vaccine or to COVID-19 disease will be done with collaborating laboratories in the UK and in other countries, including North America. Any samples or data sent to them would not include information that identifies you. However, your DNA is unique to you so it can never be completely anonymous.

Will any genetic tests be done?

We would also ask for your permission to store your DNA for research related to infectious diseases and vaccination; you can still take part in the trial if you did not want us to do this.

We are not planning to perform any genetic tests within this trial.

What will happen to the results of the research trial?

The results of this research trial may be presented at scientific meetings or conferences and published in a scientific medical journal. This may not happen until 1 or 2 years after the trial is completed. If you contact the researchers in the future, you can obtain a copy of the results. You will not be identified in any report or publication.

The de-identified data from this trial will be shared with the collaborating partners who are organising and funding this research work. You will not be paid for any part of this. Data from this trial may be used as part of a student post-graduate degree, for example a MD or PhD.

Taking part in future vaccine-related research

With your consent, we would like to keep your contact details after the trial is complete, so we may inform you of opportunities to participate in future vaccine-related research. This is entirely optional and your participation in this trial will not be affected by your decision to allow or not allow storage of your contact details beyond your participation in this trial.

Your details will be stored electronically on a secure server and only authorised individuals at the Oxford Vaccine Group will have access to it. We will not, under any circumstances, share your contact details with any third party institutions without your permission. Being contacted does not oblige you to agree to take part in future research and you can ask us to have your contact details removed from our database at any time.

Who is sponsoring, organising and funding the research? Does University Hospital Southampton NHS Foundation Trust (The Sponsor) have a financial interest in the results of this trial?

The trial is organised and sponsored by the University Hospital Southampton NHS Foundation Trust. The trial is funded through financial support to the University Hospital Southampton NHS Foundation Trust from the National Institute for Health Research (NIHR), which is a UK government funded research agency. Neither your GP nor the researchers are paid for recruiting you into this trial. Southampton NHS Foundation Trust has no financial interest in the results of this trial.

Who has reviewed the trial?

This trial has been reviewed by the NHS Research Ethics Service (RES) – South Central – Berkshire and has been given a favourable ethical opinion. The Medicines and Healthcare products Regulatory Agency (MHRA), which regulates the use of all medicines in the UK, has reviewed the trial design and has granted permission to use these unlicensed vaccine schedules in this clinical trial.

Further information and contact details

If you relocate during the course of the trial and would like to continue taking part, it may be possible if there is a trial site nearby that are able to perform the remainder of your trial visits. If this were the case, we may transfer copies of your research notes including consent forms. The responsibility for your continued care in the trial would be transferred to the new trial site.

We hope this information sheet has answered all your questions. 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 trial you may wish to contact your GP. If you would like to speak to one of our team members to discuss any aspect of this trial or **if you are interested in taking part in the trial, please contact us**:

https://covboost.org.uk/participate-oxford

Supplementary Privacy Notice for Enrolled Participants

This privacy notice is for the Evaluating COVID-19 Vaccine Boosters (COV-Boost) study participants who have signed up to NHS Digital's *'Sign up to be contacted for coronavirus vaccine studies'* service.

Data Protection

In the course of enrolling in the Evaluating COVID-19 Vaccine Boosters (COV-Boost) study you have provided information about yourself ('personal data'). We (UHS NHS FT as Sponsor of the study) are the 'data controller' for this information, which means we decide how to use it and are responsible for looking after it in accordance with the General Data Protection Regulation and associated data protection legislation.

How we use your data

NHS Digital contacted you on behalf of the University Hospital Southampton NHS Foundation Trust to invite you to join our Evaluating COVID-19 Vaccine Boosters (COV-Boost) study. This is because you signed up to NHS Digital's '*Sign up to be contacted for coronavirus vaccine studies service*'. You were contacted because you were eligible to take part in our study based on the information you provided to NHS Digital when you signed up to its service (namely your age and geographical location).

You can only be enrolled in one vaccine study at a time. This means we need to let NHS Digital know that you are now enrolled in our study. We will do this so that NHS Digital can update its records and so you are not contacted unnecessarily about joining any other vaccine studies or inadvertently enrolled in more than one study at a time.

Each site will review which of their participants had signed up to NHS Digital's *Sign up to be contacted for coronavirus vaccine studies'* service. If you had signed up to this service, the site you are enrolled with will share your name with NHS Digital to confirm your enrolment. They will keep a record of having confirmed your enrolment with NHS Digital.

We need to process your data for the above purpose in order to effectively carry out research, which is a task we carry out in the public interest. Data concerning health and ethnicity is special category data, which means that we must meet additional requirements to process it. The additional requirement we meet to process this data is that the processing is necessary for the purpose of research.

We will only use your data for the purposes for which we collected it, unless we reasonably consider that we need to use it for another related reason and that reason is compatible with

the original purpose. If we need to use your data for an unrelated purpose, we will seek your consent to use it for that new purpose.

Who has access to your data?

Access to your data will be provided to those who need to view it as part of their work in carrying out the purposes described above.

Where we share your data will with NHS Digital, we will seek to share the minimum amount necessary (please see NHS Digital's privacy notice for how it uses your data).

Retaining your data

Once we have confirmed your enrolment to NHS Digital, we will securely destroy the list of people that NHS Digital contacted about our study on our behalf.

We will retain a record of having confirmed your enrolment with NHS Digital along with other identifiable information about you for 5 years and with a review of this every 5 years after the trial has finished. The need to store this information for longer in relation to licensing of the vaccine will be subject to ongoing review.

Security

Your data will be held securely in accordance with the University of Oxford or equivalent University Hospital Southampton policies and procedures. Further information is available on the University of Oxford's Information Security website here.

Where we store and use your data

We store and use your data electronically on a secure server, and paper notes will be kept in a key-locked filing cabinet or restricted access office at the NIHR Southampton Clinical Research Facility or on University premises.

Your rights

Information on your rights in relation to your personal data are explained here.

Contact

If you wish to raise any queries or concerns about our use of your data, please contact us at info@ovg.ox.ac.uk . Alternatively, you may contact the University Hospital Southampton NHS FT on Data Protection Office at dataprotection@uhs.nhs.uk or telephone: 023 8120 4743