PARTICIPANT INFORMATION SHEET: COV002

Investigating a Vaccine Against COVID-19

"A phase 2/3 study to assess the efficacy and safety of a recombinant adenovirus-based vaccine against Coronavirus Disease (COVID-19)"

IMPORTANT: If you develop a fever or cough, shortness of breath or become unwell then you must contact the study team on <<contact details>> for advice before attending any visit.

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

We would like to invite you to take part in our COVID-19 vaccine study. Before you make a 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 and relatives.

What is the purpose of this research study?

The purpose of this study is to test how well a new vaccine works against COVID-19 .

A new virus causing respiratory disease emerged in Wuhan, China in December 2019 and has since rapidly spread to many other countries around the world, despite unprecedented containment efforts. The virus is part of the Coronavirus family which may cause respiratory infections ranging from the common cold to more severe diseases. This recently discovered coronavirus causes COVID-19.

Common symptoms of COVID-19 include fever, tiredness, and dry cough. Whilst about 80% of infected people have no or mild symptoms and will recover from the disease without needing special treatment, 1 in every 6 people who gets COVID-19 becomes seriously ill. Older people and those with underlying medical problems are more likely to develop serious illness. Thousands of deaths have been reported so far.

The WHO declared the COVID-19 epidemic a Public Health Emergency of International Concern on 30th January 2020 and a pandemic on 11th March 2020. This means that the epidemic is expected to spread to all countries of the world and infect 50-80% of people. There are no currently licensed vaccines or specific treatments for COVID-19. Vaccines are the most cost effective way of controlling outbreaks and the international community have stepped-up their efforts towards developing one against COVID-19.

This study will enable us to assess how well people across a broad range of ages may be protected from COVID-19 with this new vaccine called ChAdOx1 nCoV-19. It will also give us valuable information on safety aspects of the vaccine and how well participants' immune systems respond to immunisation with the vaccine.

Visits will take place in clinics at INSERT SITE DETAILS and you must be able to travel to the visits without relying on public transport or taxi. If someone else is driving you, they should be a member of your own household to comply with social distancing rules.

Part 1

We will enrol 260 volunteers who will be allocated into one of 3 groups based on their age; 56-69 years, 70 years and older and 5–12 years.

Adult participants will be randomised to receive one or two doses of either *ChAdOx1 nCoV-19* or a licensed vaccine (MenACWY) that will be used as a 'control' for comparison. Adult participants will have between 8 and 14 blood tests over the course of one year.

All participants will have a diary collecting information about any symptoms that occur in the 28 days after vaccination and serious medical events for the duration of the study. There will also be a short weekly survey to provide information about any close contact with COVID-19.

Part 2

5000 adult volunteers aged 18 years and above will be randomised to receive a single dose of *ChAdOx1 nCoV-19* or MenACWY injection. There will be 4 or 5 blood tests over the course of one year.

- For 200 volunteers there will be a diary to collect information about any symptoms that occur in the 28 days after vaccination or other medical events.
- For the remaining 4,800 volunteers there will be a diary to record any serious illness or hospitalisation.

There will also be a short weekly survey for all participants to provide information about any close contact with COVID-19.

What is the vaccine we are testing?

The vaccine we are testing in this research study is called *ChAdOx1 nCoV-19*.

ChAdOx1 nCoV-19 is made from a virus (ChAdOx1), which is a weakened version of a common cold virus (adenovirus) from chimpanzees that has been genetically changed so that it is impossible for it to grow in humans. To this virus we have added genes that make proteins from the COVID-19 virus (SARS-CoV-2) called Spike glycoprotein (S), which play an essential role in the infection pathway of the SARS-CoV-2 virus. By vaccinating with ChAdOx1 nCoV-19, we are hoping to make the body recognise and develop an immune response to the Spike protein that will help stop the SARS-CoV-2 virus from entering human cells and therefore prevent infection. Vaccines made from the ChAdOx1 virus have been given to more than 320 people to date, and have been shown to be safe and well tolerated, although they can cause temporary side effects which are explained below (see section *Are there any risks from taking part in the trial?*).

In April 2020 the vaccine ChAdOx1 nCoV-19 will be given to the first healthy adults in Oxford. By May 2020 we are expecting to have vaccinated nearly 300 people with ChAdOx1 nCoV-19. The most up to date figures will be provided at the first visit.

We will give you one or two injections with ChAdOx1 nCoV-19 or MenACWY into the muscle around the shoulder region; this is the most commonly used route for vaccination.

What is the control (comparison) vaccine, MenACWY?

In this study we will be using a licensed vaccine against group A, C, W and Y meningococcus (MenACWY) as an 'active control' vaccine, to help us understand participants' response to ChAdOx1 nCoV-19. MenACWY has been given routinely to teenagers in the UK since 2015, and protects against one of the most common causes of meningitis and sepsis. This vaccine is also given as a travel vaccine for high risk countries. We will be using one of the two licensed versions of MenACWY, either Nimenrix or Menveo. Volunteers who have had these vaccines previously can still take part in this study.

Given we don't expect MenACWY to offer any protection against COVID-19, by comparing COVID-19 disease rates, immune responses and post-vaccination symptoms between participants receiving ChAdOx1 nCoV-19 and MenACWY we will get a better understanding of how well ChAdOx1 nCoV-19 is working.

Do I have to take part?

No. It is up to you to decide whether or not 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 (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 return to the clinic/to allow an extra visit for a follow up appointment for safety reasons.

Can I take part?

In order to be enrolled into groups 1 and 2 in the study you must:

- Be a healthy adult aged 56 years or older.
- Be able and willing (in the Investigator's opinion) to comply with all study requirements and follow-up visits.
- Allow the Investigators to discuss your medical history with your GP and access all medical records when relevant to study procedures.
- Refrain from blood donation during the course of the study.

You cannot participate in this study if:

- You have been diagnosed with COVID-19 at any point (i.e. confirmed by a laboratory test)
- You have a new onset of a fever, a cough or shortness of breath since February 2020
- You have been at high risk of exposure before enrolment, including but not limited to: close contacts of confirmed COVID-19 cases, anyone who had to self-isolate as a result of a symptomatic household member, frontline healthcare professionals working in A&E, ICU and other higher risk areas and significant exposure associated with travel abroad to high incidence areas since January 2020.
- You have participated in another research study involving vaccines, medications or frequent blood samples or received any vaccines in the last 30 days.
- You are planning to participate in another study at the same time as this study.
- You have had any vaccines in the 30 days prior to enrolment, or are planning to receive any vaccines in the 30 days before or after any of the vaccines in this study
- You have previously received an investigational vaccine likely to impact on interpretation of the trial data (e.g. Adenovirus vectored vaccine, any other Coronavirus vaccines)
- You have had antibody infusions and/or any blood products (such as a blood transfusion) in the 3 months preceding your involvement in this trial.
- You have any bleeding disorders
- Continuous use of anticoagulants, such as coumarins and related anticoagulants (i.e. warfarin) or novel oral anticoagulants (i.e. apixaban, rivaroxaban, dabigatran and edoxaban)
- You have problems with your immune system.
- You are pregnant, breast feeding or intend to become pregnant during the study.
- You have a history of a severe allergic reaction.
- You have a current diagnosis of or treatment for cancer.
- You have a history of a serious psychiatric condition that may affect participation in the study.
- You have any other serious long-term illnesses requiring hospital follow-up.
- You drink on average more than 42 units of alcohol a week (a pint of beer is 2 - 3 units, a small glass of wine (125mL) one unit and a shot of spirits (25mL) one unit).
- You have injected recreational drugs at any time in the last 5 years
- Chronic respiratory disease, including asthma

- Severe and/or uncontrolled cardiovascular disease, gastrointestinal disease, liver disease, renal disease, endocrine disorder and neurological illness (mild well controlled comorbidities are allowed)
- You are seriously overweight (BMI≥40 Kg/m2)
- You have an auto-immune disease

If you are unclear whether you are eligible to be involved in the study you can contact the study team who will be able to advise you.

How is the trial going to work?

You will be allocated to one of the study groups described below; you would be in group 1 or 2. ***IMPORTANT: <u>You will not know which group you were allocated to or which treatment you received until the study is finished.</u>*** This is very important for the research group in order to reduce bias when interpreting the results.

You may receive either:

a) 1 dose of ChAdOx1 nCoV-19 or MenACWY
OR
b) 2 doses of ChAdOx1 nCoV-19 or MenACWY

Group (max numbers)	Sub group	Week 0	Week 4
1 (80 volunteers) Aged 56-69 years	a	ChAdOx1 nCoV-19 Vaccine ($5x10^{10}$ vp dose) **OR** MenACWY	-
	b	ChAdOx1 nCoV-19 Vaccine ($5x10^{10}$ vp dose) **OR** MenACWY	ChAdOx1 nCoV-19 Vaccine ($5x10^{10}$ vp dose) **OR** MenACWY
2 (120 volunteers) Aged 70 years and older	a	ChAdOx1 nCoV-19 Vaccine ($5x10^{10}$ vp dose) **OR** MenACWY	-
	b	ChAdOx1 nCoV-19 Vaccine ($5x10^{10}$ vp dose) **OR** MenACWY	ChAdOx1 nCoV-19 Vaccine ($5x10^{10}$ vp dose) **OR** MenACWY
3 (60 volunteers) Aged 5 – 12 years		ChAdOx1 nCoV-19 Vaccine ($2.5x10^{10}$ vp dose) **OR** MenACWY	-
4		ChAdOx1 nCoV-19 Vaccine ($5x10^{10}$ vp dose)	-

(5000 volunteers) Aged over 18 years		**OR** MenACWY	

vp = viral particles

What will happen if I decide to take part?

(See the final page of this document for the schedule of trial visits)

Screening Visit – *2 hours (Listen to a consent presentation, ask any questions, sign a consent form, ID check, discuss medical history, physical examination, vital signs measured, blood test and urine sample)*

If you decide you would like to take part in this trial, there will be a screening visit before the vaccination day. This should last for about two hours. Visits will take place at <<trial site>>/

At the screening visit you will be asked to watch a presentation of the information about the study to ensure you understand what to expect by taking part, the risks involved and what side-effects you might expect to experience. Then you will have opportunity to ask any questions of a member of the research team before signing a consent form, if you decide you would like to take part. You can of course expect to receive full and comprehensive answers to any questions you may have.

You will be asked to agree to allow the research team to contact your own Doctor (GP) to make sure there are no medical reasons why you should not participate.

Having signed the appropriate forms, the Investigator will go through a few questions for administrative purposes and detailed questions related to your health. After this you will be asked about your health and past medical problems in detail. This will be followed by a physical examination which will involve a doctor 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. Your blood pressure, pulse and temperature will also be recorded.

A number of blood tests will also be carried out which include tests for anaemia, tests to see how your liver and kidneys are functioning and tests to see if you have been exposed to HIV (the virus that leads to AIDS), Hepatitis B or Hepatitis C (viruses which affect the liver). In the event of you testing positive to any of these infections, we would inform you of the result and, with your permission, offer referral for medical review, confirmation of the result, and treatment if necessary.

Sometimes minor abnormalities can be found with the blood tests. In this situation you may be asked to return for a repeat blood test so that it can be checked again. If the test results are still abnormal you may not be able to participate and we will ask your permission to contact your GP or a specialist doctor, whichever is the most appropriate, to ensure the abnormality will be followed up.

Once all your test results have been checked and no problems have been highlighted, you will be contacted to arrange a date to start the trial.

Vaccination Visits - *2.5 hours (vital signs, blood test, receive vaccine, up to 1 hour observation in clinic after the vaccine)*

If you qualify to be in the trial, we will ask you to attend on the vaccination day (Day 0). We will ask you a few questions to check there have been no new problems since screening. We will check your blood pressure, pulse and temperature (observations) and we will take blood samples. You will be randomly allocated to receive one or two doses of ChAdOx1 nCoV-19 or MenACWY.

We will give you an injection with ChAdOx1 nCoV-19 or MenACWY into your arm and we will cover the vaccine site with a dressing. We will need to keep an eye on you in the waiting room of the

department for up to 1 hour after the vaccine. After this period, we will check your observations again and the injection site inspected. Overall the vaccination visit will take about two and a half hours.

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

We will give you a thermometer, tape measure and an E-diary account to record all your symptoms and your temperature every day for 7 days after vaccination. After these 7 days we will ask you to record if you feel unwell or take any medications over the next 3 weeks. The research staff will monitor the E-Diary and may phone you to ask from more information. You will also be asked to record in the diary any serious medical illnesses or hospital visits you may have over the course of the study.

Follow-up visits – *30 minutes (vital signs, blood tests, and check for side effects or new health problems)*

Following vaccination, we will ask you to attend a series of follow-up visits/ (lasting approx. 30 minutes), as detailed in the tables at the end of this document.

For groups 1 and 2 you will need to attend short visits at 3, 7, 14 and 28 days after each vaccine to ensure everything is fine, to check your symptoms, the injection site and to have blood tests done. Participants in groups 1 and 2 who are allocated to 2-dose vaccine schedules will have 3 more visits compared to the ones allocated to single dose schedules. All participants will also have a visit at day 56 after the first immunisation, and all participants at day 182 after the first dose of vaccine (see table with trial visit schedules at the end of this leaflet).

You will also be asked to attend an extra visit 1 year after your vaccination to give us further useful data about the vaccine, however this visit will be optional to attend. 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. You will be compensated for the time and inconvenience of any extra visits. After the last visit, your participation in the trial will be complete.

We may ask to photograph your vaccination site. You will not be identifiable in these photographs, as only the vaccination site and your unique trial number will be visible. These photographs may be shown to other professional staff, used for educational purposes, or included in a scientific publication.

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

Weekly survey

We will send you a survey each week by email or text to enquire about COVID-19 symptoms of you and your household contacts for the duration of the study.

Length of research

If you decide to take part in this study, you will be involved in the trial for approximately 6 months and will be asked if you are willing for an optional extra visit at 1 year after your first vaccination.

Considerations before taking part in this study

Blood Donation: Under current UK regulations, participants will not be able to donate blood during the course of the study.

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.

What should I avoid 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 interventions for COVID-19. If during the trial you require any vaccinations for health, travel, or occupational reasons, you should inform the Investigators beforehand. We will discuss with you the most appropriate time to receive them.

Are there any risks from taking part in the trial?

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

1. *Blood samples*

Drawing blood may cause slight pain and occasionally bruising at the site where the needle enters. Rarely, people feel light-headed or even faint. During the course of the trial we will need to take between 5 (approximately 1 teaspoon) and 60ml of blood (approximately 4 tablespoons) at a single visit. The total amount we will take over the period of the trial will depend on your group (Single dose = 439ml, Two doses = 554ml).

The following blood tests will be performed:

- Tests for Hepatitis B, Hepatitis C and HIV are done at the screening visit.
- HLA typing, a test of a component of the body's immune system may be done at the first vaccination visit.
- Tests of red and white blood cells, liver and kidney function are done at the screening visit and most of the other visits (including the vaccination day), in order to check the vaccines are safe.
- Tests of the immune responses to vaccines are done at most of the visits.

If abnormal results or undiagnosed conditions are found during the course of the study 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 immunity against the COVID-19 virus.

2. *Vaccination Side Effects: ChAdOx1 nCoV-19 and MenACWY*

It is likely that you will experience some symptoms at the vaccination site as well as general symptoms due to vaccination. It is important to remember ChAdOx1 nCoV-19 is in the early stage of development and the amount of safety data available are limited. For this reason, there is a chance you could experience a side effect that is more severe than what is described below, or that has not been seen before.

Other ChAdOx1 viral vector vaccines have previously been administered in many other clinical trials. We can predict from past experience what the symptoms should be like with this new vaccine. We expect that symptoms will be mild in strength most of the time, although symptoms may also be moderate or severe. All symptoms should resolve completely within a few days. The chimpanzee adenovirus has been weakened so that it cannot grow in human cells. The SARS-CoV-2 protein it carries cannot cause COVID-19 disease.

a) The MenACWY vaccines are licensed vaccines, meaning they have been approved for use in the general population. They have been given to many hundreds of thousands of people, with no safety concerns.*Local Reactions at vaccination site*

Following vaccination with either the *ChAdOx1 nCoV-19* or MenACWY vaccine you may experience some discomfort at the injection site as the vaccination is given. This usually gets better within 5 minutes. Later, you might experience pain resulting in some difficulty moving your arm, but this should resolve within a few days. In addition to pain, you may experience redness, swelling, itchiness or warmth at the injection site.

b) General reactions

During the first 24-48 hours after vaccination you may experience flu-like symptoms such as muscle aches, joint aches, feverishness, chills, headache, nausea, tiredness and/or feeling generally unwell. These symptoms should usually resolve within a few days and can be experienced whichever vaccine you are given

c) Serious Reactions

With any vaccination there is a 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, but can be fatal. In case of this unlikely event, medication for treating allergic reactions is available and the investigators are appropriately trained in the management of anaphylaxis. Reactions in the nervous system are also extremely rare, but can cause an illness called Guillain-Barré syndrome. This is a condition in which people can develop severe weakness and can be fatal. These adverse events have not previously been seen following administration of similar vaccines using ChAdOx1 as a viral vector.

With any new medicine or vaccine there is always a possibility of an unexpected side effect. You will be provided with a 24h study mobile number. If you experience unexpected events or become in any way concerned you can use this to contact one of the study doctors at any time. We will ask you to record these symptoms in the E-Diary too.

Theoretical Concerns – could immunisation with ChAdOx1 nCoV-19 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. These problems were not seen in animal studies with ChAdOx1-MersCoV vaccine, which is very similar to the vaccine being used in this study, when the animals were exposed to the wild virus Studies of the ChAdOx1 nCoV-19 vaccine in animals are currently ongoing but: *we do not yet know whether this could also be a side effect of exposure to the pandemic COVID-19 virus in this COVID-19 vaccine study, whether this effect could occur in humans or whether this might lead to more severe COVID-19 disease in some cases.*

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What are the advantages of taking part?

You will not necessarily gain any direct benefit from the trial, but the information gained from the study might help to develop an effective vaccine against COVID-19. If in the future you become exposed to COVID-19, ***you should not assume that the vaccine you received in this study will give you any protection against COVID-19***. Participants who receive MenACWY will reduce their risk of meningitis and sepsis caused by group A, C, W or Y meningococcus.

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

If you believe that you may have COVID-19 while enrolled in the study then you must immediately inform the study team on <<contact details>>. Do not attend the clinical trial site unless you have been informed to by the study team. If you are at all unsure please contact the study team.

When calling to inform the study team that you may have COVID-19 we will arrange for a COVID-19 testing visit. At this visit we will use a nose and/or throat swab to collect a sample and check if you have the virus or not. We will also be taking a blood sample at this stage for safety and immunology monitoring. We will see you again 7 days later to collect another swab and blood sample.

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

If you are diagnosed as having COVID-19 disease while in the study then you must contact the study team and should not attend the clinical trial site until the trial team have informed you it is safe to do so. We would also contact you regularly to check your health.

If you are admitted to hospital during the study 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.

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 paid for taking part in this trial?

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 **£<<XXX>>** depending on the exact number of visits and whether any repeat or additional visits are necessary.

Trial reimbursement will be made by bank transfer within six weeks of your completion of 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).

What if new information becomes available?

Sometimes during the course of 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 study. If you decide to continue to take part, you will 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 study. Your participation in this study may also be stopped at any time by the study doctor or the Sponsor for other reasons.

What will happen if I don't want to carry on with the trial?

If, at any time after agreeing to participate, you change your mind about being involved with this study 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 to check the injection site or a blood result. Your decision will not result in any penalty. Unless you state otherwise, any blood taken whilst you have been in the study will continue to be stored and used for research as detailed above. You are free to request that your blood samples are destroyed at any time during or after the study. If you choose to withdraw from the trial, your standard medical care will not be affected.

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 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 study 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 study, you should contact the research investigators who will do their best to address your concerns by sending us an email to INSERT SITE EMAIL. Alternatively you may contact the University of Oxford Clinical Trials and Research Governance (CTRG) office on 01865 616480 or the head of CTRG, email ctrg@admin.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 study number and kept confidential. The information is available to the trial team, authorised collaborators, ethical review committees, INSERT LOCAL TRUST, government regulatory agencies and the Sponsor (University of Oxford), 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. Any information about you that leaves the hospital/clinic will have your name and address removed so that you cannot be recognised from it. However, any samples collected for the purposes of COVID-19 diagnosis might be sent to reference labs in the UK alongside your personal data. If you are diagnosed with COVID-19 during the course of the study then we must pass your details on to the local health protection team as COVID-19 is a "notifiable disease" and this is legal requirement in the UK.

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 at the INSERT SITE NAME. Trial results will be published in a scientific journal but nothing that could identify you will be included in any report or publication.

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.' The University of Oxford 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 study and will use the minimum personally-identifiable information possible. 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 in relation to licensing of the vaccine will be subject to ongoing review. 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. We store research data 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 copy of your consent form until such time as your details are removed from our database but will keep the consent form and your details separate.
The study team will use your name and contact details, to contact you about the research study, and make sure that relevant information about the study is recorded for your care, in relation to your health during the study and to oversee the quality of the study. 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 exceptional circumstances concerning your safety. If you consent to take part in another study carried out by the INSERT SITE NAME, personal information and medical information including blood test results may be accessed to avoid unnecessary repetition.

Your bank details will be stored for 7 years in line with university financial policy.

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://compliance.web.ox.ac.uk/individual-rights

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

In order to enrol into this study, you will be required to sign a form documenting that you consent for us to contact your GP. This is to inform them that you are interested in being involved in the study, and 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. We will write to your GP to let them know about your enrolment and study completion status, so they can update your medical records accordingly.

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. This is optional; your participation in this study 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.

To avoid repeat testing, if you are not enrolled into this study and you apply to enter another study conducted by the INSERT SITE NAME based at the INSERT LOCATION, the results from your screening visit blood tests may be used to determine whether you are eligible for the trial you applied for.

Your study visit blood tests will be analysed in the site (hospital) laboratories and Oxford University research laboratories. Other blood tests to look at the response of your body to the vaccine will be done with collaborating laboratories in the UK and in other countries. Any samples or data sent to them would not include information that identifies you.

Will any genetic tests be done?

We may do genetic tests on your blood samples to look at the patterns of genes that regulate your own individual immune response (these are called Human Leukocyte Antigen genes). Doing this helps us to work out which aspects of the immune response to vaccines are due to genetic differences between individuals. We may also look at the expression of certain genes which relate specifically to the immune response to COVID-19, but no genetic tests concerning diseases or conditions other than COVID-19 and other vaccine related responses.

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 may not happen until 1 or 2 years after the study 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 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, licence vaccines in the future or make profits in other ways. You will 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.

Taking part in future vaccine-related research

With your consent, we would like to keep your contact details after your participation in this study 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 study 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 INSERT SITE NAME 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?

The study is organised and sponsored by the University of Oxford. The study is primarily funded through financial support to the University of Oxford from United Kingdom Research and Innovation (UKRI) which is a UK government funded research agency and the Coalition for Epidemic Preparedness Innovations. Neither your GP nor the researchers are paid for recruiting you into this study.

Who has reviewed the study?

This study 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 study design and has granted permission to use this unlicensed vaccine in this clinical study.

Further information and contact details

We hope this information sheet has answered all of 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 study, please contact us**:

<<Insert Site recruitment contact details (address, email, phone)>>

Trial Visit Schedule

GROUP 1a (56 – 69 years) and 2a (70 years and over):

1 Screening visit, 1 Vaccination visit, 6 follow up visits (plus one optional visit at 1 year)

										If necessary	
	Screening	Day 0 VACCINATION	Day 3	Day 7	Day 14	Day 28	Day 56	Day 182	Day 365 (optional)	COVID-19 Testing	COVD-19 Testing + 7 days
Vaccination		X									
Blood Tests	X	X	X	X	X	X	X	X	X	X	x
Swab										X	X

Group 1b (56 – 69 years) and 2b (70 years and over):

1 screening visit, 2 vaccination visits, 8 follow up visits (plus one optional visit at 1 year)

													If necessary	
	Screening	Day 0 VACCINATION	Day 3	Day 7	Day 14	Day 28	Day 31	Day 35	Day 42	Day 56	Day 182	Day 365 (optional)	COVID-19 Testing	COVD-19 Testing + 7 days
Vaccination		X				X								
Blood Tests	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Swab													X	X