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)"

Responses to SARS-Cov-2 prophylactic vaccine (ChAdOx1 nCoV-19) amongst people living with HIV

Updated information about side effects can be found on p16.

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

If you have received any additional COVID-19 vaccine(s) outside of the study and have not already informed your local trial team please register these details at this link:

<<external vaccine registration website URL>>

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, specifically people living with HIV. 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. The study will also assess how well the immune system of people living with HIV responds to the vaccine.

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.

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 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.

The COV002 study will assess how well people may be protected from COVID-19 with a vaccine called ChAdOx1 nCoV-19. We would like to give the same vaccine to people living with HIV to see if their immune system responds in the same way as people who do not have HIV.

Summary of the study

In total, this study will enrol 12, 390 adults and children including 60 people living with HIV in the UK.

- Participants will receive two doses of the *ChAdOx1 nCoV-19* vaccine
- Around 12 blood tests will be taken over the course of a year to check if there are any problems and to look at immune responses to the vaccine
- The study will take a year to complete

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?*).

The vaccine ChAdOx1 nCoV-19 was first given to 500 healthy adults in Oxford in April 2020 as part of a separate safety trial (COV001). Including in this current trial (COV002), the vaccine has now been given to over 5000 people in total. The most up to date recruitment figures will be provided at the first visit.

Although during a pandemic it would be preferable to give a single dose of vaccine, data from the first COVID-19 vaccine trial suggests that 2 doses of vaccine stimulates the immune system more than a single dose.

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 allow an extra visit for a follow up appointment for safety reasons.

Can I take part?

Adults that are aged 18 - 55 years, are HIV positive and receiving antiretroviral therapy with an undetectable viral load and CD4 count more than 350 are eligible. In order to be enrolled in the study;

- you must be willing to allow the investigators to discuss your medical history with your General Practitioner (GP)
- for females of childbearing potential only, willingness to practice continuous effective contraception during the study and a negative pregnancy test on the day(s) of screening and vaccination

You cannot take part in this study if you:

- are taking part in a COVID-19 drug trial
- are taking part in a serological study where you are informed if there is evidence of SARS-CoV-2 in your blood
- have any vaccine in the 30 days before or after this study vaccine. The exception to this is the seasonal influenza vaccine and the pneumococcal vaccine. 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 the study vaccine.
- have previously had other similar vaccines that might impact on understanding your results such as adenovirus vectored vaccines or coronavirus vaccines
- have received immunoglobulins or blood products in the 3 months before having the study vaccine
- have immunosuppression or immunodeficiency (other than HIV infection)
- have a history of angioedema
- have a history of anaphylaxis
- have a current diagnosis or are having treatment for cancer
- have a history of serious psychiatric condition likely to affect participation in the study
- have a bleeding disorder
- continuously take anticoagulants, such as coumarins and related anticoagulants (i.e. warfarin) or novel oral anticoagulants (i.e. apixaban, rivaroxaban, dabigatran and edoxaban)
- have suspected or known current alcohol or drug dependency
- are pregnant, breast feeding or intend to become pregnant during the study
- have severe and/or uncontrolled cardiovascular disease, respiratory disease, gastrointestinal disease, liver disease, renal disease, endocrine disorder and neurological illness

If you were to develop symptoms of COVID-19, we will ask you to attend for a visit. If you would rely on public transport to attend this visit, this may put other people at risk, so we would not be able to enrol you in the study.

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.

What will happen if I decide to take part?

If you decide you would like to take part in this trial there will be a screening visit before the vaccination day.

Screening Visit – *1.5 hours (Listen to a consent presentation, ask any questions, sign a consent form, ID check, medical history, physical examination if required, temperature check, blood test and urine sample pregnancy test for females)*

We will ask you to watch a video 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.

Having signed the appropriate forms, a doctor will ask questions about your current health and discuss details of your medical history, 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. Your height, weight and temperature will be recorded and if necessary your blood pressure and pulse may be recorded.

A blood sample may be taken to check if you have had contact with the COVID-19 virus. If results indicate you have, you will not be able to continue with the study. It is important to note that this is a research test that has not been validated for diagnostic purposes, so results cannot be used to provide certainty of prior infection nor of protection from future infection.

Additional blood tests will be 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 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 - *1.5 hours (vital signs, blood test, receive vaccine, up to 30 minutes observation in clinic after the vaccine)*

If you qualify to be in the trial, we will ask you to attend on the first 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 temperature and we will take blood samples.

We will give you an injection with ChAdOx1 nCoV-19 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 15 – 30 minutes after the vaccine. After this period the dressing will be

removed and the injection site inspected. Overall the vaccination visit will take about an hour and a half. You will receive a booster dose of the vaccine 28 days after the first dose. This visit will take between 45 minutes and 1 hour.

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 for 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.

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. If you work in a clinical area you will not be asked to complete this survey.

If you developed COVID-19 symptoms and have had a positive PCR test since the first vaccination, you can only receive a booster dose after a minimum 4 weeks interval from your PCR positive test, provided your symptoms have significantly improved. The decision to proceed with booster vaccinations in those cases will be at clinical discretion of the investigators. For participants who are asymptomatic and have a positive PCR test a minimum of 2 weeks from PCR positivity will be required before boosting.

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 short follow-up visits to ensure everything is fine, to check your symptoms, the injection site and to have blood tests done.

Weekly COVID-19 swabbing – *2 minutes plus time for posting*

In order to monitor for exposure to COVID-19, in those who do not develop symptoms, we will ask you to collect weekly throat/nasal swabs or saliva samples. These samples will be processed as part of the ongoing community testing programme conducted by the Department of Health and Social Care (DHSC). You will be given instructions about how to collect these samples yourself and how to send them to the laboratory for testing. For further information on how the DHSC will handle data from your weekly swabs, please see INSERT CURRENT GOVERNMENT LINK.

If the results of your swab indicate that you have been exposed to COVID-19 or if you develop symptoms of COVID-19 disease, we may ask your permission to collect a stool sample. You would receive instructions for how to collect the sample, how to use the packaging provided and how to arrange a courier to collect the sample.

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.

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.

Unblinding of all participants

The main analysis of the study objectives looking at how effective the ChAdOx1 nCoV-19 vaccine is at preventing COVID-19 disease has been completed and this shows that the vaccine is 100% effective at preventing severe COVID-19 disease in the trials. The number of new infections in the UK has now fallen, and due to a significant number of participants already being unblinded as part of the national vaccine rollout we have decided to unblind all participants in the trial. This is for your information only, as you are in a group that was not blind to the vaccine they received.

National roll out of 3rd doses of COVID-19 vaccines

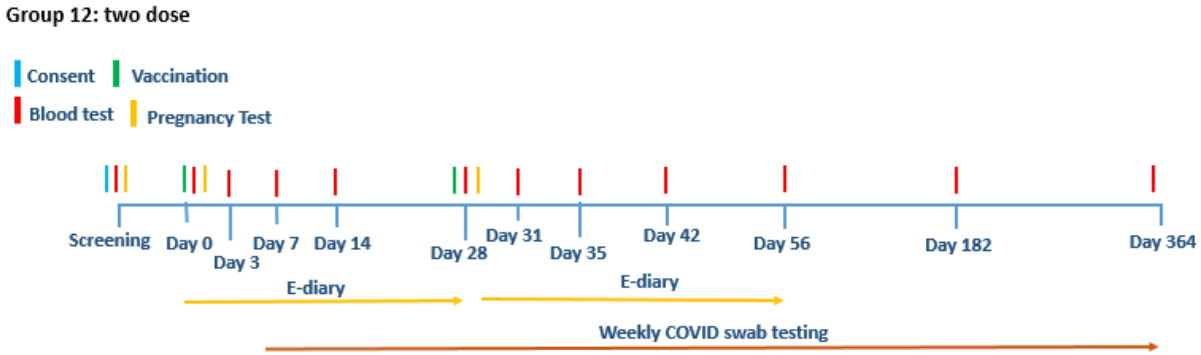
The UK government is now beginning a national roll out of a 3rd dose of an approved COVID-19 vaccine to individuals who have already received 2 active doses of vaccine. The vaccine will be rolled out according to the government prioritisation plan, so it may be some time before participants receive an invitation for vaccination. Before you are given this vaccine as part of the national roll out programme, your site may ask you to come for an extra visit to collect a blood sample. You will also be asked to complete an online form <<external vaccine registration website URL>> with details of the vaccine you were given and the dates you had them. We also ask that you continue to attend your remaining visit(s) as scheduled.

What happens now?

There are still a lot of important questions that your continued participant in the trial can help us answer such as determining long term immune responses, monitoring for exposure to COVID-19 in those who do not develop symptoms and continued monitoring for safety. We are particularly interested in the minority of cases where vaccinated individuals still go on to develop COVID-19 and whether this can be predicted in the future by doing blood tests. For the reasons above we are asking all participants to continue to attend for their remaining follow up visits. It is also important that you continue to contact the study team should you develop symptoms of COVID-19.

Visit schedule

The picture below represents the visit schedule



*The extra visit before you have your 3rd dose as part of the national roll out would take place between day 182 and day 364.

Considerations before taking part in this 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 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 (if you do not develop symptoms of COVID-19) will be 1080mls

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*

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) *Local Reactions at vaccination site*

Following vaccination with either the *ChAdOx1 nCoV-19* 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 include an illness called Guillain-Barré syndrome, 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. In the current trial we have undertaken safety reviews when volunteers in the trials of ChAdOx1 nCoV-19 developed unexplained neurological symptoms including changed sensation or limb weakness, and have paused the study while a safety review took place. After independent review, these illnesses were either considered unlikely to be associated with the vaccine or there was insufficient evidence to say for certain that the illnesses were or were not related to the vaccine. In our trial for each of these cases, after considering the information, the independent reviewers recommended that vaccinations should continue. Close monitoring of the affected individuals and other participants will be continued. Almost 200 million doses have now been administered worldwide and these neurological illnesses have not been identified as a side effect.

With any new medicine or vaccine there is always a possibility of an unexpected side effect. Following reports of blood clots with lowered platelets a review has been undertaken by the MHRA (Medicines and Healthcare products Regulatory Agency) and the EMA (European Medicines Agency). The reports were into a very rare type of blood clot in the brain, known as cerebral venous sinus thrombosis (CVST), and in some other organs together with low levels of platelets (thrombocytopenia) that might be associated with vaccination with ChAdOx1 nCoV-19. Up to and including 31 March 2021 there have been 79 UK reports of these blood clots and unfortunately 19 people died. By 31 March 2021 20.2 million doses of the ChAdOx1 nCoV-19 vaccine had been given in the UK. This means the overall risk of these blood clots is extremely rare, approximately 4 people in a million who receive the vaccine.

More investigations are needed, but as a precaution the JCVI (Joint Committee on Vaccination and Immunisation), that advises the UK government on vaccination policy, have recommended that those under 30 years old who have not yet had a first dose of the ChAdOx1 nCoV-19 vaccine, have an alternative COVID-19 vaccine. This decision was made by looking at the risk of clots following vaccination versus the benefits of receiving protection from COVID-19 disease. Severe COVID-19 disease is much less common in young adults.

To remain in line with this guidance, participants in the study who are under 30 years and were randomised to the control group will not be offered a first dose of the study vaccine as had previously been planned. Instead they should wait until they receive an invitation for vaccination via the NHS roll out. For those over 30 years of age, ChAdOx1 nCoV-19 vaccine will be offered after unblinding as a study procedure, also in line with JCVI guidance.

The JCVI recommended that second doses of the ChAdOx1 nCoV-19 vaccine should continue, as there were no reports of clots associated with the second dose. So participants who have

received a single dose of vaccine, can continue to attend for an Extra Visit B following unblinding.

Updated, 7th May 2021: The latest guidance from the JCVI extends the above and advises a preference for adults aged 30 to 39 without underlying health conditions to receive an alternative to ChAdOx1 nCoV 19.
The full reports released by MHRA and JCVI can be found at the following links:

[INSERT LINKS]

Additional side effects to be alert for in the 28 days following vaccination are;

- Sudden severe headache that does not improve with usual pain killers or is getting worse
- An unusual headache which seems worse when lying down or bending over, or may be accompanied by blurred vision, nausea and vomiting, difficulty with speech, weakness, drowsiness or seizures
- New and unexplained pinprick bruising or bleeding
- Shortness of breath, chest pain, leg swelling or persistent abdominal pain

You will be provided with a 24h study mobile number. If you experience any of the above events or become in any way concerned you can use this to contact one of the study doctors at any time.

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.*

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***.

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 ask you to arrange for a COVID-19 test locally. If you have a swab result that is positive for COVID-19 we will ask you to attend a visit within 7 days of the symptoms starting (cough, fever, loss of taste and smell and shortness of breath). At the visit we will use a nose and/or throat swab to collect a sample. We will also be taking a blood sample at this stage for immunology monitoring. Around a week later , you will receive a telephone or video call to review your health. You may be asked to attend for a visit if the study team feel an in person review is necessary.

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 have a positive swab performed outside the study or 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?

The total amount compensated will be approximately between **£XXX-XXX.**

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. The electronic diary is sent to you by email to complete online. Your email address will be stored on a secure University of Oxford server, access to the diary system is password controlled and only study site staff and sponsor IT management can view the email address.

Samples collected using home swab kits may be processed at laboratories within and outside the UK, as determined by the community testing programme. These processing laboratories receive only the swab and barcode label; your personally-identifiable information is not shared with these laboratories. The laboratories provide a test result for the barcode to an NHS database (NPEx (National Pathology Exchange)) and this result is then recombined with your personally- identifiable information by NHS Digital.

NHS Digital provide your results along with personally-identifiable information to the Sponsor (University of Oxford) who will match this with personal data including identifying contact information sent to them by your hospital/clinic in order to centralise the processing of weekly surveillance results.

If you have a positive swab result for COVID-19 during the course of the study then the Public Health Authority will be notified as COVID-19 is a “notifiable disease” and this is legal requirement in the UK. This may mean your personal information (test results, name, contact details) from your health records will be shared with Public Health either by the processing lab or the study site. You may also be contacted by the NHS Test and Trace service.

If you consent to collect a stool sample when required; the stool sample (in an anonymised form) will be collected from you by a courier and processed in a laboratory by International Health Management Associates (IHMA), an accredited central laboratory. The sample will then be shipped for analysis by Astra Zeneca in a laboratory in the US. You would need to provide your name and address to the courier company.

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 the INSERT SITE NAME or at the Centre for Clinical Vaccinology and Tropical Medicine (CCVTM), University of Oxford. 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.

If you are diagnosed with COVID-19 during the course of the study your personal information (test results, name, contact details) from your health records will be shared with Public Health either by the processing lab or the study site. You may also be contacted by the NHS Test and Trace service.

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 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 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.

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 samples will be analysed in the site (hospital) laboratories, Oxford University or Imperial College research laboratories or other specialist laboratories. Any samples or data sent to the laboratories will not include information that identifies you.

Your weekly swab tests for COVID-19 will be performed in partnership with the Department of Health and Social Care national community testing programme.

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 funded through financial support to the University of Oxford from the National Institute for Health Research (NIHR), which is a UK government funded research agency. Funding for analysis of some exploratory objectives has been received from AstraZeneca. 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

If you have to relocate during the course of the study and would like to continue taking part, it may be possible if there is a study site nearby that are able to perform the remainder of your study 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 study would be transferred to the new study site.

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)>>